From: (b)(6)
Sent: Thu, 2 Feb 2023 22:00:27 -0700
To: Vaccine Safety (CDC); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Subject: Fwd: Question about TGA's recent Tinnitus & Novavax decision CCEMS:01820000562 [SEC=OFFICIAL]
Attachments: image001.png

Please see the message I received from the TGA.

Sincerely,
(b)(6)

---------- Forwarded message ---------
From: **ADR Reports** <ADR.Reports@health.gov.au>
Date: Thu, Feb 2, 2023, 9:44 PM
Subject: RE: Question about TGA's recent Tinnitus & Novavax decision CCEMS:01820000562 [SEC=OFFICIAL]
To: (b)(6)

Dear (b)(6)

Thank you for your enquiry to Therapeutic Goods Administration (TGA).

At the time of evaluation of this safety signal, there were 61 reports of tinnitus in the WHO adverse event database [VigiBase] in association with Nuvaxovid worldwide. Of these, 30 (49%) were from Australia. Following further investigation, this was viewed as evidence supportive of a local signal and warranted inclusion in the Australian PI for Nuvaxovid.

Kind Regards

Tracey

Adverse Event and Medicine Defect Section

Pharmacovigilance Branch

Therapeutic Goods Administration

Australian Government, Department of Health and Aged Care

E: adr.reports@health.gov.au

PO Box 100, Woden ACT 2606, Australia

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

---------- Original Message ----------
From: Robert Edmonds (b)(6)
Received: Tue Jan 31 2023 08:19:57 GMT+1100 (Australian Eastern Daylight Time)
To: info@tga.gov.au <info@tga.gov.au>; info-Queue <info@tga.gov.au>;
Subject: Question about TGA's recent Tinnitus & Novavax decision

Dear TGA,

My name is (b)(6) I am an administrator to an international group of nearly 1000 tinnitus adverse event sufferers, this is our specific and only focus. I recently noticed your decision about tinnitus being added to the label of Novavax (i.e. https://www.tga.gov.au/news/covid-19-vaccine-safety-reports/covid-19-vaccine-safety-report-27-01-2023). I was wondering if there is any additional information or analysis you could provide about this update, specifically regarding tinnitus. I emailed the

International Network of Special Immunization Services (https://insisvaccine.org/) that I have been a guest to meetings about tinnitus they have hosted, unfortunately they have no additional information to provide about your decision as well. Thus I am contacting you directly, trying to better understand your decision.

Sincerely,

(b)(6)

To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Subject: FW: CDC Response - National Geographic interview request - AEs from COVID vaccines

Hi Tom: I have a reporter following up on tinnitus.

On 11/10/22 I sent her this email:

> At this time, vaccine safety monitoring efforts in CDC have identified no evidence of a causal association between COVID-19 vaccination and tinnitus or other hearing loss.
> The VSD analysis is in progress but the Immunization Safety Office can't discuss preliminary findings.
> No target date for completion has been given.
> Thanks,
> Martha

On 1/8/23 I updated her with the Dorney et al study and let her know that CDC doesn't have enough evidence to justify an epidemiologic study on tinnitus in VSD.

Current inquiry:

> It sounds like that analysis was stopped at some point between November, when we last corresponded about it, and now. Can you tell me when it was decided that the CDC doesn't have enough evidence to justify the VSD analysis and what happened to the one that was started in the fall? If you can give me a call at (b)(6) I would greatly appreciate it.
>
> Thank you,
> Tara Haelle

Proposed Response: (b)(5)

(b)(5)

Martha Sharan
Public Affairs
CDC/Division of Healthcare Quality Promotion
Off.: 404-639-2683
Cell: 404-998-1787

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Sent: Thursday, November 10, 2022 10:11 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Sharan, Martha (CDC/DDID/NCEZID/DHQP)

<liu4@cdc.gov>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <mmm2@cdc.gov>
Subject: RE: CDC Response - National Geographic interview request - AEs from COVID vaccines

And I believe the VSD analysis is in progress and we can't discuss preliminary findings.

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Sent: Thursday, November 10, 2022 10:08 AM
To: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <mmm2@cdc.gov>
Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Subject: RE: CDC Response - National Geographic interview request - AEs from COVID vaccines

Hi Martha,

As Tom stated, monitoring of AEs (including tinnitus and sudden and sensorineural hearing loss) is an ongoing process, so there's no real "end point". I can say at this time, vaccine safety monitoring efforts in CDC have identified no evidence of a causal association between COVID-19 vaccination and tinnitus or other hearing loss.

- John

From: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Sent: Thursday, November 10, 2022 9:50 AM
To: McNeil, Michael (CDC/DDID/NCEZID/DHQP) <mmm2@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Subject: RE: CDC Response - National Geographic interview request - AEs from COVID vaccines

Hi Mike and John:
We indicated to this reporter interested in doing a story on tinnitus after vaccination that we were doing additional analysis in VSD. Do you know if that has been done? When we might have that completed. Is there a timeline I can share with the reporter?

The reporter is just checking back – see chain below.

Thanks,
Martha

Martha Sharan
Public Affairs
CDC/Division of Healthcare Quality Promotion
Off.: 404-639-2683
Cell: 404-998-1787

From: Tara Haelle (b)(6)
Sent: Thursday, November 10, 2022 7:40 AM

To: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Subject: Re: CDC Response - National Geographic interview request - AEs from COVID vaccines

Hi Martha,
I wanted to check back in to see if you had any update on the additional analysis that you mentioned using VSD. Do you know when it will be started, when it will be complete, or when results from it might be available? I need to file my story this week or next, so I'm wondering if I could still briefly speak with Dr. Shimabukuro, especially regarding the specific way CDC conducts its statistical analysis for associations.

Thank you,
Tara

Tara Haelle • @tarahaelle
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tarahaelle.net
Journalist, author, public speaker & AHCJ Medical Studies Core Topic Leader
Books: Vaccination Investigation, The Informed Parent, various children's titles

On Mon, Oct 3, 2022 at 7:56 AM Tara Haelle <(b)(6)> wrote:
Martha,
Thank you very much for the update. I look forward to hearing more when the analysis is complete.

Thanks,
Tara

—Sent from a buzzing brain probably clumsily dictating to a miniature magical box

****

www.tarahaelle.com
Mob 817.458.8133

On Oct 3, 2022, at 7:53 AM, Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov> wrote:

Hi Tara:
Received word from Dr. Shimabukuro that he would like to delay this interview due to an additional analyses that CDC is going to do in one of the safety monitoring systems known as the Vaccine Safety Datalink (VSD). We may have updated information on tinnitus and he would prefer to hold off until the analysis is completed to avoid giving you outdated information.

I don't have a target date for completion at this time. Dr. Shimabukuro indicated that it would be "relatively soon."
I will try to keep you informed, however, please feel free to check back with me.
Thanks,
Martha

From: Tara Haelle (b)(6)
Sent: Friday, September 30, 2022 5:31 PM
To: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Subject: Re: CDC Response - National Geographic interview request - AEs from COVID vaccines

Martha,
A Monday interview would be fantastic. Thank you so much. Let me know what time works best. Thanks also for the note about CDC not commenting on non-CDC studies. I'll keep that in mind and adjust my questions accordingly.

Thank you,
Tara

– –

These are incredibly tough, strange times. Feeling awful and frustrated you can't "snap out of it?" Read this. If you're thinking of hurting yourself, please call the Suicide Hotline at 1-800-273-8255 or text 741741. You matter.

Tara Haelle • @tarahaelle
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Books: Vaccination Investigation, The Informed Parent, various children's titles

On Fri, Sep 30, 2022 at 7:39 AM Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov> wrote:
Hi Tara – I can try to arrange a short interview on Monday. Dr. Shimabukuro i (b)(6) (b)(6) , so his schedule will be impossible.

Please note, as a general rule, CDC does not comment on studies/findings that did not involve CDC experts and were conducted outside of the agency.

Thanks,
Martha

From: Tara Haelle [(b)(6)]
Sent: Friday, September 30, 2022 6:22 AM
To: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Subject: Re: CDC Response - National Geographic interview request - AEs from COVID vaccines

Martha,
Thank you very much for sending these along. In reading the responses, I notice that several of the responses explain things I'm already aware of, such as the difference between incidence and prevalence; the difference between VAERS and VSD; and the substantial limitations of a passive monitoring system like VAERS. (I've reported on vaccine safety for over a decade, so I'm very familiar with all these issues and the CDC's mechanisms.)

I'm not sure if my questions weren't worded well or there was a misunderstanding otherwise, but I have follow-up questions to try to get better clarification on what I was asking. Would it be possible to set up a brief phone call with Dr. Shimabukuro to discuss this issue? It doesn't seem as though email questions are adequate for the level of specificity and nuance I'm seeking for this story. I'm a little different than most reporters in writing about vaccine adverse events because I've reported on them for so long, and I'm very familiar with all the tropes and misconceptions promoted by those who are anti-vaccine or who otherwise are unfamiliar with the specifics of CDC vaccine safety surveillance and research.

Thank you,
Tara Haelle

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On Thu, Sep 29, 2022 at 7:07 AM Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov> wrote:
Hi Tara:
Yes, I have responses from Dr. Shimabukuro, Director, CDC's Immunization Safety Office. I will pass along your additional questions.

Please see below:

> **A recent paper by Harpaz et al (doi: 10.1007/s40264-022-01186-z) suggests a strong association exists in VAERS reports for tinnitus and each of the three COVID-19 vaccines initially authorized by the FDA, but that the association is masked because of the high number**

of overall reports. Is this something that the CDC safety researchers have considered and/or that they are looking into?

CDC did not participate in this analysis and recommends that you contact the authors if you have questions about their analysis.

One of the challenges of considering tinnitus as a presumptive AE is that it is so common as a background condition in the general population. Does a condition's prevalence in the general population affect how CDC safety researchers consider potential associations from AEs reported in VAERS? Would shortening the time after vaccination that they looked for an association be likely to change any likelihood of finding an association?

Per CDC (Principles of Epidemiology | Lesson 3 - Section 2 (cdc.gov)), "Prevalence refers to proportion of persons who have a condition at or during a particular time period, whereas incidence refers to the proportion or rate of persons who develop a condition during a particular time period. So prevalence and incidence are similar, but prevalence includes new and pre-existing cases whereas incidence includes new cases only." For vaccine safety monitoring, we are most concerned with incident cases, or new cases occurring following vaccination. Expected incidence (background incidence) is taken into consideration when conducting vaccine safety evaluations.

A vaccine adverse event is an adverse health event or other outcome or event (e.g., a medical error) occurring in temporal association with a vaccination. CDC monitors all VAERS data and can take into consideration incident versus prevalent conditions when information is available in the report, as well as biologically plausible risk intervals for symptom onset of the adverse event following vaccination. VAERS is a spontaneous reporting (passive surveillance) system that accepts all reports regardless of the plausibility of the vaccine causing the event or the clinical seriousness of the event. VAERS is a signal detection (hypothesis generating) system and is not designed to determine causality.

Many of the individuals I have spoken to have said that they either did not file a VAERS report because they were told it was pointless, or they asked their doctor to file one and the doctor refused or referred them to a different doctor to report it (who then refused or referred them back to the original doctor). I heard this frequently enough to wonder whether tinnitus was underreported in VAERS. How likely might it be that tinnitus is similarly underreported in the healthcare systems involved in VSD? Is there a way to take this into account in analyses of a potential association?

The Vaccine Safety Datalink (VSD) is an electronic health record (EHR)-based system that collects data (in the EHR) on patients with health insurance when they receive healthcare. This is one of the main differences between passive surveillance in VAERS and active surveillance in VSD; VAERS depends upon people filing reports, while in VSD, a diagnosis of tinnitus would be recorded in the EHR during a patient visit as part of standard healthcare practice.VSD data are not impacted by the types of reporting biases inherent to VAERS.

Is there any possibility that the CDC will initiate another study in the future, using VSD again or another data set, to investigate tinnitus as a potential AE correlated with any of the COVID-19 vaccines? Or is the matter considered settled? Why or why not?

CDC will continue to monitor COVID-19 vaccine safety in VAERS, VSD, and other systems. If we observe data that indicates a potential safety problem we will further investigate. Additional assessments of safety signals may include epidemiologic studies if appropriate.

It seems statistically possible that a condition that has a naturally high prevalence in the general population (as tinnitus does) but is very rare as a vaccine adverse event could easily be missed as a true signal by traditional VSD analysis methods. How, if at all, have CDC safety researchers accounted for this possibility. (I'd wager that tinnitus is likely the most common condition that's ever been considered as a serious AE, which would make it fairly unique among presumptive AEs.)

Please refer to our original response and the above response to your question on common conditions. Other relatively common conditions have been evaluated in vaccine safety research, such as febrile seizure and shoulder injury. While tinnitus prevalence in the general population is relatively high, the incidence of new onset tinnitus is a different concept.

VSD uses TreeScan data mining methods, which can detect pattens of clustering of diagnoses in a post-vaccination observation period, even if few diagnoses are made (because the diagnosis is rare). To date, VSD TreeScan data mining has not observed clustering of tinnitus in a post-vaccination observation period.

Thanks,
Martha

From: Tara Haelle (b)(6)
Sent: Thursday, September 29, 2022 5:31 AM
To: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Subject: Re: FW: National Geographic interview request - AEs from COVID vaccines

Hi Martha,
I wanted to check in on the status of the questions I sent, and I had some additional questions that arose in the process of my reporting on this story. Those additional questions are below. I certainly realize this will extend the time Dr. Shimabukuro needs to respond to my questions.

6) The WHO identified tinnitus as having a signal with the adenovirus vector vaccines (see attached), and the European Medicines Agency listed tinnitus as a possible side effect from the adenovirus vector vaccine, but the CDC has not. Can you comment on why the CDC has not followed the WHO's and EMA's lead on this and why an association would be seen with adenovirus vector vaccines?

7) When the CDC did their investigation into any associations between tinnitus and vaccination, did that analysis only look at a binary association (tinnitus did/did not occur within 90 days after vaccination), or did the analysis look at temporal patterns within that 90-day period (ie, whether there was a clustering of tinnitus reports within a shorter time period post-vaccination vs tinnitus reporting that was consistently spread out across the 90 days)?

8A) Tinnitus in the general population nearly always follows the same pattern as gradual hearing loss, with an estimated 90% of people who have tinnitus also having hearing loss. When

the CDC did their analysis of tinnitus and COVID-19 vaccines, did that analysis also look at whether the people who reported tinnitus also had concurrent hearing loss?
8B) In the WHO report, only 15% of those who reported tinnitus also had hearing loss, suggesting that their tinnitus was distinct from the "usual" tinnitus that develops in the general population. Another unpublished analysis of data looking at tinnitus and COVID-19 vaccines similarly found that a very low percentage of people who experienced tinnitus after the vaccination also had hearing loss. Can you comment on whether this information might strengthen the potential possibility of an association between tinnitus and COVID-19 vaccines?

Thank you,
Tara

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Books: Vaccination Investigation, The Informed Parent, various children's titles

On Thu, Sep 22, 2022 at 2:13 PM Tara Haelle (b)(6) wrote:
Thank you.

These are incredibly tough, strange times. Feeling awful and frustrated you can't "snap out of it?" Read this. If you're thinking of hurting yourself, please call the Suicide Hotline at 1-800-273-8255 or text 741741. You matter.

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On Thu, Sep 22, 2022 at 11:56 AM Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov> wrote:
Hi Tara:

Dr. Shimabukuro will look at these, but he will not have time to get back to you until next week.
Thanks for your patience,
Martha

Martha Sharan
Public Affairs
CDC/Division of Healthcare Quality Promotion
Off.: 404-639-2683
Cell: 404-998-1787

From: Tara Haelle (b)(6)
Sent: Thursday, September 22, 2022 2:31 AM
To: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Subject: Re: FW: National Geographic interview request - AEs from COVID vaccines

Martha,
Thank you for this. Is that VSD analysis published somewhere? If so, could you share the citation with me? Meanwhile, I've adjusted some of the questions below, including the order of them.

Thanks,
Tara

—A recent paper by Harpaz et al (doi: 10.1007/s40264-022-01186-z) suggests a strong association exists in VAERS reports for tinnitus and each of the three COVID-19 vaccines initially authorized by the FDA, but that the association is masked because of the high number of overall reports. Is this something that the CDC safety researchers have considered and/or that they are looking into?

—One of the challenges of considering tinnitus as a presumptive AE is that it is so common as a background condition in the general population. Does a condition's prevalence in the general population affect how CDC safety researchers consider potential associations from AEs reported in VAERS? Would shortening the time after vaccination that they looked for an association be likely to change any likelihood of finding an association?

—Many of the individuals I have spoken to have said that they either did not file a VAERS report because they were told it was pointless, or they asked their doctor to file one and the doctor refused or referred them to a different doctor to report it (who then refused or referred them back to the original doctor). I heard this frequently enough to wonder whether tinnitus was underreported in VAERS. How likely might it be that tinnitus is similarly underreported in the healthcare systems involved in VSD? Is there a way to take this into account in analyses of a potential association?

—Is there any possibility that the CDC will initiate another study study in the future, using VSD again or another data set, to investigate tinnitus as a potential AE correlated with any of the COVID-19 vaccines? Or is the matter considered settled? Why or why not?

—It seems statistically possible that a condition that has a naturally high prevalence in the general population (as tinnitus does) but is very rare as a vaccine adverse event could easily be missed as a true signal by traditional VSD analysis methods. How, if at all, have CDC safety researchers accounted for this possibility. (I'd wager that tinnitus is likely the most common condition that's ever been considered as a serious AE, which would make it fairly unique among presumptive AEs.)

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Books: Vaccination Investigation, The Informed Parent, various children's titles

On Wed, Sep 21, 2022 at 2:52 PM Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov> wrote:
Hi Tara:
CDC now has a statement that I am including below – not sure if this will have an impact on your list of questions. Let me know if you need to adjust any of them:

> CDC is aware of reports to the Vaccine Adverse Event Reporting System (VAERS) of tinnitus occurring in temporal association with COVID-19 vaccination (i.e., following vaccination). Tinnitus is a common condition and heterogenous in clinical presentation and course. There are some established risk factors, such as exposure to loud noise; however, in many cases, no discernable cause for tinnitus is identified.
>
> Hundreds of millions of people have received COVID-19 vaccinations under the most intensive monitoring in U.S. history. Because so many people have been vaccinated and because tinnitus is so common in the population, temporally-associated cases are expected, with some expected to occur shortly after vaccination. To further evaluate concerns about reports of tinnitus following COVID-19 vaccination, CDC conducted an analysis in the Vaccine Safety Datalink (VSD). Unlike VAERS, which relies primarily on voluntary reports from healthcare providers, patients, and others, the VSD uses data from electronic health records. Consequently, the VSD data are less likely to be affected by the reporting biases and other biases that impact spontaneous reporting patterns to VAERS and data quality. The VSD looked for clustering of tinnitus diagnoses in COVID-19 vaccinated patients during a post-vaccination observation period out to

70 days after vaccination. In the VSD's patient population of approximately 12 million people with 6.6 million COVID-19 vaccine doses administered, to date no clustering of tinnitus diagnoses has been observed post-vaccination.

Currently, the information from vaccine safety monitoring systems does not suggest a link between COVID-19 vaccination and tinnitus. CDC will continue to monitor the safety of COVID-19 vaccines and continue to evaluate the outcome of tinnitus as additional data are collected.

Thanks,
Martha

Martha Sharan
Public Affairs
CDC/Division of Healthcare Quality Promotion
Off.: 404-639-2683
Cell: 404-998-1787

From: Tara Haelle (b)(6)
Sent: Wednesday, September 21, 2022 3:27 PM
To: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Subject: Re: FW: National Geographic interview request - AEs from COVID vaccines

Hi Martha,
It took me a while to pull these questions together because most of my questions will depend on the answers he gives to the first questions. In other words, I'm almost certainly going to have follow-up questions in response to these because of the nature of the questions. I've tried to include that in these questions, but I wanted to give you a heads up about likely having follow-up questions. If it's at all possible to set up a phone or Zoom interview, that would be far preferable given the challenging nature of discussing adverse effects and vaccines and nuance required in those discussions.

Please let me know when Dr. Shimabukuro will be able to respond to these. If it's possible by the end of this week, that would be particularly helpful.

Thank you,
Tara Haelle

—Has the CDC investigated the potential association between tinnitus and COVID-19 vaccines? If so, can you tell me what the CDC vaccine safety researchers have done and found? Or, if not, can explain the reasoning behind that decision?

—One of the challenges of considering tinnitus as a presumptive AE is that it is so common as a background condition in the general population. Does a condition's prevalence in the general population affect how CDC safety researchers consider potential associations from AEs reported in VAERS?

—Does the CDC have plans to initiate a case control or other epidemiological study, using VSD or another data set, to investigate tinnitus as a potential AE correlated with any of the COVID-19

vaccines? Why or why not?

—A recent paper by Harpaz et al (doi: 10.1007/s40264-022-01186-z) suggests a strong association exists in VAERS reports for tinnitus and each of the three COVID-19 vaccines initially authorized by the FDA, but that the association is masked because of the high number of overall reports. Is this something that the CDC safety researchers have considered and/or that they are looking into?

– –

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Journalist, author, public speaker & AHCJ Medical Studies Core Topic Leader
Books: Vaccination Investigation, The Informed Parent, various children's titles

On Thu, Sep 1, 2022 at 7:24 AM Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov> wrote:
Hi Tara:
Your request was forwarded to me. I work closely with Dr. Shimabukuro on media inquiries.
Would it be possible for you to send us a list of questions that you would like him to address. It would be easier for him to respond in writing.

Thanks,
Martha

Martha Sharan
Public Affairs
CDC/Division of Healthcare Quality Promotion
Off.: 404-639-2683
Cell: 404-998-1787

From: Tara Haelle (b)(6)
Sent: Wednesday, August 31, 2022 6:32 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Subject: National Geographic interview request - AEs from COVID vaccines

Hello Dr. Shimabukuro,
I'm not sure if you remember me, but I believe we met while I was on a CDC fellowship for AHCJ a number of years ago. I've been writing about vaccines for more than a decade, and I'm now writing an article for National Geographic about whether there is adequate evidence to determine whether tinnitus could be a potential adverse event linked to any of the COVID-19 vaccines.

I spoke with Patsy Stinchfield, and she mentioned you would be a good source on this since I have questions about the CDC's process in going through VAERS reports and determining what to further investigate using VSD or other epi studies.

Would you have time for an interview this week or next to discuss this topic for my article?

Thank you,
Tara Haelle

P.S. I realize discussing vaccine AEs with a reporter can be a precarious decision, so please feel free to contact others who might vouch for my credibility and reliance on the evidence, such as Dan Salmon, Paul Offit, Patsy Stinchfield, Walter Orenstein, Bruce Gellin, or Saad Omer, all of whom are familiar with me and my work.

– –

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From: Sharan, Martha (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 7 Feb 2023 20:05:58 +0000
To: Tara Haelle
Subject: FW: CDC Response - National Geographic interview request - AEs from COVID vaccines
Attachments: Dorney et al._2022.pdf

Tara… please see enclosed document.

Martha Sharan
Public Affairs
CDC/Division of Healthcare Quality Promotion
Off.: 404-639-2683
Cell: 404-998-1787

Dear Ms. Haelle,

CDC continues to monitor the safety of COVID-19 vaccines and has not observed any changes in patterns or any new findings for tinnitus. You might consider talking to the authors of a fairly recently published article on prevalence of new-onset tinnitus following vaccination (attached). This study used a large electronic heath record database and is not subject to many of the limitations of anecdotal/spontaneous reports and small clinical assessments. CDC was not involved in this work and cannot comment on it and that's why we suggest you might want to speak to the authors directly.

From: Tara Haelle (b)(6)
Sent: Monday, February 6, 2023 2:12 AM
To: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Subject: Re: CDC Response - National Geographic interview request - AEs from COVID vaccines

Hi Martha and Dr. Shimabukuro,
We are looking to publish the article at National Geographic on tinnitus as a possible/presumptive adverse event of COVID vaccines this week. The story was put on hold while I was out of the country from the holidays through January. I wanted to check in to see if you had any additional information for me regarding CDC's progress on investigating this issue since we last corresponded. If it's at all possible to speak with Shimabukuro in the next few days before it's published, please let me know.

Thank you,
Tara Haelle

Tara Haelle • @tarahaelle • @tarahaelle@mastodon.social

Pronouns: She/Her • 817.458.8133 CST (no PR calls please)
tarahaelle.net
Journalist, author, public speaker & AHCJ Medical Studies Core Topic Leader
Books: Vaccination Investigation, The Informed Parent, various children's titles

On Mon, Nov 14, 2022 at 9:11 AM Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov> wrote:
Hi Tara – unfortunately I don't have any more information to share at this time.

Martha Sharan
Public Affairs
CDC/Division of Healthcare Quality Promotion
Off.: 404-639-2683
Cell: 404-998-1787

From: Tara Haelle (b)(6)
Sent: Thursday, November 10, 2022 11:22 PM
To: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Subject: Re: CDC Response - National Geographic interview request - AEs from COVID vaccines

Thank you! Do you know if it's possible to find out the precise methodology that the ISO is using for the VSD analysis?

Thanks,
Tara

– –

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On Thu, Nov 10, 2022 at 9:31 AM Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov> wrote:
Hi Tara:

Here's what the Immunization Safety Office is telling me:

> At this time, vaccine safety monitoring efforts in CDC have identified no evidence of a causal association between COVID-19 vaccination and tinnitus or other hearing loss.

The VSD analysis is in progress but the Immunization Safety Office can't discuss preliminary findings.

No target date for completion has been given.
Thanks,
Martha

Martha Sharan
Public Affairs
CDC/Division of Healthcare Quality Promotion
Off.: 404-639-2683
Cell: 404-998-1787

From: Sharan, Martha (CDC/DDID/NCEZID/DHQP)
Sent: Thursday, November 10, 2022 9:51 AM
To: Tara Haelle (b)(6)
Subject: RE: CDC Response - National Geographic interview request - AEs from COVID vaccines

Checking on this for you!

Martha Sharan
Public Affairs
CDC/Division of Healthcare Quality Promotion
Off.: 404-639-2683
Cell: 404-998-1787

From: Tara Haelle (b)(6)
Sent: Thursday, November 10, 2022 7:40 AM
To: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Subject: Re: CDC Response - National Geographic interview request - AEs from COVID vaccines

Hi Martha,
I wanted to check back in to see if you had any update on the additional analysis that you mentioned using VSD. Do you know when it will be started, when it will be complete, or when results from it might be available? I need to file my story this week or next, so I'm wondering if I could still briefly speak with Dr. Shimabukuro, especially regarding the specific way CDC conducts its statistical analysis for associations.

Thank you,
Tara

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On Mon, Oct 3, 2022 at 7:56 AM Tara Haelle (b)(6) wrote:
Martha,
Thank you very much for the update. I look forward to hearing more when the analysis is complete.

Thanks,
Tara

—Sent from a buzzing brain probably clumsily dictating to a miniature magical box

****
www.tarahaelle.com
Mob 817.458.8133

On Oct 3, 2022, at 7:53 AM, Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov> wrote:

Hi Tara:
Received word from Dr. Shimabukuro that he would like to delay this interview due to an additional analyses that CDC is going to do in one of the safety monitoring systems known as the Vaccine Safety Datalink (VSD). We may have updated information on tinnitus and he would prefer to hold off until the analysis is completed to avoid giving you outdated information.

I don't have a target date for completion at this time. Dr. Shimabukuro indicated that it would be "relatively soon."
I will try to keep you informed, however, please feel free to check back with me.
Thanks,
Martha

From: Tara Haelle <(b)(6)
Sent: Friday, September 30, 2022 5:31 PM
To: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Subject: Re: CDC Response - National Geographic interview request - AEs from COVID vaccines

Martha,
A Monday interview would be fantastic. Thank you so much. Let me know what time works best. Thanks also for the note about CDC not commenting on non-CDC studies. I'll keep that in mind and adjust my questions accordingly.

Thank you,
Tara

These are incredibly tough, strange times. Feeling awful and frustrated you can't "snap out of it?" Read this. If you're thinking of hurting yourself, please call the Suicide Hotline at 1-800-273-8255 or text 741741. You matter.

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Books: Vaccination Investigation, The Informed Parent, various children's titles

On Fri, Sep 30, 2022 at 7:39 AM Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov> wrote:
Hi Tara – I can try to arrange a short interview on Monday. Dr. Shimabukuro (b)(6) (b)(6) so his schedule will be impossible.

Please note, as a general rule, CDC does not comment on studies/findings that did not involve CDC experts and were conducted outside of the agency.

Thanks,
Martha

From: Tara Haelle (b)(6)
Sent: Friday, September 30, 2022 6:22 AM
To: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Subject: Re: CDC Response - National Geographic interview request - AEs from COVID vaccines

Martha,
Thank you very much for sending these along. In reading the responses, I notice that several of the responses explain things I'm already aware of, such as the difference between incidence and prevalence; the difference between VAERS and VSD; and the substantial limitations of a passive monitoring system like VAERS. (I've reported on vaccine safety for over a decade, so I'm very familiar with all these issues and the CDC's mechanisms.)

I'm not sure if my questions weren't worded well or there was a misunderstanding otherwise, but I have follow-up questions to try to get better clarification on what I was asking. Would it be possible to set up a brief phone call with Dr. Shimabukuro to discuss this issue? It doesn't seem as though email questions are adequate for the level of specificity and nuance I'm seeking for this story. I'm a little different than most reporters in writing about vaccine adverse events because I've reported on them for so long, and I'm very familiar with all the tropes and misconceptions promoted by those who are anti-vaccine or who otherwise are unfamiliar with the specifics of CDC vaccine safety surveillance and research.

Thank you,

Tara Haelle

– –

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On Thu, Sep 29, 2022 at 7:07 AM Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov> wrote:
Hi Tara:
Yes, I have responses from Dr. Shimabukuro, Director, CDC's Immunization Safety Office. I will pass along your additional questions.

Please see below:

> **A recent paper by Harpaz et al (doi: 10.1007/s40264-022-01186-z) suggests a strong association exists in VAERS reports for tinnitus and each of the three COVID-19 vaccines initially authorized by the FDA, but that the association is masked because of the high number of overall reports. Is this something that the CDC safety researchers have considered and/or that they are looking into?**

CDC did not participate in this analysis and recommends that you contact the authors if you have questions about their analysis.

One of the challenges of considering tinnitus as a presumptive AE is that it is so common as a background condition in the general population. Does a condition's prevalence in the general population affect how CDC safety researchers consider potential associations from AEs reported in VAERS? Would shortening the time after vaccination that they looked for an association be likely to change any likelihood of finding an association?

> Per CDC (Principles of Epidemiology | Lesson 3 - Section 2 (cdc.gov)), "Prevalence refers to proportion of persons who have a condition at or during a particular time period, whereas incidence refers to the proportion or rate of persons who develop a condition during a particular time period. So prevalence and incidence are similar, but prevalence includes new and pre-existing cases whereas incidence includes new cases only." For vaccine safety monitoring, we are most concerned with incident cases, or new cases occurring following vaccination. Expected incidence (background incidence) is taken into consideration when conducting vaccine safety evaluations.
>
> A vaccine adverse event is an adverse health event or other outcome or event (e.g., a medical error) occurring in temporal association with a vaccination. CDC monitors all VAERS data and can take into consideration incident versus prevalent conditions when information is available in the report, as well as biologically plausible risk intervals for symptom onset of the adverse event

following vaccination. VAERS is a spontaneous reporting (passive surveillance) system that accepts all reports regardless of the plausibility of the vaccine causing the event or the clinical seriousness of the event. VAERS is a signal detection (hypothesis generating) system and is not designed to determine causality.

Many of the individuals I have spoken to have said that they either did not file a VAERS report because they were told it was pointless, or they asked their doctor to file one and the doctor refused or referred them to a different doctor to report it (who then refused or referred them back to the original doctor). I heard this frequently enough to wonder whether tinnitus was underreported in VAERS. How likely might it be that tinnitus is similarly underreported in the healthcare systems involved in VSD? Is there a way to take this into account in analyses of a potential association?

The Vaccine Safety Datalink (VSD) is an electronic health record (EHR)-based system that collects data (in the EHR) on patients with health insurance when they receive healthcare. This is one of the main differences between passive surveillance in VAERS and active surveillance in VSD; VAERS depends upon people filing reports, while in VSD, a diagnosis of tinnitus would be recorded in the EHR during a patient visit as part of standard healthcare practice.VSD data are not impacted by the types of reporting biases inherent to VAERS.

Is there any possibility that the CDC will initiate another study in the future, using VSD again or another data set, to investigate tinnitus as a potential AE correlated with any of the COVID-19 vaccines? Or is the matter considered settled? Why or why not?

CDC will continue to monitor COVID-19 vaccine safety in VAERS, VSD, and other systems. If we observe data that indicates a potential safety problem we will further investigate. Additional assessments of safety signals may include epidemiologic studies if appropriate.

It seems statistically possible that a condition that has a naturally high prevalence in the general population (as tinnitus does) but is very rare as a vaccine adverse event could easily be missed as a true signal by traditional VSD analysis methods. How, if at all, have CDC safety researchers accounted for this possibility. (I'd wager that tinnitus is likely the most common condition that's ever been considered as a serious AE, which would make it fairly unique among presumptive AEs.)

Please refer to our original response and the above response to your question on common conditions. Other relatively common conditions have been evaluated in vaccine safety research, such as febrile seizure and shoulder injury. While tinnitus prevalence in the general population is relatively high, the incidence of new onset tinnitus is a different concept.

VSD uses TreeScan data mining methods, which can detect pattens of clustering of diagnoses in a post-vaccination observation period, even if few diagnoses are made (because the diagnosis is rare). To date, VSD TreeScan data mining has not observed clustering of tinnitus in a post-vaccination observation period.

Thanks,
Martha

From: Tara Haelle (b)(6)
Sent: Thursday, September 29, 2022 5:31 AM
To: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Subject: Re: FW: National Geographic interview request - AEs from COVID vaccines

Hi Martha,
I wanted to check in on the status of the questions I sent, and I had some additional questions that arose in the process of my reporting on this story. Those additional questions are below. I certainly realize this will extend the time Dr. Shimabukuro needs to respond to my questions.

6) The WHO identified tinnitus as having a signal with the adenovirus vector vaccines (see attached), and the European Medicines Agency listed tinnitus as a possible side effect from the adenovirus vector vaccine, but the CDC has not. Can you comment on why the CDC has not followed the WHO's and EMA's lead on this and why an association would be seen with adenovirus vector vaccines?

7) When the CDC did their investigation into any associations between tinnitus and vaccination, did that analysis only look at a binary association (tinnitus did/did not occur within 90 days after vaccination), or did the analysis look at temporal patterns within that 90-day period (ie, whether there was a clustering of tinnitus reports within a shorter time period post-vaccination vs tinnitus reporting that was consistently spread out across the 90 days)?

8A) Tinnitus in the general population nearly always follows the same pattern as gradual hearing loss, with an estimated 90% of people who have tinnitus also having hearing loss. When the CDC did their analysis of tinnitus and COVID-19 vaccines, did that analysis also look at whether the people who reported tinnitus also had concurrent hearing loss?
8B) In the WHO report, only 15% of those who reported tinnitus also had hearing loss, suggesting that their tinnitus was distinct from the "usual" tinnitus that develops in the general population. Another unpublished analysis of data looking at tinnitus and COVID-19 vaccines similarly found that a very low percentage of people who experienced tinnitus after the vaccination also had hearing loss. Can you comment on whether this information might strengthen the potential possibility of an association between tinnitus and COVID-19 vaccines?

Thank you,
Tara

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Books: Vaccination Investigation, The Informed Parent, various children's titles

On Thu, Sep 22, 2022 at 2:13 PM Tara Haelle (b)(6) wrote:
Thank you.

– –

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On Thu, Sep 22, 2022 at 11:56 AM Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov> wrote:
Hi Tara:

Dr. Shimabukuro will look at these, but he will not have time to get back to you until next week.
Thanks for your patience,
Martha

Martha Sharan
Public Affairs
CDC/Division of Healthcare Quality Promotion
Off.: 404-639-2683
Cell: 404-998-1787

From: Tara Haelle (b)(6)
Sent: Thursday, September 22, 2022 2:31 AM
To: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Subject: Re: FW: National Geographic interview request - AEs from COVID vaccines

Martha,
Thank you for this. Is that VSD analysis published somewhere? If so, could you share the citation with me? Meanwhile, I've adjusted some of the questions below, including the order of them.

Thanks,

Tara

—A recent paper by Harpaz et al (doi: 10.1007/s40264-022-01186-z) suggests a strong association exists in VAERS reports for tinnitus and each of the three COVID-19 vaccines initially authorized by the FDA, but that the association is masked because of the high number of overall reports. Is this something that the CDC safety researchers have considered and/or that they are looking into?

—One of the challenges of considering tinnitus as a presumptive AE is that it is so common as a background condition in the general population. Does a condition's prevalence in the general population affect how CDC safety researchers consider potential associations from AEs reported in VAERS? Would shortening the time after vaccination that they looked for an association be likely to change any likelihood of finding an association?

—Many of the individuals I have spoken to have said that they either did not file a VAERS report because they were told it was pointless, or they asked their doctor to file one and the doctor refused or referred them to a different doctor to report it (who then refused or referred them back to the original doctor). I heard this frequently enough to wonder whether tinnitus was underreported in VAERS. How likely might it be that tinnitus is similarly underreported in the healthcare systems involved in VSD? Is there a way to take this into account in analyses of a potential association?

—Is there any possibility that the CDC will initiate another study study in the future, using VSD again or another data set, to investigate tinnitus as a potential AE correlated with any of the COVID-19 vaccines? Or is the matter considered settled? Why or why not?

—It seems statistically possible that a condition that has a naturally high prevalence in the general population (as tinnitus does) but is very rare as a vaccine adverse event could easily be missed as a true signal by traditional VSD analysis methods. How, if at all, have CDC safety researchers accounted for this possibility. (I'd wager that tinnitus is likely the most common condition that's ever been considered as a serious AE, which would make it fairly unique among presumptive AEs.)

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On Wed, Sep 21, 2022 at 2:52 PM Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov> wrote:
Hi Tara:
CDC now has a statement that I am including below – not sure if this will have an impact on your list of questions. Let me know if you need to adjust any of them:

> CDC is aware of reports to the Vaccine Adverse Event Reporting System (VAERS) of tinnitus occurring in temporal association with COVID-19 vaccination (i.e., following vaccination). Tinnitus is a common condition and heterogenous in clinical presentation and course. There are some established risk factors, such as exposure to loud noise; however, in many cases, no discernable cause for tinnitus is identified.
>
> Hundreds of millions of people have received COVID-19 vaccinations under the most intensive monitoring in U.S. history. Because so many people have been vaccinated and because tinnitus is so common in the population, temporally-associated cases are expected, with some expected to occur shortly after vaccination. To further evaluate concerns about reports of tinnitus following COVID-19 vaccination, CDC conducted an analysis in the Vaccine Safety Datalink (VSD). Unlike VAERS, which relies primarily on voluntary reports from healthcare providers, patients, and others, the VSD uses data from electronic health records. Consequently, the VSD data are less likely to be affected by the reporting biases and other biases that impact spontaneous reporting patterns to VAERS and data quality. The VSD looked for clustering of tinnitus diagnoses in COVID-19 vaccinated patients during a post-vaccination observation period out to 70 days after vaccination. In the VSD's patient population of approximately 12 million people with 6.6 million COVID-19 vaccine doses administered, to date no clustering of tinnitus diagnoses has been observed post-vaccination.
>
> Currently, the information from vaccine safety monitoring systems does not suggest a link between COVID-19 vaccination and tinnitus. CDC will continue to monitor the safety of COVID-19 vaccines and continue to evaluate the outcome of tinnitus as additional data are collected.

Thanks,
Martha

Martha Sharan
Public Affairs
CDC/Division of Healthcare Quality Promotion
Off.: 404-639-2683
Cell: 404-998-1787

From: Tara Haell (b)(6)
Sent: Wednesday, September 21, 2022 3:27 PM
To: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Subject: Re: FW: National Geographic interview request - AEs from COVID vaccines

Hi Martha,
It took me a while to pull these questions together because most of my questions will depend on the answers he gives to the first questions. In other words, I'm almost certainly going to have follow-up questions in response to these because of the nature of the questions. I've tried to include that in these questions, but I wanted to give you a heads up about likely having follow-

up questions. If it's at all possible to set up a phone or Zoom interview, that would be far preferable given the challenging nature of discussing adverse effects and vaccines and nuance required in those discussions.

Please let me know when Dr. Shimabukuro will be able to respond to these. If it's possible by the end of this week, that would be particularly helpful.

Thank you,
Tara Haelle

—Has the CDC investigated the potential association between tinnitus and COVID-19 vaccines? If so, can you tell me what the CDC vaccine safety researchers have done and found? Or, if not, can explain the reasoning behind that decision?

—One of the challenges of considering tinnitus as a presumptive AE is that it is so common as a background condition in the general population. Does a condition's prevalence in the general population affect how CDC safety researchers consider potential associations from AEs reported in VAERS?

—Does the CDC have plans to initiate a case control or other epidemiological study, using VSD or another data set, to investigate tinnitus as a potential AE correlated with any of the COVID-19 vaccines? Why or why not?

—A recent paper by Harpaz et al (doi: 10.1007/s40264-022-01186-z) suggests a strong association exists in VAERS reports for tinnitus and each of the three COVID-19 vaccines initially authorized by the FDA, but that the association is masked because of the high number of overall reports. Is this something that the CDC safety researchers have considered and/or that they are looking into?

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Books: Vaccination Investigation, The Informed Parent, various children's titles

On Thu, Sep 1, 2022 at 7:24 AM Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov> wrote:
Hi Tara:
Your request was forwarded to me. I work closely with Dr. Shimabukuro on media inquiries.
Would it be possible for you to send us a list of questions that you would like him to address. It would be easier for him to respond in writing.

Thanks,
Martha

Martha Sharan
Public Affairs
CDC/Division of Healthcare Quality Promotion
Off.: 404-639-2683
Cell: 404-998-1787

From: Tara Haelle (b)(6)
Sent: Wednesday, August 31, 2022 6:32 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Subject: National Geographic interview request - AEs from COVID vaccines

Hello Dr. Shimabukuro,
I'm not sure if you remember me, but I believe we met while I was on a CDC fellowship for AHCJ a number of years ago. I've been writing about vaccines for more than a decade, and I'm now writing an article for National Geographic about whether there is adequate evidence to determine whether tinnitus could be a potential adverse event linked to any of the COVID-19 vaccines.

I spoke with Patsy Stinchfield, and she mentioned you would be a good source on this since I have questions about the CDC's process in going through VAERS reports and determining what to further investigate using VSD or other epi studies.

Would you have time for an interview this week or next to discuss this topic for my article?

Thank you,
Tara Haelle

P.S. I realize discussing vaccine AEs with a reporter can be a precarious decision, so please feel free to contact others who might vouch for my credibility and reliance on the evidence, such as Dan Salmon, Paul Offit, Patsy Stinchfield, Walter Orenstein, Bruce Gellin, or Saad Omer, all of whom are familiar with me and my work.

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The Laryngoscope

Prevalence of New-Onset Tinnitus after COVID-19 Vaccination with Comparison to Other Vaccinations

Ian Dorney, BS; Lukas Bobak, BS; Todd Otteson, MD, MPH; David C. Kaelber, MD, PhD, MPH

Objective: To investigate how often patients are diagnosed with new-onset tinnitus within 21 days after COVID-19 vaccination in comparison to after three other common vaccinations: influenza, Tdap (tetanus, diphtheria, and acellular pertussis), and polysaccharide pneumococcus.

Methods: The TriNetX Analytics Network, a federated health research network that aggregates the de-identified electronic health record (EHR) data of over 78 million patients, was queried for patients receiving each vaccination. Instances of new-onset tinnitus within 21 days of vaccination were recorded and reported.

Results: Out of 2,575,235 patients receiving a first dose of the mRNA COVID-19 vaccine without any prior tinnitus diagnosis, 0.038% (95% CI: 0.036%–0.041%) of patients had a new diagnosis of tinnitus within 21 days. There was a higher risk of a new tinnitus diagnosis after the influenza vaccine (RR: 1.95, 95% CI: 1.72–2.21), Tdap vaccine (RR: 2.36, 95% CI: 1.93–2.89), and pneumococcal vaccine (RR: 1.97, 95% CI: 1.48–2.64) than after the first dose of the COVID-19 vaccine. There was a lower risk of a new tinnitus diagnosis after the second dose of COVID-19 than after the first dose (RR: 0.80, 95% CI: 0.71–0.91).

Conclusion: The rate of newly diagnosed tinnitus acutely after the first dose of the COVID-19 vaccine is very low. There was a higher risk of newly diagnosed tinnitus after influenza, Tdap, and pneumococcal vaccinations than after the COVID-19 vaccine. The present findings can help to address COVID-19 vaccine hesitancy during the ongoing pandemic.

Key Words: COVID-19 Vaccine, Epidemiology, Tinnitus, Vaccine Adverse Effect.

Level of Evidence: Level 3

***Laryngoscope*, 00:1–4, 2022**

INTRODUCTION

Vaccine hesitancy and fear of adverse effects from the mRNA COVID-19 vaccine are becoming more widespread and represent a significant national health concern. Consequently, the sequelae of the COVID-19 vaccine have been the topic of significant research throughout the COVID-19 pandemic. In recent months, there has been growing interest in tinnitus as a potential adverse effect of the mRNA COVID-19 vaccination. Recent case reports[1–4] describe patients experiencing life-altering tinnitus within days of the COVID-19 vaccination that may be accompanied by impaired hearing, significantly affect a patient's quality of life, and last for months. Post-vaccination otologic symptoms observed within 30 days of COVID-19 vaccination included tinnitus, hearing loss, dizziness, or vertigo.[5,6] Earlier this year, 555 cases of sudden sensorineural hearing loss after COVID-19 vaccination were reported in the North American Vaccine Related Adverse Effects System (VAERS) were investigated and no association was found between sudden sensorineural hearing loss and vaccination.[7] Symptom patterns and potential pathophysiologic mechanisms for post-vaccine tinnitus were discussed in a recent review of over 12,000 cases of tinnitus post-COVID-19 vaccination, reported by the CDC.[8] A 2021 study of national vaccine adverse event databases in Italy and the United Kingdom examining audiovestibular pathologies related to COVID-19 vaccination investigated tinnitus as a possible adverse effect but was unable to control for timing of symptomatology or provide comparisons to other vaccinations.[6] To our knowledge, there has not been a large-scale investigation into the prevalence of new tinnitus diagnoses after the COVID-19 vaccination in comparison to other common vaccinations.

Using a sample size of over 2.5 million patients who received a COVID-19 vaccine, the present study aims to investigate how often episodes of new-onset tinnitus are diagnosed within 21 days after vaccination. The purpose of this investigation is to use population-level data to examine how frequently newly diagnosed tinnitus occurs after COVID-19 vaccination in comparison to other common vaccinations for influenza, Tdap (tetanus, diphtheria, and acellular pertussis), and polysaccharide pneumococcus. The large sample size provides a unique opportunity to

From the School of Medicine (I.D., L.B., T.O.), Case Western Reserve University, Cleveland, Ohio, USA; Department of Otolaryngology-Head and Neck Surgery (T.O.), University Hospitals Cleveland Medical Center, Cleveland, Ohio, USA; Departments of Internal Medicine, Pediatrics, and Population and Quantitative Health Sciences (D.C.K.), Case Western Reserve University, Cleveland, Ohio, USA; and the The Center for Clinical Informatics Research and Education (D.C.K.), The MetroHealth System, Cleveland, Ohio, USA.

Additional supporting information may be found in the online version of this article.

Editor's Note: This Manuscript was accepted for publication on August 14, 2022.

The authors have no funding, financial relationships, or conflicts of interest to disclose.

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Email: ixd84@case.edu

DOI: 10.1002/lary.30395

acquire meaningful data for this likely rare adverse effect. To give a frame of reference for the number of diagnosed tinnitus cases observed after COVID-19 vaccination, large populations of patients receiving other common vaccinations were compared to the mRNA COVID-19 group. These three other vaccination groups were analyzed as secondary outcomes and served as a reference group for the first dose COVID-19 vaccinated group.

MATERIALS AND METHODS

A retrospective cohort design was implemented using the TriNetX Analytics Network, a federated health research network that aggregates the de-identified electronic health record (EHR) data of over 78 million patients across 45 health care organizations (HCOs) within the US. There were 78,058,186 patients with any EHR contained in the US Collaborative Network of the TriNetX platform that was queried for vaccination events. Five patient groups were identified (Supplementary Cohort Criteria):

1. Received First mRNA COVID-19 Vaccine from December 15, 2020 to March 1, 2022
2. Received Second mRNA COVID-19 Vaccine from December 15, 2020 to March 1, 2022
3. Received Influenza Vaccine from January 1, 2019 to December 1, 2019
4. Received Tdap Vaccine from January 1, 2019 to December 1, 2019
5. Received Pneumococcal Vaccine from January 1, 2019 to December 1, 2019

The dates for the COVID-19 vaccinated group span from the first day of vaccine administration in the US to an arbitrary date that gave over a three-week window before the data was collected. The three other common vaccination groups were examined throughout the 2019 year to eliminate the possibility of COVID-19 vaccination within these three groups. Patients with any history of tinnitus before each respective vaccination event were excluded from all groups to more precisely focus on vaccine-related tinnitus and have findings applicable to the vast majority of the population without a history of tinnitus. Notably, the vaccination event was defined as the first time that the patients met the criteria within the time window, meaning that the first dose of the COVID-19 vaccination series was analyzed in the first dose group. The second dose COVID-19 group underwent exactly two recorded vaccination procedures. Because patients in the second dose group were excluded if they had a previous history of tinnitus, patients experiencing diagnosed tinnitus after the first dose were excluded from this population. New-onset tinnitus was defined as an encounter with a diagnosis of tinnitus in patients with no prior history of tinnitus.

Each patient group was indexed to the event of receiving the respective vaccination, and any occurrence of an encounter diagnosis of tinnitus within 21 days of vaccination was recorded. The timeline of 21 days was arbitrarily decided based on the symptomatology described in existing case reports and reviews that suggested acute to subacute onset within hours to days of vaccination.[1–5,8] Because 21 days is the earliest recommended time frame to receive a second dose of the COVID-19 vaccine after receiving the first dose, this timeline also served to exclude tinnitus caused by the second dose while examining the first dose group. The three common vaccinations were selected arbitrarily based on the most common vaccinations administered in the US in an effort to provide applicable comparison groups to the COVID-19 vaccine.

After the total number of diagnosed tinnitus cases were recorded for each of the five vaccination groups, four separate 1:1 propensity score matching procedures were performed using TriNetX's built-in logistic regression model. Full data sets and results of each propensity score matching procedure are provided in the Data S1, including standardized mean differences for each ICD-10 variable before and after matching. Matching was performed between the following groups: second dose COVID-19 vaccine to first dose COVID-19 vaccine (Table S1); influenza vaccine to first dose COVID-19 vaccine (Table S2), Tdap vaccine to first dose COVID-19 vaccine (Table S3); and polysaccharide pneumococcal vaccine to first dose COVID-19 vaccine (Table S4). Matching was performed for each group relative to the first dose COVID-19 vaccine group because our primary outcome was exploring the risk of new-onset tinnitus after the first dose of the COVID-19 vaccination as compared to other common vaccinations. Patients were matched between these groups based on age at vaccination, sex, race, and ethnicity (Supplementary Matching Criteria).

RESULTS

Out of 2,575,235 patients receiving a first dose of the mRNA COVID-19 vaccine without any prior tinnitus diagnosis, 0.038% (95% CI: 0.036%–0.041%) of patients had a new diagnosis of tinnitus within 21 days. Out of 1,477,890 patients receiving a second dose of the mRNA COVID-19 vaccine without any prior tinnitus diagnosis, 0.031% (95% CI: 0.029%–0.034%) of patients had a new diagnosis of tinnitus within 21 days of the second dose. The numbers and percentages of patients in each vaccination group with a new diagnosis of tinnitus are shown in Table I.

After four separate 1:1 propensity score matching procedures based on age at vaccination, sex, race, and ethnicity between patients receiving the first dose of the

TABLE I.
Numbers and Percentages of Patients with a New Encounter Diagnoses of Tinnitus within 21 days After Vaccination.

Vaccination Received	Vaccinated Patients without Any History of Encounter Diagnoses of Tinnitus	Patients with New Encounter Diagnoses of Tinnitus within 21 Days after Vaccination	Proportion with a New Encounter Diagnoses of Tinnitus (%) (95% CI)
First Dose mRNA COVID-19	2,575,235	986	0.038 (0.036–0.041)
Second Dose mRNA COVID-19	1,477,890	465	0.031 (0.029–0.034)
Influenza	1,200,749	745	0.062 (0.058–0.067)
Tetanus and diphtheria (Tdap)	456,306	314	0.069 (0.061–0.077)
Polysaccharide Pneumococcus	153,522	135	0.088 (0.074–0.100)

TABLE II.
Relative Risks for Post Vaccination New Encounter Diagnoses of Tinnitus Compared to the First Dose of COVID-19 Vaccine.

Vaccination Received	Relative Risk for New Encounter Diagnoses of Tinnitus Compared to First Dose COVID-19 Vaccination (after propensity score matching)
First Dose mRNA COVID-19	1
Second Dose mRNA COVID-19	0.80 (95% CI: 0.71–0.91)
Influenza	1.95 (95% CI: 1.72–2.21)
Tetanus and diphtheria (Tdap)	2.36 (95% CI: 1.93–2.89)
Polysaccarhide Pneumococcus	1.97 (95% CI: 1.48–2.64)

COVID-19 vaccine and the four other selected vaccinations, there was a higher risk of a new-onset diagnosed tinnitus after influenza vaccination, Tdap vaccination, and pneumococcal vaccination than after the first dose of the COVID-19 vaccine (Table II). There was a lower risk of a new diagnosis of tinnitus after the second dose of the COVID-19 vaccination series than after the first dose (RR: 0.80, 95% CI: 0.71–0.91). In the comparison for the influenza group, there were 998,991 influenza vaccine patients compared to 1,009,935 first dose COVID-19 vaccine patients, with 720 cases of a new encounter diagnosis of tinnitus in the influenza group and 374 cases of a new encounter diagnosis of tinnitus in the first dose COVID-19 group (RR: 1.95, 95% CI: 1.72–2.21). In comparison to the Tdap group, there were 444,708 Tdap vaccine patients compared to 444,721 first dose COVID-19 vaccine patients, with 314 cases of a new encounter diagnosis of tinnitus in the Tdap group and 133 cases of a new encounter diagnosis of tinnitus in the first dose COVID-19 group (RR: 2.36, 95% CI: 1.93–2.89). In the comparison for the polysaccharide pneumococcal vaccine group, there were 153,344 pneumococcal vaccine patients compared to 154,825 patients who received first dose of COVID-19 vaccine, with 132 cases of a new encounter diagnosis of tinnitus in the pneumococcal group and 79 cases of a new encounter diagnosis of tinnitus in the first dose of COVID-19 group (RR: 1.97, 95% CI: 1.48–2.64). In the comparison for the second dose of COVID-19 group, there were 1,516,282 patients who received second dose of COVID-19 vaccine compared to 1,516,282 patients who received first dose COVID-19 vaccine, with 465 cases of a new encounter diagnosis of tinnitus in the second dose COVID-19 group and 577 cases of a new encounter diagnosis of tinnitus in the first dose of COVID-19 group (RR: 0.80, 95% CI: 0.71–0.91).

DISCUSSION

In this retrospective cohort study examining over 2.5 million patients receiving a first dose of the mRNA COVID-19 vaccine, there was a low rate (0.038%, 95% CI: 0.036%–0.041%) of a new encounter diagnosis of tinnitus within 21 days of vaccination. After matching similar patients between COVID-19 vaccination groups, the likelihood of having a new encounter diagnosis of tinnitus was lower after the second dose of the COVID-19 vaccine than after the first dose (RR = 0.80, 95% CI: 0.71–0.91). This finding may suggest that patients with a predisposition to vaccine-related tinnitus may be more vulnerable after the first dose than after the second dose, or that the first dose provokes an inflammatory response more likely to cause tinnitus. There was a higher risk of a new encounter diagnosis of tinnitus after the influenza vaccine, Tdap vaccine, and polysaccharide pneumococcal vaccine than after the first dose of COVID-19 vaccination. It is important to consider that while the risk of a new encounter diagnosis of tinnitus was higher after these three common vaccinations than after the first dose of COVID-19 vaccination, the rates of a new encounter diagnosis of tinnitus for each of these groups were extremely low (≤0.1% in each of these groups). With such low rates of a new encounter diagnosis of tinnitus after each vaccination, consideration should be given to the baseline risk of developing a new encounter diagnosis of tinnitus independent of any vaccine. However, the lower risk of a new encounter diagnosis of tinnitus after the COVID-19 vaccination than the other three common vaccinations is not obviously explained by a difference in baseline risk between patient groups. The differences in tinnitus based on vaccinations may be due to different patterns of inflammation invoked by each vaccine or may be explained by uncontrolled variables.

In the discussion of post-COVID-19 vaccination tinnitus, the risk of a new tinnitus encounter diagnosis following COVID-19 infection should be considered. COVID-19 infection, like many other viral infections, has been shown to be associated with audiological and vestibular pathologies.[9,10] A recent meta-analysis of COVID-19 infection symptomatology found tinnitus as a statistically significant side effect of infection.[11] Multiple case reports[12–14] and reviews[15,16] describe tinnitus as a direct symptom of COVID-19 infection, likely secondary to systemic inflammation. Pathophysiological explanations posit cochleovestibular inflammation, the cross-reaction of immune cells to inner ear antigens, and endothelial dysfunction leading to microvascular damage of the inner ear as explanations for the significant audiovestibular sequela of COVID-19 infection.[14] Given the current body of evidence, tinnitus is more clearly causally linked to COVID-19 infection than to COVID-19 vaccination, and the risk of developing tinnitus after the vaccine is likely lower than after the infection prevented by the vaccine.

The present findings should not be used to discourage the administration of common vaccinations but rather serve as an impetus for further exploration into mRNA vaccine side effects. When provided with evidence of low incidences of adverse effects of the vaccine, patients may be more likely to consider being vaccinated.[17] The present findings do not speak to the severity of tinnitus or the long-lasting effects of post-vaccination tinnitus, but provide important information on how often patients are diagnosed with tinnitus subacutely after vaccination on a large population level. With the advent of mRNA vaccination in humans occurring on such a widespread scale, the complications of the vaccine should be researched thoroughly and medical providers should be up to date on the prevalence of adverse events for patient

discussion and education. The rate of diagnosed new-onset tinnitus seen in this investigation provides valuable clinical information for medical providers talking to patients with fear of the vaccine or vaccine hesitancy. The present findings provide evidence for medical providers to answer patient questions about the risk of tinnitus after vaccination.

There are limitations to this population-level study with such a large EHR data set. Notably, undiagnosed or uncoded tinnitus is not included and may be better studied with a smaller cohort and direct researcher oversight. This study excluded patients with any encounter diagnosis history of tinnitus in an effort to focus on vaccine-related tinnitus, which excludes information about the reactivation of tinnitus symptoms by vaccination. Additionally, this study did not separate the specific formulations of the COVID-19 vaccine. The timeline of 21 days was arbitrarily decided based on preliminary research and case reports and could potentially miss late-onset cases of tinnitus if too short or include unrelated events if too long. The common vaccination groups were studied throughout 2019 as opposed to the COVID-19 group, which was examined from 2020 to 2022, and widespread hesitation to present to the hospital during the pandemic could have masked cases of tinnitus post-COVID-19 vaccination.[18] However, it has been posited that the emotional burden widely experienced during pandemic lockdowns increased the perceived loudness of tinnitus[19] and may have increased the perception of otherwise subclinical tinnitus symptoms. Hearing outcomes from episodes of tinnitus were not examined in this study as they are not easily quantifiable from our data set but serve as an important direction for further research.

CONCLUSION

The rate of newly diagnosed tinnitus within 3 weeks of the first dose of COVID-19 vaccination is very low. Patients are more likely to develop a new encounter diagnosis of tinnitus after the three other common vaccinations for influenza, Tdap, and pneumococcus than after the first dose of the COVID-19 vaccine. The results of this study will be valuable to medical providers providing patient education about the COVID-19 vaccine, addressing vaccine hesitancy in the ongoing pandemic, and researching the side effect profile of mRNA vaccinations.

BIBLIOGRAPHY

1. Canales Medina M, Ramirez GM. Tinnitus, sudden sensorineural hearing loss, and vestibular neuritis as complications of the Astra Zeneca COVID-19 vaccine. *Cureus*. 2022;14(1):e20906. https://doi.org/10.7759/cureus.20906.
2. Parrino D, Frosolini A, Gallo C, De Siati RD, Spinato G, de Filippis C. Tinnitus following COVID-19 vaccination: report of three cases. *Int J Audiol*. 2021;13:1-4. https://doi.org/10.1080/14992027.2021.1931969.
3. Tseng PT, Chen TY, Sun YS, Chen YW, Chen JJ. The reversible tinnitus and cochleopathy followed first-dose AstraZeneca COVID-19 vaccination. *QJM*. 2021;114(9):663-664. https://doi.org/10.1093/qjmed/hcab210.
4. Finsterer J, Edmonds R. Persisting, unilateral tinnitus 22 days after first dose of an mRNA-based SARS-CoV-2 vaccine. *J Family Med Prim Care*. 2022;11(6):3330-3332. https://doi.org/10.4103/jfmpc.jfmpc_1927_21.
5. Wichova H, Miller ME, Derebery MJ. Otologic manifestations after COVID-19 vaccination: the house ear clinic experience. *Otol Neurotol*. 2021;42(9):e1213-e1218. https://doi.org/10.1097/MAO.0000000000003275.
6. Ciorba A, Bianchini C, Caranti A, Skarżyński PH, Pelucchi S, Hatzopoulos S. Incidence of audiological adverse effects induced by COVID-19 vaccines: a preliminary study. *Ear Nose Throat J*. 2021;0145561321104898. https://doi.org/10.1177/01455613211048975.
7. Formeister EJ, Wu MJ, Chari DA, et al. Assessment of sudden sensorineural hearing loss after COVID-19 vaccination. *JAMA Otolaryngol Head Neck Surg*. 2022;148(4):307-315. https://doi.org/10.1001/jamaoto.2021.4414.
8. Ahmed SH, Waseem S, Shaikh TG, et al. SARS-CoV-2 vaccine-associated-tinnitus: a review. *Ann Med Surg*. 2022;75:103293. https://doi.org/10.1016/j.amsu.2022.103293.
9. Viola P, Ralli M, Pisani D, et al. Tinnitus and equilibrium disorders in COVID-19 patients: preliminary results. *Eur Arch Otorhinolaryngol*. 2021;278(10):3725-3730. https://doi.org/10.1007/s00405-020-06440-7.
10. Kaliyappan K, Chen YC, Krishnan Muthaiah VP. Vestibular Cochlear manifestations in COVID-19 cases. *Front Neurol*. 2022;18(13):850337. https://doi.org/10.3389/fneur.2022.850337.
11. Jafari Z, Kolb BE, Mohajerani MH. Hearing loss, tinnitus, and dizziness in COVID-19: a systematic review and meta-analysis. *Can J Neurol Sci*. 2022;49(2):184-195. https://doi.org/10.1017/cjn.2021.63.
12. Daher GS, Nassiri AM, Vanichkachorn G, Carlson ML, Neff BA, Driscoll CLW. New onset tinnitus in the absence of hearing changes following COVID-19 infection. *Am J Otolaryngol*. 2022;43(1):103208. https://doi.org/10.1016/j.amjoto.2021.103208.
13. Chirakkal P, Al Hail AN, Zada N, Vijayakumar DS. COVID-19 and tinnitus. *Ear Nose Throat J*. 2021;100(2_suppl):160S-162S. https://doi.org/10.1177/0145561320974849.
14. Di Mauro P, La Mantia I, Cocuzza S, et al. Acute vertigo after COVID-19 vaccination: case series and literature review. *Front Med*. 2022;6(8):790931. https://doi.org/10.3389/fmed.2021.790931.
15. Ong KMC, Cruz TLG. Otologic and vestibular symptoms in COVID-19: a scoping review. *World J Otorhinolaryngol Head Neck Surg*. 2022;1-10. https://doi.org/10.1002/wjo2.57.
16. Maharaj S, Bello Alvarez M, Mungul S, Hari K. Otologic dysfunction in patients with COVID-19: a systematic review. *Laryngoscope Investig Otolaryngol*. 2020;5(6):1192-1196. https://doi.org/10.1002/lio2.498.
17. Kreps S, Prasad S, Brownstein JS, et al. Factors associated with US Adults' likelihood of accepting COVID-19 vaccination. *JAMA Netw Open*. 2020;3(10):e2025594. https://doi.org/10.1001/jamanetworkopen.2020.25594.
18. Beukes EW, Onozuka J, Brazell TP, Manchaiah V. Coping with tinnitus during the COVID-19 pandemic. *Am J Audiol*. 2021;30(2):385-393. https://doi.org/10.1044/2021_AJA-20-00188.
19. Aydoğan Z, Çinar Satekin M, Ocak E, Tokgoz YS. Effects of the coronavirus disease 2019 pandemic on subjective tinnitus perception. *J Laryngol Otol*. 2022;136(5):410-413. https://doi.org/10.1017/S0022215122000640.

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Sent: Wed, 31 Aug 2022 12:09:13 +0000
To: Sharan, Martha (CDC/DDID/NCEZID/DHQP)
Subject: FW: National Geographic interview request - AEs from COVID vaccines
Attachments: RE: Tinnitus

(b)(6) I'll call you about this when I get back. My understanding is that this activity has (b)(5) so it's a bit tricky.

From: Tara Haell (b)(6)
Sent: Wednesday, August 31, 2022 6:32 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Subject: National Geographic interview request - AEs from COVID vaccines

Hello Dr. Shimabukuro,
I'm not sure if you remember me, but I believe we met while I was on a CDC fellowship for AHCJ a number of years ago. I've been writing about vaccines for more than a decade, and I'm now writing an article for National Geographic about whether there is adequate evidence to determine whether tinnitus could be a potential adverse event linked to any of the COVID-19 vaccines.

I spoke with Patsy Stinchfield, and she mentioned you would be a good source on this since I have questions about the CDC's process in going through VAERS reports and determining what to further investigate using VSD or other epi studies.

Would you have time for an interview this week or next to discuss this topic for my article?

Thank you,
Tara Haelle

P.S. I realize discussing vaccine AEs with a reporter can be a precarious decision, so please feel free to contact others who might vouch for my credibility and reliance on the evidence, such as Dan Salmon, Paul Offit, Patsy Stinchfield, Walter Orenstein, Bruce Gellin, or Saad Omer, all of whom are familiar with me and my work.

– –

These are incredibly tough, strange times. Feeling awful and frustrated you can't "snap out of it?" Read this. If you're thinking of hurting yourself, please call the Suicide Hotline at 1-800-273-8255 or text 741741. You matter.

Tara Haelle • @tarahaelle
Pronouns: She/Her • 817.458.8133 CST (no PR calls please)
tarahaelle.net
Journalist, author, public speaker & AHCJ Medical Studies Core Topic Leader
Books: Vaccination Investigation, The Informed Parent, various children's titles

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 30 Aug 2022 14:24:30 +0000
To: stinc021 University of Minnesota
Cc: Vaccine Safety (CDC)
Subject: RE: Tinnitus

Hi Patsy – See my responses below.

Elaine – Can you look at #1 and see if you can provide a current report count. Thanks.

Tom

From: stinc021 University of Minnesota <stinc021@umn.edu>
Sent: Tuesday, August 30, 2022 8:45 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Subject: Re: Tinnitus

Thanks so much Tom for your quick response. You've outlined the issues as I understand them as well.

Some questions:
1. What is the latest number of VAERS reports, last I read was 15,000? (Again, relatively small considering the denominator) (b)(5)

(b)(5)

2. VSafe has an open comment if I remember correctly if you choose you are not doing well. Are people writing in there? Can we add "ear ringing" to the list of symptoms which could at least give us time frames of onset yet causality would still need to be weeded out? (b)(5)

(b)(5)

3. To temporal vs causal, can CDC set up a study with a control group like vaccinated and unvaccinated with tinnitus visits to ENT in a large enough scale to be meaningful? We would have to have fairly

(b)(5)

4. There are over 1000 people in this support group who have an IRB approved survey of questions but cannot find funding for a study which is increasing their frustration. Does CDC have ability to fund such a survey? Do you know of any researcher who would be interested in taking this on? Similar to #3,

(b)(5)

(b)(5)

Maybe consider adding a comment about tinnitus in an upcoming safety report to ACIP so these folks with compelling stories feel heard.

Thanks Tom.
Best regards,
Patsy

On Tue, Aug 30, 2022 at 07:01 Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov> wrote:
Hi Patsy,

Good to hear from you and I hope you are doing well. We have been receiving reports of tinnitus following COVID-19 vaccination since early in the pandemic and we are aware that there is public concern regarding tinnitus as a potential adverse event. As you point out, the situation is complicated by the fact that tinnitus is so common. By some estimates, up to a quarter of all people will experience tinnitus at some point in their lives. The clinical presentation is varied as are the causes, and in many cases no cause is found. With three-quarters of the U.S. adult population having received at least one COVID-19 vaccination, we anticipate a substantial number of temporally associated tinnitus cases following vaccination, with the possibility of many cases occurring within days or weeks of vaccination by chance alone. The number of reports to VAERS are relatively small given the number of doses administered, but for a common condition like tinnitus in the context of massive amounts of vaccination, VAERS data may not be that helpful.

We have looked in the Vaccine Safety Datalink for clustering of tinnitus diagnoses in a post-vaccination observation period and have not observed any pattern of clustering that would indicate an association. The bottom line is that there is a lack of evidence to support a link between COVID-19 vaccination and tinnitus. I always try to market v-safe when I get a chance, but v-safe is probably not the best system to evaluate tinnitus. There is no pre-specified sign or symptom question for hearing conditions. I hope this helps.

Regards,

Tom

Tom Shimabukuro, MD, MPH, MBA
Captain, U.S. Public Health Service
Director
Immunization Safety Office
Centers for Disease Control and Prevention (CDC)
1600 Clifton Road, MS V18-4, Atlanta, GA 30329

Phone: 404-498-0679, Fax: 404-498-0666
Email: TShimabukuro@cdc.gov

From: stinc021 University of Minnesota <stinc021@umn.edu>
Sent: Monday, August 29, 2022 11:43 PM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Subject: Tinnitus

Hi Tom;
Hope all is well with you.
There is some chatter on Twitter about tinnitus after COVID vaccine and they reached out to a couple of us ACIP members for help.

The primary concern is about the lack of understanding of incidence, causation and treatment and awareness of tinnitus after COVID vaccine. There is also some underlying sentiment that ACIP doesn't care about less common and perhaps less severe AE's like tinnitus. I noted we do care. The challenge is because the background rate is ~ 10%

Journalist Tara Haelle is doing a story on this for Nat Geo as you may know and wants to talk to me Tuesday afternoon. If you have anything on post COVID vaccine tinnitus that you can share with me that would be great. I am emphasizing, among other things, that enrollment in VSafe is so important to help us better understand situations like this.

Thanks. "Talk" to you Thursday and Friday of this week. Feel free to call me if that's easier.
Patsy Stinchfield, MS, CPNP
ACIP Liaison Rep
Cell (b)(6)
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Patricia (Patsy) Stinchfield, RN, MS, CPNP-PC
~Children's Minnesota. Retired Pediatric Nurse Practitioner & Sr. Director, Infectious Disease, Current Honorary Professional Staff
~National Foundation for Infectious Diseases. President
~University of Minnesota, School of Nursing, Affiliate Faculty
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From: Advisory Committee on Immunization Practices (CDC)
Sent: Mon, 13 Feb 2023 19:04:04 +0000
To: NIPINFO (CDC); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Subject: FW: RFI Pfizer Protocol - DHA OIG INTAKE BRANCH
Attachments: DD Form 2949, JOINT INSPECTOR GENERAL ACTION REQUEST - dd2949.pdf

Hi,
Sharing with you in case you need to see it.

Stephanie Thomas
ACIP

From (b)(6)
Sent: Monday, February 13, 2023 12:21 PM
To: Advisory Committee on Immunization Practices (CDC) <acip@cdc.gov>
Subject: Fwd: RFI Pfizer Protocol - DHA OIG INTAKE BRANCH

Hello,
My phone number is: 2 (b)(6) I have suffered from a "functional neurological disorder", optical injuries including glaucoma and binocular dysfunction, tinnitus, 24/7 "migraine" and multiple other malfunctions since getting the Pfizer covid vaccine on December 2020/January 2021. I lost my memory for nearly 2 years. I am just waking up to what hell I have been through and I want to know what/why the Defense Health Agency doesn't seem to have any protocols for the treatment of adverse reactions to the Covid vaccines.
I have zero complaints about my doctors; they have done everything they knew to do and followed the protocols they had available; unfortunately, I now know those protocols don't include anything to do with the initial cause of my condition.
I don't know who, what, where, when, why and how because if I didn't write it it down or take a photo I have lost the knowledge and information.
I'm disgusted. As a federal employee there were at least 1600 other employees who also worked for the Army who filed workers compensation claims. We were citizens who had public trust investigations and security clearances. We were trusted and we should have had the option after being forced to take the vaccine that ruined our lives to be studied by researchers. Yet we were apparently ignored. We filled out the vsafe information. I had no idea what was happening to me. It took 14 months to start finding the problems and 2 years to actually get solutions to where I can remember more than 5 minutes.
This is disgusting and it has been done to us. I see nothing about monitoring children in their development for memory loss. I know what hell that is. If there are children going through what I went through they are not going to learn how to speak. They are not going to be functional and they have parents who are not going to be believed.
I lost my words. I stuttered trying to speak; I couldn't find my words at times to speak simple sentences. If I as an adult could not; how is a child supposed to?
We need help and denying that we exist is sickening. Denying a treatment protocol is even worse. As a DoD beneficiary my doctors can only order the test you and the fda have listed in your published protocols. The lack of a protocol has led to a delay in my treatment which is a TORT lawsuit. Given that I have lost my career and I am bankrupt I can't afford a lawyer to sue. So how about being decent himself beings and start with a list of tests and treatment plans?

---------- Forwarded message ---------
From: (b)(6)
Date: Tue, Jan 31, 2023 at 13:34
Subject: Re: DHA OIG INTAKE BRANCH
To: (b)(6)

Sorry about that. I printed it as a pdf this time.

On Tue, Jan 31, 2023 at 1:30 PM Coleman, David CIV DHA OFC IG (USA) <david.coleman48.civ@health.mil> wrote:
Hello (b)(6)

We have received your DD 2949 to begin inquiry into your reported concern. It was not dated nor signed. Would you be so kind, if possible, to sign your document and send it back to us.

Thank you.

vr/dc

David Coleman
Intake Case Manager, Hotline Branch
Office of the Inspector General
Defense Health Agency
5109 Leesburg Pike, Suite 817
Falls Church, VA 22041
DHHQ - 1M211
Cell: (571) 635-5425
Email: david.coleman48.civ@health.mil
DHA HOTLINE: 703.681.9700
DHA HOTLINE: dha.ncr.dir-support.mbx.ig-hotline@health.mil

The OIG mission is to conduct, supervise, monitor, and initiate inspections, execute Hotline program, provide assistance and conduct investigations relating to programs and operations of the DHA OIG mission supports and aligns to (M1 and M4).

Prescribed by: DoDI 5106.04, DoDI 5106.05 **CONTROLLED** when filled

JOINT INSPECTOR GENERAL ACTION REQUEST
Personal and Fraud, Waste and Abuse Complaint Registration

PRIVACY ACT STATEMENT

AUTHORITY: Title 10 U.S.C. 141; DoDD 5106.04; DoDI 5106.05.

PRINCIPAL PURPOSE(S): To secure sufficient information to inquire into the matters presented and to provide a response to the requestor(s) and/or take action to correct deficiencies.

ROUTINE USE(S): Information is used for official purposes within the Department of Defense; to answer complainants or respond to requests for assistance, advice, or information; by members of Congress and other Government agencies when determined by The Inspector General to be in the best interest of the Department of Defense; and, in certain cases, in trial by courts-martial and other military matters as authorized by the Uniform Code of Military Justice. Department of Defense "Blanket Routine Uses" also apply.

DISCLOSURE: Disclosure of personal information is voluntary; however, failure to provide complete information may hinder proper identification of the requestor, accomplishment of the requested action(s), and response to the requestor.

WARNING: Those who knowingly and intentionally provide false statements in this complaint are subject to potential punitive and administrative actions (UCMJ Art. 107; 18 U.S.C. 1001).

1. NAME *(Last, First, Middle Initial)*
(b)(6)

2. GRADE/RANK
GS11-04 Medically Retired

3. SSN *(Optional)*
(b)(6)

4. STATUS *(X as applicable)*

- [ ] MILITARY
  - [ ] Air Force [ ] Army [ ] Navy [ ] Marine Corps
  - [ ] Coast Guard
  - [ ] Active [ ] Reserve [ ] National Guard [ ] Other:
- [x] CIVILIAN
  - [ ] Appropriated Fund [ ] Nonappropriated Fund
  - [ ] Contractor [ ] Foreign or Local National [x] Other:

Spouse and Retired DoD (

5. UNIT IDENTIFICATION CODE (UIC)/ORGANIZATION ADDRESS
Previously
(b)(6)

6. PREFERRED MAILING ADDRESS *(If different from above)*
(b)(6)

7. CONTACT TELEPHONE NUMBER(S) *(Include area code/DSN)*

a. DUTY	b. HOME	c. CELL
		(b)(6)

8. E-MAIL ADDRESS(ES)
(b)(6)

9. SPECIFIC ACTION REQUESTED *(What do you want the IG to do for you?)*

Investigate Covid Vaccination Adverse Reaction issues. Establish standardized guidelines, a research program and protocols for testing individuals who report ongoing adverse reactions post vaccination.

10. INFORMATION PERTAINING TO THIS REQUEST *(Background, list attached documents, who else (commander, agency) you have talked with about this matter, etc.)*

I lost my memory for most of 2021/2022. From my records I contacted patient advocacy and utilized the open door policy at (b)(6)
On January 8 2022 an MRI was ordered with contrast in the Emergency Room for a stroke protocol. The MRI was halted prior to the contrast. I do not have a complaint about that. The problem stems from the fact the computer stated I had an MRI with contrast and every time my PCM (Primary care manager) attempted to order an MRI with contrast someone at Madigan cancelled the request. I want to know who continued to cancel the requests and why they felt it was necessary to over rule my doctor's wishes.
I subsequently ordered and paid out of pocket for my own MRI in December of 2022 and ordered neuro optometrist review who prescribed prism glasses which has greatly improved my quality of life. I believe the delay in obtaining the MRI caused further damage.
1. Politicization of the covid vaccine created problems for individuals seeking treatment for adverse reactions. Despite having a Top Secret Security Clearance when I reported to my PCM in April of 2021 that I had an adverse reaction that was not going away it was not reported or recorded as such. When I requested from my PCM if the adverse reaction was going to be reported to VAERS in June of 2021; the request was denied and I self reported to VAERS. I continued to decline in health.
2. There are / were no standards of testing for vaccine adverse events for individuals with cases that resemble long term covid. Multiple attempts by my doctors to refer me to subject matter experts at the (b)(6) were refused as I had never had covid despite showing the classic symptoms of the disease. I am not anti vaccine. I was ordered to get the vaccine in December of 2020 and I did. I unfortunately got sick on 6 January 2021 and have

11. STATEMENT OF UNDERSTANDING

[x] I do [ ] I do not consent to release my personal information inside official channels in order to resolve the matter(s) listed above.
I understand that if I do not agree to release my personal information, my request for assistance may go unresolved.

a. DATE *(YYYYMMDD)*	b. SIGNATURE	**12. IG/CASE NUMBER** *(Assigned by Joint IG)*
20220131	(b)(6)	

DD FORM 2949, SEP 2(

Reset

From: Bulletin Intelligence
Sent: 13 Feb 2023 07:35:47 -0500
To: HHS@bulletinintelligence.com
Subject: HHS News Briefing for Monday, February 13, 2023
Attachments: HHSNewsBriefing230213.doc

Click to access mobile-optimized online version, including download options and an audio reader.

HHS.gov News Briefing

TO: THE SECRETARY AND SENIOR STAFF

DATE: MONDAY, FEBRUARY 13, 2023 7:30 AM EST

Today's Table of Contents

• Lack Of Contact With Cold Viruses Could Drive Perception Of More Severe Symptoms, Experts Say.
• End Of Public Health Emergency Could Mean Uncertainty For COVID-19 Treatments.
• Microgrants For Community Organizations Proved Effective At Improving COVID-19 Vaccination Rates.
• Epidemiologists Discuss Need For More Research On COVID-19's Impact On Cardiovascular Health.
• CDC Data Show Low Uptake Of Newest COVID-19 Vaccine Booster Correlates With Low Instances Of Severe Disease In Americans Under 65.
• Commentary Criticizes CDC On Masking Recommendations For School Children.
• Former National Security Adviser Calls For Investigation Into COVID-19 Origins.
• HHS Announces Resumption Of Regular Review Policies For Research Projects.
• Iowa Senator Calls For Cessation Of Grants For EcoHealth Alliance.
• Calls For Investigation Into Possible Link Between Tinnitus And COVID-19 Vaccines Mounting.
• COVID-19 Hospital Admissions Hit Two-Month Low In Florida.
• People Claiming Adverse Reactions To COVID-19 Vaccines Struggling To Secure Payments From Federal Program.
• COVID-19 Cases On The Decline In Oklahoma.
• Providers Comment On Impact Of COVID-19 Pandemic On People Struggling With Eating Disorders.
• Commentaries Point To End Of COVID-19 Pandemic Public Health Emergency As Threat To Biden Administration's Student Debt Relief Measure.
• Reuters Finds Claim Moderna Made COVID-19 Vaccines Before Pandemic Began Are False.
• AP: Report That Fauci Wrote COVID-19 Vaccines Don't Work Is False.
• Georgia High School Form On Cardiac Arrest Is Not Related To COVID-19 Vaccinations.
• Claim That CDC Official Admitted COVID-19 Vaccines Cause "Debilitating Illnesses" Is False.

HHS in the News

• FDA Gives Green Light To Limited Health Claims For Some Products Made With Cocoa Powder.
• Coalition Calls For FDA To Rescind Final Guidance On Clinical Decision Support.

• FDA Working On Initiatives To Speed Development Of Medical Countermeasures To Disease Outbreaks.
• Opinion: FDA's Proposed Changes To Blood Donation Rules Will Likely Reduce Stigma For Gay Men.
• CMS Administrator: Medicare Spending Is Something "We Always Have To Look At."
• Opinion: Market-Based Reforms Are Needed To Prevent Collapse Of Medicare, Medicaid.
• NIH Leaders Discuss Medical Wrongs Against Black Community.
• WHO Report Says Eight Nations Eliminated A Neglected Tropical Disease in 2020.
• NCI Increases R01 Payline To 12th Percentile For 2023.
• US Surgeon General Admits 13 Years Old Is "Too Early" To Be Using Social Media.
• HHS Appoints New Director For Office Of Research Integrity.
• CDC Maintains Super Bowl Ad Spot Since 2019.

Overdose Prevention

• Veterinary Tranquilizer Xylazine Worsening US Fentanyl Crisis.
• Harm Reduction Strategies Remain Vastly Underfunded.
• Bipartisan Panel Of Governors Agrees On Ideas To Address Addiction, Fentanyl Crisis.
• Overdose Deaths In NYC Rose From Less Than 1,500 In 2019 To 2,670 In 2021, Data Show.
• Data Show Vast Majority Of People Sentenced For Fentanyl Trafficking Are US Citizens.
• HEALing Communities Study Teams Up With University Of Kentucky To Implement Narcan Kits Across Campus.
• Meth Contamination At Several Colorado Libraries Shines Light On "Silent Epidemic."
• Suicides Continue In New York Prisons, Jails Likely Due To Drug Withdrawal.
• Court Documents Following Student Fentanyl Overdoses Reveal Supplier Lived Blocks Away From Schools.
• New Colorado Legislation Could Allow Supervised Drug Use Sites To Open.
• Gabapentin Finding Its Way Into Maine's Illicit Drug Market.
• Target Dates Set For Ohio Opioid Settlement Distribution.

• University Of Arkansas Develops Smartphone App To Decrease Opioid Cravings, Optimize Medication-Assisted Treatment.
• Opinion: Low-Cost Solution To Reduce Overdose Deaths Is To Tell Physicians when Patients Die.
• Opinion: Public Health Message That "One Pill Can Kill" Needs To Be Spread To Youth.
• Opinion: Compassion, Empathy Should Be At Heart Of Opioid Strike Force.

Mental Illness

• 988 Suicide And Crisis Lifeline Contact, Answer Rates Risen Dramatically Since Launch.
• After Two Year Decline, Suicide Rates Increased Among Younger Americans, People Of Color, CDC Finds.
• Analysis: Biden's Initiatives To Address Youth Mental Health "Promising" If Quick Action Is Taken.
• Study Emphasizes Need For Pediatric Outpatient Mental Health Follow-Up Care.
• Undergraduate Peer Counselors Help Address Increased Number Of Students Seeking Mental Health Counseling.
• New Schizophrenia Drug Xanomeline-Trospium Showing Promise Of Fewer Side Effects.
• Commentary: Using Ketamine To Treat Depression Does Not Help Everyone.

Healthcare Fraud

• Centene Agrees To Pay Medi-Cal $215M To Settle Overcharging Allegations.

Prescription Drug Pricing

• Generic Drugmakers Likely To Benefit From IRA Drug Pricing Laws.
• Opinion: Senator Hawley's Proposed Insulin Cap Legislation Will Make Quality Healthcare Unaffordable.

Health Care & Insurance Reform

• Maryland Officials, Advocates Touting Program Which Allows Residents To Enroll In Healthcare Coverage Through Tax Returns.
• Kaiser Permanente Reports Loss Of $4.47B In 2022 Amid Rising Costs.
• Despite Another Year With Net Loss, Oscar Health Optimistic For Growth In 2023.
• Providers Preparing To Use Misoprostol Alone If Lawsuit Over FDA Approval Of Mifepristone Proves Successful.

• Abortions Occurring Later Due To Increased Demand From Out-Of-State Patients.
• Maryland Governor, Dems Unveil Measures Which Seek To Expand Protections For Reproductive Rights.
• GOP Legislators Attempting To Bypass DAs Who Refuse To Prosecute Violations Of Abortion Bans.
• Abortion Rights Groups, Dems In Colorado Working On Legislation To Regulate Crisis Pregnancy Centers.
• Oklahoma Senate Panel Advances Measures Which Outline Legal Abortion.
• Lawsuit Alleges Security Guards At National Archives Ordered Anti-Abortion Advocates Not To Display Pro-Life Slogans.
• Almost 70% Of Americans Dissatisfied With Abortion Policies, Poll Finds.
• Company Has Been Trying For Years To Expand US Women's Access To Birth Control Pills.
• Columnist Criticizes Judge Presiding Over Lawsuit Challenging FDA Approval Of Abortion Drug.

Health Information Technology

• Editorial Commends FTC For Fining GoodRx Over HIPAA Breach.

Human Services News

• Biden Administration Credits New Migration Programs For Drop In Border Crossings.
• Migrants Looking For US Sponsors Encounter "Underground Market."
• Judge Delays Order Setting Schedule Determining When North Carolina Health Officials Must Provide More Accommodations For People With Disabilities.
• Child Care In Philadelphia Costs 22.5% The Median Household Income Per Child.
• Brett Favre Files To Have Welfare Fraud Lawsuit Dismissed.
• Kristof: New Strategies Needed To Teach Children How To Read.
• Opinion: Tax Benefit Parents Use To Offset Child Care Is "Hopelessly Outdated."
• Editorial: Hochul Should Appoint Wheelchair User To MTA Board Vacancy.
• Jeffries Claims "Extreme MAGA" Republicans View Social Security As A "Ponzi Scheme."

Food & Import Safety

• Consumer Reports Says Bindle Brand Water Bottles Pose Potential Risk Of Lead Poisoning.

• Purina Recalls Certain Units Of Dog Food After Two Dogs Exhibit Signs Of Vitamin D Toxicity.

Medicare

• CMS Announces Medicare Rebate Program Under Inflation Reduction Act.
• Republican Senator Warns Medicare, Social Security In Danger Unless Congress Acts Now.
• Biden Has Yet To Be Specific About How He Would Strengthen Social Security And Medicare.
• Biden Aims To Brand Republicans As Extreme On Social Security, Medicare.
• McConnell Piles On To Biden's Criticism Of Rick Scott's Plan To Sunset Medicare, Social Security.
• Advocacy Groups Say CMS' Lack Of Insurance Coverage For New Alzheimer's Drug Is Discriminatory.
• Column: Republicans "Haven't Earned A Whole Lot Of Trust" On Social Security, Medicare.
• Letter: Seniors Can't Afford Benefit Cuts, But Wealthy Can Afford To Pay More.

Medicaid & CHIP

• Biden Administration Begins Approving Medicaid Funds To Be Spent On Food Programs.
• Medicaid Could Be Next Target For Republican Cuts.
• Many States Not Prepared For End Of Automatic Medicaid Enrollment.
• "Influential Group Of Conservative Intellectuals" Back Family Benefits.

Health & Medical News

• Some Scientists Say Biden's Cancer Moonshot Most Likely To Help Already Rich Industry.
• Biden Places Cancer Research At Top Of Unity Agenda.
• Data Indicate So Far This Year, State Legislators Have Introduced 80 Bills Seeking To Limit Access To Gender-Affirming Care.
• Florida Physicians' Board Expands Ban On Gender-Affirming Care.
• Missouri AG Says Provider Should Halt Treatments For Transgender Youth Following Complaint About Alleged Misconduct.
• Nebraska Legislators Mulling Bill That Would Allow Medical Providers To Cite Religious, Ethical Beliefs In Denying Certain Treatments.
• Utah Governor Defends New Law Which Bans Gender-Affirming Care For Minors.

• Chicago-Area Children Staying Longer In Hospitals Due To Shortage Of In-Home Pediatric Nurses.
• Shkreli Urges Judge To Not Hold Him In Civil Contempt For Failure To Provide Information.
• Novartis Expanding Production, Facilities Of Cancer Treatment Radioligand Therapy.
• RedHill Biopharma Exchanges Rights For Top Commercial Drug Movantik To Cancel Debt With HealthCare Royalty Partners.
• Cleveland Clinic Partners With Anixa Biosciences For Triple-Negative Breast Cancer Vaccine Phase 1b Study.
• Spruce Biosciences Raises $53.6M PIPE Deal To Fund Clinical Trials For CAH Drug.
• FDA Recalls Alfia Weight Loss Capsules For Containing A Harmful Drug.
• Sanders To Summon Corporate Executives To Testify Before Congress As Senate Health Committee Chairman.
• FDA Places Partial Hold On Blueprint Medicines Cancer Drug Trial.
• Study Finds Minnesotans Experiencing Homelessness Have Three-Times Higher Death Rate.
• Scientists Frustrated With Chinese Biophysicist's Refusal To Discuss Research On Heritable Genome-Editing Technology.
• Analysis Identifies Highly-Cited Cancer-Genetics Papers With DNA, RNA Sequence Errors.
• Scientists To Publish Entire Genome Of One Human Before End Of 2023.
• Financial Filings Reveal Hospital Oligarchy In Orlando, Florida.
• Transgender Advocacy Group Sues SD Governor, Alleging Contract With State Government Was Terminated Due To Discrimination.
• Opinion: CVS, Walgreens Ventures Into Primary Care Will Not Fix Broken US Healthcare System.
• Sanford, Fairview Agree To Delay Merger Until May 31 Amid Pressure Campaign.
• Kentucky Receives First "Baby Box" Drop Off.
• Lawsuit Seeks Health Monitoring For Residents Potentially Affected By Toxic Train Derailment.
• DOT Investigating Neuralink Over Shipping Methods Of "Contaminated" Devices.
• Women Fear Seeking Treatment For Cervical, Breast Cancer In Kenya Because Of Stigma, Physician Says.

• Highest-Income Black Families At Greater Risk For Maternal, Infant Mortality, Than White Families, Study Finds.
• Opinion: Higher Education Needs To Retire "Weed-Out" Mentality In STEM Fields.
• Opinion: Pregnancy Represents Unique Opportunity To Increase Funding For Women's Health.
• Wildfire Smoke Exposure During Pregnancy Tied To Increased Risk Of Preterm Birth, Study Finds.
• Analysis Identifies Factors That May Explain Differences In Cognitive Ability Among Older Adults.
• Montana Weighs Proposal Allowing Physician Assistants To Practice Unsupervised.
• Louisiana Accidentally Legalized Recreational THC.
• Weak Grip Could Indicate Risk Of Early Death, Study Suggests.
• Federal Government Awards Medical Schools Funding To Integrate Behavioral Health, Primary Care.
• Use Of Telehealth Among Clinicians Treating Patients With OUD Dropped 15%, Survey Finds.
• Editorial: New Mexico Legislators Need To Take Action To Prevent Physicians From Fleeing To Other States.
• Florida Nursing Homes See Surge In Citations.
• Approximately 383K Illinoisans Struggle With Sports Gambling Addiction, Department Of Human Services Says.
• Residents Not Convinced It Is Safe To Return Home After Toxic Train Derailment.
• Exposure To Traffic Noise At Home May Cause Tinnitus, Study Suggests.
• Anti-Tobacco Advocates Support New York Governor's Effort To Ban Flavored Cigarettes.
• Anti-Smoking Advocate Raises Awareness About Risks Of Teen Vaping.
• New Mexico Considers Proposals To Make It Harder To Access Vape, Tobacco Products.
• Connecticut Considers Permitting Cigar Lounges To Sell Liquor.
• City In Tennessee Restricts Smoke, Vape, CBD Shops To Manufacturing Districts.
• North Dakota Refuses To Raise Cigarette Taxes.
• Youth Vaping Increases As Youth Smoking Decreases.
• Wild Ducks Found Dead In Maine Test Positive For Type Of Bird Flu.

• Suburban Detroit Schools Shuts Down After Norovirus Outbreak Sickens Students, Staff.
• "Canadian Horse Disease" Crippled US Cities 150 Years Ago.
• Number Of Mississippi Babies Being Treated For Congenital Syphilis Spikes By 900%.
• Scientists Monitor Possible Danger To Humans As Bird Flu Makes Leap To Mammals.
• CDC: Pediatric Flu Deaths Top 100 For First Time Since Beginning Of Pandemic.
• Some Regions Of US Hit Harder By Norovirus Outbreaks.
• Milwaukee County Identifies Chronic Wasting Disease In Wild Deer.
• Michigan School Shut Down After Students, Staff After Suspected Norovirus Outbreak.
• Pittsburgh-Area Physicians Worried About Effect Of Measles Outbreak In Columbus, Ohio.
• Florida Woman Files Suit Against Maker Of Eyedrops Allegedly Linked To Infections.
• Research Shows Telehealth Improved Equitable Cancer Care Access, Delivery Before COVID-19 Pandemic.
• Study Finds Restrictive Calorie Diet May Extend Life Span.
• Billionaire Bill Ackman Announces Foundation Funding For Controversial Biologist Ousted For Alleged Sexual Misconduct.
• Casino Workers Eagerly Await Hearing On Legislation That Could Prohibit Smoking In Nine Atlantic City Casinos.
• New York Governor's Proposed Menthol Ban, Cigarette Tax Receives Mixed Reactions.
• VA Urges Camp Lejeune Veterans To Apply For Disability, Lawsuits Despite Possible Legal Complications.
• Experts Seek Out Internal, External Cause Behind "TikTok Tics" Phenomenon.
• Opinion: Americans Need To Have More, Pleasurable Sex To Offset Loneliness.

Global Health

• Chinese Health, Family Planning Experts Call For Government Action To Reduce Financial Burden Of Raising Children.
• Over-Priced Child Care Costs Becoming Top UK Political Issue.
• EMA Begins Review Of Decongestant Medicines With Pseudoephedrine Over Safety Concerns.
• WHO Discussing Ending Mpox Global Public-Health Emergency.

• US, South Korea Warn Of New Ransomware Tactics From North Korea Targeting Critical Infrastructure.
• Brazil's Yanomami Health Crisis Drawing People Out Of Isolation.
• More Than 250K Spaniards Protest Healthcare Services In Madrid.
• UK Anti-Smoking Organization Calls For Excise Tax On Disposable Vapes.
• UK Regulatory Body Finds Poisons In Some Fake Vapes.
• Equatorial Guinea Places More Than 200 People In Quarantine After Deaths From Unknown Hemorrhagic Fever.
• Spain Detects Atypical Mad Cow Disease Case, WOAH Says.
• Professor Says "Mass Suicide" Of Japan's Elderly Comment "Taken Out Of Context."

National News

• US Military Shoots Down Unidentified Object Over Lake Huron.
• Comer Defends Oversight Probes As Partisanship Defines Current Congress.
• Whitmer Says Democrats Will Support Biden's Reelection Bid.
• Sununu Says If He Decides To Run, 2024 Bid Would Focus On Bringing "Better Attitude" To Politics.
• Cox Says Republicans Should Nominate A Governor For President.
• DeSantis Must Determine When, How Hard To Hit Back At Trump.
• Brazile: Trump May Regret Announcing 2024 Candidacy So Early.
• All In Together CEO: Haley Faces "High Hurdle" To Securing GOP's 2024 Nomination.
• California Senate Race Taking Shape While Feinstein Has Not Made Her Intentions Known.
• Barnes Reelected As Michigan Democratic Party Chair.
• Kansas Republicans Choose Election Conspiracy Promoter To Lead State Party.
• Lake Delivers Election Denial Message During Visit To Iowa.
• Black Voters In Wisconsin Not Surprised By Revelations Of GOP Election Tactics.
• Kansas City Chiefs Defeat Philadelphia Eagles In Close Super Bowl.
• Celia Cruz To Be First Afro-Latina Depicted On US Quarter.
• Jackson Appoints New Public Works Director Amid Ongoing Water Crisis.
• Advocates Call For Republicans To Become "Aspirational Conservatives."
• Joint Center Board Chair Laments Insufficient Diversity Among Senate Staff Leadership.

Editorial Wrap-Up

• Wall Street Journal.

- Washington Post.
- New York Times.

The Big Picture

- Headlines From Today's Front Pages.

Last Laughs

- Late Night Political Humor.

Leading the News

State AGs File Competing Briefs In Lawsuit Challenging FDA Approval Of Abortion Pill.

The Washington Post (2/11, Kaur, 10.52M) reported GOP "and Democratic attorneys general filed competing arguments on Friday in a heated Texas lawsuit that seeks to reverse the Food and Drug Administration's approval of abortion pills, the most common method to terminate pregnancy in the United States." In an amicus brief, 22 Republican AGs contended that "the FDA 'undermined the public interest' by allowing the medication." For their part, 22 Democratic AGs argued "in court filings that revoking the drug's approval would have 'devastating consequences' for Americans. The clashing briefs are the latest in rising tensions around the case, which could undo the FDA's decades-old approval of mifepristone, the drug used in medication abortions."

Reuters (2/10, Pierson) reported the plaintiffs, "anti-abortion groups including the Alliance for Hippocratic Medicine, claim the U.S. Food and Drug Administration used an improper process to approve the drug mifepristone in 2000, and did not adequately consider its safety." By filing the lawsuit in Amarillo, Texas, the plaintiffs "ensured that the case would go before U.S. District Judge Matthew Kacsmaryk, a reliable conservative and former Christian activist."

The AP (2/10, Whitehurst) reported the lawsuit poses "a threat to the nationwide availability of medication abortion, which now accounts for the majority of abortions in the U.S." Should Kacsmaryk, who was appointed by former President Trump, rule in favor of the plaintiffs, this "could halt the supply of the drug mifepristone in all states, both where abortion is banned and where it remains legal." Mini Timmaraju, president of NARAL Pro-Choice America, said, "It could have an immediate impact on the country. ... In some ways this is a backdoor ban on abortion."

CNBC (2/10, Kimball, 7.34M) reported that NARAL, "in an analysis published Friday, said 40 million women would lose access to the abortion pill if the court overturns the FDA's approval." Also on "Friday, 67 Republican members of Congress filed a brief calling the FDA's approval of mifepristone 'unlawful,' arguing it should be overturned. They claimed that the agency's actions subverted Congress' safeguards for patients." However, "the FDA has had regulations in place for years to monitor the safety of mifepristone, which it has gradually eased as more evidence has come in."

The Hill (2/11, Weixel, 5.69M) reported physicians "and reproductive rights advocates are bracing for a decision in" the lawsuit "that, if successful, could end legal access to abortion pills nationwide." The "pills have become one of the next major fronts in the fight over reproductive health care in the wake of the Supreme Court's decision overturning Roe v. Wade, and the lawsuit is seen by both sides as the start of the battle to come."

Among other news outlets covering the story were NBC News (2/10, Atkins, 4.91M), Forbes (2/10, Durkee, 10.33M), the New York Daily News (2/10, Assuncao, 2.51M), Axios (2/10, Gonzalez, 1.26M), the Portland (ME) Press Herald (2/10, Murphy, 174K), the Washington Times (2/12, Richardson, 626K), and Columbia (SC) State (2/10, Hughes, 330K).

The Secretary in the News

Acting NIAID Director Auchincloss Taking Over Amid Republican Pandemic Probe.

STAT (2/11, Mershon, 262K) reported that the person who replaced Dr. Anthony Fauci as acting Director of the National Institute for Allergy and Infectious Diseases, Dr. Hugh Auchincloss, "a respected transplant surgeon and medical researcher, served for more than 16 years as Fauci's low-key right-hand man at NIAID." Now Fauci's position "--and all the political heat that goes with it – went to Auchincloss" as "the new House Republican majority launches a series of hearings on Covid-19." Auchincloss "is likely to face questions" due to a 2020 email to Fauci, as "some conservatives believe the message indicates that US health officials might have downplayed the possibility" that COVID-19 was created in a Chinese laboratory with US funds. NIH acting Director Dr. Lawrence Tabak, HHS Secretary Xavier Becerra, and CDC Director Dr. Rochelle Walensky are mentioned.

Coronavirus

Other Coronavirus News

FDA Commissioner Blasts "Snake-Oil Salesmen" Who Seized On Damar Hamlin's Collapse.

Bloomberg (2/12, Rutherford, 3.57M) reports behind a paywall, "When Buffalo Bills safety Damar Hamlin collapsed during a National Football League game in January, dozens of Twitter trolls quickly blamed it on Covid-19 shots." FDA Commissioner Robert Califf "said in an interview: 'Snake-oil salesmen' seized on the event.'" The "#diedsuddenly hashtag, which appeared in tweets about the incident, is often used to discredit vaccines by linking them to deaths and injuries without evidence."

New York Allows Mask Mandate For People Inside Healthcare Facilities To Expire.

The New York Times (2/10, Fadulu, 20.6M) reported New York has elected not to renew a requirement for staff and visitors inside healthcare facilities in the state to wear face masks. The change, which took effect today, "brings the state's guidance in line with that of the" CDC as it "lifted the federal mandate requiring masks in health care facilities in September." Currently, "new coronavirus cases in New York have dropped 30 percent in the past 14 days, according to The New York Times's Covid-19 tracker."

The AP (2/10) reported the policy change, announced Thursday, comes as the state's acting Health Commissioner Dr. James McDonald said New York is "moving to a transition" and has access to "safe and effective vaccines, treatments, and more." The decision allows "hospitals, nursing homes, treatment centers and other facilities to enact their own masking rules in accordance with guidance from the" CDC.

Forbes (2/12, 10.33M) contributor Bruce Y. Lee reports advocacy organizations in New York like Mandate Masks NY reacted adversely to the state's decision to lift the mask mandate for healthcare facilities. A Substack post from Mandate Masks NY stated the "decision puts all New Yorkers at risk, particularly people who are at higher risk and the most vulnerable." Additionally, public health experts pointed out that "many healthcare settings can be rather crowded, chaotic, and poorly ventilated" in their arguments for why the decision to let the requirement expire was flawed. Those experts recommend New Yorkers at high

risk of severe disease "pay close attention to whether your healthcare facility will be maintaining face mask requirements despite the state's lifting its mandates."

Among other outlets providing coverage are the New York Post (2/10, Campanile, 7.45M) and the Rochester (NY) Democrat & Chronicle (2/10, Robinson, 410K).

COVID-19 Still Deadly For Older Americans.

The New York Times (2/11, Span, 20.6M) reported on the continued threat that COVID-19 poses to people in the United States 65 years of age and older. To date, "about three-quarters of Covid deaths have occurred in people over 65, with the greatest losses concentrated among those over 75." Additionally, "hospital admissions...remain more than five times as high for people over 70 than for those in their 50s." Part of the issue, infectious disease experts believe, is that "only 40.8 percent of seniors have received a bivalent booster" and "some who have not believe they have strong protection against infection" according to a CDC survey.

Labor Statistics Show Women Are Returning To Workforce At Higher Rate Than Men.

The Washington Post (2/12, A1, Bhattarai, Melgar, 10.52M) reports on women returning to the workforce. "The percentage of working-age women in the labor force has nearly recovered from pre-pandemic levels" and "when compared to the pandemic low point in April 2020, women's labor force participation rates are up by 3.4 percentage points." Both of those statistics are higher than they are for men of the same ages. It's a marked reversal as "the covid downturn was unique in that it took an outsize toll on women...in terms of job losses." Aiding the return to work among women is "employers' increased willingness to offer more remote alternatives to office work" and rising prices for necessities like groceries.

Lack Of Contact With Cold Viruses Could Drive Perception Of More Severe Symptoms, Experts Say.

ABC News (2/11, Egan, 2.44M) reported infectious disease experts' commentary on why people in the United States could be perceiving their cold symptoms as more severe than in previous winters. Such "experts say there is currently no evidence to suggest the viruses that cause cold symptoms are any more severe than they were pre-COVID" but there are some factors possibly behind the perception. Among them is that "people may have forgotten how miserable cold

symptoms can feel after a few years without them" due to a lack of socialization and increased mask-wearing during earlier years of the COVID-19 pandemic. Also, "people who haven't had a cold in a while won't have as much immunity to viruses." The National Institutes of Health state that "there are over 200 known viruses that can cause symptoms of the common cold."

End Of Public Health Emergency Could Mean Uncertainty For COVID-19 Treatments.

Kaiser Health News (2/10, Appleby) reported on potential forthcoming changes to cost structures for COVID-19 test kits, treatments, and vaccines. As the federal government's COVID-19 pandemic public health emergency will end May 11, "time is running out for free-to-consumer covid vaccines, at-home test kits, and even some treatments." For example, "an August blog post" from HHS' "Administration for Strategic Preparedness and Response noted that government-purchased supplies of the drug Paxlovid are expected to last through midyear before the private sector takes over." At that time, it could become unclear "what the companies will charge once government supplies run out." For people on Medicare, coverage of the drug could "be limited until the treatment goes through the regular" Food and Drug Administration process.

Microgrants For Community Organizations Proved Effective At Improving COVID-19 Vaccination Rates.

Kaiser Health News (2/10, Hawryluk) reported on funding for community organizations to improve healthcare outcomes. In Colorado, "when COVID-19 vaccines became available" the state gave grants "to community organizations serving immigrants and minorities." The grants came with ample latitude to spend the funds as the organizations saw fit within the scope of improving vaccination rates among those populations. The approach worked as "over time, disparities in vaccine rates in and around Denver narrowed." Now, "the microgrant approach could well be the future of public health messaging for diverse populations." To further determine the efficacy of the approach, Colorado "has now expanded to include all routine adult vaccinations and is funded through April."

Epidemiologists Discuss Need For More Research On COVID-19's Impact On Cardiovascular Health.

US News & World Report (2/10, Smith-Schoenwalder, 1.91M) reported on the impact of the COVID-19 virus on cardiovascular health. The effects of the virus on the heart are important "to understand as more than 100 million Americans have had COVID-19" and that figure "continues to grow each day with no signs of ceasing." Epidemiologists believe COVID-19 "has both direct and indirect impacts on cardiovascular health" like "new clotting and inflammation" and the potential to cause "issues in other parts of the body that can cause heart damage." Currently, "research on COVID-19's effect on the heart is expanding, but researchers agree that more attention is needed."

CDC Data Show Low Uptake Of Newest COVID-19 Vaccine Booster Correlates With Low Instances Of Severe Disease In Americans Under 65.

CNN (2/10, Cohen, 89.21M) reported that data "indicate that even though a small percentage of people under age 65 have gotten the new Covid-19 booster, people this age are not becoming severely ill" from the virus. CDC data show that "nationally, only about 16% of the population has gotten" the latest COVID-19 vaccine booster "and the rates are especially low for people under 65." At the same time, CDC data also show "about 12% of all Covid deaths in the US have been among people younger than 65." This data could help drive future vaccine policy as the "Food and Drug Administration has proposed a framework for annual Covid vaccinations" and CDC vaccine advisers "are scheduled to meet February 24 to discuss the future of the US Covid-19 vaccination program."

Commentary Criticizes CDC On Masking Recommendations For School Children.

In an op-ed for the Washington Examiner (2/10, 888K), Zachary Faria wrote about recent comments from CDC Director Dr. Rochelle Walensky regarding masking recommendations for school children. Walensky said, "our masking guidance doesn't really change with time" and "what it changes with is disease. So when there's a lot of disease in the community, we recommend that those communities and those schools mask. When there's less disease in the community, we recommend that those masks can come off." Faria argues that "masking did far more damage to children than the virus" as it "was associated with decreases in communication and the development of socialization skills."

Former National Security Adviser Calls For Investigation Into COVID-19 Origins.

The Washington Examiner (2/10, Dunleavy, 888K) reported Trump Administration "national security adviser Matt Pottinger called it 'inexcusable' that there still hasn't been a full investigation into COVID-19's origins." In a piece for the Wall Street Journal, Pottinger and OneSharedWorld founder Jamie Metzl made their case for a more robust inquiry, criticizing Dr. Anthony Fauci and former National Institutes of Health Director Dr. Francis Collins for allegedly planning "to push the public conversation away from the lab-accident hypothesis and toward the natural-origins explanation." Pottinger said while "the malfeasance of China's rulers is the primary reason the international community doesn't have access to" records and data concerning activity at the bat coronavirus lab in Wuhan, "the US could do far more to get to the bottom of what happened."

HHS Announces Resumption Of Regular Review Policies For Research Projects.

Behind a paywall, Bloomberg Law (2/10, Baumann, Subscription Publication, 4K) reported "research institutions must revert to using the same ethics board when collaborating on studies once an exception tied to the Covid-19 public health emergency ends in May" according to an announcement from HHS' Office for Human Research Protections Friday. The regular policy "implements safeguards for research volunteers" and ensures "participants are enrolling voluntarily." HHS had "lifted mandate to use same ethics review board during [the] Covid[-19]" pandemic.

Iowa Senator Calls For Cessation Of Grants For EcoHealth Alliance.

The New York Post (2/11, Vincent, 7.45M) reported US Sen. Joni Ernst (R-Iowa) claims EcoHealth Alliance "continues to receive millions in grants from the US government to do research on viruses." Ernst has already "called on Congress to stop giving out grants to EcoHealth Alliane for 'dangerous' new projects" and lobbied for investigations into their activity regarding a Wuhan laboratory. In 2022, "EcoHealth Alliance received a $653,392 grant from the National Institute of Allergy and Infectious Diseases" under the leadership of Dr. Anthony Fauci which represented "the first installment of a five-years award totaling $3.3 million." Currently, EcoHealth projects include "experiments with bats on the Nipah virus in Bangladesh as well as research into viruses in Thailand, Singapore and Malaysia."

Calls For Investigation Into Possible Link Between Tinnitus And COVID-19 Vaccines Mounting.

National Geographic (2/10, Haelle, 30.3M) reported on evidence which "suggests that there might be a connection between COVID vaccines and rare cases of severe tinnitus." While "the World Health Organization advised investigating whether there's a link between multiple COVID vaccines and tinnitus" last year and "Johnson & Johnson listed it as a possible adverse effect on its US COVID-19 vaccine fact sheet in February 2021," CDC spokesperson Martha Sharan "said the agency has determined it does 'not have sufficient evidence from our surveillance to justify launching an epidemiologic study.'" Regardless, "the CDC has come under criticism from Poland and others who have asked it to study the issue" and "other experts express skepticism that there could be a link between a vaccine and an adverse event that occurs so quickly."

COVID-19 Hospital Admissions Hit Two-Month Low In Florida.

The Palm Beach Post (USA) (2/10, Persaud, 223K) reported on a further decline of COVID-19 hospitalizations and infections in Florida. According to HHS data, there were "19,000 new infections, the fewest since the week ending Dec. 26" in Florida last week. Also, Florida hospitals are currently treating 1,978 patients for symptoms of COVID-19 and this is "the first time since late December" that number has been under 2,000. Additionally, wastewater testing "shows viral levels falling in just about every Florida county where sewage is tested." At the same time, there were "341 more deaths recorded this week, more than twice as high as pre-surge weeks in late October" and November according to the CDC.

People Claiming Adverse Reactions To COVID-19 Vaccines Struggling To Secure Payments From Federal Program.

The Minneapolis Star Tribune (2/10, Olson, 855K) reported on injury claims filed by COVID-19 vaccine recipients in Minnesota. So far, "the federal Countermeasures Injury Compensation Program...has received 11,196 claims related to COVID, including 8,447 related to vaccines" but "only 543 have been resolved." Furthermore, although "19 claims have been declared eligible" for payments due to substantiated damages, none of those claims have actually been paid according to Health Resources and Services Administration records. Part of the problem is that COVID-19 vaccines do not have a federally recognized "list of

vaccine-connected conditions" and without that documentation, claimants must "prove a connection to their illnesses" on a case-by-case basis.

COVID-19 Cases On The Decline In Oklahoma.

The Tulsa (OK) World (2/11, 241K) reported on a remission of respiratory disease infections in Oklahoma. According to data from the CDC and state agencies, "active COVID-19 infections are down nearly 35% in the past month" and "the three-day average for COVID-related ICU patients is down about 50%" over the same period of time. Furthermore, "the seven-day average for new COVID-19 cases reported to state health officials has decreased 36% since the Jan. 12 update." However, "the vast majority of the state continues to be in the red, or high, level for COVID-19 community transmission for the week ending Feb. 4."

Providers Comment On Impact Of COVID-19 Pandemic On People Struggling With Eating Disorders.

The Baltimore Sun (2/10, Roberts, 629K) reported on the impact of the COVID-19 pandemic on people with eating disorders. For such individuals, "the coronavirus outbreak's sudden destruction of eating routines and treatment schedules and the way it amplified stress and isolation were especially devastating." During the first three years of the pandemic, "inpatient stays for eating disorders rose nationwide." That coincided with "emergency department visits for eating disorders" doubling among adolescents. Specialists treating the disorders also shared that they "saw changes in the patient pool" with the people presenting for treatment skewing younger.

Commentaries Point To End Of COVID-19 Pandemic Public Health Emergency As Threat To Biden Administration's Student Debt Relief Measure.

In an op-ed for the Wall Street Journal (2/10, Subscription Publication, 8.41M), Gabriel Rubin wrote the decision to end the federal government's COVID-19 pandemic public health emergency (PHE) could compromise the Biden Administration's plan to cancel student debt. After failing to secure Congressional approval, the Biden Administration exercised expanded powers connected to the PHE to put the plan into motion.

In a column for USA Today (2/10, 12.7M), Ingrid Jacques wrote that "by announcing the end to the" PHE, "Biden is admitting that the flimsy justification for the debt plan is going away." The issue of student debt cancellation "demands

debate in Congress" and "not makeshift responses that skirt the legislative body." Jacques states, "my concern is that the Biden Administration will continue finding excuses to prolong" the PHE "because the president has relied too heavily on this power."

Reuters Finds Claim Moderna Made COVID-19 Vaccines Before Pandemic Began Are False.

Reuters (2/10, Check) reported in a fact-check article that online claims that Moderna CEO Stephane Bancel said in a panel discussion at Davos 2023 that the company "had made 100,000 COVID vaccine doses before the pandemic began" are false. Instead, Reuters says, Bancel "spoke about how quickly the company was able to scale up vaccine production at the start of the COVID-19 pandemic."

AP: Report That Fauci Wrote COVID-19 Vaccines Don't Work Is False.

The AP (2/10, Marcelo) reported that a claim that Dr. Anthony Fauci wrote "in a recent science paper...that COVID-19 vaccines don't work" is false. The AP says the "article's authors say their paper acknowledges current vaccines for respiratory viruses don't prevent all infections, but that they do prevent the most serious symptoms." Fauci and a coauthor "said the article makes the case for exploring new approaches to make respiratory virus vaccines more effective." The article "was written by Fauci and two top officials at the National Institute of Allergy and Infectious Diseases: Jeffery Taubenberger, deputy chief of its infectious disease lab, and David Morens, a senior advisor to the agency's director."

Georgia High School Form On Cardiac Arrest Is Not Related To COVID-19 Vaccinations.

In a fact-check article, USA Today (2/9, 12.7M) reported that a Facebook post claiming a form distributed by the Georgia High School Association "that describes the early warning signs of 'sudden cardiac arrest' and explains what should happen if one occurs" is related to COVID vaccinations is false. The form "is not new, Georgia High School Association spokesperson, Steve Figueroa, told USA TODAY" and dates to 2019.

Claim That CDC Official Admitted COVID-19 Vaccines Cause "Debilitating Illnesses" Is False.

In a fact-check article, the AP (2/10, Tulp) reported that a claim that CDC deputy director Dr. Tom Shimabukuro "admitted that COVID-19 vaccines are causing 'debilitating illnesses'" is false. The AP says the claim "takes [his] comments at the January meeting of the Food and Drug Administration's Vaccines and Related Biological Products Advisory Committee out of context." Shimabukuro's remarks "came during a wider discussion of vaccine safety monitoring in which Shimabukuro was describing accounts in the Vaccine Adverse Event Reporting System, an early warning system kept by the FDA and the CDC to monitor signals of possible side effects from vaccines."

HHS in the News

FDA Gives Green Light To Limited Health Claims For Some Products Made With Cocoa Powder.

NPR (2/12, Aubrey, 3.69M) reports that Barry Callebaut AG Switzerland, which makes chocolate and cocoa products, in 2018 "petitioned the U.S. Food and Drug Administration to allow the use of a health claim on labels, pointing to the link between the consumption of flavanol-rich cocoa and a reduced risk of cardiovascular disease." Early this month, "after an exhaustive review of studies, the FDA has responded." The agency "gave a green light to use certain, limited health claims on products made with high-flavanol cocoa powder." However, it "says there's not enough evidence to support claims on regular chocolate, the kind most of us consume."

Coalition Calls For FDA To Rescind Final Guidance On Clinical Decision Support.

Healthcare IT News (2/10, 2K) reported, "The CDS Coalition is asking the U.S. Food and Drug Administration to pull back on its clinical decision support guidance in order to ensure that the agency better balances its regulatory oversight with the healthcare sector's need for innovation while comporting with the statutory language of the 21st Century Cures Act." Healthcare IT News says "the coalition's stakeholders – clinical decision support software developers, patient advocacy organizations, clinical societies, healthcare providers and healthcare payers – say FDA's guidance exceeds Congress's statutory definitions of what is considered CDS and threatens to undermine lawmakers' goals." The coalition "said in its February 6 petition prepared by Epstein Becker & Green, P.C.: 'The Office of the National Coordinator for Health Information Technology

and the Centers for Medicare and Medicaid Services strongly believe that CDS software will help improve the quality of care, and that innovation must be encouraged in this space.'"

FDA Working On Initiatives To Speed Development Of Medical Countermeasures To Disease Outbreaks.

BioCentury (2/10, Usdin, Subscription Publication) reported behind a paywall that the FDA "is working on two initiatives that have the potential to make drug development and manufacturing more efficient, enhance U.S. competitiveness and increase supply chain resilience." BioCentury says "both projects, the establishment of designation programs for platform technologies and for advanced manufacturing technologies, were tucked inside the 4,155-page omnibus spending bill Congress passed in December." The proposals "were crafted with input from FDA and were informed by the COVID-19 experience, especially imperatives to speed the development of medical countermeasures in the face of infectious disease outbreaks and to reduce reliance on overseas manufacturing facilities."

Opinion: FDA's Proposed Changes To Blood Donation Rules Will Likely Reduce Stigma For Gay Men.

In an opinion piece for the Los Angeles Times (2/11, 3.37M), physician Eric Kutscher wrote, "As a sophomore in college in 2011, I was deferred from donating blood for being a gay man. I was confronting the homophobia built into the FDA's blood donation ban for men who have sex with men. After imposing that rule in 1985 and making a few minor revisions since, the FDA is at long last considering meaningful updates to consider donors based on their sexual behavior regardless of their orientation." Kutscher wrote, "The FDA is clearly trying to create more inclusive and evidence-backed policies. The proposed changes will likely reduce stigma for some Americans and possibly reduce the number of young men who are outed at work and school during blood donation drives. Yet as a doctor, I'm disappointed by the lack of nuance that still exists in the new donation rules – and I hope to see further changes."

CMS Administrator: Medicare Spending Is Something "We Always Have To Look At."

NPR (2/10, 3.69M) reported with a transcript of its Morning Edition program in which the host "speaks with Chiquita Brooks-LaSure, the administrator for the

Centers for Medicare and Medicaid Services, about the future of both programs." During the interview, Brooks-LaSure said Medicare spending is something "that we always have to look at. Every couple of years, it's important for Congress to continue to make adjustments."

Opinion: Market-Based Reforms Are Needed To Prevent Collapse Of Medicare, Medicaid.

In an opinion piece for the Wall Street Journal (2/12, Subscription Publication, 8.41M), former CMS chief Seema Verma writes that, despite President Biden's rhetoric, failure to take action will cause Medicare and Medicaid to collapse. Verma writes that market-based reforms such as value-based care for providers are the solution.

NIH Leaders Discuss Medical Wrongs Against Black Community.

The Atlanta Journal-Constitution (2/10, J. Thomas, 1.46M) reported, "Decades later, the descendants of Black people harmed by medical research in the past say they are still dealing with the impact of those transgressions, but hope discussing what took place can begin a new phase for Black healthcare." Now, "health and research leaders from the National Institutes of Health are meeting today in Tuskegee, Alabama to hold discussions with those descendants." On Thursday evening, All of Us Chief Engagement Officer Dr. Karriem Watson said, "We have to acknowledge that there's a historical context in which we do this work. Bringing people together to talk about the importance of diverse participation in clinical trials is so important, but we have to acknowledge why some communities don't participate."

WHO Report Says Eight Nations Eliminated A Neglected Tropical Disease in 2020.

Nature (2/13, Coleman, 194K) reports, "Malawi, Vanuatu and Uganda were among the eight nations that eliminated a neglected tropical disease" (NTD), "last year, according to a World Health Organization (WHO) report." This "takes the number of countries that have done so since the late 1990s to almost 50, with 11 banishing more than one disease." The WHO report "comes two years after the agency released a plan to control or eliminate neglected tropical diseases (NTDs) by 2030." But, "the pandemic also disrupted elimination progress in many countries." US National Institute of Allergy and Infectious Diseases group leader for leishmaniasis Shaden Kamhawi said, "We really need to think and be

innovative in how we would be prepared if another [pandemic] comes before we reach our goals," but she added, "any progress is good progress."

NCI Increases R01 Payline To 12th Percentile For 2023.

Cancer Letter (2/10, Ong) reported behind a paywall, "NCI is increasing the R01 payline to the 12th percentile in fiscal year 2023, up from the 11th percentile in FY22 – bringing the institute's payline to a level not seen since 2010."

US Surgeon General Admits 13 Years Old Is "Too Early" To Be Using Social Media.

Fox News (2/10, Sudhakar, 23.99M) reported, "U.S. Surgeon General Vivek Murthy recently warned that age 13 and younger is too early for America's kids to be using social media platforms – despite this being the minimum age to join many of these popular sites, such as Facebook, TikTok, Snapchat and Instagram." Murthy said last week about children using social media, "I, personally, based on the data I've seen, believe that 13 is too early." He added, "It's a time when it's really important for us to be thoughtful about what's going into how they think about their own self-worth and their relationships – and the skewed and often distorted environment of social media often does a disservice to many of those children."

HHS Appoints New Director For Office Of Research Integrity.

Bloomberg Law (2/10, Baumann, Subscription Publication, 4K) reported, "The HHS has appointed" Sheila Garrity as "a new director for its Office of Research Integrity, filling a post that's been vacant for more than two and a half years with George Washington University's research integrity officer." Garrity "joins the Department of Health and Human Services after about three decades leading research integrity programs in academia." She "will assume her post as ORI director the week of March 26. Wanda K. Jones has been the acting director since June 2021."

CDC Maintains Super Bowl Ad Spot Since 2019.

Behind a paywall, Bloomberg Law (2/13, Burgott, Subscription Publication, 4K) reports, "Super Bowl commercials usually focus on commodities like snack food or technology for keeping up with the Joneses, but the federal government is no stranger to using the event for public outreach." And the Centers for Disease Control and Prevention "has spent $75,000 annually in Super Bowl advertising

since fiscal 2019." Commercials are not a normal part of the government, "despite an uptick over the last nine full fiscal years in federal marketing procurement," including an increase of "68% since fiscal 2014, with notable bumps from the Defense Department in fiscal 2017 and" the HHS.

Overdose Prevention

Veterinary Tranquilizer Xylazine Worsening US Fentanyl Crisis.

The Wall Street Journal (2/12, Kamp, Wernau, Subscription Publication, 8.41M) reports that the veterinary tranquilizer xylazine is spreading rapidly within the illicit drug supply and causing serious wounds for regular users. Xylazine is typically mixed with fentanyl, and oftentimes, the volatile mixing of drugs means that drug users do not know what they are taking. According to the DEA, there were 3,000 xylazine-related deaths in 2021 and the drug is now spreading from the Northeast to other parts of the US.

Harm Reduction Strategies Remain Vastly Underfunded.

The New York Times (2/10, Weiland, 20.6M) reported "harm reduction" as a strategy to reduce overdose deaths in America has received more federal support in recent years, with President Biden even endorsing the strategy during his State of the Union address this week. Harm reduction, however, "remains underfunded and partially outlawed in many states," with organizations and their volunteers and employees "functioning as brokers between drug users and the resources they need to manage their consumption." RTI International researchers "estimate that there are only around 1,100 full-time workers nationwide" at syringe exchange organizations, "aided by a cast of around 600 part-time staff members and roughly 2,000 volunteers." In contrast, "over 100,000 Americans die each year from drug overdoses – one every five minutes, the White House estimates."

Bipartisan Panel Of Governors Agrees On Ideas To Address Addiction, Fentanyl Crisis.

Politico (2/12, Olander, 6.73M) reports, "A bipartisan panel of governors from Maryland, New Hampshire, New Mexico and North Dakota said they agreed on elements of each other's ideas to address addiction and the fentanyl crisis, speaking Sunday on CBS' 'Face the Nation.'" New Mexico Gov. Michelle Lujan Grisham (D) said, "That is probably going to be the nexus of real bipartisan work," to North Dakota Gov. Doug Burgum (R) "after he described treating

addiction as a disease." The panel of governors "were in Washington, D.C., for the National Governors Association conference, and dealing with fentanyl was one area where they clearly found common cause."

Overdose Deaths In NYC Rose From Less Than 1,500 In 2019 To 2,670 In 2021, Data Show.

The New York Daily News (2/10, Stratman, 2.51M) reported amid the COVID-19 pandemic, overdose deaths in New York City have risen "from just under 1,500 overdose deaths in 2019 to around 2,670 two years later, according to a recent city report. The pandemic aggravated a problem already on the rise: In 2015, just 942, or 13.8 of every 100,000 city residents, died of an overdose." The article added, "The Mott-Haven-Hunts Point area in the Bronx has long struggled with overdose deaths, but in 2021, deaths skyrocketed – by 42.2 per 100,000 residents from the prior year." Overall, "the neighborhood saw a staggering 119.3 per 100,000 residents die of an overdose in 2021." By comparison, "18.8 of 100,000 people died of an overdose in the area" in 2015.

Data Show Vast Majority Of People Sentenced For Fentanyl Trafficking Are US Citizens.

PolitiFact (2/10, Cercone, Ramirez Uribe, 153K) reported, "Deaths from fentanyl jumped 23% in President Joe Biden's first year in office to more than 70,000, but they've been increasing since 2014 and also rose during Donald Trump's administration." Even though "immigration encounters at the southern U.S. border have spiked under Biden's watch, experts say most of the fentanyl coming into the U.S. from Mexico is coming through legal ports of entry." Data show that "the vast majority of people sentenced for fentanyl trafficking are U.S. citizens."

HEALing Communities Study Teams Up With University Of Kentucky To Implement Narcan Kits Across Campus.

WKYT-TV Lexington, KY (2/11, 50K) reported, "Unfortunately, overdoses are not foreign to college students," which "is why the HEALing Communities Study team at the University of Kentucky implemented naloxone (name brand Narcan) kits around campus." The move is an effort to end "overdose deaths in the Commonwealth of Kentucky. They wanted to make sure that the naloxone kits were easily accessible."

WTVQ-TV Lexington, KY (2/10, 11K) also reported.

Meth Contamination At Several Colorado Libraries Shines Light On "Silent Epidemic."

Denver 7 (2/11, Richard) reported, "The closure of several Colorado libraries due to meth contamination has put the spotlight back on the methamphetamine epidemic, which is sometimes called 'the silent epidemic.'" University of Colorado Department of Psychiatry addiction psychiatrist and associate professor Dr. Joseph Sakai said, "People sometimes talk about it as the epidemic that folks don't look at." Sakai "says unlike opioids, which can be treated with several medications, there is no FDA-approved medication to treat meth addiction." Searching for "an alternative, Sakai and a team of researchers at the CU CONA (Colorado Neuromodulation of Addiction) Lab are putting together a study to see if Deep Brain Stimulation can help people addicted to meth." He "says if the results seem promising, the National Institute on Drug Abuse may provide them with more grant money to expand the study."

Suicides Continue In New York Prisons, Jails Likely Due To Drug Withdrawal.

The Albany (NY) Times Union (2/12, Manno, 315K) reports, "The New York Commission of Correction concluded investigations on at least 90 inmate suicides at state prisons and local jails between 2016 and 2021, according to records provided to the Times Union." In fact, "a common thread emerging from the fatal incidents is a pattern of inadequate mental health services and shoddy supervision that preceded the deaths." According to the National Institute on Drug Abuse, "drug addiction places many prisoners at an especially high risk of suicide, with 85 percent of the nation's prison population having an active substance abuse disorder or a conviction for a crime involving drugs." Consequently, the "Food and Drug Administration issued an advisory in 2019 on the risk of suicide among individuals addicted to opiates whose medication is abruptly discontinued or decreased."

Court Documents Following Student Fentanyl Overdoses Reveal Supplier Lived Blocks Away From Schools.

CNN (2/11, Sun, Norman, 89.21M) reported, "Parents across the Carrollton-Farmers Branch Independent School District (CFBISD), located in a Dallas, Texas, suburb, are reeling following a string fentanyl overdoses by nine students who attend schools in the district." Court documents show that "law enforcement

officers traced the drugs the students overdosed on to a house within walking distance from a middle school and a high school."

New Colorado Legislation Could Allow Supervised Drug Use Sites To Open.

The Denver Post (2/10, Klamann, 660K) reported that a new proposal, which is being drafted in the Colorado House, "would let local governments decide whether to allow" supervised drug-use "sites to open in their jurisdiction, said Rep. Elisabeth Epps, a Denver Democrat and the bill's primary sponsor." However, the bill "wouldn't set aside any money to fund any facilities, and cities would still have to provide their own approval, which Epps said is a pro-local control approach." Colorado "drug laws also wouldn't change; any illicit substances brought into a sanctioned site would have to be acquired elsewhere."

Gabapentin Finding Its Way Into Maine's Illicit Drug Market.

The Bangor (ME) Daily News (2/13, Loftus, 178K) reports gabapentin, "a medication marketed as a nonaddictive nerve-pain reliever and anticonvulsant, is finding its way into Maine's illicit drug market." Recently 1,253 gabapentin pills were seized in Old Town. It "is part of a growing national trend of the drug being found in fatal overdoses." Meanwhile, "prescription rates for gabapentin continue to climb." The rise in misuse of the medication "has prompted states across the country to more heavily regulate the drug and the federal Food and Drug Administration to issue warnings about the dangers it poses."

Target Dates Set For Ohio Opioid Settlement Distribution.

The Youngstown (OH) Vindicator (2/13, 135K) reports, "Funding from the OneOhio National Opioid Settlement could begin to come to local communities this fall, but policy delays could impede funding until 2024." Recently, the OneOhio Region 7 Board "got the chance to meet with the interim executive director of" the private nonprofit "OneOhio Recovery Foundation, Kathryn Whittington, who is also an Ashtabula County commissioner." The foundation has been "tasked with distributing 55 percent of the money Ohio will receive from the pharmaceutical industry as a result of its role in the national opioid epidemic." But "because this is so new, much of the structure and processes still are being decided by the 29-member board governing the foundation."

University Of Arkansas Develops Smartphone App To Decrease Opioid Cravings, Optimize Medication-Assisted Treatment.

The Little Rock (AR) Daily Record (2/13, Grajeda) reports, "University of Arkansas for Medical Sciences researchers have developed an award-winning smartphone app designed to decrease opioid cravings and optimize medication-assisted treatment for people with opioid use disorder." The research team is "supported by a $2.8 million grant from the National Institute on Drug Abuse," and "is testing the effectiveness of OptiMAT (Optimizing Medication Assisted Treatment) among individuals receiving medication-assisted treatment for opioid use disorder at the UAMS Center for Addiction Services and Treatment."

Opinion: Low-Cost Solution To Reduce Overdose Deaths Is To Tell Physicians when Patients Die.

USC Sol Price School of Public Policy Department of Health Policy and Management Chair Jason Doctor and USC Schaeffer Center Aging and Cognition Program Co-Director Mireille Jacobson write in The Hill (2/12, 5.69M), "Despite billions of dollars in settlements from drug companies and distributors, thousands of patients still die each year from overdoses of prescription opioids." The current "systems may no longer be enough to reduce dangerous opioid prescribing." However, "authorities have a promising new tool at hand: low-cost letters that apply different amounts of social persuasion to clinicians to adhere to prescribing recommendations, including telling them when a patient has died." The authors write, "As health economists, we separately participated in two recent studies that showed the payoffs from straightforward and inexpensive mailings." The studies "show that clinicians can be effectively prodded to participate in, and search, state databases and to reduce prescribing."

Opinion: Public Health Message That "One Pill Can Kill" Needs To Be Spread To Youth.

University of North Texas Health Science Center reagent professor Scott Walters writes for the Dallas Morning News (2/13, 772K) that more often "we are seeing overdoses among young people who have no substantial history of drug use and no idea what kind of drug they are taking." Over "the last five years, there has been a spike in overdoses nationally, and especially among young people. Between 2019 and 2021, fentanyl overdose deaths doubled in the U.S., increasing nearly fourfold among children. Statewide, fentanyl was present in 97% of drug overdoses last year." Walters says, "Fortunately, there are proven strategies to protect children against poison. First, we need to prioritize public health messages that 'One pill can kill.'" Also, "communication campaigns need to

be designed to appeal to teens, much like the successful tobacco campaigns that dramatically reduced teen cigarette smoking."

Opinion: Compassion, Empathy Should Be At Heart Of Opioid Strike Force.

Dallas council member for District 7 Adam Bazaldua and Dallas council member for District 9 Paula Blackmon wrote for the Dallas Morning News (2/13, 772K), "As the opioid epidemic continues to devastate American communities and families, Dallas families are not immune to this epidemic." Last year, "Dallas Fire-Rescue paramedics administered just shy of 2,000 doses of Narcan, a medication used to reverse or reduce the effects of opioids, through the end of year 2022." And recently, "we learned that three Carrollton-Farmers Branch ISD students died and six others have been hospitalized in a string of overdoses from fentanyl-laced pills." The authors conclude, "If we are to combat this epidemic, we must address the public health element. Keeping a caring, proactive and pressing approach in our response will allow for mental and physical health to be prioritized. Compassion, empathy and understanding, as well as personal experience, are at the heart of the Opioid Strike Force."

Mental Illness

988 Suicide And Crisis Lifeline Contact, Answer Rates Risen Dramatically Since Launch.

ABC News (2/11, Livingston, 2.44M) reported, "In the six months since the launch of the national, government-backed 988 Suicide and Crisis Lifeline, contact and answer rates have risen dramatically, while the average speed to answer has dropped, according to Substance Abuse and Mental Health Services Administration data." Suicide and Crisis Lifeline interim executive director April Naturale told ABC News, "As we expected, there's been a significant increase in the use of the 988 Suicide and Crisis Lifeline service since this transition to a three-digit number. ... And actually, we're really grateful that more people are contacting the line with this change. That was the whole goal." According to SAMHSA, "in December, 87% of calls, 96% of chats and 99% of texts were answered across the nation...a 91% overall answer rate."

After Two Year Decline, Suicide Rates Increased Among Younger Americans, People Of Color, CDC Finds.

The New York Times (2/11, Barry, 20.6M) said, "A two-year decline in yearly suicides ended in 2021, as suicide rates rose among younger Americans and people of color, according to a new report from the Centers for Disease Control and Prevention." Per the report, "for decades, suicide rates among Black and Hispanic Americans were comparatively low;" however, "a gradual shift is underway." The CDC found that between 2018 and 2021, "the only racial group that saw a decrease in suicide rates across age cohorts was non-Hispanic white people."

CBS News (2/10, Tin, 5.39M) reported, "Preliminary data suggests suicide rates had not significantly improved overall through the first quarter of 2022, according to estimates published by the CDC's National Center for Health Statistics."

Analysis: Biden's Initiatives To Address Youth Mental Health "Promising" If Quick Action Is Taken.

In an analysis for ABC News (2/12, 2.44M), BeMe Health Chief Medical Officer Dr. Neha Chaudhary says, "The Biden-Harris administration's commitment to youth mental health is encouraging, and the doors appear to be open for bipartisan efforts to invest in, protect and promote the well-being of young people everywhere." In his State of the Union Address, President Biden highlighted some initiatives that "would positively impact the mental health of young people on a societal level." Chaudhary discusses the pros, cons, and barriers these initiative may face. But, she concludes, "Overall, the initiatives are promising – as long as stated priorities turn quickly into action in response to this crisis."

Study Emphasizes Need For Pediatric Outpatient Mental Health Follow-Up Care.

CNN (2/13, Christensen, 89.21M) reports that while emergency department "staffers may be able to stabilize a child in a mental health care crisis...research has shown that timely follow-up with a provider is key to their success long-term." But "unfortunately, there just doesn't seem to be enough of it, according to a new study co-authored by" Ann & Robert H. Lurie Children's Hospital Dr. Jennifer Hoffmann. In the study "published Monday in the journal Pediatrics," Hoffmann and co-authors "found that less than a third of the children had the benefit of an outpatient mental health visit within seven days of being discharged from the ER." And "a little more than 55% had a follow-up within 30 days." The study found, "without a follow-up, more than a quarter of the children had to go

back to the ER for additional mental health care within six months of their initial visit."

Undergraduate Peer Counselors Help Address Increased Number Of Students Seeking Mental Health Counseling.

The Wall Street Journal (2/12, Petersen, Subscription Publication, 8.41M) reported on the role specially trained undergraduate peer counselors play in helping address the increased number of college and university students seeking mental health counseling.

New Schizophrenia Drug Xanomeline-Trospium Showing Promise Of Fewer Side Effects.

Wired (2/10, Browne, 3.42M) reported that since the first "rush of discoveries" over schizophrenia "in the middle of the 20th century, the field hasn't progressed much." Current drugs "do achieve a degree of relief for many people...but they have a poor effect for some patients, zero effect for others, and are notorious for triggering unwanted and sometimes overwhelming side effects." But now "xanomeline-trospium, or KarXT, has a novel way of diminishing dopamine transmission that's showing promise at reducing symptoms while also limiting side effects."

Commentary: Using Ketamine To Treat Depression Does Not Help Everyone.

Contributing columnist Steven Petrow writes for the Washington Post (2/12, 10.52M) about his experience with using "ketamine, the anesthetic and hallucinogenic drug that has found a new market as an antidepressant," for his own clinical depression. Petrow writes, "As I read the buoyant reports of ketamine successes I decided it was time for me to try it – under the supervision of a professional therapist." The FDA "approved the use of a nasal-spray form of ketamine for use in treatment-resistant, unipolar major depression," and the psychiatrist "briefed me in detail on all the possible side effects." But "looking back I realize I didn't fully appreciate what all that meant." Petrow concludes that while "according to reputable studies, ketamine can be life-changing for a significant majority," that "leaves 25 percent, like me, who are not so fortunate."

Healthcare Fraud

Centene Agrees To Pay Medi-Cal $215M To Settle Overcharging Allegations.

HealthPayerIntelligence (2/10, Bailey) reported that Centene "must pay Medi-Cal, California's state Medicaid program, over $215 million to settle allegations that it two of its managed care plans overcharged the program by reporting inaccurate prescription drug costs." According to the settlement, "the costs were incurred by Centene managed care plans California Health & Wellness and Health Net." State Department of Justice Investigators "found that California Health & Wellness and Health Net reported inflated costs they incurred for prescription drugs provided to patients between January 2017 and December 2018."

Prescription Drug Pricing

Generic Drugmakers Likely To Benefit From IRA Drug Pricing Laws.

STAT (2/10, Wilkerson, 262K) reported, "Generic drugmakers lobbied hard against Democrats'" Inflation Reduction Act "empowering Medicare to negotiate prescription drug prices." But now "industry experts and lobbyists acknowledge the package is more of a mixed bag for generics makers...not an existential threat." And "the law could actually end up encouraging more generic competition" by incentivizing drugmakers to allow generic competition. Under the IRA law, "Medicare can't negotiate prices for any drug that competes against a marketed generic medicine." The "change in tone is yet another indication that government price controls are not likely to damage the generic and brand drug industries nearly as much as lobbying groups for those industries claimed during the debate over the...the Inflation Reduction Act."

Opinion: Senator Hawley's Proposed Insulin Cap Legislation Will Make Quality Healthcare Unaffordable.

Cato Institute senior fellow and general surgeon Jeffrey A. Singer wrote for The Hill (2/10, 5.69M), "Not long ago, conservative Republicans opposed ObamaCare's mandated benefits regulations" which could drive up insurance costs. But "alas, the era of limited government Republicans is fading." Sen. Josh Hawley (R-MO) "recently sponsored legislation" to cap out-of-pocket "insulin expenditures at $25 and ban insurance companies from requiring patients to try less expensive insulin products" first. Hawley's legislation "would insulate consumers from the cost of" insulin while driving up insurance costs for both insurers and consumers. Hawley should "work to streamline FDA regulations,

reform pharmaceutical patent laws, and eliminate the FDA's authority to impose prescription requirements on drug manufacturers and consumers." But instead Hawley "chooses to add more mandates to the ones already making quality health care increasingly unaffordable and out of reach."

Health Care & Insurance Reform

Maryland Officials, Advocates Touting Program Which Allows Residents To Enroll In Healthcare Coverage Through Tax Returns.

The AP (2/11) reported, "Maryland officials and advocates are highlighting a state program that enables residents to begin signing up for health insurance by checking a box on their state tax return." In 2019, "Maryland became the first state in the nation to establish a tax-based easy enrollment program."

Kaiser Permanente Reports Loss Of $4.47B In 2022 Amid Rising Costs.

Modern Healthcare (2/10, Hudson, Subscription Publication, 215K) reported, "Kaiser Permanente is the latest health system showing signs of struggle amid rising costs." On Friday, the company "reported a $4.47 billion net loss in 2022, compared with a $8.08 billion gain in 2021." While revenue increase 2.4% to $95.41 billion, "expenses rose 4.5% to $96.68 billion, driven by increased care volume due to previously deferred procedures, higher costs of goods and increased spending on labor." Additionally, "Kaiser lost $3.2 billion due to poor market performance on investments."

Despite Another Year With Net Loss, Oscar Health Optimistic For Growth In 2023.

Modern Healthcare (2/10, Turner, Subscription Publication, 215K) reported, "Oscar Health made gains on some vital financial metrics last year and beat analysts' expectations for the fourth quarter, triggering its share price to rise Friday." Oscar's "medical loss ratio improved from 88.9% in 2021 to 85.3% last year and its administrative expense ratio declined from 21.8% to 20.6%, the company reported Thursday." In the fourth quarter of 2022, the company "recorded a $226.6 million net loss," beating "analyst expectations of $261.3 million in net losses." For the whole year, Oscar "endured a $610 million net loss," which was "up from $571 million the year before;" however, "the health insurer predicted a better 2023," expecting a loss of just "$75 million to $175 million."

Providers Preparing To Use Misoprostol Alone If Lawsuit Over FDA Approval Of Mifepristone Proves Successful.

STAT (2/10, Boodman, 262K) reported "stories about medication abortion...often give mifepristone a starring role." Therefore, "it might seem surprising that American abortion providers are responding to" a lawsuit which seeks to reverse the FDA's approval of the drug "by preparing to forego mifepristone and use misoprostol alone. How could that be? Wasn't mifepristone the abortion pill, the critical tool for ending a pregnancy in the first trimester?" The piece said the "narrative has been backward. Biologically speaking, mifepristone is the sidekick, and misoprostol the superhero, mifepristone the opening act while its counterpart carries the show. ... Both regimens – either the two drugs together, or just misoprostol – are extremely safe. And they're both very effective. Chances are, taking misoprostol alone will work to end a pregnancy early on, but it's likely to come with more discomfort, cramping, and nausea."

Abortions Occurring Later Due To Increased Demand From Out-Of-State Patients.

The Wall Street Journal (2/12, Kusisto, Subscription Publication, 8.41M) reports abortion clinics say months after the demise of Roe v. Wade, state restrictions are leading to later abortions. That is because clinics are getting more out-of-state patients in addition to the regular number from states where abortion remains legal. In general, this is adding weeks to the amount of time it takes to get appointments.

Maryland Governor, Dems Unveil Measures Which Seek To Expand Protections For Reproductive Rights.

The Hill (2/10, Gans, 5.69M) reported, "Maryland Gov. Wes Moore (D) and Democratic lawmakers are moving to make the state a 'safe haven for abortion' in the aftermath of the end of Roe v. Wade and more than a dozen states moving to severely restrict access to the procedure." On Thursday, he, "Lt. Gov. Aruna Miller, the leaders of the state House and Senate and other state lawmakers announced a legislative package to expand protections for reproductive rights at a press conference."

GOP Legislators Attempting To Bypass DAs Who Refuse To Prosecute Violations Of Abortion Bans.

Politico (2/12, Ollstein, Messerly, 6.73M) reports Republican "lawmakers see a major flaw in their states' near-total abortion bans: Some local prosecutors won't enforce them." Georgia, Indiana, South Carolina, and Texas GOP legislators – "frustrated by progressive district attorneys who have publicly pledged not to bring charges under their state's abortion laws – have introduced bills that would allow state officials to either bypass the local prosecutors or kick them out of office if their abortion-related enforcement is deemed too lenient."

Abortion Rights Groups, Dems In Colorado Working On Legislation To Regulate Crisis Pregnancy Centers.

The Denver Post (2/12, Klamann, 660K) reports pregnancy centers represent "contested outposts in the escalating fight over abortion access in Colorado and the United States. The facilities – known as crisis pregnancy centers – are staunchly anti-abortion and offer limited medical services and family counseling, with the intent of steering women away from terminating their pregnancies. There are dozens of the facilities in Colorado, more than doubling the number of abortion providers." Critics contend "the organizations – which they call anti-abortion centers – use deceptive advertising and promote the use of unproven medical treatments." Several "abortion access groups, together with Democrats in the Colorado statehouse, are preparing a landmark bill to regulate how the centers operate and confront those concerns."

Oklahoma Senate Panel Advances Measures Which Outline Legal Abortion.

The Oklahoman (USA) (2/10, Denwalt, 371K) reported on Thursday, legislators on an Oklahoma Senate panel "advanced two bills...that would clarify what is (and isn't) a legal abortion in Oklahoma." The article added, "One was introduced to clarify the Legislature's intent when it comes to medical procedures that terminate pregnancy. The other stipulates that Oklahoma's abortion laws shouldn't limit access to birth control drugs."

Lawsuit Alleges Security Guards At National Archives Ordered Anti-Abortion Advocates Not To Display Pro-Life Slogans.

The Washington Post (2/11, Kunkle, 10.52M) reported, "Antiabortion advocates hoping to view the Constitution at the National Archives were ordered not to display their slogans during their visit, in violation of their constitutional rights, according to a federal lawsuit filed against the agency this week." The pro-lifers, "who were in the District attending the 50th Annual March for Life last month,

allege that a group of security guards at the National Archives and Record Administration's building told them to hide or remove buttons, hats and clothing that contained messages such as 'Life is a HUMAN RIGHT' and 'Pro-Love is the New Pro-Life' when they entered the Rotunda, where the Constitution and its Bill of Rights are on display."

Almost 70% Of Americans Dissatisfied With Abortion Policies, Poll Finds.

The Hill (2/10, Melillo, 5.69M) reported almost "7 in 10 Americans are dissatisfied with the country's abortion policies, marking the highest rate measured in 23 years, a new Gallup poll found." These findings "come more than seven months after the Supreme Court struck down Roe vs. Wade, the ruling that guaranteed a woman's right to an abortion. Since then, many states have banned the practice or moved to significantly curb abortion access."

Company Has Been Trying For Years To Expand US Women's Access To Birth Control Pills.

Fortune (2/10, Aspan, 3.68M) reported, "It's been a long seven months for Perrigo's HRA Pharma, the company making a historic request to expand American access to birth control." Still, "after nine years of regulatory red tape, its executives know how to be patient." Last "July, the pharmaceutical company made a landmark – and tragically well-timed – application to the U.S. Food and Drug Administration. The Supreme Court had just overturned Roe v. Wade. And as tens of millions of women lost access to abortion almost overnight, the Court also signaled that access to contraceptives could be next in the legal crosshairs."

Columnist Criticizes Judge Presiding Over Lawsuit Challenging FDA Approval Of Abortion Drug.

In her Washington Post (2/10, 10.52M) column, Alexandra Petri wrote, "In another thrilling development in this best of all possible worlds, a ruling from a single Trump-appointed judge in Texas might undo the Food and Drug Administration's approval of one of the two key drugs used in medication-based abortions and render it inaccessible nationwide. I hear you asking a question: Can a judge just do that? Just un-approve a drug? One that's been tested and found extraordinarily safe over two whole decades?" Petri said this "is a real possibility, because our legal system is working just the way it ought to work! In an ideal society, your rights and ability to access medicine and direct the course of your

own life are guaranteed and unalterable – unless a Trump-appointed judge named Matt decides to say, 'Nah.'"

Health Information Technology

Editorial Commends FTC For Fining GoodRx Over HIPAA Breach.

In an editorial, the Los Angeles Times (2/10, 3.37M) wrote, "Since 2017, GoodRx has helped millions of people find deals on prescription drugs via an app and website." However, "what its customers may not have known is that the Santa Monica-based health company had also been sharing information about their prescriptions and illnesses with third parties such as Google and Facebook for advertising purposes." For this, the FTC has "fined GoodRx $1.5 million for violating customers' privacy by failing to notify them about how their data were being used." The Times adds, "The enforcement action is a warning to other tech firms at a time of growth in the industry. Increasingly consumers are using apps and wearable devices to monitor their health, and they should know exactly how their personal information is being used."

Human Services News

Biden Administration Credits New Migration Programs For Drop In Border Crossings.

Roll Call (2/10, Monyak, 130K) reported that the volume of migrants "encountered monthly at the southwest border dropped significantly in January, a dip that Biden administration officials attribute to recent 'carrot-and-stick' style migration programs." Roll Call says border agents "reported a 40 percent drop in total encounters with migrants last month, decreasing from a record 252,000 encounters in December to about 156,000 in January, according to data released Friday by Customs and Border Protection." Biden Administration officials "attributed the decline in border crossings to recent programs aimed at discouraging migrants from crossing the border in between ports of entry."

Migrants Looking For US Sponsors Encounter "Underground Market."

The AP (2/11, Snow) reported, "Pedro Yudel Bruzon was looking for someone in the U.S. to support his effort to seek asylum when he landed on a Facebook page filled with posts demanding up to $10,000 for a financial sponsor." The AP says the ads are "part of an underground market that's emerged since the Biden

administration announced it would accept 30,000 immigrants each month arriving by air from Venezuela, Cuba, Nicaragua and Haiti." Applicants "need someone in the U.S., often a friend or relative, to promise to provide financial support for at least two years."

Judge Delays Order Setting Schedule Determining When North Carolina Health Officials Must Provide More Accommodations For People With Disabilities.

The AP (2/10) reported, "A trial judge has agreed to delay enforcement of his order setting a robust schedule upon which North Carolina health officials must provide significantly more community services for people with intellectual and developmental disabilities while the state appeals his ruling." The judge "had in November set thresholds that the Department of Health and Human Services would have to meet regularly over the next decade." In part, that order "required at least 3,000 people must be diverted or shifted to community-based programs by early 2031. And he told DHHS to eliminate by mid-2032 a waiting list of people qualified to participate in a Medicaid-funded program that helps them live at home or outside of an institution."

Child Care In Philadelphia Costs 22.5% The Median Household Income Per Child.

The Philadelphia Inquirer (2/10, Ravitch) reported, "Philadelphia families are forced to spend a larger chunk of their pay on childcare than in any other Pennsylvania county, new federal data show, and it's likely affecting the number of women in the workforce." A new US Labor Department database "shows the cost of childcare as a proportion of median income in every Pennsylvania county, as well as all counties in most U.S. states. In Philadelphia, infant care costs about 22.5% of the median household income, and that's for just one child." Beyond the price, "availability is a challenge as well. The number of childcare providers in the country decreased sharply with the onset of the COVID-19 pandemic and has not fully recovered, according to a recent report from the U.S. Department of Health and Human Services."

Brett Favre Files To Have Welfare Fraud Lawsuit Dismissed.

The AP (2/11, Pettus) reported, "Brett Favre's lawyers filed papers Friday again asking a Mississippi judge to dismiss the retired NFL quarterback from a lawsuit that demands repayment of millions of dollars of welfare money intended to help

some of the poorest people in the U.S." Last year, the Mississippi Department of Human Services "sued Favre and more than three dozen other people or businesses" over allegations he was involved in the improper allocation of funds from the Temporary Assistance to Needy Families program. Favre "has repaid $1.1 million he received for speaking fees from a nonprofit group that spent TANF money with approval from the Mississippi Department of Human Services." Favre allegedly never gave the speech for which he was paid.

Kristof: New Strategies Needed To Teach Children How To Read.

In his column for the New York Times (2/11, 20.6M), Nicholas Kristof wrote that "two-thirds of fourth graders in the United States are not proficient in reading." Kristof relays the growing belief that "we grown-ups have bungled the task of teaching kids to read" along with studies that show that "the United States has adopted reading strategies that just don't work very well and that we haven't relied enough on a simple starting point – helping kids learn to sound out words with phonics."

Opinion: Tax Benefit Parents Use To Offset Child Care Is "Hopelessly Outdated."

In a Bloomberg Opinion (2/12) column, contributor Alexis Leondis writes, "Over the last four decades, the cost of child care has skyrocketed in the US. It now takes up almost 20% of median family income per child in major cities." However, "the tax benefit some workers use to offset those day care or nanny expenses has stayed the same – since 1986! When the amount was temporarily increased during Covid, it only became more obvious that the cap was hopelessly outdated." Leondis concludes, "With per-child childcare costs increasing 2,000% since the 1970s, it just doesn't make sense to leave the tax code stuck in the past."

Editorial: Hochul Should Appoint Wheelchair User To MTA Board Vacancy.

In an editorial, the New York Daily News (2/12, 2.51M) writes, "Last spring the state Senate approved a bill 63 to zero and the Assembly did so 149 to zero...requiring state transportation authorities have on their boards a voting member 'who is limited to public transit as their primary mode of transportation because the individual has a temporary or permanent disability.'" This "means a person who uses a wheelchair will help run the agency." However, the measure "does not apply to" NYC's Metropolitan Transportation Authority (MTA). However,

with two vacancies on the MTA's board, the Daily News says Hochul "doesn't have to wait for the new law to be amended. She should put at least one wheelchair user on the board now."

Jeffries Claims "Extreme MAGA" Republicans View Social Security As A "Ponzi Scheme."

The Hill (2/10, Gans, 5.69M) reported House Minority Leader Jeffries "said on Friday that 'extreme MAGA' Republicans view Social Security as a 'Ponzi scheme,' calling on Democrats to work to protect the program."

Food & Import Safety

Consumer Reports Says Bindle Brand Water Bottles Pose Potential Risk Of Lead Poisoning.

CBS News (2/10, Cerullo, 5.39M) reported, "A popular brand of insulated bottle poses a risk of lead poisoning, according to Consumer Reports." Consumer Reports performed a test of the product, and "found that the Bindle bottle could expose users to 'extremely high' levels of lead," and "said some bottles contained bisphenol A (BPA), a chemical known to cause fertility problems and some kinds of cancers." The advocacy group "said it found lead on the bottle's 'sealing dot,' a small, circular piece of metal at the bottle's base," containing "lead levels that are roughly 1,100 times higher than what's generally considered safe, according to the publication, noting that anything that comes into contact with the dot is at risk of lead contamination."

Purina Recalls Certain Units Of Dog Food After Two Dogs Exhibit Signs Of Vitamin D Toxicity.

The Washington Post (2/10, Gregg, 10.52M) reported, "Nestlé Purina Petcare Co. is recalling select units of dry dog food after two dogs fell ill, the Food and Drug Administration announced this week." The notice "applies to certain units of Purina Pro Plan, EL Elemental, which may contain elevated levels of vitamin D." The agency "said there are two confirmed cases of a dog exhibiting signs of vitamin D toxicity while on the diet. Both recovered."

USA Today (2/10, Alund, 12.7M) also reported.

Medicare

CMS Announces Medicare Rebate Program Under Inflation Reduction Act.

USA Today (2/10, Alltucker, 12.7M) reported, "Medicare will begin collecting penalties in 2025 from pharmaceutical companies that raise prices on prescription drugs faster than the rate of inflation, the Centers for Medicare and Medicaid Service said" last week. Also, "on April 1, Medicare enrollees on Part B drugs, typically administered by a doctor, might benefit from more moderate coinsurance charges, CMS officials said." CMS "released draft guidance Thursday on the rebate program and will solicit feedback from the public over the next 30 days before finalizing details."

Republican Senator Warns Medicare, Social Security In Danger Unless Congress Acts Now.

CNN (2/12, LeBlanc, Fossum, 89.21M) reports that Sen. Mike Rounds (R-SD) "offered Sunday a stark warning about the future of Social Security and Medicare if Congress fails to take action now." Appearing on CNN's Jake Tapper on "State of the Union," Rounds said: "In the next 11 years, we have to have a better plan in place than what we do today. Or we're going to see – under existing circumstances – some reductions of as much as 24% in some sort of a benefit. So, let's start talking now because it's easier to fix it now that it would be five years or six years from now." CNN says President Biden recently "has made a forceful argument against Republicans by highlighting his support for Social Security and Medicare."

Meanwhile, Politico (2/12, Olander, 6.73M) reports Rounds said that most Republicans "don't agree with Sen. Rick Scott's plan to sunset programs including Medicare and Social Security." Rounds told Tapper: "The vast majority of us would say that we prefer to look at it in a different direction, one of managing it, as opposed to a discussion about having everything start over again."

Biden Has Yet To Be Specific About How He Would Strengthen Social Security And Medicare.

CNN (2/10, Luhby, 89.21M) reported, "In his latest move to differentiate himself from House Republicans on entitlement programs, President Joe Biden is making a pretty big promise" by "vowing to shore up the shaky finances of Medicare's trust fund, extending its solvency to the middle of the century instead of the expected depletion date of 2028." CNN says, "But just how he will accomplish this objective – as well as one to strengthen Social Security – remains to be seen."

When reporters "asked for more information, the White House said, 'We will provide more details on March 9, when the president releases his budget, backed up by full, transparent accounting.'"

Biden Aims To Brand Republicans As Extreme On Social Security, Medicare.

The Hill (2/11, 5.69M) reported President Biden focused on attacking Republicans over Social Security and Medicare at his State of the Union speech this week, with one strategist suggesting he has found a "sweet spot" on the issues. The speech also served "as a preview of what's to come," with Biden expected "to try to label Republicans as extreme by pointing to GOP proposals that he says would lead to changes" in both programs.

Forbes (2/10, Dorn, 10.33M) reported that Biden "headed to Florida on Thursday, where he again attacked Republicans on the issue, telling an audience at the University of Tampa: 'A lot of Republicans, their dream is to cut Social Security and Medicare. Well let me say this: If that's your dream, I'm your nightmare.'"

McConnell Piles On To Biden's Criticism Of Rick Scott's Plan To Sunset Medicare, Social Security.

The Washington Post (2/10, Wagner, 10.52M)reported that President Biden "has been hammering Sen. Rick Scott (R-Fla.) for his plan that would require Congress to reauthorize even popular programs such as Social Security and Medicare every five years to keep them operating." And, on Thursday, Senate Minority Leader Mitch McConnell (R-KY) "joined in the criticism, suggesting that provisions in Scott's plan could hurt him in his bid for reelection next year in Florida, a state with the greatest share of seniors in the nation." McConnell "told longtime Kentucky radio host Terry Meiners, 'That's not a Republican plan. That was the Rick Scott plan.'"

Meanwhile, The Hill (2/10, Shapero, 5.69M) reported that Scott "announced a new bill on Friday to increase funding for Social Security and Medicare and institute a higher standard for making cuts to the entitlement programs, following President Biden's pointed accusations during his annual address before Congress on Tuesday." The Hill said the legislation "aims to rescind the nearly $80 billion in funding for the Internal Revenue Service that was approved in last year's Inflation Reduction Act and redirect it towards Social Security and Medicare." It "would also require that any cuts to Social Security or Medicare be approved by a two-

thirds vote in Congress and would block Medicare savings from being used for other spending initiatives."

Also reporting the story was Roll Call (2/10, Lesniewski, 130K).

Advocacy Groups Say CMS' Lack Of Insurance Coverage For New Alzheimer's Drug Is Discriminatory.

TIME (2/10, Park, 18.1M) reported that despite the hope offered by newly-approved Alzheimer's disease treatment lecanemab (Leqembi), for many patients, "at $26,500 a year, the treatment is financially out of reach." However, "Medicare won't cover it" without more evidence on efficacy, as Leqembi is "only the second medication approved by the U.S. Food and Drug Administration (FDA) to target amyloid." Advocacy groups are calling out CMS, "which oversees Medicare, for adding treatment coverage restrictions that weren't put in place for other first-in-class therapies to treat diseases like HIV or cancer." And legislators "proposed a bill last November that would prevent CMS from restricting access to entire classes of approved drugs without evaluating the merits of each individually." HHS is mentioned.

Column: Republicans "Haven't Earned A Whole Lot Of Trust" On Social Security, Medicare.

In a column for the Washington Post (2/10, 10.52M), Paul Waldman wrote, "After Republicans' heckling of" President Biden's comments that they "dream" of cutting Social Security and Medicare during his State of the Union address, "the White House clearly thinks it has struck political gold and has sent the president out to keep up this drumbeat." Waldman wrote that "if Republicans want the public to believe that their passion for defending those popular safety-net programs should be beyond doubt, they are on shaky ground. Even if Biden might sometimes exaggerate what his opponents believe, this debate carries with it a history and a context that make it hard for Republicans to claim they are being unfairly maligned." Waldman wrote, "The trouble is, Republicans haven't earned a whole lot of trust when it comes to programs that were created by Democrats, and that have been sustained and defended by Democrats in the face of decades of Republican attacks."

Letter: Seniors Can't Afford Benefit Cuts, But Wealthy Can Afford To Pay More.

In a letter to the Washington Post (2/10, 10.52M), National Committee to Preserve Social Security and Medicare President and CEO Max Richtman wrote, "Most of the plans endorsed in the editorial "Yes, entitlements need to be reformed" ultimately would cut benefits and undermine the fundamental nature of both programs. The assertion that only high-income earners would be affected by these "reforms" is either disingenuous or naive. Raising the eligibility age for either program would be a huge benefit cut for all seniors. Means-testing benefits would have to reach deep into the middle class to significantly improve solvency. Investing some of Social Security's reserves on Wall Street would put the program on a slippery slope toward privatization." Richtman wrote, "Most seniors cannot withstand benefit cuts, but the wealthy can afford to pay more to help keep these programs financially viable for future generations."

Medicaid & CHIP

Biden Administration Begins Approving Medicaid Funds To Be Spent On Food Programs.

The Wall Street Journal (2/12, Armour, Peterson, Subscription Publication, 8.41M) reports the Biden Administration has begun approving requests from states to use Medicaid to pay for food programs. This comes as policymakers explore the potential health and cost benefits of the so-called food as medicine approach.

Medicaid Could Be Next Target For Republican Cuts.

HuffPost (2/10, Cohn, 363K) reported that if GOP leaders "manage to keep their party away from Medicare and Social Security" and that Republicans also "carry out their threat to block an increase in the federal government's borrowing authority, jeopardizing America's and maybe the world's economy, until Democrats agree to major spending cuts," their actions "would almost certainly force cuts in another big program: Medicaid." HuffPost says Medicaid "now covers more people than Medicare, the beloved Great Society-era program that provides basic insurance to the nation's elderly" and that growth "is a problem, as most Republicans and their conservative allies see it."

Many States Not Prepared For End Of Automatic Medicaid Enrollment.

Vox (2/13, Scott, 1.88M) reports, "Perhaps the greatest success of the American health care system these last few benighted years is" that the "uninsured rate has reached a historic low of about 8 percent." The low rate is due to "the slew of

emergency provisions that the government enacted in response to the Covid crisis," with the freeze on Medicaid eligibility "likely the single largest factor." But "in April, that will end," and the Biden Administration "estimates upward of 15 million people...could lose coverage, a finding that independent analysts pretty much agree with." And many, "-- even most, according to some projections – could be people who are actually still eligible for Medicaid but slip between the cracks of the system." Although automatic re-enrollment using public information is mandatory under the ACA, many states do not enforce the law, and several states are not taking re-enrollment issues seriously, especially Florida.

"Influential Group Of Conservative Intellectuals" Back Family Benefits.

The New York Times (2/10, A1, Goldstein, 20.6M) highlighted "an influential group of conservative intellectuals with a direct line to elected politicians" have endorsed policies that "sound like part of a progressive platform," like "sending cash to parents, with few strings attached," expanding Medicaid, and "providing child care subsidies to families earning six figures." The Times added while these conservatives "generally oppose abortion rights," and "often resist the trans rights movement," they assert providing financial support to families "is a pragmatic way to prop up conservative values alongside new restrictions on abortion."

Health & Medical News

Some Scientists Say Biden's Cancer Moonshot Most Likely To Help Already Rich Industry.

Politico (2/10, Schumaker, 6.73M) reported, "President Joe Biden's pledge to 'end cancer as we know it' is a rare sliver of common ground between Democrats and Republicans." However, "cancer researchers are less unified about the moonshot than Washington policymakers." Contrarian scientists said that "cancer research is funded well enough...and investing more in high-tech individualized treatments is more likely to help the wealthy live longer than it is to save those most likely to die of the disease: the poor and people of color." Recently, Biden "asked Congress to reauthorize the National Cancer Act," which "would help the National Cancer Institute support researchers around the country by building clinical trial networks and more robust data systems, according to Danielle Carnival, the White House's moonshot coordinator."

Biden Places Cancer Research At Top Of Unity Agenda.

Cancer Letter (2/10, Ong) reported behind a paywall, "President Joe Biden mentioned cancer 13 times in his impassioned State of the Union address and placed cancer research at the top of his Unity Agenda – an indication that his administration would continue to prioritize funding for cancer research in fiscal year 2024."

Data Indicate So Far This Year, State Legislators Have Introduced 80 Bills Seeking To Limit Access To Gender-Affirming Care.

CNN (2/11, Cole, 89.21M) reported several "bills seeking to restrict access to gender-affirming care for trans youth have been introduced by Republican state lawmakers this year, with debates around the issue reaching new heights thanks to proposals that would dramatically expand the scope of bans on such care." Over "80 bills seeking to restrict access to gender-affirming care have been introduced around the country through February 9, according to data compiled by the American Civil Liberties Union and shared with CNN."

Florida Physicians' Board Expands Ban On Gender-Affirming Care.

The AP (2/10, Schneider) reported a ban on "puberty blocking hormones and gender-affirming surgeries for minors in Florida was tightened further after a board overseeing doctors eliminated an exception for clinical trials Friday at the request of Florida Gov. Ron DeSantis' administration." Certain "members of the public attending the meeting in Tallahassee shouted expletives, and law enforcement officers positioned themselves in the front of the room after the vote by the Florida Board of Osteopathic Medicine."

The Tampa Bay (FL) Times (2/10, Ellenbogen, Ogozalek, 762K) also covered the story.

Missouri AG Says Provider Should Halt Treatments For Transgender Youth Following Complaint About Alleged Misconduct.

The Washington Post (2/10, Gowen, 10.52M) reported Missouri Attorney General Andrew Bailey (R) "on Friday called for a halt to drug treatments for transgender youth at a pediatric care center in St. Louis after a whistleblower complaint alleged misconduct by those treating children for gender dysphoria and other issues." Bailey "said his office was investigating Washington University's Transgender Center at St. Louis Children's Hospital after a former case manager

alleged that medical professionals had used experimental drugs on children and distributed puberty blockers and hormones without proper assessment and parental consent."

The AP (2/10, Ballentine) reported, "The state Social Services Department, state licensing agency, Republican U.S. Sen. Josh Hawley and Washington University also are investigating."

The St. Louis Post-Dispatch (2/11, Erickson, Suntrup, 694K) also covered the story.

Nebraska Legislators Mulling Bill That Would Allow Medical Providers To Cite Religious, Ethical Beliefs In Denying Certain Treatments.

The AP (2/10, Beck) reported legislators in Nebraska "are following the path of other conservative states in considering a bill that would allow medical providers, facilities and insurers to cite their religious, ethical or moral beliefs in denying some medical treatments. Critics say it's simply another way to target abortion rights and the LGBTQ community." The measure "includes nearly three pages of language protecting providers who conscientiously object to providing treatment from lawsuits, criminal charges and professional ethics charges."

The Omaha (NE) World-Herald (2/10, Bamer, Stoddard, 509K) also covered the story.

Utah Governor Defends New Law Which Bans Gender-Affirming Care For Minors.

NBC News (2/12, Concepcion, 4.91M) reports on Sunday, Utah Gov. Spencer Cox (R) "defended a bill he signed last month that bars transgender minors from receiving gender-affirming medical care, saying that he wants to see more data on the effects of those treatments." During "an interview on NBC News' 'Meet the Press,' Cox...said, 'It's not just about providing care or not providing care, it's about whether we might potentially be harming young people, not having enough evidence to see what the long-term results of this are and providing better psychiatric help for those young people who are going through this.'"

Chicago-Area Children Staying Longer In Hospitals Due To Shortage Of In-Home Pediatric Nurses.

The Chicago Tribune (2/12, Schencker, 2.03M) reports throughout "the Chicago area, children with complex, chronic conditions are finding themselves stuck in hospitals longer than they should be because it's so difficult to find in-home

pediatric nurses. That, in turn, can mean fewer available hospital beds for all kids, something that became a serious problem in the fall as respiratory illnesses in children surged." At one children's hospital, "about one-fourth of the hospital's 27 patients are stable enough to go home but can't because they can't find nurses to help them once they get there."

Shkreli Urges Judge To Not Hold Him In Civil Contempt For Failure To Provide Information.

Reuters (2/10) reported, "Martin Shkreli on Friday urged a U.S. judge not to hold him in civil contempt for failing to provide federal and state regulators with information to determine whether he is violating a lifetime ban from working in the pharmaceutical industry." In a court filing, Shkreli "said he has complied with the February 2022 ban 'as extensively as possible and in good faith,' and has provided the materials sought by the Federal Trade Commission (FTC) and seven states." The lifetime "ban also included a $64.6 million civil fine, which Shkreli said he is 'so far unable' to pay."

Novartis Expanding Production, Facilities Of Cancer Treatment Radioligand Therapy.

CNBC (2/11, Capoot, 7.34M) reported on a form of targeted cancer treatment, radioligand therapy, which, while effective, "expires within days after it's manufactured." But "pharmaceutical company Novartis believes the returns will be worth the challenge of mastering this race against time." Novartis "currently produces two radioligand" therapies – neuroendocrine tumors treatment Lutathera and prostate cancer treatment Pluvicto – "both approved by the Food and Drug Administration." Novartis "manufactures radioligand therapy at three sites in Italy, Spain and New Jersey, and has a fourth facility slated to open in Indiana next year." Fred Hutchinson Cancer Center molecular imaging and therapy Director Dr. Delphine Chen is quoted.

RedHill Biopharma Exchanges Rights For Top Commercial Drug Movantik To Cancel Debt With HealthCare Royalty Partners.

The Triangle (NC) Business Journal (2/10, Ezzone, Subscription Publication, 854K) reported Raleigh pharmaceutical company RedHill Biopharma "is moving forward after exchanging the rights to its top commercial asset," constipation treatment Movantik, "for the cancelation of more than $100 million in debt obligations." RedHill "announced Monday it has reached an agreement to transfer its drug

Movantik to Connecticut-based HealthCare Royalty Partners." RedHill "plans to replace the revenue lost from Movantik by ramping up commercial efforts of its two" FDA-approved products, Helicobacter pylori infection treatment Talicia and traveler's diarrhea treatment Aemcolo.

Cleveland Clinic Partners With Anixa Biosciences For Triple-Negative Breast Cancer Vaccine Phase 1b Study.

Popular Science (2/10, Baisas, 7.65M) reported, "Researchers at Cleveland Clinic launched their next step in a study of a vaccine aimed at preventing triple-negative breast cancer." The Clinic's "new phase 1b study will enroll cancer-free individuals who are at a high risk for developing breast cancer" and who "have also decided to voluntarily undergo prophylactic mastectomy to lower their risk of developing breast cancer." The Cleveland Clinic "study is funded by the United States Department of Defense and will be conducted at Cleveland Clinic's main campus in Cleveland, Ohio," in partnership with Anixa Biosciences, Inc. The very "first therapeutic cancer vaccine (Provenge) was approved by the Food and Drug Administration (FDA) in 2010."

Spruce Biosciences Raises $53.6M PIPE Deal To Fund Clinical Trials For CAH Drug.

The San Francisco Business Times (2/10, Leuty, Subscription Publication, 895K) reported a South San Francisco biotech company, Spruce Biosciences Inc., "hoping to deliver top-line results from key drug studies targeting a genetic hormonal disorder, raised $53.6 million in a private investment in a public entity, or PIPE, deal." The funding "extends its financial runway from first-half 2024 into early 2025." By then Spruce "will have top-line results from two mid-stage clinical trials of its drug, called tildacerfont, in adults with congenital adrenal hyperplasia" (CAH). The drug "would eliminate the need for high doses of steroids to balance out-of-control hormones." Currently "long-term use of high-dose steroids comes with side effects and there are no Food and Drug Administration-approved treatments for CAH."

FDA Recalls Alfia Weight Loss Capsules For Containing A Harmful Drug.

The Miami Herald (2/13, Cetoute, 647K) reports, "The FDA has recalled Alfia Weight Loss Capsules, made by a Broward County company, for containing a harmful hidden drug not used in decades." The FDA on Wednesday "advised to not purchase or use Alfia Weight Loss Capsules that were sold online and in some

retail stores." An "FDA laboratory analysis confirmed a finding of sibutramine in the weight loss pill," which "is known to substantially increase blood pressure and/or heart rate in some people and may create a significant risk for people with a history of coronary artery disease, congestive heart failure, arrhythmias or stroke. If the pill is mixed with other medications it could be life-threatening, the FDA said."

Sanders To Summon Corporate Executives To Testify Before Congress As Senate Health Committee Chairman.

The New York Times (2/12, Stolberg, 20.6M) reports, "In two unsuccessful bids for the White House, Senator Bernie Sanders" (D-VT) "made no secret of his disdain for billionaires." And now "in what could be his final act in Washington, he has the power to summon them to testify before Congress – and he has a few corporate executives in his sights." The list includes Moderna CEO Stéphane Bancel, Amazon founder Jeff Bezos, and Starbucks CEO Howard Schultz. Sanders "views them as union busters whose companies have resorted to 'really vicious and illegal' tactics to keep workers from organizing." As the "new chairman of the Senate Committee on Health, Education, Labor and Pensions," Sanders has "sweeping jurisdiction over issues that have animated his rise in politics, such as access to health care, the high cost of prescription drugs and workers' rights."

Rolling Stone (2/11, Voght, 12.39M) reported that as chairman, "Bernie Sanders is living, as he puts it, in a 'two-fold world.'" Sanders explains, "On the one hand, I'm trying to do what I can in a bipartisan way," referring to "a list of the cascading crises in health care, education, and labor Sanders thinks he could recruit some Republican allies to help solve." But Sanders adds, "I'm also going to continue to fight for a vision, which is not going to be passed in this Congress." Sander's wishlist includes "Medicare for All, tuition-free college, federal protections for workers to unionize – the familiar planks of his two insurgent runs for the presidency." Sanders said, "I'm not going to give up on those things."

FDA Places Partial Hold On Blueprint Medicines Cancer Drug Trial.

Reuters (2/10, Jain) reported, "Blueprint Medicines Corp said on Friday the U.S. drug regulator had put on partial hold an early-stage trial testing its experimental cancer drug due to safety concerns." Blueprint said that "some patients faced episodes of light sensitivity and blurred vision." Blueprint Medicines' Chief Medical Officer Becker Hewes "said the company was working with the Food and Drug

Administration to investigate the adverse events and amend the trial protocol to enable investigators to monitor and manage the events should they occur."

Endpoints News (2/12, Patchen) reports, "On Friday, the Massachusetts-based biotech said the FDA informed Blueprint two days ago that it is placing a partial hold on a Phase I/II study, also known as the VELA trial, looking at BLU-222 in advanced solid tumors." The FDA's "partial hold was due to adverse events being observed in a 'limited number' of patients, Blueprint said." Blueprint's "release said patients that are enrolled will continue with the study, but no more will be added until the hold is resolved."

Study Finds Minnesotans Experiencing Homelessness Have Three-Times Higher Death Rate.

The Minneapolis Star Tribune (2/11, Serres, 855K) reported, "A major new study shows that Minnesotans experiencing homelessness die at three times the rate of other Minnesotans, and substance abuse accounts for about a third of their deaths." The Minnesota Department of Health released the study in January, and "found that deaths from substance use are 10 times higher among homeless Minnesotans than the overall state population." Hennepin Healthcare Research Institute researchers, who prepared the report, "found that 20-year-olds experiencing homelessness in Minnesota have the same likelihood of dying as 50-year-olds in the general population." The report "calls for a coordinated effort to elevate housing as a 'life-saving strategy,' though it stops short of analyzing current methods for combating homelessness."

Scientists Frustrated With Chinese Biophysicist's Refusal To Discuss Research On Heritable Genome-Editing Technology.

Nature (2/12, Mallapaty, 194K) reports, "He Jiankui, the Chinese biophysicist who shocked the world by creating the first children with edited genomes" as a treatment for HIV, "says research must accept moral and ethical constraints, but is otherwise refusing to speak about the work that landed him in jail for three years." His "silence is frustrating some scientists, who say he should answer questions about his past research before publicizing his latest plans to use genome-editing technology in people" as a treatment for Duchenne muscular dystrophy (DMD). And "some researchers worry that interest in He Jiankui is diverting attention away from more important ethical issues around heritable genome editing."

Analysis Identifies Highly-Cited Cancer-Genetics Papers With DNA, RNA Sequence Errors.

Nature (2/10, Kwon, 194K) reported, "The prevalence of mistakes in published gene research could be more widespread than previously thought, according to an analysis of cancer-genetics papers in two high-impact journals." A team led by Australia's University of Sydney cancer researcher Jennifer Byrne "has identified some highly cited studies that contain errors in the DNA or RNA sequences of reagents." Reagents are used in science "for various reasons...and if the sequences are wrongly reported it could affect the reproducibility of the research." Currently "it is unclear whether the errors are accidental or indicate misconduct," and scientists agree" that the presence of such mistakes in the scientific literature is worrying." The study has not yet been peer reviewed and was "published on the preprint server bioRxiv on 3 February."

Scientists To Publish Entire Genome Of One Human Before End Of 2023.

BBC News (2/10, Marshall, 876K) reported that "before the end of 2023," there "will be a seminal moment – the publication online of the entire genome of" Leon Peshkin, a single "human being, end to end with no gaps." Although the "first draft of the human genome was released in 2001," the composite sequence from several peoples' DNA "had major gaps and errors." Only now "in the last few years has technology advanced to the point that it is possible to read the entire human genome, without gaps and with minimal errors." And "the geneticists involved" in the Human Genome Project (HGP) "now want to sequence the genomes of people from around the world" to explore genetic diversity, what DNA does, and to "help doctors diagnose and treat us when we get sick."

Financial Filings Reveal Hospital Oligarchy In Orlando, Florida.

STAT (2/10, Herman, 262K) reported, "A recent financial filing from a large, tax-exempt hospital system in Orlando provides a glimpse, and serves as a reminder, of just how concentrated America's hospital markets are." In Orlando, Florida, "just two giants run the show," with Orlando Health and AdventHealth together controlling "77% of the entire inpatient hospital market in the four-county Orlando metro area, according to Orlando Health's bond filing." Both "not-for-profit systems also own two-thirds of the pediatric hospital market," and according to older filings, they also "control closer to 90% of inpatient services in a narrower three-county slice of Orlando." But even as a "highly concentrated

oligopoly," the "numbers didn't surprise experts who have spent decades studying hospital consolidation."

Transgender Advocacy Group Sues SD Governor, Alleging Contract With State Government Was Terminated Due To Discrimination.

The AP (2/10, Biraben) reported, "A transgender advocacy group in South Dakota sued Republican Gov. Kristi Noem and the head of the state's Department of Health on Friday over the state's decision to terminate a contract with the group last December." The group, called the Transformation Project, "filed a lawsuit Friday that alleges that the decision to terminate the contract – which resulted in the group losing a nearly $136,000 grant from the U.S. Centers for Disease Control and Prevention – was discrimination." A representative for the governor "said last December that the contract had been signed without Noem's knowledge or consent. Noem's office has also said that the organization did not meet all of the terms of its contract, such as providing quarterly reports." The group denied the latter claim in a statement to the AP.

Fox News (2/12, Chasmar, 23.99M) also reports.

Opinion: CVS, Walgreens Ventures Into Primary Care Will Not Fix Broken US Healthcare System.

CEO of Hint Health Zak Holdsworth wrote in an op-ed for STAT (2/10, Holdsworth, 262K), "CVS Health's acquisition of Oak Street Health, a Medicare-focused primary care provider, for $10.6 billion is just the latest in a string of primary care clinic buyouts by other retailers and insurance companies," including Walgreens Boots Alliance. However, Holdsworth said, "while these moves could help address the severely broken U.S. healthcare system, their motives and the solutions they offer are Band-Aids at best. Companies like Amazon, Walgreens, CVS, and others aren't capable of solving the healthcare crisis, as they are so closely tied to the fundamentally flawed insurance fee-for-service infrastructure, which I believe has played a significant role in breaking the healthcare system to begin with."

Sanford, Fairview Agree To Delay Merger Until May 31 Amid Pressure Campaign.

The Minneapolis Star Tribune (2/11, Snowbeck, 855K) reported, "Sanford and Fairview have agreed to push back the closing on their mega-merger until May 31, a two-month delay that comes after weeks of pressure by lawmakers, the

University of Minnesota and Attorney General Keith Ellison." Ellison's office has alleged the health systems have failed to comply with his office's requests for information. Additionally, hours before announcement, the University of Minnesota's "Board of Regents blasted the timeline and process for the proposed merger during a meeting in Minneapolis." Of particular concern to Regents Board chair Ken Powell is the systems' "stated intent to combine systems 'with or without the University of Minnesota.'"

Kentucky Receives First "Baby Box" Drop Off.

The AP (2/11) reported, "Kentucky has seen its first infant anonymously dropped off at one of its 'baby box' safe surrender locations." Safe Haven Baby Boxes Founder and CEO Monica Kelsey "said fire department staff was able to tend to the child in less than 90 seconds." This marks the 24th child "in the country to be surrendered at one of more than 130 baby boxes and drawers the organization has established across nine states."

CNN (2/12, Riess, 89.21M) reports, "Kentucky Gov. Andy Beshear in 2021 signed a law allowing the use of a 'newborn safety device' for the anonymous surrendering of infants less than 30 days old at a participating staffed police station, staffed fire station, or a staffed hospital." The purpose of Safe Haven Baby Boxes is "to give distressed parents a safe place to drop off their newborns while remaining anonymous, preventing the illegal abandonment of newborns."

Lawsuit Seeks Health Monitoring For Residents Potentially Affected By Toxic Train Derailment.

The AP (2/10) reported, "Residents who filed a federal lawsuit in the fiery derailment of a train carrying toxic chemicals along the Ohio-Pennsylvania line are seeking to force Norfolk Southern to set up health monitoring for residents in both states." In addition to damages, the plaintiffs call "for the rail operator to pay for medical screenings and related care for anyone living within a 30-mile (48-kilometer) radius of the derailment to determine who was affected by toxic substances released after the derailment."

DOT Investigating Neuralink Over Shipping Methods Of "Contaminated" Devices.

The AP (2/10) reported the US Department of Transportation is investigating Elon Musk's brain-implant company Neuralink "over its shipping methods after an animal rights group contacted the" DOT. According to the Physicians Committee

for Responsible Medicine, "public records show untrained Neuralink employees transported 'contaminated' devices that were removed from the brains of 'infected' monkeys without safely packaging them." The alleged "incidents are said to have taken place in 2019 at the University of California, Davis."

CNBC (2/11, Capoot, 7.34M) reported the devices "may have been contaminated with viruses like Herpes B and antibiotic-resistant bacteria like Staphylococcus and Klebsiella, according to" PCRM.

Women Fear Seeking Treatment For Cervical, Breast Cancer In Kenya Because Of Stigma, Physician Says.

Reuters (2/10, Aruya, Hlatshwayo) said, "As in much of Africa, most cancer cases in Kenya are diagnosed at an advanced stage, when treatment options are limited and families make huge sacrifices by selling assets or borrowing money, according to a World Bank report." According to Nairobi Radiotherapy and Cancer Centre Physician Bridget Nyabuto, "stigma makes the problem worse," causing women to "fear seeking diagnosis for some of the most common and deadly cancers in Kenya such as cervical and breast cancer." She said, "Any topics to do with sex, the female reproductive system, are a bit taboo."

Highest-Income Black Families At Greater Risk For Maternal, Infant Mortality, Than White Families, Study Finds.

The New York Times (2/12, Cain Miller, Kliff, Buchanan, 20.6M) reports, "In the United States, the richest mothers and their newborns are the most likely to survive the year after childbirth – except when the family is Black, according to a groundbreaking new study of two million California births" that showed "the richest Black mothers and their babies are twice as likely to die as the richest white mothers and their babies." Researchers also "found that maternal mortality rates were just as high among the highest-income Black women as among low-income white women," and "infant mortality rates between the two groups were...similar."

Opinion: Higher Education Needs To Retire "Weed-Out" Mentality In STEM Fields.

In an op-ed for STAT (2/10, 262K), Wellesley College President Paula A. Johnson wrote, "Because the nation's increasingly diverse students come to college with vastly different high school experiences, it's time to retire the traditional 'weed-out' mentality in STEM teaching, which is as likely to reward privilege as ability."

She added, "The onus should be on schools to help all of their students succeed." Johnson explained how "Wellesley has created multiple pathways into STEM majors." She concluded, "Higher education can make a real difference simply by meeting women, first-generation, and underrepresented students where they are and, rather than teaching to exclude, teaching to inspire."

Opinion: Pregnancy Represents Unique Opportunity To Increase Funding For Women's Health.

In an op-ed for STAT (2/10, 262K), UCSF Pregnancy and Cardiac Treatment Program Cardiologist Nisha Parikh and OB/GYN Hospitalist Alison Cowan wrote, "While heart disease deaths are at a historic high, so too are disorders arising from high blood pressure (hypertension) during pregnancy." They added, "In addition to being a leading cause of pregnancy-related illness and death, there is now compelling evidence that preeclampsia and other complications of pregnancy increase an individual's future risk of heart disease." The experts said it is "time to address the disproportionately low funding for women's health, and the accompanying underwhelming investment, research, and progress for women's health in general, including women's cardiovascular health." They concluded, "Pregnancy is a window to the future and represents a unique opportunity to start reversing these unequal risks."

Wildfire Smoke Exposure During Pregnancy Tied To Increased Risk Of Preterm Birth, Study Finds.

NBC News (2/11, Bendix, 4.91M) reported, "A study of more than 2.5 million pregnant people in California found that those exposed to wildfire smoke for at least one day faced a higher risk of giving birth prematurely." The findings "suggested that just one day of smoke exposure slightly raised the risk of spontaneous preterm birth – defined as before the 37th week of pregnancy." However, "the odds of preterm birth increased by 0.3% with each additional day of smoke exposure."

Analysis Identifies Factors That May Explain Differences In Cognitive Ability Among Older Adults.

NBC News (2/11, Carroll, 4.91M) reported "a handful of factors, such as education, income and job type, may increase the likelihood that people in their mid-50s will still be mentally sharp," according to "an analysis of data from more than 7,000 U.S. adults" who "were 54 to 65 years old in 1996 and then 20 years

later." The results "showed that these factors could explain nearly 40% of the differences in the amount of cognitive ability people had lost by age 54." According to researchers, "education, in particular whether a person had finished college, made the biggest difference in cognitive abilities such as memory, judgment and focus."

Montana Weighs Proposal Allowing Physician Assistants To Practice Unsupervised.

Kaiser Health News (2/10, Larson) reported, "As Montana grapples with a health care provider shortage, state lawmakers are trying to find ways to increase access to care." And one proposal currently "up for debate is to give physician assistants...more independence to practice unsupervised." House Bill 313 "would let physician assistants practice without a supervision agreement."

Louisiana Accidentally Legalized Recreational THC.

The New Orleans Times-Picayune (2/12, Karlin, 691K) reports, "In November, John Williams, the top beer lobbyist in Louisiana, sent out a mass email to legislators with an alarming subject line: 'Recreational THC is now legal in Louisiana.'" He sent "pictures of gas stations and smoke shops advertising products full of THC...many of which hit the shelves after House Speaker Clay Schexnayder ushered through legislation to set up a legal hemp industry in the state." Schexnayder's 2022 bill to loosen the rules on hemp "set up an 'adult-use' market for consumable products made from hemp." He "assured fellow legislators...that his legislation wouldn't give people access to products that get them high." However, it is clear "that it hasn't worked out the way Schexnayder promised it would." Regulators and legislators are now "trying to unring the bell and crack down on a massive proliferation of THC-laden products that have become widely and legally available."

Weak Grip Could Indicate Risk Of Early Death, Study Suggests.

The New York Post (2/10, Herz, 7.45M) reported, "having a weak grip could be a harbinger of early death, according to a new study." The researchers "followed 1,275 men and women over the course of 8 to 10 years, who were aged around 70 years old during that period." They used "a Smedley spring dynamometer – a device that measures grip strength – to test the participants every two years." They also took a blood sample "to study DNA methylation levels in each participant." According to the NCI, "DNA methylation can be defined as a kind of

chemical reaction in your body where a 'small molecule' called a methyl group can enter your DNA. ... Having an increase in your DNA methylation or having too much of it can affect your risk of developing illnesses like cancer and other cardiovascular diseases." Researchers found "a correlation between normalized grip strength and DNAm age acceleration in both men and women."

Federal Government Awards Medical Schools Funding To Integrate Behavioral Health, Primary Care.

The Washington Post (2/10, Johnson, 10.52M) reported, "A growing number of providers...are integrating behavioral health and primary care to improve the continuity of treatment and lower barriers to access." The federal government is now "awarding 24 medical schools and hospitals a total of $60 million to train the next generation of primary care physicians – family medicine doctors, pediatricians, internists – to address behavioral health needs."

Use Of Telehealth Among Clinicians Treating Patients With OUD Dropped 15%, Survey Finds.

mHealth Intelligence (2/10, Vaidya) reported, "Telehealth use among clinicians who treat patients with opioid use disorder (OUD) dropped from 56.7 percent in December 2020 to 41.5 percent in March 2022, according to a recent survey." Additionally, "the use of audio-only visits declined from 20.2 percent of all OUD visits to 11.6 percent in the same period." Meanwhile, "clinicians' attitudes toward video and audio-only telehealth also changed over time." The survey found "the proportion of respondents saying that patients received higher-quality care via video rather than audio-only visits increased from 63.5 percent in December 2020 to 69.7 percent in March 2022."

Editorial: New Mexico Legislators Need To Take Action To Prevent Physicians From Fleeing To Other States.

In an editorial, the Albuquerque (NM) Journal (2/11, 188K) wrote about New Mexico's shortage of physicians and its impact on healthcare. Local physicians "say unless changes are made, the situation will become much more dire." The Journal said, "Doctors are fleeing or passing us by because of our high costs of maintaining a private practice. ... Lawmakers need to act, STAT!"

Florida Nursing Homes See Surge In Citations.

The Tampa Bay (FL) Times (2/10, Critchfield, 762K) reported, "Last year, Florida nursing homes were cited 83 times for putting their older adult residents at risk of immediate danger." According to records obtained by the Times, "since 2019, violations have nearly doubled compared to the previous six years." Meanwhile, "elder care advocates, nursing home industry leaders and long-term care researchers offered theories for the increase." They included "changes in how violations are measured to staff shortages to recent legislation that critics say weakened nursing home care standards."

Approximately 383K Illinoisans Struggle With Sports Gambling Addiction, Department Of Human Services Says.

The Chicago Tribune (2/12, Sheridan, 2.03M) reports, "An estimated 383,000 Illinoisans have a gambling problem, while an additional 761,000 are estimated to be at risk of developing one, according to a study published in 2022 by the Illinois Department of Human Services." In 2022, "wagers placed with the state's sports gambling industry soared...with gamblers betting nearly $10 billion and casinos raking in $800 million in revenue from gamblers' aggregate losses."

Residents Not Convinced It Is Safe To Return Home After Toxic Train Derailment.

The Washington Post (2/12, Salcedo, McDaniel, 10.52M) reports, "Days after a train carrying hazardous materials went off the tracks in northeastern Ohio, burst into flames and stoked fears of a 'potential explosion,' authorities assured evacuated residents that it was safe to return to town." However, residents are not convinced. A list of "chemicals that were aboard the train when it lost its course" has yet to be released. Experts and residents "told The Post that they question whether it's safe to return to their homes a week after contaminants flowed into local streams and spewed into the air" without this information.

Exposure To Traffic Noise At Home May Cause Tinnitus, Study Suggests.

The Washington Post (2/11, Blakemore, 10.52M) reported a new study suggests "exposure to road traffic noise at home" may be linked to tinnitus. Researchers analyzed "data on 3.5 million Danish residents who were 30 and older between 2000 and 2017." During that time period, "40,692 were diagnosed with tinnitus." The investigators discovered "people's risk rose 6 percent with every 10-decibel increase in road traffic noise compared with controls."

Anti-Tobacco Advocates Support New York Governor's Effort To Ban Flavored Cigarettes.

NY1-TV New York (2/10, Reisman, 13K) reported, "Anti-tobacco advocates in New York are cheering the effort to ban flavored cigarettes in the state and increase taxes on cigarette purchases, calling the move key for limiting tobacco use among young people." They are calling "the governor's tax and ban plan the right move to further reduce teen smoking." However, the proposed ban "is being opposed by tobacco groups as well as convenience store organizations, who argue the measure would simply encourage illicit sales of cigarettes, including menthol."

Anti-Smoking Advocate Raises Awareness About Risks Of Teen Vaping.

The Sun (UK) (2/11, Einstein, Rollings, 561K) reported on an anti-smoking advocate who started vaping at 11. He was attracted by the bright colors and flavors of the vape cartridges. He managed to quit vaping when he was 17, after he developed a smoker's cough. He is now working to raise awareness about the risks of teen vaping.

New Mexico Considers Proposals To Make It Harder To Access Vape, Tobacco Products.

KOB-TV Albuquerque, NM (2/10, Rushton, 69K) reported, "A new batch of bills at the New Mexico Roundhouse aim to make it harder to buy and use vape and tobacco products." The state lawmakers hope the legislation will chip away at the "many barriers to" enacting "a statewide vaping ban." The proposals "include raising tobacco taxes, banning flavored products, and allowing local governments to enact tougher restrictions against smoking," as well as "proposals to prohibit smoking in racinos and fund prevention programs."

Connecticut Considers Permitting Cigar Lounges To Sell Liquor.

The Connecticut Post (2/12, Moritz, 310K) reports, "Connecticut's cigar lounges would be allowed to seek liquor licenses for the first time in nearly twenty years under new legislation promoted by lawmakers who say that the state's strict anti-smoking laws are simply driving customers – and their money – over state lines." The proposed legislation "would require that any new tobacco bars exist in a stand-alone building or have their own heating, ventilating and air conditioning system to prevent air from co-mingling with adjacent businesses and homes."

However, health advocates "have come out in opposition to plans to loosen the state's indoor smoking ban, citing a range of concerns over second-hand smoke."

City In Tennessee Restricts Smoke, Vape, CBD Shops To Manufacturing Districts.

The Daily Memphian (TN) (2/10, Waddell) reported, "On Thursday, Feb. 9," Lakeland's "Board of Commissioners dealt with an agenda that included revising zoning for future smoke, vape and CBD shops." The city's "board unanimously approved a second and final reading of an ordinance to restrict smoke, vape and CBD shops and similar businesses to the city's manufacturing districts."

North Dakota Refuses To Raise Cigarette Taxes.

The Grand Forks (ND) Herald (2/11, Klinski, 96K) reported North Dakota legislators have voted against raising cigarette taxes three times since 2013. A supporter of increasing the cigarette taxes "said other opponents have been worried about how raising the tax would lead to lower revenues and business on border towns where neighboring states have a significantly higher cigarette tax rate." He also "said he doesn't think taxes will be raised unless the state encounters a budget crunch in the future."

Youth Vaping Increases As Youth Smoking Decreases.

The Grand Forks (ND) Herald (2/11, Otto, 96K) reported, "While youth smoking has decreased over the years, youth vaping has 'exploded over time,' according to Neil Charvat, director of the North Dakota Department of Health & Human Services' tobacco prevention and control program." Data from the North Dakota Department of Health & Human Services' tobacco surveillance found that "21.2% of high school students, as of 2021, have used electronic nicotine delivery systems" The data also showed that 5.9% of high school students have smoked cigarettes.

Wild Ducks Found Dead In Maine Test Positive For Type Of Bird Flu.

The AP (2/12) reports that six wild ducks "found dead in a stream in Winthrop," Maine "have tested positive for bird flu," according to wildlife authorities. The hooded mergansers "were found dead in Mill Stream and tested positive for a highly pathogenic avian influenza, the Maine Department of Inland Fisheries and Wildlife said Friday."

Suburban Detroit Schools Shuts Down After Norovirus Outbreak Sickens Students, Staff.

The AP (2/10) reported that classes "at a suburban Detroit school have been cancelled due to an outbreak of the norovirus among students and staff." The AP says "St. Michael the Archangel Catholic School in Livonia shut down Wednesday, WXYZ-TV reported Friday." As of Friday afternoon, "about 100 students and 15 staffers at the school had developed symptoms, according to the Wayne County Public Health Division."

ABC World News Tonight (2/12, 6:45 p.m. EST, story 6, 0:25, Johnson, 3.85M) also broadcasts the story.

"Canadian Horse Disease" Crippled US Cities 150 Years Ago.

The Washington Post (2/12, Tillman, 10.52M) reports that a virus known as "Canadian horse disease" sickened some 600 horses near Toronto in the late 1800s. The Post says the disease "spread quickly, following rail lines into bustling cities and knocking out the workhorses that had powered the United States into a new era." According to the Post, the "the outbreak of what was later determined to be the equine flu hit the vast majority of the country's horses between October 1872 and March 1873, temporarily paralyzing cities in a crisis 'comparable to what would happen today if gas pumps ran dry or the electric grid went down,' University of Tennessee historian Ernest Freeberg wrote."

Number Of Mississippi Babies Being Treated For Congenital Syphilis Spikes By 900%.

NBC News (2/11, Harris, 4.91M) reported that the "number of babies in Mississippi being treated for congenital syphilis has jumped by more than 900% over five years, uprooting the progress the nation's poorest state had made in nearly quashing what experts say is an avoidable public health crisis." NBC says "the rise in cases has placed newborns at further risk of life-threatening harm in a state that's already home to the nation's worst infant mortality rate." In 2021, "102 newborns in Mississippi were treated for the sexually transmitted disease, up from 10 in 2016, according to an analysis of hospital billing data shared by Dr. Thomas Dobbs, the medical director for the Mississippi State Department of Health's Crossroads Clinic in Jackson, which focuses on sexually transmitted infections."

Scientists Monitor Possible Danger To Humans As Bird Flu Makes Leap To Mammals.

NBC News (2/11, 4.91M) reported that scientists monitoring the leap of avian influenza to mammals such as wild sea lions and minks say such infections "are spooky reminders that a widespread outbreak in animals has potential consequences for humans." In the US, NBC says, "the most recent wave of bird flu has struck in 17 mammals and more than 160 birds." Richard Webby, "an infectious disease researcher at St. Jude Children's Research Hospital in Memphis and the director of the World Health Organization Collaborating Centre for Studies on the Ecology of Influenza in Animals and Birds, said: 'This is the number one potential pandemic virus everyone has been interested in for a long time.'"

Also reporting the story was USA Today (2/10, Rodriguez, 12.7M).

CDC: Pediatric Flu Deaths Top 100 For First Time Since Beginning Of Pandemic.

The Hill (2/10, Choi, 5.69M) reported that the "number of pediatric flu deaths during the current season has officially gone over 100, according to the Centers for Disease Control and Prevention (CDC) – more than twice the number of the pediatric deaths confirmed in the last flu season." The Hill says the CDC "reported nine pediatric flu deaths this week, bringing the total for the season up to 106." The agency "also noted that it is the highest pediatric death rate for flu since the start of the COVID-19 pandemic."

Some Regions Of US Hit Harder By Norovirus Outbreaks.

The Hill (2/10, Bartiromo, 5.69M) reported that some areas of the US are being harder hit from the "uptick in outbreaks of norovirus," according to data from the CDC. The Hill says "some parts of the country have noted especially high positivity rates slightly earlier than in previous years, mirroring an overall national trend." Participating laboratories "in the Midwest, for instance, had observed a 19.4% positivity rate among patients who took polymerase chain reaction (PCR) tests as of Feb. 4 – topping the previous year's high of 16.1%, recorded in April 2, 2022." And the Western region "also appears on track to exceed last year's top positivity rate of 13.49% (observed at the end of April) with recent positivity rates at 13.42%, and likely rising, as of Feb. 4."

Milwaukee County Identifies Chronic Wasting Disease In Wild Deer.

The Milwaukee Journal Sentinel (2/12, Smith, 844K) reports that the state Department of Natural Resources "last Wednesday announced the detection of chronic wasting disease in a wild deer in Langlade County." The discovery is "the latest in a spate of initial CWD discoveries in recent months in wild deer in Wisconsin and follows similar announcements in Buffalo and Waupaca counties."

Michigan School Shut Down After Students, Staff After Suspected Norovirus Outbreak.

The Detroit Free Press (2/10, Jordan Shamus, 2.16M) reported that "at least 115 students and staff at St. Michael the Archangel Catholic School in Livonia have been sickened by a suspected norovirus outbreak that has shut down the school." Co-principal Kathy Nold said, "We closed school the following day and spoke to the Wayne County Health Department." Also reporting the story was the Detroit News (2/11, Mackay, 1.16M).

Pittsburgh-Area Physicians Worried About Effect Of Measles Outbreak In Columbus, Ohio.

The Pittsburgh Post-Gazette (2/12, Webster, 426K) reports that some physicians in the Pittsburgh area "expressed concern" that a November measles outbreak in Columbus, Ohio "could travel eastward" and "said a changing vaccine landscape post-pandemic could put children at risk." The Columbus Public Health Department "announced on Monday that the outbreak had ended." Mark Roberts, "a distinguished professor of health policy and management and the director of the Public Health Dynamics Lab at the University of Pittsburgh School of Public Health, said: 'People also don't remember that measles is not just getting a rash. In other parts of the world, it kills 1 in 1,000 kids.'"

Florida Woman Files Suit Against Maker Of Eyedrops Allegedly Linked To Infections.

NBC News (2/10, Lovelace, 4.91M) reported that a Florida woman "filed a lawsuit late Thursday against the maker of EzriCare artificial tears and Walmart after suffering a bacterial infection that she said was caused by the eyedrops." NBC said "Houston-based Lange Law Firm, which is representing the woman, Teresa Phillips, 60, of Bradford County, said the lawsuit is the first nationwide over injuries related to eyedrops linked to a drug-resistant bacterial infection called Pseudomonas aeruginosa." The lawsuit alleges "Phillips purchased EzriCare artificial tears in the weeks before her infection."

Meanwhile, Bloomberg Law (2/10, Subscription Publication, 4K) reported behind a paywall that "clusters of infections linked to the use of eye drops have been found in four states, according to US health officials tracking the outbreak that's already led to the death of one person." Bloomberg says "at least 35 of 56 cases related to the recalled eye drops have been reported from California, Connecticut, Florida and Utah, according to US Centers for Disease Control and Prevention spokesperson."

Research Shows Telehealth Improved Equitable Cancer Care Access, Delivery Before COVID-19 Pandemic.

mHealth Intelligence (2/10, Melchionna) reported, "Recent research shows that equitable cancer care access and delivery benefited highly from telehealth before the COVID-19 pandemic." The research "notes that there is limited evidence regarding the use of telehealth to support equitable cancer care," and in order to "gain insight into pre-pandemic hospital efforts of providing telehealth and oncologic services, researchers conducted a retrospective cross-sectional analysis that considered geographic and sociodemographic statistics." The use of telehealth "to deliver cancer care is becoming more common." In fact, "funding from the National Cancer Institute in August 2022 led to the creation of the Northwestern Program for Scalable Telehealth Cancer Care, which aims to track smoking, obesity, and inactivity among cancer patients."

Study Finds Restrictive Calorie Diet May Extend Life Span.

CNN (2/10, LaMotte, 89.21M) reported, "People of normal weight may be able to extend their life span by restricting calories, according to a new study that attempted to measure the pace of aging in people asked to cut their calorie intake by 25% over two years." Published Thursday in the journal Nature Aging, the new study "culled DNA sequences from white blood cells taken at 12-month intervals from participants in CALERIE." The research team "then analyzed methylation marks – signs of epigenetic changes – on the DNA, looking for symptoms of aging." According to the National Human Genome Research Institute, "epigenes are proteins and chemicals that sit like freckles on each gene, waiting to tell the gene 'what to do, where to do it, and when to do it.'"

Fox News (2/10, Rudy, 23.99M) reported, "The study included 200 men and women between the ages of 21 and 50." It was "funded by the U.S. National Institute on Aging," and "was the first-ever research to measure the impact of prolonged calorie restriction in healthy people without obesity."

Billionaire Bill Ackman Announces Foundation Funding For Controversial Biologist Ousted For Alleged Sexual Misconduct.

CNN (2/12, del Valle, 89.21M) reports that Dr. David Sabatini, "a decorated but controversial biologist ousted for alleged sexual misconduct from the MIT-affiliated Whitehead Institute," is now "getting new funding with help from billionaire hedge fund manager Bill Ackman." The recent "funding announcement unfolded publicly on the heels of a Boston Globe Spotlight two-part report detailing a monthslong investigation into the allegations against Sabatini published in late January." During Sabatini's tenure at Whitehead, there was "a focus on improving workplace environments and weeding out sexual harassment...at institutions around the country...after a mandate from a major government grant source, the National Institutes of Health (NIH), to 'develop and implement policies and practices that foster a harassment-free environment' or risk losing funding."

Casino Workers Eagerly Await Hearing On Legislation That Could Prohibit Smoking In Nine Atlantic City Casinos.

The AP (2/13, Parry) reports, Atlantic City "dealers, cocktail servers and other casino workers – some of them with breathing ailments and other health problems they suspect are related to secondhand smoke from casino patrons – are eagerly awaiting Monday's hearing before a New Jersey Senate committee on legislation that would prohibit smoking in Atlantic City's nine casinos." The new bill "would close a loophole in the state's 2006 indoor smoking law written specifically to exempt casinos from bans on smoking indoors. Currently, smoking is permitted on 25% of a casino floor in Atlantic City."

New York Governor's Proposed Menthol Ban, Cigarette Tax Receives Mixed Reactions.

The New York Daily News (2/13, Slattery, 2.51M) reports that New York Gov. Hochul's "proposed plan to ban the sale of menthol cigarettes and hit smokers with an additional dollar-per-pack tax is sparking a heated debate over revenue and the black market sales of cigs." Hochul is "hoping to drive down tobacco use among younger New Yorkers and lower smoking levels in minority communities" through "legislative changes banning flavored cigarettes and increasing taxes on cigarette purchases in her $227 billion budget proposal earlier this month." While "anti-smoking groups and health officials have applauded the proposal," some

convenience store owners and others "say the ban on flavored tobacco products would be an unenforceable mandate that could leave a hole in state coffers and be a boon to the already thriving black market."

VA Urges Camp Lejeune Veterans To Apply For Disability, Lawsuits Despite Possible Legal Complications.

The Hill (2/13, Udasin, 5.69M) reports, "The Department of Veterans Affairs (VA) is urging former service members whose illnesses may be linked to contamination at Camp Lejeune in North Carolina to seek disability benefits – even if doing so might complicate future quests for legal recourse." The issue "for veterans who were exposed and have yet to submit claims" is that the "decision is complicated by the Honoring Our PACT Act." PACT "seeks to make significant improvements to health care for veterans who were exposed to toxins during their service," and permits lawsuits for Camp Lejeune. But with PACT, "any legal compensation awarded in court must be 'offset' by disability claims related to Camp Lejeune exposures that the individual is already receiving." This applies "to any program administered by the secretary of Veterans Affairs, Medicare or Medicaid."

Experts Seek Out Internal, External Cause Behind "TikTok Tics" Phenomenon.

The New York Times (2/13, Ghorayshi, Bracken, 20.6M) reports during the pandemic, physicians "across the world treated thousands of young people for sudden, explosive tics. Many of the patients had watched popular TikTok videos of teenagers claiming to have Tourette's syndrome. A spate of alarming headlines about 'TikTok tics' followed." However, "similar outbreaks have happened for centuries. Mysterious symptoms can spread rapidly in a close-knit community, especially one that has endured a shared stress." The phenomenon known as "TikTok tics" came "at a unique moment in history, when a once-in-a-century pandemic spurred pervasive anxiety and isolation, and social media was at times the only way to connect and commiserate." As a result, "experts are trying to tease apart the many possible factors – internal and external – that made these teenagers so sensitive to what they watched online."

Opinion: Americans Need To Have More, Pleasurable Sex To Offset Loneliness.

Contributing writer Magdalene J. Taylor writes for the New York Times (2/13, 20.6M), "Americans, in the midst of a loneliness epidemic, are not having enough

sex." While "sex isn't the sole form of fulfilling human interaction and certainly isn't a salve for loneliness," it "should be seen as a critical part of our social well-being, not an indulgence or an afterthought." The "rise in loneliness closely parallels a decline in sex," along with a drop in "partnership and cohabitation." Isolation "is demolishing Americans' social lives, love lives and happiness," and it started before the COVID-19 pandemic. Almost "every group of Americans is experiencing the absence of sex – and the consequences are profound. ... A lack of sex can easily translate into less socialization, fewer families and a sicker population." Taylor concludes, "So, anyone capable should have sex – as much as they can, as pleasurably as they can, as often as they can."

Global Health

Chinese Health, Family Planning Experts Call For Government Action To Reduce Financial Burden Of Raising Children.

Reuters (2/10, Master, Zhang) reported China's National Health Commission Population Monitoring and Family Development Department Director Yang Wen Zhuang "has urged local governments to take 'bold' steps to lower the cost of having babies and raising children to reduce the burden on families and boost fertility." He "said that worries about money and career development among women were the main factors for people opting not to have babies, adding that precise policies were needed to improve the fertility level."

In a separate article, Reuters (2/12, Wang, Orr) reports, "China should enhance incentives for people to build families and boost the birth rate as the country's now-falling population could threaten the world's second-biggest economy, a Chinese family planning expert said." China Family Planning Association Deputy Director Wang Pei'an "called for more incentives around employment, medical care, social security and housing that could encourage people to build families."

Over-Priced Child Care Costs Becoming Top UK Political Issue.

Behind a paywall, Bloomberg (2/13, Konotey-Ahulu, 3.57M) reports, "Of the multitude of problems plaguing the UK, one issue is rising toward the top of the pile --" the exorbitant cost of early-years child care. Calls to tackle the issue "are growing louder ahead of the next general election, due within two years." But "there's no easy fix for a system that's become dominated by private interests, and any meaningful reform would likely require an injection of public funds at a

time when Prime Minister Rishi Sunak is focused on tightening spending to bring down inflation."

EMA Begins Review Of Decongestant Medicines With Pseudoephedrine Over Safety Concerns.

Reuters (2/10, Roy) reported, "A European Medicines Agency (EMA) committee said on Friday it has started a review of decongestant medicines for cold and flu that contain the ingredient pseudoephedrine following safety concerns." EMA "said the review was due to reports of conditions affecting blood vessels in the brain in some patients who took pseudoephedrine-containing medicines."

WHO Discussing Ending Mpox Global Public-Health Emergency.

Nature (2/10, Kozlov, 194K) reported, "A World Health Organization (WHO) committee met earlier this week to decide whether the mpox outbreak...is still a global public-health emergency, and the agency could soon declare it over." So far "the outbreak has subsided in countries including the United Kingdom and the United States, thanks to the deployment of vaccines and therapeutics, as well as changes in awareness and social behaviour." However, "the same is not true in some nations in West and Central Africa, which have been battling the monkeypox virus for decades, and where the disease's toll has been historically highest."

US, South Korea Warn Of New Ransomware Tactics From North Korea Targeting Critical Infrastructure.

Healthcare IT News (2/10, Fox, 2K) reported, "Government agencies from the United States and the Republic of Korea are highlighting new ransomware tactics they've seen, which they say are used to conceal the affiliation of Democratic People's Republic of Korea hackers working to stage attacks against U.S. and South Korean healthcare organizations and critical infrastructure." This "new cybersecurity advisory, Ransomware Attacks on Critical Infrastructure Fund DPRK Malicious Cyber Activities, details both North Korea's historically and recently observed tactics, techniques and procedures and indicators of compromise."

Brazil's Yanomami Health Crisis Drawing People Out Of Isolation.

The AP (2/11, Maisonnave, Barros) reported on the health crisis plaguing Brazil's Yanomami people. Hundreds of homeless Yanomami, "who traditionally live in relative isolation" in the Amazon rainforest, are spread throughout Boa Vista

seeking help. Many Yanomami arrived in the area to seek shelter at "the Indigenous Health House known as Casai, a federal facility on the outskirts of Boa Vista." The facility "was built to host Yanomami under treatment and their relatives," but it only has a capacity of 200 people. Currently, "it harbors many as 700, representing 2% of the Yanomami population."

More Than 250K Spaniards Protest Healthcare Services In Madrid.

The AP (2/12) reports that on Sunday, more than 250,000 "Spaniards flooded the streets of Madrid...for the largest protest yet against the regional government's management of the capital city's health care services." The demonstration was led by health worker associations and "was backed by left-wing parties, unions and normal citizens concerned with what they see as the dismantling of the public health care system by the Madrid region's conservative-led government."

Reuters (2/12, Rodriguez, Gore) reports protestors said the Madrid government "is dismantling public health services and favouring private health providers."

UK Anti-Smoking Organization Calls For Excise Tax On Disposable Vapes.

The Telegraph (UK) (2/11, 249K) reported, "Action on Smoking and Health (ASH) are calling for an excise tax on disposable vapes to stop children from being able to buy them for less than £5" in the UK. ASH "said adding £4 to each single-use vape, which currently cost around £4.99, would make them significantly less affordable for children while still less expensive than tobacco." Additionally, ASH "argued such a tax would also have an environmental benefit, with discarded single-use vapes equating to 10 tonnes of lithium being thrown away a year."

Among other news outlets covering the story were PA Media (UK) (2/10, Clarke), The Guardian (UK) (2/11, Hall, 5.53M), and The Sun (UK) (2/10, Davies, 561K).

UK Regulatory Body Finds Poisons In Some Fake Vapes.

The Sun (UK) (2/10, Singh, 561K) reported that some fake vapes "were found to contain" poisons, which included "arsenic, lead and formaldehyde." The poisons were found in the fake vapes by Trading Standards officers, who "also found other substances that could damage your health while testing the fake vape in Derby." The regulatory body "also warned of a rapid increase of disposable fake vaping devices being sold to children."

Equatorial Guinea Places More Than 200 People In Quarantine After Deaths From Unknown Hemorrhagic Fever.

Reuters (2/10, Atabong) reported that Equatorial Guinea "has quarantined more than 200 people and restricted movement after an unknown illness causing hemorrhagic fever killed at least eight people, Health Minister Mitoha Ondo'o Ayekaba said on Friday as the government races to test samples." Reuters says "the outbreak was reported on Feb. 7, and from preliminary investigations, the deaths were linked to people who all took part in a funeral ceremony, Ayekaba said, adding the government had sent samples to neighbouring Gabon and will send others to Dakar in Senegal for further testing." Authorities "have restricted movement around the two villages that are directly linked, he said, and contact tracing was ongoing."

Spain Detects Atypical Mad Cow Disease Case, WOAH Says.

Reuters (2/10) reported that Spain "has detected atypical bovine spongiform encephalopathy (BSE) in a dead cow in the northwestern region of Galicia, the World Organisation for Animal Health (WOAH) said on Friday." Reuters says "the disease, commonly called mad cow disease, was found after a 22-year-old cow was euthanised due to signs of illness not related to BSE, Paris-based WOAH said, citing information from the Spanish authorities." The case, "which was isolated, 'didn't enter the food chain and so didn't represent any risk for public health or require any preventive health measure,' the Galicia's regional health service said on its website."

Professor Says "Mass Suicide" Of Japan's Elderly Comment "Taken Out Of Context."

The New York Times (2/12, Rich, Hida, 20.6M) reports on Yale Economics Assistant Professor Dr. Yusuke Narita's response to "the question of how to deal with the burdens of Japan's rapidly aging society." He said, "I feel like the only solution is pretty clear. ... In the end, isn't it mass suicide and mass 'seppuku' of the elderly?" But "Dr. Narita, 37, said that his statements had been 'taken out of context,' and that he was mainly addressing a growing effort to push the most senior people out of leadership positions in business and politics – to make room for younger generations."

National News

US Military Shoots Down Unidentified Object Over Lake Huron.

The Washington Post (2/12, A1, Marimow, Johnson, Horton, Brasch, 10.52M) reports the US military "shot down a fourth aerial 'object,' this time over Lake Huron on Sunday afternoon, according to the Defense Department, which described the object as 'unmanned' and not a military threat to anything on the ground." The Post adds that officials "said the object, initially detected Saturday night, was flying over Michigan's upper peninsula at about 20,000 feet – an altitude and path that raised concerns about potential interference with commercial aviation." Officials also "acknowledged that the Pentagon tried and failed to confront the object late Saturday afternoon, when radars detected something suspicious 70 miles north of the U.S. border in Canada."

Politico (2/12, Olander, Ward, 6.73M) reports the Defense Department issued a statement disclosing that President Biden "gave the order to take out the object based on the recommendations of Defense Secretary Lloyd Austin and military leadership," and USA Today (2/12, Brook, 12.7M) reports Pentagon Press Secretary Brig. Gen. Patrick Ryder revealed that an F-16 pilot "shot down the object at 2:42 p.m. ET Sunday" using "an AIM 9X sidewinder missile, the same weapon used in the previous instances."

Reuters (2/12, Stewart, Ali) reports Gen. Glen VanHerck, the Commander of North American Aerospace Defense Command (NORAD) and US Northern Command, "told reporters that the military has not been able to identify what the three most recent objects are, how they stay aloft, or where they are coming from." VanHerck explained, "We're calling them objects, not balloons, for a reason." VanHerck continued, "I'll let the intel community and the counterintelligence community figure that out." Reuters (2/13, Stewart, Ali) reports VanHerck "said...he would not rule out aliens or any other explanation yet, deferring to U.S. intelligence experts."

Meanwhile, Reuters (2/12) reports a White House National Security Council spokesperson said the objects "did not closely resemble and were much smaller than the PRC balloon and we will not definitively characterize them until we can recover the debris, which we are working on." Bloomberg (2/12, Leonard, 3.57M) states that the remarks came after Senate Majority Leader Schumer "said they are believed to have been high-altitude balloons."

The AP (2/12, Long, Baldor, Miller) highlights that the shootdown "was the fourth such downing in eight days and the latest military strike in an extraordinary chain of events over U.S. airspace that Pentagon officials believe

has no peacetime precedent." According to the New York Times (2/12, Cooper, 20.6M), "There are two big questions around the episodes: What were the craft? And why does the United States appear to be seeing more suddenly, and shooting down more?" The Times adds that while there are currently "no answers to the first question," as "American officials do not know what the objects were, much less their purpose or who sent them," when it comes to the second question, "it is not clear if there are suddenly more objects. But what is certain is that in the wake of the recent incursion by a Chinese spy balloon, the U.S. and Canadian militaries are hypervigilant in flagging some objects that might previously have been allowed to pass."

On ABC World News Tonight (2/12, 6:32 p.m. EST, lead story, 5:45, Johnson, 3.85M), White House Correspondent Mary Alice Parks characterized Biden's decision to order the shootdown as "a clear sign the US government is dramatically ramping up how it polices the skies, a week after that Chinese spy balloon was taken down and put the White House on high alert." In addition, The Hill (2/12, Sforza, 5.69M) reports that Assistant Secretary of Defense for Homeland Defense and Hemispheric Affairs Melissa Dalton "said on Sunday that the stark increase in the military spotting and shooting down aerial objects in recent days may be due to enhancing radar systems." The Wall Street Journal (2/12, A1, Youssef, Vieira, Subscription Publication, 8.41M) provides similar coverage.

Lawmakers Call For Details About Latest Shootdowns. The Hill (2/12, Mueller, 5.69M) reports lawmakers of both parties "spent Sunday questioning the Biden administration over the takedowns of two unidentified aerial objects in recent days, with some criticizing the White House over a lack of transparency about what the objects were and where they came from." Likewise, Monica Alba reported on NBC Nightly News (2/12, 6:31 p.m. EST, lead story, 4:30, Snow, 3.37M) that the news of Sunday's shootdown comes as a "bipartisan call for transparency from the White House and Pentagon grows louder."

On the CBS Weekend News (2/12, 6:31 p.m. EST, lead story, 2:50, Duncan, 10.89M), Skyler Henry summed up the response of US lawmakers "critical over...Biden's timing of shooting down the Chinese spy balloon earlier this month" as "demanding details on who is behind the latest objects," while being "pleased" the President ordered the shootdowns.

Axios (2/12, Saric, 1.26M) reports Senate Majority Leader Schumer, on ABC's This Week "acknowledged it was 'wild' the U.S. didn't know about the Chinese government's use of balloons 'until a few months ago,'" but The Hill

(2/12, Neukam, 5.69M) reports the Majority Leader "called the downing of last week's balloon a 'coup' for the U.S. in terms of intelligence gathering." In addition, The Hill (2/12, Neukam, 5.69M) reports Schumer "suggested the Chinese may have to do away with its balloon program over the ordeals of the past week."

On CBS' Face The Nation (2/12, 2.55M), Sen. Jon Tester (D-MT) said that the discovery of these unknown objects "has been nothing short of craziness." Tester continued, "I think we need to take these things seriously. I think the President and I think, more importantly, the military are taking it very seriously." However, The Hill (2/12, Neukam, 5.69M) reports Tester "admitted that he did not know whether the objects shot down in the last few days belonged to China."

Republicans were especially critical of the Administration's limited disclosures about the shootdowns. The Hill (2/12, Mueller, 5.69M) reports House Intelligence Chair Mike Turner on CNN's State Of The Union stated that the Administration "needs to stop briefing Congress through our television sets and actually come and sit down and brief us." However, CNN (2/12, LeBlanc, 89.21M) reports Turner "said...he prefers how the US shot down unidentified objects over North American airspace in recent days to allowing them to traverse the country." The Hill (2/12, Mueller, 5.69M) reports Turner "said he'd prefer the Biden administration be 'trigger happy' with suspected spy balloons than to be 'permissive' when objects enter U.S. airspace."

The Hill (2/12, Neukam, 5.69M) reports House Foreign Affairs Chair Michael McCaul on CBS' Face The Nation "split with defense and intelligence officials who have said the U.S. mitigated the amount of information that could have been picked up by the Chinese balloon," and he asserted it "did a lot of damage." On Fox News' Sunday Morning Futures (2/12, 1.39M), McCaul said, "These spy balloons have great capability to gather and collect intelligence. I would argue more so than even satellites in the sense that they're flying at, say, 40-60,000 feet above the earth. The imagery that they can capture and other intelligence data that I can't be specific about can be captured and then transmitted back to the mothership in Beijing. They have control over these balloons. This was an act of espionage in plain view of the American people. I know there have been reports of prior ones, but none quite like this."

Other Republicans called for the Administration to punish China. The Hill (2/12, Neukam, 5.69M) reports Sen. Ron Johnson (R-WI), on Fox News' Sunday Morning Futures "said...Biden is 'detached from reality' and 'delusional' about the threat posed by China," while Rep. Jim Banks (R-IN) on Fox News' Sunday

Morning Futures (2/12, 1.45M) said, "It's long past time to begin treating the Chinese Communist Party as an enemy." The Hill (2/12, Gans, 5.69M) reports Rep. Mike Gallagher (R-WI) in a radio interview "said timing the balloon to cross into U.S. airspace around [Secretary of State Blinken's now-postponed trip to China] would be 'well within the Chinese Communist Party's playbook' of trying to 'humiliate' the U.S. on the world stage."

Fox News (2/12, Hagstrom, 23.99M) says House Oversight Chair James Comer on ABC's This Week "bashed" Biden for not shooting down China's spy balloon before it crossed the US, but he also "argued...that the problem of Chinese surveillance was 'a lot bigger' than spy balloons floating over the country," and "said the failure of the Biden administration to combat intellectual property theft was the true issue."

In addition, Fox News (2/12, Betz, 23.99M) reports Sen. Steve Daines (R-MT) "slammed the Biden administration for its 'lack of communication' regarding...the recent shoot-downs." In a statement, Daines said, "The top priority should be the safety and security of the people of the United States and keeping the American people informed is a key part of fulfilling that duty." He continued, "President Biden owes Montanans and the country an immediate and full explanation. Without information, the public and media are left to rely on leaks, speculation and[,] worst off all[,] disinformation from foreign governments." Fox News (2/12, Laco, 23.99M) reports Sen. Marsha Blackburn (R-TN) "said the American people 'deserve transparency and accountability from the Biden administration,'" and The Hill (2/12, Mueller, 5.69M) reports Rep. Jim Himes (D-CT), the ranking member of the House Intelligence Committee, on NBC's Meet The Press also "said...he has 'real concerns' about the Biden administration not being 'more forthcoming' about the recent shoot-downs of objects flying over American airspace."

However, Reuters (2/12, Stewart, Ali) reports that "several Michigan lawmakers...applauded the military for downing the object." Politico (2/12, Olander, Ward, 6.73M) reports Sen. Gary Peters (D-MI) tweeted, "I'm glad the object was neutralized over Lake Huron and I'll continue pressing DoD for transparency." The Hill (2/12, Sforza, 5.69M) reports Rep. Dan Kildee (D-MI) thanked the military for its "immediate action" and said he would "keep seeking information about the incident in the coming days." But while the Detroit Free Press (2/12, Johnson, 2.16M) reports Rep. Jack Bergman (R-MI) similarly praised "the decisive action by our fighter pilots," CNBC (2/12, Capoot, 7.34M) reports that he added, "The American people deserve far more answers than we have."

In addition, the Detroit News (2/12, Nann Burke, Kozlowski, 1.16M) reports that Rep. Debbie Dingell (D-MI) "call[ed] the shootdown over Lake Huron disquieting." Reuters (2/12, Stewart, Ali) reports Dingell tweeted, "We need the facts about where they are originating from, what their purpose is, and why their frequency is increasing." Likewise, Bloomberg (2/12, Martin, Leonard, 3.57M) reports Rep. Elissa Slotkin (D-MI) said, "We're all interested in exactly what this object was."

A Wall Street Journal (2/12, Subscription Publication, 8.41M) editorial accuses the Administration of being "tight-lipped and dissembling" regarding the flying objects that are being shot down in US airspace. The Journal claims the lack of any consistent information or transparency from the White House is causing concern among Americans.

Trudeau Says Effort To Recover Object Shot Down Over Canada Continues. Reuters (2/12, Scherer) reports Canadian Prime Minister Justin Trudeau on Sunday "said teams are looking for the cylindrical object a U.S. fighter jet shot down over Yukon territory on his orders a day ago so that they can analyze it and learn more about its purpose." Axios (2/12, Habeshian, 1.26M) reports NORAD "added that its team would also 'work to recover the object in an effort to learn more.'"

Meanwhile, a senior US official told Fox News (2/12, Hagstrom, Tomlinson, 23.99M) that although "details regarding the object that was flying through Canadian airspace were scarce throughout the weekend," US officials "now describe it as a 'small metallic balloon with a tethered payload.'"

China Reportedly Plans To Shoot Down Unidentified Object Near Qingdao. Bloomberg (2/12, 3.57M) cites Chinese news outlet The Paper as reporting the Chinese military is preparing "to take down an unidentified object flying over waters near the port city of Qingdao, which is home to a major naval base for the People's Liberation Army." While Fox News (2/12, Betz, 23.99M) says that the report comes amid "increased tension between Beijing and Washington," Reuters (2/12, Brunnstrom, Martina) states that analysts "say [the US and China] have strong reasons to manage their disagreements. The question now is when, not whether, they find their way back to the negotiating table." However, Reuters adds resuming the talks "won't be easy." A Wall Street Journal (2/12, Wei, Youssef, Hutzler, Subscription Publication, 8.41M) article titled "How a Balloon Opened a New Flashpoint in U.S.-China Ties" provides similar coverage.

In his Los Angeles Times (2/12, 3.37M) column, Doyle McManus says the Chinese spy balloon "began its journey as a curiosity" before becoming "a symbol

of U.S. weakness to Republicans [and] a sign of...Biden's prudence to Democrats. Now, a week after the U.S. Air Force shot it down, the errant balloon is gone, but its impact is still reverberating." McManus says while the Chinese balloon "may not have collected much useful intelligence," its discovery, "and the larger Chinese program it revealed," poses "a serious obstacle to one of Biden's top foreign policy goals: stabilizing the prickly U.S. relationship with Beijing." According to McManus, "it appears China has scored the espionage equivalent of an own goal." However, he adds that "the stakes are far greater than spy-versus-spy drama. The balloon episode is a reminder that, just as in the Cold War, detente between nuclear powers is harder to manage than it looks."

Comer Defends Oversight Probes As Partisanship Defines Current Congress.

On ABC's This Week (2/12, 2.31M), House Oversight Chair James Comer said "everything's on the table" for his committee's investigations into President Biden, his family, and the Administration. According to the Wall Street Journal (2/12, Andrews, Subscription Publication, 8.41M), Comer has two primary jobs: managing the investigations into the President, his family, and the Administration while also ensuring conservative lawmakers do not derail the probes with their efforts to grab media attention via political stunts.

Axios (2/12, Solender, 1.26M) suggests, "Biden's baiting of Republican hecklers wasn't just a signature moment in his State of the Union speech – it was in line with a series of partisan stunts that have marked the new Congress." Lawmakers of both parties "have jumped on opportunities to score political points and try to make things awkward for the other side."

In her Washington Post (2/12, 10.52M) column, Jennifer Rubin asserts that the "MAGA Republicans in charge of House committees are having a difficult time conducting their inquests into made-up scandals" because "savvy Democrats are effectively turning the tables to use the committees against Republicans." Rubin cites last week's House Oversight Committee hearing featuring former Twitter executives and the hearing for the subcommittee on the weaponization of the federal government. She adds Democrats, who "came to these hearings prepared and focused," both "eviscerated GOP conspiracy theories" and "did a bang-up job exposing Republicans as the ones who have 'weaponized' the government."

Whitmer Says Democrats Will Support Biden's Reelection Bid.

Axios (2/12, Kraushaar, 1.26M) reports that while President Biden "has all but erased internal Democratic Party criticism," there is "a gaping divide in the Democratic Party between institutional public opinion – party leaders, lawmakers, donors, consultants – and the actual voters who ultimately decide elections, recent polling shows." However, Politico (2/12, Olander, 6.73M) reports Michigan Gov. Gretchen Whitmer (D) on CNN's State Of The Union "dismissed concerns over an apparent lack of enthusiasm among Democratic voters for...Biden's possible reelection campaign." CNN (2/12, LeBlanc, Sarisohn, 89.21M) reports Whitmer on CNN's State Of The Union also "said...serving in her current role is '100% my focus' as the Democrat's national profile and speculation about a future White House bid continue to grow." A Wall Street Journal (2/12, Subscription Publication, 8.41M) article headlined "Biden Appears Set To Run In 2024, But Many Democratic Voters Have Doubts" provides similar coverage.

Christie Has "No Doubt" Biden Is Running For Reelection. The Hill (2/12, Neukam, 5.69M) reports as Biden, "the oldest president ever, gears up for a potential reelection campaign in 2024, former New Jersey Gov. Chris Christie (R) said on Sunday that Biden's age puts a spotlight on Vice President Harris." On ABC's "This Week," Christie "said...if Biden, 80, decides to run in 2024, voters would be paying sharper attention to Harris, and the possibility that she could become president." Christie added he has "no doubt" that Biden will seek reelection following the State of the Union address last week.

Sununu Says If He Decides To Run, 2024 Bid Would Focus On Bringing "Better Attitude" To Politics.

The Hill (2/12, Mueller, 5.69M) reports New Hampshire Gov. Chris Sununu (R) on CBS' Face The Nation "said...a potential 2024 presidential run would be 'an opportunity to change things' and put 'a little better attitude' in Washington, D.C." Sununu "hasn't officially announced a 2024 campaign, but has taken recent steps that sparked speculation that he'll run, including setting up a political action committee, 'Live Free or Die,' with its name grabbed from New Hampshire's motto." Axios (2/12, Saric, 1.26M) reports Sununu "decried the prevalence of 'woke cancel culture,' which he claimed sowed 'divisiveness' in American schools and communities," although he "noted that the government was unlikely to be the one to fix a 'cultural problem.'"

Cox Says Republicans Should Nominate A Governor For President.

Politico (2/12, Cohen, 6.73M) reports that during a joint interview with New Jersey Gov. Phil Murphy (D), Utah Gov. Spencer Cox (R) on NBC's Meet The Press "said...he'd prefer that Republicans pick a governor to be their presidential nominee in 2024." In particular, Cox said New Hampshire Gov. Chris Sununu (R), Florida Gov. Ron DeSantis (R) and South Dakota Gov. Kristi Noem (R) as well as former Arkansas Gov. Asa Hutchinson (R) and former South Carolina Gov. Nikki Haley (R) were "all fantastic" choices, while Politico reports that "for his part, Murphy, who has been pushing for President Joe Biden to run for another term, did suggest that one Republican governor run for president: 'Spencer Cox.'" However, Politico adds Cox "said he was running for reelection as governor of Utah."

DeSantis Must Determine When, How Hard To Hit Back At Trump.

The New York Times (2/12, Bender, Haberman, 20.6M) reports Florida Gov. Ron DeSantis (R) has, for months, "pursued a strategy of conflict avoidance" with former President Donald Trump, "his top rival in the shadow 2024 Republican presidential primary, delaying what is likely to be a hostile and divisive clash that forces the party's voters to pick sides. But now he faces the pressing question of how long this approach can work." Trump "has spent weeks trying to goad Mr. DeSantis into a fight" and is "stepping up his social media-fueled assault, even as polls and interviews show that Mr. DeSantis has become the leading alternative to the former president for many voters and donors." DeSantis "must also decide just how forcefully to counterattack once he engages with Mr. Trump, and whether he has left himself enough room to effectively parry the former president's taunts and smears without offending his loyal supporters."

Brazile: Trump May Regret Announcing 2024 Candidacy So Early.

The Hill (2/12, Polus, 5.69M) reports former DNC Chair Donna Brazile on ABC's This Week "said...Trump, who kicked off his reelection campaign just one week after the midterms, may regret entering the 2024 race too soon as Republican Nikki Haley prepares her White House bid." Brazile said, "The big donors in the Republican Party, they're now showing him the cold shoulder. So this may be Donald Trump's week to regret that he put his hat in the ring so soon." Haley is expected to announce her candidacy on Feb. 15. Brazile said, "The interesting thing about Nikki Haley is she's going to make a generational argument, similar to what Sarah Huckabee Sanders made in her rebuttal to Joe Biden. I don't know

if Donald Trump is going to attack her the day before, which is Valentine's Day, or the day after. But clearly he benefits from a large field."

All In Together CEO: Haley Faces "High Hurdle" To Securing GOP's 2024 Nomination.

Lauren Leader, co-founder and CEO of All In Together, writes in an op-ed for Politico Magazine (2/12, 6.68M) that 10 years ago, Nikki Haley "would be a candidate with enviable advantages, having served as a South Carolina governor and United Nations ambassador," but "given the reality of Republican Party politics today, her presidential dream could become a nightmare." Haley "could very likely have it worse than the candidates did in 2016, encountering a veritable buzz saw of sexist and racist attacks from the moment she declares her presidential run" because "the base of the Republican Party, the most rabid and committed primary voters, has become more male and more far-right since Trump became the party standard bearer." Leader warns Haley "faces a high hurdle in even convincing Republican voters that a woman can be president."

California Senate Race Taking Shape While Feinstein Has Not Made Her Intentions Known.

The AP (2/12, Blood) reports the California Senate race "is unfolding at a furious pace." The contest "is shaping up as a marquee match-up between nationally known rivals and is likely to become one of the most expensive Senate races in the country next year." On Saturday, Rep. Adam Schiff (D) "gathered hundreds of supporters in a union hall parking lot for a rally in his hometown of Burbank, California," and the day before, Rep. Katie Porter (S) "brought her Senate campaign to Los Angeles, where she met with local leaders to discuss pollution in lower-income neighborhoods." Meanwhile, Sen. Dianne Feinstein (D) "has yet to say if she will seek a seventh term" and "her reticence about her future has created a publicly awkward dynamic – the race to replace her is rapidly taking shape, even as the senator remains unclear about her intentions."

Barnes Reelected As Michigan Democratic Party Chair.

The AP (2/11, Cappelletti) reports Michigan Democratic Party Chair Lavora Barnes has been reelected for a third two-year term "after she helped lead the party to historic wins in the battleground state in the 2022 midterms." Barnes, who ran unopposed, was reelected Saturday during the Michigan Democratic Party's spring convention in Detroit.

Kansas Republicans Choose Election Conspiracy Promoter To Lead State Party.

The AP (2/11) reports Kansas Republicans on Saturday "narrowly picked an activist who has promoted unfounded election conspiracies and promised a shakeup" to lead the state party for the next two years. The committee elected Mike Brown, "who has long been active in the GOP in the Kansas City area, as its new chair through the 2024 elections." Retiring chair, Mike Kuckelman, and the Kansas party's "two other Republican National Committee members supported RNC Chair Ronna McDaniel when she won reelection last month. But Brown called on McDaniel to resign in December, and he said Saturday that the national GOP is seeing an internal 'uprising' from members still upset over COVID-19 pandemic restrictions."

Lake Delivers Election Denial Message During Visit To Iowa.

The Washington Post (2/12, 10.52M) reports Kari Lake (R-AZ) delivered "a clear message" as she visited Iowa over the weekend. Lake "falsely claimed the 2020 election was stolen from Donald Trump. She baselessly insisted that votes were rigged against her in her run for Arizona governor last year. And she warned without evidence that future races will be compromised." Lake "is traveling the country as one of the most vocal standard-bearers of an animated if wounded election denialism movement as she weighs a run for U.S. Senate and hears encouragement from some to set her sights on national office." Lake "drew enthusiastic crowds" in Iowa but "others in the party have been sharply critical of her rhetoric, seeing her as a part of a Trump-era scourge at the ballot box that cost the GOP winnable races last fall and could doom its chances in 2024."

Black Voters In Wisconsin Not Surprised By Revelations Of GOP Election Tactics.

The AP (2/12, Venhuizen) reports, "A Wisconsin election commissioner bragged about low turnout in predominantly Black and Latino neighborhoods during last year's elections," and weeks later, "an audio recording surfaced that showed then-President Donald Trump's Wisconsin campaign team laughing behind closed doors about efforts to reach Black voters in 2020." But the revelations "about Republican election strategies targeting minority communities...came as no surprise to many Black voters." Many "said they had long felt targeted by Republicans. The difference now is the public display of strategies that at best

ignore the priorities of Black voters and at worst actively look to keep them from voting." Black voters "said they are tired of the countless hurdles that disproportionately try to keep them from being heard at the ballot box. Voters said their experiences with the GOP have been as voices to silence, not to win over."

Kansas City Chiefs Defeat Philadelphia Eagles In Close Super Bowl.

The Washington Post (2/12, 10.52M) reports that "the Kansas City Chiefs won another Super Bowl, elevated the statures of quarterback Patrick Mahomes and Coach Andy Reid among the all-time greats and secured major bragging rights within the Kelce family." In a Super Bowl LVII "filled with connections between competitors and carrying historical significance, the Chiefs used a big fourth quarter to beat the Philadelphia Eagles, 38-35, on Sunday at State Farm Stadium." Kicker Harrison Butker's "27-yard field goal with eight seconds left won it." Mahomes "had a 26-yard run to set up the winning kick." The Eagles "had a key defensive holding penalty, and Chiefs tailback Jerick McKinnon slid down at the 2-yard line when the Philadelphia defense appeared to be trying to allow him to score." Butker's kick "came after two kneel-downs by Mahomes."

All-Female Piloted Flyover Makes Super Bowl History. The Hill (2/12, 5.69M) reports that "the first all-female piloted military flyover, commemorating 50 years of women flying in the U.S. Navy, flies over State Farm Stadium before the NFL Super Bowl 57 football game between the Kansas City Chiefs and the Philadelphia Eagles, Sunday, Feb. 12, 2023, in Glendale, Ariz." The group "of seven female aviators flew in a diamond formation over the State Farm Stadium in Glendale, Arizona, where the Kansas City Chiefs are facing off against the Philadelphia Eagles."

Black National Anthem Performed At Super Bowl For First Time. The Hill (2/12, 5.69M) reports that "the performance of "Lift Every Voice and Sing" at Sunday's Super Bowl marks the first time the so-called Black National Anthem has been performed on-field at the NFL's championship game." Actress "and singer Sheryl Lee Ralph belted out the song prior to kickoff on Sunday." The historic performance "was the first time the song has been performed in an official capacity on a Super Bowl game field."

Celia Cruz To Be First Afro-Latina Depicted On US Quarter.

The New York Times (2/12, Simonetti, 20.6M) reports that "Celia Cruz, a Cuban American singer who was known as the Queen of Salsa, will be the first Afro-

Latina woman to appear on American quarters as part of a U.S. Mint initiative." The mint "said in a news release on Feb. 1 that Ms. Cruz would be featured as a 2024 honoree of the American Women Quarters Program, which portrays prominent women throughout history on the quarter."

Jackson Appoints New Public Works Director Amid Ongoing Water Crisis.

The AP (2/12, Long) reports that "as the most populous city in Mississippi attempts to improve its troubled water system, it has appointed a new interim director to lead the agency that runs local infrastructure." City Engineer Robert Lee "was named interim director of the Jackson Public Works Department Friday as Jackson begins a nationwide search to find a permanent candidate to fill the position." Over "the past few years, repeated breakdowns have upended consistent access to safe running water in Jackson, which is also the state capital." The crisis "culminated in late Augustand early September when the system came to near collapse and most people in the city of 150,000 went several days without running water."

Advocates Call For Republicans To Become "Aspirational Conservatives."

Stephen Goldsmith, the Derek Bok Professor of the Practice of Urban Policy at Harvard University's Kennedy School of Government, and Ryan Streeter, the Director of Domestic Policy Studies at the American Enterprise Institute, write in a Politico Magazine (2/12, 6.68M) op-ed that the Republican Party "has been adrift and lacking a coherent agenda for several years now." They advocate for an "aspirational conservatism," and argue Republicans "should create a clear set of policy objectives to support opportunity, individual initiative and hope," while being "the voice of reason on crime and justice." They also say "aspirational conservatives should break from a growing preference on the right for wielding federal power in pursuit of moral goals." Aspirational conservatives, they write, "have a chance to show they are on the side of the majority of Americans who care most about a good quality of life, ample opportunity and a government that works for them."

Joint Center Board Chair Laments Insufficient Diversity Among Senate Staff Leadership.

In an op-ed for the Washington Post (2/12, 10.52M), Paul N.D. Thornell, a principal at Mehlman Consulting and board chair of the Joint Center for Political and Economic Studies, writes inadequate diversity "in leadership roles is common

in workplaces across the country, including, arguably, one of the most important locations: the U.S. Senate." Among Senate workers, "there is only one Black chief of staff, four Black legislative directors and one Black communications director. On the Senate committees where legislation takes shape, there are zero Black people in top committee staff director positions." Thornell argues there is "value in having some top Black Senate staff 'at the table' to help develop measures based on their personal insights, experiences or those of family and communities [and this] could be said of virtually any other federal policy issue, from health care to education to housing to transportation issues. But with the makeup of top Senate staff, that perspective is missing."

Editorial Wrap-Up

Wall Street Journal.

"The University Of North Carolina Fight Escalates." In an editorial, the Wall Street Journal (2/12, Subscription Publication, 8.41M) argues that the creation of a new school for free expression at the University of North Carolina is becoming more complicated, with opponents of the plan now claiming that UNC's accreditation could be jeopardized by its board's support for the school. The Journal urges the board of UNC to remain steadfast, even in the face of what they describe as politically-motivated threats.

"Watch Out, Gigi Sohn Is Back." A Wall Street Journal (2/12, Subscription Publication, 8.41M) editorial argues that the Administration is making another mistake by re-nominating Gigi Sohn for the top position at the FCC, due to her ideological positions as well as support for what they consider "dangerous rule-making." The Journal says that Sohn's organization, Public Knowledge, which she co-founded, supports a very broad mandate for the FCC to micromanage content, competition, and development. The Journal criticizes President Biden for nominating a progressive activist to the position instead of a more moderate alternative.

"What's Going On Up There, Mr. President?" A Wall Street Journal (2/12, Subscription Publication, 8.41M) editorial accuses the Administration of being "tight-lipped and dissembling" regarding the flying objects that are being shot down in US airspace. The Journal claims the lack of any consistent information or transparency from the White House is causing concern among Americans.

"Overruling The District Of Crazy." A Wall Street Journal (2/12, Subscription Publication, 8.41M) editorial supports a decision by the House to overturn a pair

of District of Columbia laws. One of the laws would have eased sentences for carjacking, burglary and other felonies. The other would have granted noncitizens the right to vote in local elections. The Journal says the fate of the House bills in the Senate is uncertain, but predicts that Majority Leader Schumer will allow some Democrats facing reelection in 2024 to vote with the House, but not enough to provide enough votes to break a filibuster.

Washington Post.

"In A Hong Kong Courtroom, Freedom Itself Is On Trial." The Washington Post (2/12, 10.52M) editorializes the 16 democracy activists being put on trial in Hong Kong beginning last week "had done one thing that truly frightens China's leaders: They held a vote." The activists are charged with "subverting state power," which carries a "carries a maximum sentence of life in prison, and 31 others who have already pleaded guilty will be sentenced at the trial's conclusion." The Post says that China's Communist Party and its "minions who run Hong Kong cannot stand the sight of people expressing their preferences for who should lead them." The Post adds, "Freedom itself is now on trial."

"A Shakeup In Ukraine Masks Deeper Problems." In an editorial, the Washington Post (2/12, 10.52M) writes Zelensky's administration faces "the threat posed by scandal or misuse of funds...to what has been solid U.S. and European support of Kyiv" following "recent reports that officials in his government were profiteering from wildly inflated prices" on certain goods. The Post adds Zelensky would be "shrewd not to ignore graft, sweetheart deals and the vestiges of oligarch capitalism that were a stain on the country's reputation long before Moscow launched its full-scale invasion," as "Ukraine's day of reckoning cannot be delayed indefinitely," and "Kyiv's own aspirations depend on establishing the rule of law."

New York Times.

"India's Proud Tradition Of A Free Press Is At Risk." A New York Times (2/12, 20.6M) editorial says efforts to "intimidate, censor, silence or punish independent news media" are "an alarming hallmark of populist and authoritarian leaders," and warns Modi is on this path. The Times says Modi's actions to "suppress freedom of the press are undermining India's proud status as 'the world's largest democracy,'" while adding that since Modi took office in 2014, journalists have "increasingly risked their careers, and their lives, to report what the government doesn't want them to." The Times says that what began as a

"potential embarrassment" for Modi has "thus escalated into a furor over press freedoms – and into a test for the rest of the world."

The Big Picture

Headlines From Today's Front Pages.

Wall Street Journal:
Investors Are Exiting US Stock Funds During 2023 Rally
US Military Shoots Down Fourth High-Altitude Object Over North America
From Apple To VW, CEOs Gradually Returning To China After Its Reopening
Hard Or Soft Landing? Some Economists See Neither If Growth Accelerates
Couples Who Stay Together Don't Ski Together
Blackstone's Big New Idea Leaves It Bruised

Washington Post:
A Fourth Aerial 'Object' Is Shot Down Over Lake Huron
Women Returning Faster To Workforce Than Men
Rescues Continue As Hopes Wane
Ukraine Readies Its Defenses On Every Front

Financial Times:
Taiwan Reveals Chinese Military Balloons Fly 'Very Frequently' Into Its Airspace
Erdoğan Targets Construction Firms As Earthquake Death Toll Tops 33,000
Goldman Chief Tells Partners He Should Have Cut Jobs Earlier

Story Lineup From Last Night's Network News:
ABC: Unidentified Object Shot Down Over Great Lakes; New Mexico State University Suspends Men's Basketball Program; Aftermath Of Earthquake In Turkey And Syria; US Severe Weather; War In Ukraine; Rise In Norovirus Cases; Super Bowl; Search For Missing Woman In Houston; Engine On Delta Flight Catches Fire; Interview With Damar Hamlin; Woman Receives Liver Donation From Her Husband.
CBS: Unidentified Object Shot Down Over Great Lakes; Aftermath Of Earthquake In Turkey And Syria; War In Ukraine; NYC Terrorist Could Receive Death Penalty; Super Bowl; Florida Education Reforms; Rickie Fowler Shoots A Hole In One; Lebron James Surprises Young Fan At NBA Game; Mother And Daughter Hike The

Appalachian Trail.
NBC: Unidentified Object Shot Down Over Great Lakes; Aftermath Of Earthquake In Turkey And Syria; War In Ukraine; Engine On Delta Flight Catches Fire; New Mexico State University Suspends Men's Basketball Program; Fallout After New Jersey Student Commits Suicide; US Coast Guard Operations To Intercept Migrants; Teenage Volunteer Gets To Go To The Super Bowl.

Network TV At A Glance:
Unidentified Object Shot Down Over Great Lakes – 13 minutes, 5 seconds
Aftermath Of Earthquake In Turkey And Syria – 9 minutes
Super Bowl – 7 minutes, 25 seconds
War In Ukraine – 6 minutes, 20 seconds
New Mexico State University Suspends Men's Basketball Program – 3 minutes, 40 seconds
Florida Education Reforms – 2 minutes, 50 seconds

Last Laughs

Late Night Political Humor.

Last Week Tonight With John Oliver did not air on February 12, 2023.

HHS NEWS BRIEFING

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TO: **THE SECRETARY AND SENIOR STAFF**

DATE: **MONDAY, FEBRUARY 13, 2023 7:30 AM EST**

TODAY'S EDITION

Overdose Prevention

Mental Illness

Healthcare Fraud

Prescription Drug Pricing

Health Care & Insurance Reform

Global Health

LEADING THE NEWS

State AGs File Competing Briefs In Lawsuit Challenging FDA Approval Of Abortion Pill. The Washington Post (2/11, Kaur, 10.52M) reported GOP "and Democratic attorneys general filed competing arguments on Friday in a heated Texas lawsuit that seeks to reverse the Food and Drug Administration's approval of abortion pills, the most common method to terminate pregnancy in the United States." In an amicus brief, 22 Republican AGs contended that "the FDA 'undermined the public interest' by allowing the medication." For their part, 22 Democratic AGs argued "in court filings that revoking the drug's approval would have 'devastating consequences' for Americans. The clashing briefs are the latest in rising tensions around the case, which could undo the FDA's decades-old approval of mifepristone, the drug used in medication abortions."

Reuters (2/10, Pierson) reported the plaintiffs, "anti-abortion groups including the Alliance for Hippocratic Medicine, claim the U.S. Food and Drug Administration used an improper process to approve the drug mifepristone in 2000, and did not adequately consider its safety." By filing the lawsuit in Amarillo, Texas, the plaintiffs "ensured that the case would go before U.S. District Judge Matthew Kacsmaryk, a reliable conservative and former Christian activist."

The AP (2/10, Whitehurst) reported the lawsuit poses "a threat to the nationwide availability of medication abortion, which now accounts for the majority of abortions in the U.S." Should Kacsmaryk, who was appointed by former President Trump, rule in favor of the plaintiffs, this "could halt the supply of the drug mifepristone in all states, both where abortion is banned and where it remains legal." Mini Timmaraju, president of NARAL Pro-Choice America, said, "It could have an immediate impact on the country. ... In some ways this is a backdoor ban on abortion."

CNBC (2/10, Kimball, 7.34M) reported that NARAL, "in an analysis published Friday, said 40 million women would lose access to the abortion pill if the court overturns the FDA's approval." Also on "Friday, 67 Republican members of Congress filed a brief calling the FDA's approval of mifepristone 'unlawful,' arguing it should be overturned. They claimed that the agency's actions subverted Congress' safeguards for patients." However, "the FDA has had regulations in place for years to monitor the safety of mifepristone, which it has gradually eased as more evidence has come in."

The Hill (2/11, Weixel, 5.69M) reported physicians "and reproductive rights advocates are bracing for a decision in" the lawsuit "that, if successful, could end legal access to abortion pills nationwide." The "pills have become one of the next major fronts in the fight over reproductive health care in the wake of the Supreme Court's decision overturning Roe v. Wade, and the lawsuit is seen by both sides as the start of the battle to come."

Among other news outlets covering the story were NBC News (2/10, Atkins, 4.91M), Forbes (2/10, Durkee, 10.33M), the New York Daily News (2/10, Assuncao, 2.51M), Axios (2/10, Gonzalez, 1.26M), the Portland (ME) Press Herald (2/10, Murphy, 174K), the Washington Times (2/12, Richardson, 626K), and Columbia (SC) State (2/10, Hughes, 330K).

THE SECRETARY IN THE NEWS

Acting NIAID Director Auchincloss Taking Over Amid Republican Pandemic Probe. STAT (2/11, Mershon, 262K) reported that the person who replaced Dr. Anthony Fauci as acting Director of the National Institute for Allergy and Infectious Diseases, Dr. Hugh Auchincloss, "a respected transplant surgeon and medical researcher, served for more than 16 years as Fauci's low-key right-hand man at NIAID." Now Fauci's position "--and all the political heat that goes with it – went to Auchincloss" as "the new House Republican majority launches a series of hearings on Covid-19." Auchincloss "is likely to face questions" due to a 2020 email to Fauci, as "some conservatives believe the message indicates that US health officials might have downplayed the possibility" that COVID-19 was created in a Chinese laboratory with US funds. NIH acting Director Dr. Lawrence Tabak, HHS Secretary Xavier Becerra, and CDC Director Dr. Rochelle Walensky are mentioned.

CORONAVIRUS

OTHER CORONAVIRUS NEWS

FDA Commissioner Blasts "Snake-Oil Salesmen" Who Seized On Damar Hamlin's Collapse. Bloomberg (2/12, Rutherford, 3.57M) reports behind a paywall, "When Buffalo Bills safety Damar Hamlin collapsed during a National Football League game in January, dozens of Twitter trolls quickly blamed it on Covid-19 shots." FDA Commissioner Robert Califf "said in an interview: 'Snake-oil salesmen' seized on the event.'" The "#diedsuddenly hashtag, which appeared in tweets about the incident, is often used to discredit vaccines by linking them to deaths and injuries without evidence."

New York Allows Mask Mandate For People Inside Healthcare Facilities To Expire. The New York Times (2/10, Fadulu, 20.6M) reported New York has elected not to renew a requirement for staff and visitors inside healthcare facilities in the state to wear face masks. The change, which took effect today, "brings the state's guidance in line with that of the" CDC as it "lifted the federal mandate requiring masks in health care facilities in September." Currently, "new coronavirus cases in New York have dropped 30 percent in the past 14 days, according to The New York Times's Covid-19 tracker."

The AP (2/10) reported the policy change, announced Thursday, comes as the state's acting Health Commissioner Dr. James McDonald said

New York is "moving to a transition" and has access to "safe and effective vaccines, treatments, and more." The decision allows "hospitals, nursing homes, treatment centers and other facilities to enact their own masking rules in accordance with guidance from the" CDC.

Forbes (2/12, 10.33M) contributor Bruce Y. Lee reports advocacy organizations in New York like Mandate Masks NY reacted adversely to the state's decision to lift the mask mandate for healthcare facilities. A Substack post from Mandate Masks NY stated the "decision puts all New Yorkers at risk, particularly people who are at higher risk and the most vulnerable." Additionally, public health experts pointed out that "many healthcare settings can be rather crowded, chaotic, and poorly ventilated" in their arguments for why the decision to let the requirement expire was flawed. Those experts recommend New Yorkers at high risk of severe disease "pay close attention to whether your healthcare facility will be maintaining face mask requirements despite the state's lifting its mandates."

Among other outlets providing coverage are the New York Post (2/10, Campanile, 7.45M) and the Rochester (NY) Democrat & Chronicle (2/10, Robinson, 410K).

COVID-19 Still Deadly For Older Americans. The New York Times (2/11, Span, 20.6M) reported on the continued threat that COVID-19 poses to people in the United States 65 years of age and older. To date, "about three-quarters of Covid deaths have occurred in people over 65, with the greatest losses concentrated among those over 75." Additionally, "hospital admissions...remain more than five times as high for people over 70 than for those in their 50s." Part of the issue, infectious disease experts believe, is that "only 40.8 percent of seniors have received a bivalent booster" and "some who have not believe they have strong protection against infection" according to a CDC survey.

Labor Statistics Show Women Are Returning To Workforce At Higher Rate Than Men. The Washington Post (2/12, A1, Bhattarai, Melgar, 10.52M) reports on women returning to the workforce. "The percentage of working-age women in the labor force has nearly recovered from pre-pandemic levels" and "when compared to the pandemic low point in April 2020, women's labor force participation rates are up by 3.4 percentage points." Both of those statistics are higher than they are for men of the same ages. It's a marked reversal as "the covid downturn was unique in that it took an outsize toll on women...in terms of job losses." Aiding the return to work among women is "employers' increased willingness to offer more remote alternatives to office work" and rising prices for necessities like groceries.

Lack Of Contact With Cold Viruses Could Drive Perception Of More Severe Symptoms, Experts Say. ABC News (2/11, Egan, 2.44M) reported infectious disease experts' commentary on why people in the United States could be perceiving their cold symptoms as more severe than in previous winters. Such "experts say there is currently no evidence to suggest the viruses that cause cold symptoms are any more severe than they were pre-COVID" but there are some factors possibly behind the perception. Among them is that "people may have forgotten how miserable cold symptoms can feel after a few years without them" due to a lack of socialization and increased mask-wearing during earlier years of the COVID-19 pandemic. Also, "people who haven't had a cold in a while won't have as much immunity to viruses." The National Institutes of Health state that "there are over 200 known viruses that can cause symptoms of the common cold."

End Of Public Health Emergency Could Mean Uncertainty For COVID-19 Treatments. Kaiser Health News (2/10, Appleby) reported on potential forthcoming changes to cost structures for COVID-19 test kits, treatments, and vaccines. As the federal government's COVID-19 pandemic public health emergency will end May 11, "time is running out for free-to-consumer covid vaccines, at-home test kits, and even some treatments." For example, "an August blog post" from HHS' "Administration for Strategic Preparedness and Response noted that government-purchased supplies of the drug Paxlovid are expected to last through midyear before the private sector takes over." At that time, it could become unclear "what the companies will charge once government supplies run out." For people on Medicare, coverage of the drug could "be limited until the treatment goes through the regular" Food and Drug Administration process.

Microgrants For Community Organizations Proved Effective At Improving COVID-19 Vaccination Rates. Kaiser Health News (2/10, Hawryluk) reported on funding for community organizations to improve healthcare outcomes. In Colorado, "when COVID-19 vaccines became available" the state gave grants "to community organizations serving immigrants and minorities." The grants came with ample latitude to spend the funds as the organizations saw fit within the scope of improving vaccination rates among those populations. The approach worked as "over time, disparities in vaccine rates in and around Denver narrowed." Now, "the microgrant approach could well be the future of public health messaging for diverse populations." To further determine the efficacy of the approach, Colorado "has now expanded to include all routine adult vaccinations and is funded through April."

Epidemiologists Discuss Need For More Research On COVID-19's Impact On Cardiovascular Health. US News & World Report (2/10, Smith-Schoenwalder, 1.91M) reported on the impact of the COVID-19 virus on cardiovascular health. The effects of the virus on the heart are important "to understand as more than 100 million Americans have had COVID-19" and that figure "continues to grow each day with no signs of ceasing." Epidemiologists believe COVID-19 "has both direct and indirect impacts on cardiovascular health" like "new clotting and inflammation" and the potential to cause "issues in other parts of the body that can cause heart damage." Currently, "research on COVID-19's effect on the heart is expanding, but researchers agree that more attention is needed."

CDC Data Show Low Uptake Of Newest COVID-19 Vaccine Booster Correlates With Low Instances Of Severe Disease In Americans Under 65. CNN (2/10, Cohen, 89.21M) reported that data "indicate that even though a small percentage of people under age 65 have gotten the new Covid-19 booster, people this age are not becoming severely ill" from the virus. CDC data show that "nationally, only about 16% of the population has gotten" the latest COVID-19 vaccine booster "and the rates are especially low for people under 65." At the same time, CDC data also show "about 12% of all Covid deaths in the US have been among people younger than 65." This data could help drive future vaccine policy as the "Food and Drug Administration has proposed a framework for annual Covid vaccinations" and CDC vaccine advisers "are scheduled to meet February 24 to discuss the future of the US Covid-19 vaccination program."

Commentary Criticizes CDC On Masking Recommendations For School Children. In an op-ed for the Washington Examiner (2/10, 888K), Zachary Faria wrote about recent comments from CDC Director Dr. Rochelle Walensky regarding masking recommendations for school children. Walensky said, "our masking guidance doesn't really change with time" and "what it changes with is disease. So when there's a lot of disease in the community, we recommend that those communities and those schools mask. When there's less disease in the community, we recommend that those masks can come off." Faria argues that "masking did far more damage to children than the virus" as it "was associated with decreases in communication and the development of socialization skills."

Former National Security Adviser Calls For Investigation Into COVID-19 Origins. The Washington Examiner (2/10, Dunleavy, 888K) reported Trump Administration "national security adviser Matt Pottinger called it 'inexcusable' that there still hasn't been a full investigation into COVID-19's origins." In a piece for the Wall Street Journal, Pottinger and OneSharedWorld founder Jamie Metzl made their case for a more robust inquiry, criticizing Dr. Anthony Fauci and former National Institutes of Health Director Dr. Francis Collins for allegedly planning "to push the public conversation away from the lab-accident hypothesis and toward the natural-origins explanation." Pottinger said while "the malfeasance of China's rulers is the primary reason the international community doesn't have access to" records and data concerning activity at the bat coronavirus lab in Wuhan, "the US could do far more to get to the bottom of what happened."

HHS Announces Resumption Of Regular Review Policies For Research Projects. Behind a paywall, Bloomberg Law (2/10, Baumann, Subscription Publication, 4K)

reported "research institutions must revert to using the same ethics board when collaborating on studies once an exception tied to the Covid-19 public health emergency ends in May" according to an announcement from HHS' Office for Human Research Protections Friday. The regular policy "implements safeguards for research volunteers" and ensures "participants are enrolling voluntarily." HHS had "lifted mandate to use same ethics review board during [the] Covid[-19]" pandemic.

Iowa Senator Calls For Cessation Of Grants For EcoHealth Alliance. The New York Post (2/11, Vincent, 7.45M) reported US Sen. Joni Ernst (R-Iowa) claims EcoHealth Alliance "continues to receive millions in grants from the US government to do research on viruses." Ernst has already "called on Congress to stop giving out grants to EcoHealth Alliane for 'dangerous' new projects" and lobbied for investigations into their activity regarding a Wuhan laboratory. In 2022, "EcoHealth Alliance received a $653,392 grant from the National Institute of Allergy and Infectious Diseases" under the leadership of Dr. Anthony Fauci which represented "the first installment of a five-years award totaling $3.3 million." Currently, EcoHealth projects include "experiments with bats on the Nipah virus in Bangladesh as well as research into viruses in Thailand, Singapore and Malaysia."

Calls For Investigation Into Possible Link Between Tinnitus And COVID-19 Vaccines Mounting. National Geographic (2/10, Haelle, 30.3M) reported on evidence which "suggests that there might be a connection between COVID vaccines and rare cases of severe tinnitus." While "the World Health Organization advised investigating whether there's a link between multiple COVID vaccines and tinnitus" last year and "Johnson & Johnson listed it as a possible adverse effect on its US COVID-19 vaccine fact sheet in February 2021," CDC spokesperson Martha Sharan "said the agency has determined it does 'not have sufficient evidence from our surveillance to justify launching an epidemiologic study.'" Regardless, "the CDC has come under criticism from Poland and others who have asked it to study the issue" and "other experts express skepticism that there could be a link between a vaccine and an adverse event that occurs so quickly."

COVID-19 Hospital Admissions Hit Two-Month Low In Florida. The Palm Beach Post (USA) (2/10, Persaud, 223K) reported on a further decline of COVID-19 hospitalizations and infections in Florida. According to HHS data, there were "19,000 new infections, the fewest since the week ending Dec. 26" in Florida last week. Also, Florida hospitals are currently treating 1,978 patients for symptoms of COVID-19 and this is "the first time since late December" that number has been under 2,000. Additionally, wastewater testing "shows viral levels falling in just about every Florida county where sewage is tested." At the same time, there were "341 more deaths recorded this week, more than twice as high as pre-surge weeks in late October" and November according to the CDC.

People Claiming Adverse Reactions To COVID-19 Vaccines Struggling To Secure Payments From Federal Program. The Minneapolis Star Tribune (2/10, Olson, 855K) reported on injury claims filed by COVID-19 vaccine recipients in Minnesota. So far, "the federal Countermeasures Injury Compensation Program...has received 11,196 claims related to COVID, including 8,447 related to vaccines" but "only 543 have been resolved." Furthermore, although "19 claims have been declared eligible" for payments due to substantiated damages, none of those claims have actually been paid according to Health Resources and Services Administration records. Part of the problem is that COVID-19 vaccines do not have a federally recognized "list of vaccine-connected conditions" and without that documentation, claimants must "prove a connection to their illnesses" on a case-by-case basis.

COVID-19 Cases On The Decline In Oklahoma. The Tulsa (OK) World (2/11, 241K) reported on a remission of respiratory disease infections in Oklahoma. According to data from the CDC and state agencies, "active COVID-19 infections are down nearly 35% in the past month" and "the three-day average for COVID-related ICU patients is down about 50%" over the same period of time. Furthermore, "the seven-day average for new COVID-19 cases reported to state health officials has decreased 36% since the Jan. 12 update." However, "the vast majority of the state continues to be in the red, or high, level

for COVID-19 community transmission for the week ending Feb. 4."

Providers Comment On Impact Of COVID-19 Pandemic On People Struggling With Eating Disorders. The Baltimore Sun (2/10, Roberts, 629K) reported on the impact of the COVID-19 pandemic on people with eating disorders. For such individuals, "the coronavirus outbreak's sudden destruction of eating routines and treatment schedules and the way it amplified stress and isolation were especially devastating." During the first three years of the pandemic, "inpatient stays for eating disorders rose nationwide." That coincided with "emergency department visits for eating disorders" doubling among adolescents. Specialists treating the disorders also shared that they "saw changes in the patient pool" with the people presenting for treatment skewing younger.

Commentaries Point To End Of COVID-19 Pandemic Public Health Emergency As Threat To Biden Administration's Student Debt Relief Measure. In an op-ed for the Wall Street Journal (2/10, Subscription Publication, 8.41M), Gabriel Rubin wrote the decision to end the federal government's COVID-19 pandemic public health emergency (PHE) could compromise the Biden Administration's plan to cancel student debt. After failing to secure Congressional approval, the Biden Administration exercised expanded powers connected to the PHE to put the plan into motion.

In a column for USA Today (2/10, 12.7M), Ingrid Jacques wrote that "by announcing the end to the" PHE, "Biden is admitting that the flimsy justification for the debt plan is going away." The issue of student debt cancellation "demands debate in Congress" and "not makeshift responses that skirt the legislative body." Jacques states, "my concern is that the Biden Administration will continue finding excuses to prolong" the PHE "because the president has relied too heavily on this power."

Reuters Finds Claim Moderna Made COVID-19 Vaccines Before Pandemic Began Are False. Reuters (2/10, Check) reported in a fact-check article that online claims that Moderna CEO Stephane Bancel said in a panel discussion at Davos 2023 that the company "had made 100,000 COVID vaccine doses before the pandemic began" are false. Instead, Reuters says, Bancel "spoke about how quickly the company was able to scale up vaccine production at the start of the COVID-19 pandemic."

AP: Report That Fauci Wrote COVID-19 Vaccines Don't Work Is False. The AP (2/10, Marcelo) reported that a claim that Dr. Anthony Fauci wrote "in a recent science paper...that COVID-19 vaccines don't work" is false. The AP says the "article's authors say their paper acknowledges current vaccines for respiratory viruses don't prevent all infections, but that they do prevent the most serious symptoms." Fauci and a coauthor "said the article makes the case for exploring new approaches to make respiratory virus vaccines more effective." The article "was written by Fauci and two top officials at the National Institute of Allergy and Infectious Diseases: Jeffery Taubenberger, deputy chief of its infectious disease lab, and David Morens, a senior advisor to the agency's director."

Georgia High School Form On Cardiac Arrest Is Not Related To COVID-19 Vaccinations. In a fact-check article, USA Today (2/9, 12.7M) reported that a Facebook post claiming a form distributed by the Georgia High School Association "that describes the early warning signs of 'sudden cardiac arrest' and explains what should happen if one occurs" is related to COVID vaccinations is false. The form "is not new, Georgia High School Association spokesperson, Steve Figueroa, told USA TODAY" and dates to 2019.

Claim That CDC Official Admitted COVID-19 Vaccines Cause "Debilitating Illnesses" Is False. In a fact-check article, the AP (2/10, Tulp) reported that a claim that CDC deputy director Dr. Tom Shimabukuro "admitted that COVID-19 vaccines are causing 'debilitating illnesses'" is false. The AP says the claim "takes [his] comments at the January meeting of the Food and Drug Administration's Vaccines and Related Biological Products Advisory Committee out of context." Shimabukuro's remarks "came during a wider discussion of vaccine safety monitoring in which Shimabukuro was describing accounts in the Vaccine Adverse Event Reporting System, an

early warning system kept by the FDA and the CDC to monitor signals of possible side effects from vaccines."

HHS IN THE NEWS

FDA Gives Green Light To Limited Health Claims For Some Products Made With Cocoa Powder. NPR (2/12, Aubrey, 3.69M) reports that Barry Callebaut AG Switzerland, which makes chocolate and cocoa products, in 2018 "petitioned the U.S. Food and Drug Administration to allow the use of a health claim on labels, pointing to the link between the consumption of flavanol-rich cocoa and a reduced risk of cardiovascular disease." Early this month, "after an exhaustive review of studies, the FDA has responded." The agency "gave a green light to use certain, limited health claims on products made with high-flavanol cocoa powder." However, it "says there's not enough evidence to support claims on regular chocolate, the kind most of us consume."

Coalition Calls For FDA To Rescind Final Guidance On Clinical Decision Support. Healthcare IT News (2/10, 2K) reported, "The CDS Coalition is asking the U.S. Food and Drug Administration to pull back on its clinical decision support guidance in order to ensure that the agency better balances its regulatory oversight with the healthcare sector's need for innovation while comporting with the statutory language of the 21st Century Cures Act." Healthcare IT News says "the coalition's stakeholders – clinical decision support software developers, patient advocacy organizations, clinical societies, healthcare providers and healthcare payers – say FDA's guidance exceeds Congress's statutory definitions of what is considered CDS and threatens to undermine lawmakers' goals." The coalition "said in its February 6 petition prepared by Epstein Becker & Green, P.C.: 'The Office of the National Coordinator for Health Information Technology and the Centers for Medicare and Medicaid Services strongly believe that CDS software will help improve the quality of care, and that innovation must be encouraged in this space.'"

FDA Working On Initiatives To Speed Development Of Medical Countermeasures To Disease Outbreaks. BioCentury (2/10, Usdin, Subscription Publication) reported behind a paywall that the FDA "is working on two initiatives that have the potential to make drug development and manufacturing more efficient, enhance U.S. competitiveness and increase supply chain resilience." BioCentury says "both projects, the establishment of designation programs for platform technologies and for advanced manufacturing technologies, were tucked inside the 4,155-page omnibus spending bill Congress passed in December." The proposals "were crafted with input from FDA and were informed by the COVID-19 experience, especially imperatives to speed the development of medical countermeasures in the face of infectious disease outbreaks and to reduce reliance on overseas manufacturing facilities."

Opinion: FDA's Proposed Changes To Blood Donation Rules Will Likely Reduce Stigma For Gay Men. In an opinion piece for the Los Angeles Times (2/11, 3.37M), physician Eric Kutscher wrote, "As a sophomore in college in 2011, I was deferred from donating blood for being a gay man. I was confronting the homophobia built into the FDA's blood donation ban for men who have sex with men. After imposing that rule in 1985 and making a few minor revisions since, the FDA is at long last considering meaningful updates to consider donors based on their sexual behavior regardless of their orientation." Kutscher wrote, "The FDA is clearly trying to create more inclusive and evidence-backed policies. The proposed changes will likely reduce stigma for some Americans and possibly reduce the number of young men who are outed at work and school during blood donation drives. Yet as a doctor, I'm disappointed by the lack of nuance that still exists in the new donation rules – and I hope to see further changes."

CMS Administrator: Medicare Spending Is Something "We Always Have To Look At." NPR (2/10, 3.69M) reported with a transcript of its Morning Edition program in which the host "speaks with Chiquita Brooks-LaSure, the administrator for the Centers for Medicare and Medicaid Services, about the future of both programs." During the interview, Brooks-LaSure said Medicare spending is

something "that we always have to look at. Every couple of years, it's important for Congress to continue to make adjustments."

Opinion: Market-Based Reforms Are Needed To Prevent Collapse Of Medicare, Medicaid. In an opinion piece for the Wall Street Journal (2/12, Subscription Publication, 8.41M), former CMS chief Seema Verma writes that, despite President Biden's rhetoric, failure to take action will cause Medicare and Medicaid to collapse. Verma writes that market-based reforms such as value-based care for providers are the solution.

NIH Leaders Discuss Medical Wrongs Against Black Community. The Atlanta Journal-Constitution (2/10, J. Thomas, 1.46M) reported, "Decades later, the descendants of Black people harmed by medical research in the past say they are still dealing with the impact of those transgressions, but hope discussing what took place can begin a new phase for Black healthcare." Now, "health and research leaders from the National Institutes of Health are meeting today in Tuskegee, Alabama to hold discussions with those descendants." On Thursday evening, All of Us Chief Engagement Officer Dr. Karriem Watson said, "We have to acknowledge that there's a historical context in which we do this work. Bringing people together to talk about the importance of diverse participation in clinical trials is so important, but we have to acknowledge why some communities don't participate."

WHO Report Says Eight Nations Eliminated A Neglected Tropical Disease in 2020. Nature (2/13, Coleman, 194K) reports, "Malawi, Vanuatu and Uganda were among the eight nations that eliminated a neglected tropical disease" (NTD), "last year, according to a World Health Organization (WHO) report." This "takes the number of countries that have done so since the late 1990s to almost 50, with 11 banishing more than one disease." The WHO report "comes two years after the agency released a plan to control or eliminate neglected tropical diseases (NTDs) by 2030." But, "the pandemic also disrupted elimination progress in many countries." US National Institute of Allergy and Infectious Diseases group leader for leishmaniasis Shaden Kamhawi said, "We really need to think and be innovative in how we would be prepared if another [pandemic] comes before we reach our goals," but she added, "any progress is good progress."

NCI Increases R01 Payline To 12th Percentile For 2023. Cancer Letter (2/10, Ong) reported behind a paywall, "NCI is increasing the R01 payline to the 12th percentile in fiscal year 2023, up from the 11th percentile in FY22 – bringing the institute's payline to a level not seen since 2010."

US Surgeon General Admits 13 Years Old Is "Too Early" To Be Using Social Media. Fox News (2/10, Sudhakar, 23.99M) reported, "U.S. Surgeon General Vivek Murthy recently warned that age 13 and younger is too early for America's kids to be using social media platforms – despite this being the minimum age to join many of these popular sites, such as Facebook, TikTok, Snapchat and Instagram." Murthy said last week about children using social media, "I, personally, based on the data I've seen, believe that 13 is too early." He added, "It's a time when it's really important for us to be thoughtful about what's going into how they think about their own self-worth and their relationships – and the skewed and often distorted environment of social media often does a disservice to many of those children."

HHS Appoints New Director For Office Of Research Integrity. Bloomberg Law (2/10, Baumann, Subscription Publication, 4K) reported, "The HHS has appointed" Sheila Garrity as "a new director for its Office of Research Integrity, filling a post that's been vacant for more than two and a half years with George Washington University's research integrity officer." Garrity "joins the Department of Health and Human Services after about three decades leading research integrity programs in academia." She "will assume her post as ORI director the week of March 26. Wanda K. Jones has been the acting director since June 2021."

CDC Maintains Super Bowl Ad Spot Since 2019. Behind a paywall, Bloomberg Law (2/13, Burgott, Subscription Publication, 4K) reports, "Super Bowl commercials usually focus on commodities like snack food or technology for keeping up with the Joneses, but the federal government is no stranger to using the event for

public outreach." And the Centers for Disease Control and Prevention "has spent $75,000 annually in Super Bowl advertising since fiscal 2019." Commercials are not a normal part of the government, "despite an uptick over the last nine full fiscal years in federal marketing procurement," including an increase of "68% since fiscal 2014, with notable bumps from the Defense Department in fiscal 2017 and" the HHS.

OVERDOSE PREVENTION

Veterinary Tranquilizer Xylazine Worsening US Fentanyl Crisis. The Wall Street Journal (2/12, Kamp, Wernau, Subscription Publication, 8.41M) reports that the veterinary tranquilizer xylazine is spreading rapidly within the illicit drug supply and causing serious wounds for regular users. Xylazine is typically mixed with fentanyl, and oftentimes, the volatile mixing of drugs means that drug users do not know what they are taking. According to the DEA, there were 3,000 xylazine-related deaths in 2021 and the drug is now spreading from the Northeast to other parts of the US.

Harm Reduction Strategies Remain Vastly Underfunded. The New York Times (2/10, Weiland, 20.6M) reported "harm reduction" as a strategy to reduce overdose deaths in America has received more federal support in recent years, with President Biden even endorsing the strategy during his State of the Union address this week. Harm reduction, however, "remains underfunded and partially outlawed in many states," with organizations and their volunteers and employees "functioning as brokers between drug users and the resources they need to manage their consumption." RTI International researchers "estimate that there are only around 1,100 full-time workers nationwide" at syringe exchange organizations, "aided by a cast of around 600 part-time staff members and roughly 2,000 volunteers." In contrast, "over 100,000 Americans die each year from drug overdoses – one every five minutes, the White House estimates."

Bipartisan Panel Of Governors Agrees On Ideas To Address Addiction, Fentanyl Crisis. Politico (2/12, Olander, 6.73M) reports, "A bipartisan panel of governors from Maryland, New Hampshire, New Mexico and North Dakota said they agreed on elements of each other's ideas to address addiction and the fentanyl crisis, speaking Sunday on CBS' 'Face the Nation.'" New Mexico Gov. Michelle Lujan Grisham (D) said, "That is probably going to be the nexus of real bipartisan work," to North Dakota Gov. Doug Burgum (R) "after he described treating addiction as a disease." The panel of governors "were in Washington, D.C., for the National Governors Association conference, and dealing with fentanyl was one area where they clearly found common cause."

Overdose Deaths In NYC Rose From Less Than 1,500 In 2019 To 2,670 In 2021, Data Show. The New York Daily News (2/10, Stratman, 2.51M) reported amid the COVID-19 pandemic, overdose deaths in New York City have risen "from just under 1,500 overdose deaths in 2019 to around 2,670 two years later, according to a recent city report. The pandemic aggravated a problem already on the rise: In 2015, just 942, or 13.8 of every 100,000 city residents, died of an overdose." The article added, "The Mott-Haven-Hunts Point area in the Bronx has long struggled with overdose deaths, but in 2021, deaths skyrocketed – by 42.2 per 100,000 residents from the prior year." Overall, "the neighborhood saw a staggering 119.3 per 100,000 residents die of an overdose in 2021." By comparison, "18.8 of 100,000 people died of an overdose in the area" in 2015.

Data Show Vast Majority Of People Sentenced For Fentanyl Trafficking Are US Citizens. PolitiFact (2/10, Cercone, Ramirez Uribe, 153K) reported, "Deaths from fentanyl jumped 23% in President Joe Biden's first year in office to more than 70,000, but they've been increasing since 2014 and also rose during Donald Trump's administration." Even though "immigration encounters at the southern U.S. border have spiked under Biden's watch, experts say most of the fentanyl coming into the U.S. from Mexico is coming through legal ports of entry." Data show that "the vast majority of people sentenced for fentanyl trafficking are U.S. citizens."

HEALing Communities Study Teams Up With University Of Kentucky To Implement Narcan Kits Across Campus. WKYT-TV Lexington, KY (2/11, 50K)

reported, "Unfortunately, overdoses are not foreign to college students," which "is why the HEALing Communities Study team at the University of Kentucky implemented naloxone (name brand Narcan) kits around campus." The move is an effort to end "overdose deaths in the Commonwealth of Kentucky. They wanted to make sure that the naloxone kits were easily accessible."

WTVQ-TV Lexington, KY (2/10, 11K) also reported.

Meth Contamination At Several Colorado Libraries Shines Light On "Silent Epidemic." Denver 7 (2/11, Richard) reported, "The closure of several Colorado libraries due to meth contamination has put the spotlight back on the methamphetamine epidemic, which is sometimes called 'the silent epidemic.'" University of Colorado Department of Psychiatry addiction psychiatrist and associate professor Dr. Joseph Sakai said, "People sometimes talk about it as the epidemic that folks don't look at." Sakai "says unlike opioids, which can be treated with several medications, there is no FDA-approved medication to treat meth addiction." Searching for "an alternative, Sakai and a team of researchers at the CU CONA (Colorado Neuromodulation of Addiction) Lab are putting together a study to see if Deep Brain Stimulation can help people addicted to meth." He "says if the results seem promising, the National Institute on Drug Abuse may provide them with more grant money to expand the study."

Suicides Continue In New York Prisons, Jails Likely Due To Drug Withdrawal. The Albany (NY) Times Union (2/12, Manno, 315K) reports, "The New York Commission of Correction concluded investigations on at least 90 inmate suicides at state prisons and local jails between 2016 and 2021, according to records provided to the Times Union." In fact, "a common thread emerging from the fatal incidents is a pattern of inadequate mental health services and shoddy supervision that preceded the deaths." According to the National Institute on Drug Abuse, "drug addiction places many prisoners at an especially high risk of suicide, with 85 percent of the nation's prison population having an active substance abuse disorder or a conviction for a crime involving drugs." Consequently, the "Food and Drug Administration issued an advisory in 2019 on the risk of suicide among individuals addicted to opiates whose medication is abruptly discontinued or decreased."

Court Documents Following Student Fentanyl Overdoses Reveal Supplier Lived Blocks Away From Schools. CNN (2/11, Sun, Norman, 89.21M) reported, "Parents across the Carrollton-Farmers Branch Independent School District (CFBISD), located in a Dallas, Texas, suburb, are reeling following a string fentanyl overdoses by nine students who attend schools in the district." Court documents show that "law enforcement officers traced the drugs the students overdosed on to a house within walking distance from a middle school and a high school."

New Colorado Legislation Could Allow Supervised Drug Use Sites To Open. The Denver Post (2/10, Klamann, 660K) reported that a new proposal, which is being drafted in the Colorado House, "would let local governments decide whether to allow" supervised drug-use "sites to open in their jurisdiction, said Rep. Elisabeth Epps, a Denver Democrat and the bill's primary sponsor." However, the bill "wouldn't set aside any money to fund any facilities, and cities would still have to provide their own approval, which Epps said is a pro-local control approach." Colorado "drug laws also wouldn't change; any illicit substances brought into a sanctioned site would have to be acquired elsewhere."

Gabapentin Finding Its Way Into Maine's Illicit Drug Market. The Bangor (ME) Daily News (2/13, Loftus, 178K) reports gabapentin, "a medication marketed as a nonaddictive nerve-pain reliever and anticonvulsant, is finding its way into Maine's illicit drug market." Recently 1,253 gabapentin pills were seized in Old Town. It "is part of a growing national trend of the drug being found in fatal overdoses." Meanwhile, "prescription rates for gabapentin continue to climb." The rise in misuse of the medication "has prompted states across the country to more heavily regulate the drug and the federal Food and Drug Administration to issue warnings about the dangers it poses."

Target Dates Set For Ohio Opioid Settlement Distribution. The Youngstown

(OH) Vindicator (2/13, 135K) reports, "Funding from the OneOhio National Opioid Settlement could begin to come to local communities this fall, but policy delays could impede funding until 2024." Recently, the OneOhio Region 7 Board "got the chance to meet with the interim executive director of" the private nonprofit "OneOhio Recovery Foundation, Kathryn Whittington, who is also an Ashtabula County commissioner." The foundation has been "tasked with distributing 55 percent of the money Ohio will receive from the pharmaceutical industry as a result of its role in the national opioid epidemic." But "because this is so new, much of the structure and processes still are being decided by the 29-member board governing the foundation."

University Of Arkansas Develops Smartphone App To Decrease Opioid Cravings, Optimize Medication-Assisted Treatment. The Little Rock (AR) Daily Record (2/13, Grajeda) reports, "University of Arkansas for Medical Sciences researchers have developed an award-winning smartphone app designed to decrease opioid cravings and optimize medication-assisted treatment for people with opioid use disorder." The research team is "supported by a $2.8 million grant from the National Institute on Drug Abuse," and "is testing the effectiveness of OptiMAT (Optimizing Medication Assisted Treatment) among individuals receiving medication-assisted treatment for opioid use disorder at the UAMS Center for Addiction Services and Treatment."

Opinion: Low-Cost Solution To Reduce Overdose Deaths Is To Tell Physicians when Patients Die. USC Sol Price School of Public Policy Department of Health Policy and Management Chair Jason Doctor and USC Schaeffer Center Aging and Cognition Program Co-Director Mireille Jacobson write in The Hill (2/12, 5.69M), "Despite billions of dollars in settlements from drug companies and distributors, thousands of patients still die each year from overdoses of prescription opioids." The current "systems may no longer be enough to reduce dangerous opioid prescribing." However, "authorities have a promising new tool at hand: low-cost letters that apply different amounts of social persuasion to clinicians to adhere to prescribing recommendations, including telling them when a patient has died." The authors write, "As health economists, we separately participated in two recent studies that showed the payoffs from straightforward and inexpensive mailings." The studies "show that clinicians can be effectively prodded to participate in, and search, state databases and to reduce prescribing."

Opinion: Public Health Message That "One Pill Can Kill" Needs To Be Spread To Youth. University of North Texas Health Science Center reagent professor Scott Walters writes for the Dallas Morning News (2/13, 772K) that more often "we are seeing overdoses among young people who have no substantial history of drug use and no idea what kind of drug they are taking." Over "the last five years, there has been a spike in overdoses nationally, and especially among young people. Between 2019 and 2021, fentanyl overdose deaths doubled in the U.S., increasing nearly fourfold among children. Statewide, fentanyl was present in 97% of drug overdoses last year." Walters says, "Fortunately, there are proven strategies to protect children against poison. First, we need to prioritize public health messages that 'One pill can kill.'" Also, "communication campaigns need to be designed to appeal to teens, much like the successful tobacco campaigns that dramatically reduced teen cigarette smoking."

Opinion: Compassion, Empathy Should Be At Heart Of Opioid Strike Force. Dallas council member for District 7 Adam Bazaldua and Dallas council member for District 9 Paula Blackmon wrote for the Dallas Morning News (2/13, 772K), "As the opioid epidemic continues to devastate American communities and families, Dallas families are not immune to this epidemic." Last year, "Dallas Fire-Rescue paramedics administered just shy of 2,000 doses of Narcan, a medication used to reverse or reduce the effects of opioids, through the end of year 2022." And recently, "we learned that three Carrollton-Farmers Branch ISD students died and six others have been hospitalized in a string of overdoses from fentanyl-laced pills." The authors conclude, "If we are to combat this epidemic, we must address the public health element. Keeping a caring, proactive and pressing approach in our response will allow for mental and physical health to be prioritized. Compassion, empathy and understanding, as well

as personal experience, are at the heart of the Opioid Strike Force."

MENTAL ILLNESS

988 Suicide And Crisis Lifeline Contact, Answer Rates Risen Dramatically Since Launch. ABC News (2/11, Livingston, 2.44M) reported, "In the six months since the launch of the national, government-backed 988 Suicide and Crisis Lifeline, contact and answer rates have risen dramatically, while the average speed to answer has dropped, according to Substance Abuse and Mental Health Services Administration data." Suicide and Crisis Lifeline interim executive director April Naturale told ABC News, "As we expected, there's been a significant increase in the use of the 988 Suicide and Crisis Lifeline service since this transition to a three-digit number. ... And actually, we're really grateful that more people are contacting the line with this change. That was the whole goal." According to SAMHSA, "in December, 87% of calls, 96% of chats and 99% of texts were answered across the nation...a 91% overall answer rate."

After Two Year Decline, Suicide Rates Increased Among Younger Americans, People Of Color, CDC Finds. The New York Times (2/11, Barry, 20.6M) said, "A two-year decline in yearly suicides ended in 2021, as suicide rates rose among younger Americans and people of color, according to a new report from the Centers for Disease Control and Prevention." Per the report, "for decades, suicide rates among Black and Hispanic Americans were comparatively low;" however, "a gradual shift is underway." The CDC found that between 2018 and 2021, "the only racial group that saw a decrease in suicide rates across age cohorts was non-Hispanic white people."

CBS News (2/10, Tin, 5.39M) reported, "Preliminary data suggests suicide rates had not significantly improved overall through the first quarter of 2022, according to estimates published by the CDC's National Center for Health Statistics."

Analysis: Biden's Initiatives To Address Youth Mental Health "Promising" If Quick Action Is Taken. In an analysis for ABC News (2/12, 2.44M), BeMe Health Chief Medical Officer Dr. Neha Chaudhary says, "The Biden-Harris administration's commitment to youth mental health is encouraging, and the doors appear to be open for bipartisan efforts to invest in, protect and promote the well-being of young people everywhere." In his State of the Union Address, President Biden highlighted some initiatives that "would positively impact the mental health of young people on a societal level." Chaudhary discusses the pros, cons, and barriers these initiative may face. But, she concludes, "Overall, the initiatives are promising – as long as stated priorities turn quickly into action in response to this crisis."

Study Emphasizes Need For Pediatric Outpatient Mental Health Follow-Up Care. CNN (2/13, Christensen, 89.21M) reports that while emergency department "staffers may be able to stabilize a child in a mental health care crisis...research has shown that timely follow-up with a provider is key to their success long-term." But "unfortunately, there just doesn't seem to be enough of it, according to a new study co-authored by" Ann & Robert H. Lurie Children's Hospital Dr. Jennifer Hoffmann. In the study "published Monday in the journal Pediatrics," Hoffmann and co-authors "found that less than a third of the children had the benefit of an outpatient mental health visit within seven days of being discharged from the ER." And "a little more than 55% had a follow-up within 30 days." The study found, "without a follow-up, more than a quarter of the children had to go back to the ER for additional mental health care within six months of their initial visit."

Undergraduate Peer Counselors Help Address Increased Number Of Students Seeking Mental Health Counseling. The Wall Street Journal (2/12, Petersen, Subscription Publication, 8.41M) reported on the role specially trained undergraduate peer counselors play in helping address the increased number of college and university students seeking mental health counseling.

New Schizophrenia Drug Xanomeline-Trospium Showing Promise Of Fewer Side Effects. Wired (2/10, Browne, 3.42M) reported that since the first "rush of discoveries"

over schizophrenia "in the middle of the 20th century, the field hasn't progressed much." Current drugs "do achieve a degree of relief for many people...but they have a poor effect for some patients, zero effect for others, and are notorious for triggering unwanted and sometimes overwhelming side effects." But now "xanomeline-trospium, or KarXT, has a novel way of diminishing dopamine transmission that's showing promise at reducing symptoms while also limiting side effects."

Commentary: Using Ketamine To Treat Depression Does Not Help Everyone. Contributing columnist Steven Petrow writes for the Washington Post (2/12, 10.52M) about his experience with using "ketamine, the anesthetic and hallucinogenic drug that has found a new market as an antidepressant," for his own clinical depression. Petrow writes, "As I read the buoyant reports of ketamine successes I decided it was time for me to try it – under the supervision of a professional therapist." The FDA "approved the use of a nasal-spray form of ketamine for use in treatment-resistant, unipolar major depression," and the psychiatrist "briefed me in detail on all the possible side effects." But "looking back I realize I didn't fully appreciate what all that meant." Petrow concludes that while "according to reputable studies, ketamine can be life-changing for a significant majority," that "leaves 25 percent, like me, who are not so fortunate."

HEALTHCARE FRAUD

Centene Agrees To Pay Medi-Cal $215M To Settle Overcharging Allegations. HealthPayerIntelligence (2/10, Bailey) reported that Centene "must pay Medi-Cal, California's state Medicaid program, over $215 million to settle allegations that it two of its managed care plans overcharged the program by reporting inaccurate prescription drug costs." According to the settlement, "the costs were incurred by Centene managed care plans California Health & Wellness and Health Net." State Department of Justice Investigators "found that California Health & Wellness and Health Net reported inflated costs they incurred for prescription drugs provided to patients between January 2017 and December 2018."

PRESCRIPTION DRUG PRICING

Generic Drugmakers Likely To Benefit From IRA Drug Pricing Laws. STAT (2/10, Wilkerson, 262K) reported, "Generic drugmakers lobbied hard against Democrats'" Inflation Reduction Act "empowering Medicare to negotiate prescription drug prices." But now "industry experts and lobbyists acknowledge the package is more of a mixed bag for generics makers...not an existential threat." And "the law could actually end up encouraging more generic competition" by incentivizing drugmakers to allow generic competition. Under the IRA law, "Medicare can't negotiate prices for any drug that competes against a marketed generic medicine." The "change in tone is yet another indication that government price controls are not likely to damage the generic and brand drug industries nearly as much as lobbying groups for those industries claimed during the debate over the...the Inflation Reduction Act."

Opinion: Senator Hawley's Proposed Insulin Cap Legislation Will Make Quality Healthcare Unaffordable. Cato Institute senior fellow and general surgeon Jeffrey A. Singer wrote for The Hill (2/10, 5.69M), "Not long ago, conservative Republicans opposed ObamaCare's mandated benefits regulations" which could drive up insurance costs. But "alas, the era of limited government Republicans is fading." Sen. Josh Hawley (R-MO) "recently sponsored legislation" to cap out-of-pocket "insulin expenditures at $25 and ban insurance companies from requiring patients to try less expensive insulin products" first. Hawley's legislation "would insulate consumers from the cost of" insulin while driving up insurance costs for both insurers and consumers. Hawley should "work to streamline FDA regulations, reform pharmaceutical patent laws, and eliminate the FDA's authority to impose prescription requirements on drug manufacturers and consumers." But instead Hawley "chooses to add more mandates to the ones already making quality health care increasingly unaffordable and out of reach."

HEALTH CARE & INSURANCE REFORM

Maryland Officials, Advocates Touting Program Which Allows Residents To Enroll In Healthcare Coverage Through Tax Returns. The AP (2/11) reported, "Maryland officials and advocates are highlighting a state program that enables residents to begin signing up for health insurance by checking a box on their state tax return." In 2019, "Maryland became the first state in the nation to establish a tax-based easy enrollment program."

Kaiser Permanente Reports Loss Of $4.47B In 2022 Amid Rising Costs. Modern Healthcare (2/10, Hudson, Subscription Publication, 215K) reported, "Kaiser Permanente is the latest health system showing signs of struggle amid rising costs." On Friday, the company "reported a $4.47 billion net loss in 2022, compared with a $8.08 billion gain in 2021." While revenue increase 2.4% to $95.41 billion, "expenses rose 4.5% to $96.68 billion, driven by increased care volume due to previously deferred procedures, higher costs of goods and increased spending on labor." Additionally, "Kaiser lost $3.2 billion due to poor market performance on investments."

Despite Another Year With Net Loss, Oscar Health Optimistic For Growth In 2023. Modern Healthcare (2/10, Turner, Subscription Publication, 215K) reported, "Oscar Health made gains on some vital financial metrics last year and beat analysts' expectations for the fourth quarter, triggering its share price to rise Friday." Oscar's "medical loss ratio improved from 88.9% in 2021 to 85.3% last year and its administrative expense ratio declined from 21.8% to 20.6%, the company reported Thursday." In the fourth quarter of 2022, the company "recorded a $226.6 million net loss," beating "analyst expectations of $261.3 million in net losses." For the whole year, Oscar "endured a $610 million net loss," which was "up from $571 million the year before;" however, "the health insurer predicted a better 2023," expecting a loss of just "$75 million to $175 million."

Providers Preparing To Use Misoprostol Alone If Lawsuit Over FDA Approval Of Mifepristone Proves Successful. STAT (2/10, Boodman, 262K) reported "stories about medication abortion...often give mifepristone a starring role." Therefore, "it might seem surprising that American abortion providers are responding to" a lawsuit which seeks to reverse the FDA's approval of the drug "by preparing to forego mifepristone and use misoprostol alone. How could that be? Wasn't mifepristone the abortion pill, the critical tool for ending a pregnancy in the first trimester?" The piece said the "narrative has been backward. Biologically speaking, mifepristone is the sidekick, and misoprostol the superhero, mifepristone the opening act while its counterpart carries the show. ... Both regimens – either the two drugs together, or just misoprostol – are extremely safe. And they're both very effective. Chances are, taking misoprostol alone will work to end a pregnancy early on, but it's likely to come with more discomfort, cramping, and nausea."

Abortions Occurring Later Due To Increased Demand From Out-Of-State Patients. The Wall Street Journal (2/12, Kusisto, Subscription Publication, 8.41M) reports abortion clinics say months after the demise of Roe v. Wade, state restrictions are leading to later abortions. That is because clinics are getting more out-of-state patients in addition to the regular number from states where abortion remains legal. In general, this is adding weeks to the amount of time it takes to get appointments.

Maryland Governor, Dems Unveil Measures Which Seek To Expand Protections For Reproductive Rights. The Hill (2/10, Gans, 5.69M) reported, "Maryland Gov. Wes Moore (D) and Democratic lawmakers are moving to make the state a 'safe haven for abortion' in the aftermath of the end of Roe v. Wade and more than a dozen states moving to severely restrict access to the procedure." On Thursday, he, "Lt. Gov. Aruna Miller, the leaders of the state House and Senate and other state lawmakers announced a legislative package to expand protections for reproductive rights at a press conference."

GOP Legislators Attempting To Bypass DAs Who Refuse To Prosecute Violations Of Abortion Bans. Politico (2/12, Ollstein, Messerly, 6.73M) reports Republican "lawmakers see a major flaw in their states' near-total abortion bans: Some local prosecutors won't enforce them." Georgia, Indiana, South Carolina, and Texas GOP legislators – "frustrated by progressive district attorneys who have publicly pledged not to bring charges under their state's abortion laws – have introduced bills that would allow state officials to either bypass the local prosecutors or kick them out of office if their abortion-related enforcement is deemed too lenient."

Abortion Rights Groups, Dems In Colorado Working On Legislation To Regulate Crisis Pregnancy Centers. The Denver Post (2/12, Klamann, 660K) reports pregnancy centers represent "contested outposts in the escalating fight over abortion access in Colorado and the United States. The facilities – known as crisis pregnancy centers – are staunchly anti-abortion and offer limited medical services and family counseling, with the intent of steering women away from terminating their pregnancies. There are dozens of the facilities in Colorado, more than doubling the number of abortion providers." Critics contend "the organizations – which they call anti-abortion centers – use deceptive advertising and promote the use of unproven medical treatments." Several "abortion access groups, together with Democrats in the Colorado statehouse, are preparing a landmark bill to regulate how the centers operate and confront those concerns."

Oklahoma Senate Panel Advances Measures Which Outline Legal Abortion. The Oklahoman (USA) (2/10, Denwalt, 371K) reported on Thursday, legislators on an Oklahoma Senate panel "advanced two bills...that would clarify what is (and isn't) a legal abortion in Oklahoma." The article added, "One was introduced to clarify the Legislature's intent when it comes to medical procedures that terminate pregnancy. The other stipulates that Oklahoma's abortion laws shouldn't limit access to birth control drugs."

Lawsuit Alleges Security Guards At National Archives Ordered Anti-Abortion Advocates Not To Display Pro-Life Slogans. The Washington Post (2/11, Kunkle, 10.52M) reported, "Antiabortion advocates hoping to view the Constitution at the National Archives were ordered not to display their slogans during their visit, in violation of their constitutional rights, according to a federal lawsuit filed against the agency this week." The pro-lifers, "who were in the District attending the 50th Annual March for Life last month, allege that a group of security guards at the National Archives and Record Administration's building told them to hide or remove buttons, hats and clothing that contained messages such as 'Life is a HUMAN RIGHT' and 'Pro-Love is the New Pro-Life' when they entered the Rotunda, where the Constitution and its Bill of Rights are on display."

Almost 70% Of Americans Dissatisfied With Abortion Policies, Poll Finds. The Hill (2/10, Melillo, 5.69M) reported almost "7 in 10 Americans are dissatisfied with the country's abortion policies, marking the highest rate measured in 23 years, a new Gallup poll found." These findings "come more than seven months after the Supreme Court struck down Roe vs. Wade, the ruling that guaranteed a woman's right to an abortion. Since then, many states have banned the practice or moved to significantly curb abortion access."

Company Has Been Trying For Years To Expand US Women's Access To Birth Control Pills. Fortune (2/10, Aspan, 3.68M) reported, "It's been a long seven months for Perrigo's HRA Pharma, the company making a historic request to expand American access to birth control." Still, "after nine years of regulatory red tape, its executives know how to be patient." Last "July, the pharmaceutical company made a landmark – and tragically well-timed – application to the U.S. Food and Drug Administration. The Supreme Court had just overturned Roe v. Wade. And as tens of millions of women lost access to abortion almost overnight, the Court also signaled that access to contraceptives could be next in the legal crosshairs."

Columnist Criticizes Judge Presiding Over Lawsuit Challenging FDA

Approval Of Abortion Drug. In her Washington Post (2/10, 10.52M) column, Alexandra Petri wrote, "In another thrilling development in this best of all possible worlds, a ruling from a single Trump-appointed judge in Texas might undo the Food and Drug Administration's approval of one of the two key drugs used in medication-based abortions and render it inaccessible nationwide. I hear you asking a question: Can a judge just do that? Just un-approve a drug? One that's been tested and found extraordinarily safe over two whole decades?" Petri said this "is a real possibility, because our legal system is working just the way it ought to work! In an ideal society, your rights and ability to access medicine and direct the course of your own life are guaranteed and unalterable – unless a Trump-appointed judge named Matt decides to say, 'Nah.'"

HEALTH INFORMATION TECHNOLOGY

Editorial Commends FTC For Fining GoodRx Over HIPAA Breach. In an editorial, the Los Angeles Times (2/10, 3.37M) wrote, "Since 2017, GoodRx has helped millions of people find deals on prescription drugs via an app and website." However, "what its customers may not have known is that the Santa Monica-based health company had also been sharing information about their prescriptions and illnesses with third parties such as Google and Facebook for advertising purposes." For this, the FTC has "fined GoodRx $1.5 million for violating customers' privacy by failing to notify them about how their data were being used." The Times adds, "The enforcement action is a warning to other tech firms at a time of growth in the industry. Increasingly consumers are using apps and wearable devices to monitor their health, and they should know exactly how their personal information is being used."

HUMAN SERVICES NEWS

Biden Administration Credits New Migration Programs For Drop In Border Crossings. Roll Call (2/10, Monyak, 130K) reported that the volume of migrants "encountered monthly at the southwest border dropped significantly in January, a dip that Biden administration officials attribute to recent 'carrot-and-stick' style migration programs." Roll Call says border agents "reported a 40 percent drop in total encounters with migrants last month, decreasing from a record 252,000 encounters in December to about 156,000 in January, according to data released Friday by Customs and Border Protection." Biden Administration officials "attributed the decline in border crossings to recent programs aimed at discouraging migrants from crossing the border in between ports of entry."

Migrants Looking For US Sponsors Encounter "Underground Market." The AP (2/11, Snow) reported, "Pedro Yudel Bruzon was looking for someone in the U.S. to support his effort to seek asylum when he landed on a Facebook page filled with posts demanding up to $10,000 for a financial sponsor." The AP says the ads are "part of an underground market that's emerged since the Biden administration announced it would accept 30,000 immigrants each month arriving by air from Venezuela, Cuba, Nicaragua and Haiti." Applicants "need someone in the U.S., often a friend or relative, to promise to provide financial support for at least two years."

Judge Delays Order Setting Schedule Determining When North Carolina Health Officials Must Provide More Accommodations For People With Disabilities. The AP (2/10) reported, "A trial judge has agreed to delay enforcement of his order setting a robust schedule upon which North Carolina health officials must provide significantly more community services for people with intellectual and developmental disabilities while the state appeals his ruling." The judge "had in November set thresholds that the Department of Health and Human Services would have to meet regularly over the next decade." In part, that order "required at least 3,000 people must be diverted or shifted to community-based programs by early 2031. And he told DHHS to eliminate by mid-2032 a waiting list of people qualified to participate in a Medicaid-funded program that helps them live at home or outside of an institution."

Child Care In Philadelphia Costs 22.5% The Median Household Income Per Child. The Philadelphia Inquirer (2/10,

Ravitch) reported, "Philadelphia families are forced to spend a larger chunk of their pay on childcare than in any other Pennsylvania county, new federal data show, and it's likely affecting the number of women in the workforce." A new US Labor Department database "shows the cost of childcare as a proportion of median income in every Pennsylvania county, as well as all counties in most U.S. states. In Philadelphia, infant care costs about 22.5% of the median household income, and that's for just one child." Beyond the price, "availability is a challenge as well. The number of childcare providers in the country decreased sharply with the onset of the COVID-19 pandemic and has not fully recovered, according to a recent report from the U.S. Department of Health and Human Services."

Brett Favre Files To Have Welfare Fraud Lawsuit Dismissed. The AP (2/11, Pettus) reported, "Brett Favre's lawyers filed papers Friday again asking a Mississippi judge to dismiss the retired NFL quarterback from a lawsuit that demands repayment of millions of dollars of welfare money intended to help some of the poorest people in the U.S." Last year, the Mississippi Department of Human Services "sued Favre and more than three dozen other people or businesses" over allegations he was involved in the improper allocation of funds from the Temporary Assistance to Needy Families program. Favre "has repaid $1.1 million he received for speaking fees from a nonprofit group that spent TANF money with approval from the Mississippi Department of Human Services." Favre allegedly never gave the speech for which he was paid.

Kristof: New Strategies Needed To Teach Children How To Read. In his column for the New York Times (2/11, 20.6M), Nicholas Kristof wrote that "two-thirds of fourth graders in the United States are not proficient in reading." Kristof relays the growing belief that "we grown-ups have bungled the task of teaching kids to read" along with studies that show that "the United States has adopted reading strategies that just don't work very well and that we haven't relied enough on a simple starting point – helping kids learn to sound out words with phonics."

Opinion: Tax Benefit Parents Use To Offset Child Care Is "Hopelessly Outdated." In a Bloomberg Opinion (2/12) column, contributor Alexis Leondis writes, "Over the last four decades, the cost of child care has skyrocketed in the US. It now takes up almost 20% of median family income per child in major cities." However, "the tax benefit some workers use to offset those day care or nanny expenses has stayed the same – since 1986! When the amount was temporarily increased during Covid, it only became more obvious that the cap was hopelessly outdated." Leondis concludes, "With per-child childcare costs increasing 2,000% since the 1970s, it just doesn't make sense to leave the tax code stuck in the past."

Editorial: Hochul Should Appoint Wheelchair User To MTA Board Vacancy. In an editorial, the New York Daily News (2/12, 2.51M) writes, "Last spring the state Senate approved a bill 63 to zero and the Assembly did so 149 to zero...requiring state transportation authorities have on their boards a voting member 'who is limited to public transit as their primary mode of transportation because the individual has a temporary or permanent disability.'" This "means a person who uses a wheelchair will help run the agency." However, the measure "does not apply to" NYC's Metropolitan Transportation Authority (MTA). However, with two vacancies on the MTA's board, the Daily News says Hochul "doesn't have to wait for the new law to be amended. She should put at least one wheelchair user on the board now."

Jeffries Claims "Extreme MAGA" Republicans View Social Security As A "Ponzi Scheme." The Hill (2/10, Gans, 5.69M) reported House Minority Leader Jeffries "said on Friday that 'extreme MAGA' Republicans view Social Security as a 'Ponzi scheme,' calling on Democrats to work to protect the program."

FOOD & IMPORT SAFETY

Consumer Reports Says Bindle Brand Water Bottles Pose Potential Risk Of Lead Poisoning. CBS News (2/10, Cerullo, 5.39M) reported, "A popular brand of insulated bottle poses a risk of lead poisoning, according to Consumer Reports." Consumer Reports performed a test of the product, and "found that the Bindle bottle could expose users to 'extremely

high' levels of lead," and "said some bottles contained bisphenol A (BPA), a chemical known to cause fertility problems and some kinds of cancers." The advocacy group "said it found lead on the bottle's 'sealing dot,' a small, circular piece of metal at the bottle's base," containing "lead levels that are roughly 1,100 times higher than what's generally considered safe, according to the publication, noting that anything that comes into contact with the dot is at risk of lead contamination."

Purina Recalls Certain Units Of Dog Food After Two Dogs Exhibit Signs Of Vitamin D Toxicity. The Washington Post (2/10, Gregg, 10.52M) reported, "Nestlé Purina Petcare Co. is recalling select units of dry dog food after two dogs fell ill, the Food and Drug Administration announced this week." The notice "applies to certain units of Purina Pro Plan, EL Elemental, which may contain elevated levels of vitamin D." The agency "said there are two confirmed cases of a dog exhibiting signs of vitamin D toxicity while on the diet. Both recovered."

USA Today (2/10, Alund, 12.7M) also reported.

MEDICARE

CMS Announces Medicare Rebate Program Under Inflation Reduction Act. USA Today (2/10, Alltucker, 12.7M) reported, "Medicare will begin collecting penalties in 2025 from pharmaceutical companies that raise prices on prescription drugs faster than the rate of inflation, the Centers for Medicare and Medicaid Service said" last week. Also, "on April 1, Medicare enrollees on Part B drugs, typically administered by a doctor, might benefit from more moderate coinsurance charges, CMS officials said." CMS "released draft guidance Thursday on the rebate program and will solicit feedback from the public over the next 30 days before finalizing details."

Republican Senator Warns Medicare, Social Security In Danger Unless Congress Acts Now. CNN (2/12, LeBlanc, Fossum, 89.21M) reports that Sen. Mike Rounds (R-SD) "offered Sunday a stark warning about the future of Social Security and Medicare if Congress fails to take action now." Appearing on CNN's Jake Tapper on "State of the Union," Rounds said: "In the next 11 years, we have to have a better plan in place than what we do today. Or we're going to see – under existing circumstances – some reductions of as much as 24% in some sort of a benefit. So, let's start talking now because it's easier to fix it now that it would be five years or six years from now." CNN says President Biden recently "has made a forceful argument against Republicans by highlighting his support for Social Security and Medicare."

Meanwhile, Politico (2/12, Olander, 6.73M) reports Rounds said that most Republicans "don't agree with Sen. Rick Scott's plan to sunset programs including Medicare and Social Security." Rounds told Tapper: "The vast majority of us would say that we prefer to look at it in a different direction, one of managing it, as opposed to a discussion about having everything start over again."

Biden Has Yet To Be Specific About How He Would Strengthen Social Security And Medicare. CNN (2/10, Luhby, 89.21M) reported, "In his latest move to differentiate himself from House Republicans on entitlement programs, President Joe Biden is making a pretty big promise" by "vowing to shore up the shaky finances of Medicare's trust fund, extending its solvency to the middle of the century instead of the expected depletion date of 2028." CNN says, "But just how he will accomplish this objective – as well as one to strengthen Social Security – remains to be seen." When reporters "asked for more information, the White House said, 'We will provide more details on March 9, when the president releases his budget, backed up by full, transparent accounting.'"

Biden Aims To Brand Republicans As Extreme On Social Security, Medicare. The Hill (2/11, 5.69M) reported President Biden focused on attacking Republicans over Social Security and Medicare at his State of the Union speech this week, with one strategist suggesting he has found a "sweet spot" on the issues. The speech also served "as a preview of what's to come," with Biden expected "to try to label Republicans as extreme by pointing to GOP proposals that he says would lead to changes" in both programs.

Forbes (2/10, Dorn, 10.33M) reported that Biden "headed to Florida on Thursday, where he again attacked Republicans on the issue, telling an audience at the University of Tampa: 'A lot of Republicans, their dream is to cut Social Security and Medicare. Well let me say this: If that's your dream, I'm your nightmare.'"

McConnell Piles On To Biden's Criticism Of Rick Scott's Plan To Sunset Medicare, Social Security. The Washington Post (2/10, Wagner, 10.52M)reported that President Biden "has been hammering Sen. Rick Scott (R-Fla.) for his plan that would require Congress to reauthorize even popular programs such as Social Security and Medicare every five years to keep them operating." And, on Thursday, Senate Minority Leader Mitch McConnell (R-KY) "joined in the criticism, suggesting that provisions in Scott's plan could hurt him in his bid for reelection next year in Florida, a state with the greatest share of seniors in the nation." McConnell "told longtime Kentucky radio host Terry Meiners, 'That's not a Republican plan. That was the Rick Scott plan.'"

Meanwhile, The Hill (2/10, Shapero, 5.69M) reported that Scott "announced a new bill on Friday to increase funding for Social Security and Medicare and institute a higher standard for making cuts to the entitlement programs, following President Biden's pointed accusations during his annual address before Congress on Tuesday." The Hill said the legislation "aims to rescind the nearly $80 billion in funding for the Internal Revenue Service that was approved in last year's Inflation Reduction Act and redirect it towards Social Security and Medicare." It "would also require that any cuts to Social Security or Medicare be approved by a two-thirds vote in Congress and would block Medicare savings from being used for other spending initiatives."

Also reporting the story was Roll Call (2/10, Lesniewski, 130K).

Advocacy Groups Say CMS' Lack Of Insurance Coverage For New Alzheimer's Drug Is Discriminatory. TIME (2/10, Park, 18.1M) reported that despite the hope offered by newly-approved Alzheimer's disease treatment lecanemab (Leqembi), for many patients, "at $26,500 a year, the treatment is financially out of reach." However, "Medicare won't cover it" without more evidence on efficacy, as Leqembi is "only the second medication approved by the U.S. Food and Drug Administration (FDA) to target amyloid." Advocacy groups are calling out CMS, "which oversees Medicare, for adding treatment coverage restrictions that weren't put in place for other first-in-class therapies to treat diseases like HIV or cancer." And legislators "proposed a bill last November that would prevent CMS from restricting access to entire classes of approved drugs without evaluating the merits of each individually." HHS is mentioned.

Column: Republicans "Haven't Earned A Whole Lot Of Trust" On Social Security, Medicare. In a column for the Washington Post (2/10, 10.52M), Paul Waldman wrote, "After Republicans' heckling of" President Biden's comments that they "dream" of cutting Social Security and Medicare during his State of the Union address, "the White House clearly thinks it has struck political gold and has sent the president out to keep up this drumbeat." Waldman wrote that "if Republicans want the public to believe that their passion for defending those popular safety-net programs should be beyond doubt, they are on shaky ground. Even if Biden might sometimes exaggerate what his opponents believe, this debate carries with it a history and a context that make it hard for Republicans to claim they are being unfairly maligned." Waldman wrote, "The trouble is, Republicans haven't earned a whole lot of trust when it comes to programs that were created by Democrats, and that have been sustained and defended by Democrats in the face of decades of Republican attacks."

Letter: Seniors Can't Afford Benefit Cuts, But Wealthy Can Afford To Pay More. In a letter to the Washington Post (2/10, 10.52M), National Committee to Preserve Social Security and Medicare President and CEO Max Richtman wrote, "Most of the plans endorsed in the editorial "Yes, entitlements need to be reformed" ultimately would cut benefits and undermine the fundamental nature of both programs. The assertion that only high-income earners would be affected by these "reforms" is either disingenuous or naive. Raising the eligibility age for either program would be a huge benefit cut for all seniors. Means-testing benefits would have to reach deep into the middle class to significantly improve solvency. Investing some of

Social Security's reserves on Wall Street would put the program on a slippery slope toward privatization." Richtman wrote, "Most seniors cannot withstand benefit cuts, but the wealthy can afford to pay more to help keep these programs financially viable for future generations."

MEDICAID & CHIP

Biden Administration Begins Approving Medicaid Funds To Be Spent On Food Programs. The Wall Street Journal (2/12, Armour, Peterson, Subscription Publication, 8.41M) reports the Biden Administration has begun approving requests from states to use Medicaid to pay for food programs. This comes as policymakers explore the potential health and cost benefits of the so-called food as medicine approach.

Medicaid Could Be Next Target For Republican Cuts. HuffPost (2/10, Cohn, 363K) reported that if GOP leaders "manage to keep their party away from Medicare and Social Security" and that Republicans also "carry out their threat to block an increase in the federal government's borrowing authority, jeopardizing America's and maybe the world's economy, until Democrats agree to major spending cuts," their actions "would almost certainly force cuts in another big program: Medicaid." HuffPost says Medicaid "now covers more people than Medicare, the beloved Great Society-era program that provides basic insurance to the nation's elderly" and that growth "is a problem, as most Republicans and their conservative allies see it."

Many States Not Prepared For End Of Automatic Medicaid Enrollment. Vox (2/13, Scott, 1.88M) reports, "Perhaps the greatest success of the American health care system these last few benighted years is" that the "uninsured rate has reached a historic low of about 8 percent." The low rate is due to "the slew of emergency provisions that the government enacted in response to the Covid crisis," with the freeze on Medicaid eligibility "likely the single largest factor." But "in April, that will end," and the Biden Administration "estimates upward of 15 million people...could lose coverage, a finding that independent analysts pretty much agree with." And many, "-- even most, according to some projections – could be people who are actually still eligible for Medicaid but slip between the cracks of the system." Although automatic re-enrollment using public information is mandatory under the ACA, many states do not enforce the law, and several states are not taking re-enrollment issues seriously, especially Florida.

"Influential Group Of Conservative Intellectuals" Back Family Benefits. The New York Times (2/10, A1, Goldstein, 20.6M) highlighted "an influential group of conservative intellectuals with a direct line to elected politicians" have endorsed policies that "sound like part of a progressive platform," like "sending cash to parents, with few strings attached," expanding Medicaid, and "providing child care subsidies to families earning six figures." The Times added while these conservatives "generally oppose abortion rights," and "often resist the trans rights movement," they assert providing financial support to families "is a pragmatic way to prop up conservative values alongside new restrictions on abortion."

HEALTH & MEDICAL NEWS

Some Scientists Say Biden's Cancer Moonshot Most Likely To Help Already Rich Industry. Politico (2/10, Schumaker, 6.73M) reported, "President Joe Biden's pledge to 'end cancer as we know it' is a rare sliver of common ground between Democrats and Republicans." However, "cancer researchers are less unified about the moonshot than Washington policymakers." Contrarian scientists said that "cancer research is funded well enough...and investing more in high-tech individualized treatments is more likely to help the wealthy live longer than it is to save those most likely to die of the disease: the poor and people of color." Recently, Biden "asked Congress to reauthorize the National Cancer Act," which "would help the National Cancer Institute support researchers around the country by building clinical trial networks and more robust data systems, according to Danielle Carnival, the White House's moonshot coordinator."

Biden Places Cancer Research At Top Of Unity Agenda. Cancer Letter (2/10, Ong) reported behind a paywall, "President Joe Biden mentioned cancer 13 times in his impassioned State of the Union address and placed cancer

research at the top of his Unity Agenda – an indication that his administration would continue to prioritize funding for cancer research in fiscal year 2024."

Data Indicate So Far This Year, State Legislators Have Introduced 80 Bills Seeking To Limit Access To Gender-Affirming Care. CNN (2/11, Cole, 89.21M) reported several "bills seeking to restrict access to gender-affirming care for trans youth have been introduced by Republican state lawmakers this year, with debates around the issue reaching new heights thanks to proposals that would dramatically expand the scope of bans on such care." Over "80 bills seeking to restrict access to gender-affirming care have been introduced around the country through February 9, according to data compiled by the American Civil Liberties Union and shared with CNN."

Florida Physicians' Board Expands Ban On Gender-Affirming Care. The AP (2/10, Schneider) reported a ban on "puberty blocking hormones and gender-affirming surgeries for minors in Florida was tightened further after a board overseeing doctors eliminated an exception for clinical trials Friday at the request of Florida Gov. Ron DeSantis' administration." Certain "members of the public attending the meeting in Tallahassee shouted expletives, and law enforcement officers positioned themselves in the front of the room after the vote by the Florida Board of Osteopathic Medicine."

The Tampa Bay (FL) Times (2/10, Ellenbogen, Ogozalek, 762K) also covered the story.

Missouri AG Says Provider Should Halt Treatments For Transgender Youth Following Complaint About Alleged Misconduct. The Washington Post (2/10, Gowen, 10.52M) reported Missouri Attorney General Andrew Bailey (R) "on Friday called for a halt to drug treatments for transgender youth at a pediatric care center in St. Louis after a whistleblower complaint alleged misconduct by those treating children for gender dysphoria and other issues." Bailey "said his office was investigating Washington University's Transgender Center at St. Louis Children's Hospital after a former case manager alleged that medical professionals had used experimental drugs on children and distributed puberty blockers and hormones without proper assessment and parental consent."

The AP (2/10, Ballentine) reported, "The state Social Services Department, state licensing agency, Republican U.S. Sen. Josh Hawley and Washington University also are investigating."

The St. Louis Post-Dispatch (2/11, Erickson, Suntrup, 694K) also covered the story.

Nebraska Legislators Mulling Bill That Would Allow Medical Providers To Cite Religious, Ethical Beliefs In Denying Certain Treatments. The AP (2/10, Beck) reported legislators in Nebraska "are following the path of other conservative states in considering a bill that would allow medical providers, facilities and insurers to cite their religious, ethical or moral beliefs in denying some medical treatments. Critics say it's simply another way to target abortion rights and the LGBTQ community." The measure "includes nearly three pages of language protecting providers who conscientiously object to providing treatment from lawsuits, criminal charges and professional ethics charges."

The Omaha (NE) World-Herald (2/10, Bamer, Stoddard, 509K) also covered the story.

Utah Governor Defends New Law Which Bans Gender-Affirming Care For Minors. NBC News (2/12, Concepcion, 4.91M) reports on Sunday, Utah Gov. Spencer Cox (R) "defended a bill he signed last month that bars transgender minors from receiving gender-affirming medical care, saying that he wants to see more data on the effects of those treatments." During "an interview on NBC News' 'Meet the Press,' Cox...said, 'It's not just about providing care or not providing care, it's about whether we might potentially be harming young people, not having enough evidence to see what the long-term results of this are and providing better psychiatric help for those young people who are going through this.'"

Chicago-Area Children Staying Longer In Hospitals Due To Shortage Of In-Home Pediatric Nurses. The Chicago Tribune (2/12, Schencker, 2.03M) reports throughout "the Chicago area, children with complex, chronic conditions are finding themselves stuck in hospitals longer than they

should be because it's so difficult to find in-home pediatric nurses. That, in turn, can mean fewer available hospital beds for all kids, something that became a serious problem in the fall as respiratory illnesses in children surged." At one children's hospital, "about one-fourth of the hospital's 27 patients are stable enough to go home but can't because they can't find nurses to help them once they get there."

Shkreli Urges Judge To Not Hold Him In Civil Contempt For Failure To Provide Information. Reuters (2/10) reported, "Martin Shkreli on Friday urged a U.S. judge not to hold him in civil contempt for failing to provide federal and state regulators with information to determine whether he is violating a lifetime ban from working in the pharmaceutical industry." In a court filing, Shkreli "said he has complied with the February 2022 ban 'as extensively as possible and in good faith,' and has provided the materials sought by the Federal Trade Commission (FTC) and seven states." The lifetime "ban also included a $64.6 million civil fine, which Shkreli said he is 'so far unable' to pay."

Novartis Expanding Production, Facilities Of Cancer Treatment Radioligand Therapy. CNBC (2/11, Capoot, 7.34M) reported on a form of targeted cancer treatment, radioligand therapy, which, while effective, "expires within days after it's manufactured." But "pharmaceutical company Novartis believes the returns will be worth the challenge of mastering this race against time." Novartis "currently produces two radioligand" therapies – neuroendocrine tumors treatment Lutathera and prostate cancer treatment Pluvicto – "both approved by the Food and Drug Administration." Novartis "manufactures radioligand therapy at three sites in Italy, Spain and New Jersey, and has a fourth facility slated to open in Indiana next year." Fred Hutchinson Cancer Center molecular imaging and therapy Director Dr. Delphine Chen is quoted.

RedHill Biopharma Exchanges Rights For Top Commercial Drug Movantik To Cancel Debt With HealthCare Royalty Partners. The Triangle (NC) Business Journal (2/10, Ezzone, Subscription Publication, 854K) reported Raleigh pharmaceutical company RedHill Biopharma "is moving forward after exchanging the rights to its top commercial asset," constipation treatment Movantik, "for the cancelation of more than $100 million in debt obligations." RedHill "announced Monday it has reached an agreement to transfer its drug Movantik to Connecticut-based HealthCare Royalty Partners." RedHill "plans to replace the revenue lost from Movantik by ramping up commercial efforts of its two" FDA-approved products, Helicobacter pylori infection treatment Talicia and traveler's diarrhea treatment Aemcolo.

Cleveland Clinic Partners With Anixa Biosciences For Triple-Negative Breast Cancer Vaccine Phase 1b Study. Popular Science (2/10, Baisas, 7.65M) reported, "Researchers at Cleveland Clinic launched their next step in a study of a vaccine aimed at preventing triple-negative breast cancer." The Clinic's "new phase 1b study will enroll cancer-free individuals who are at a high risk for developing breast cancer" and who "have also decided to voluntarily undergo prophylactic mastectomy to lower their risk of developing breast cancer." The Cleveland Clinic "study is funded by the United States Department of Defense and will be conducted at Cleveland Clinic's main campus in Cleveland, Ohio," in partnership with Anixa Biosciences, Inc. The very "first therapeutic cancer vaccine (Provenge) was approved by the Food and Drug Administration (FDA) in 2010."

Spruce Biosciences Raises $53.6M PIPE Deal To Fund Clinical Trials For CAH Drug. The San Francisco Business Times (2/10, Leuty, Subscription Publication, 895K) reported a South San Francisco biotech company, Spruce Biosciences Inc., "hoping to deliver top-line results from key drug studies targeting a genetic hormonal disorder, raised $53.6 million in a private investment in a public entity, or PIPE, deal." The funding "extends its financial runway from first-half 2024 into early 2025." By then Spruce "will have top-line results from two mid-stage clinical trials of its drug, called tildacerfont, in adults with congenital adrenal hyperplasia" (CAH). The drug "would eliminate the need for high doses of steroids to balance out-of-control hormones." Currently "long-term use of high-dose steroids comes with side effects and

there are no Food and Drug Administration-approved treatments for CAH."

FDA Recalls Alfia Weight Loss Capsules For Containing A Harmful Drug. The Miami Herald (2/13, Cetoute, 647K) reports, "The FDA has recalled Alfia Weight Loss Capsules, made by a Broward County company, for containing a harmful hidden drug not used in decades." The FDA on Wednesday "advised to not purchase or use Alfia Weight Loss Capsules that were sold online and in some retail stores." An "FDA laboratory analysis confirmed a finding of sibutramine in the weight loss pill," which "is known to substantially increase blood pressure and/or heart rate in some people and may create a significant risk for people with a history of coronary artery disease, congestive heart failure, arrhythmias or stroke. If the pill is mixed with other medications it could be life-threatening, the FDA said."

Sanders To Summon Corporate Executives To Testify Before Congress As Senate Health Committee Chairman. The New York Times (2/12, Stolberg, 20.6M) reports, "In two unsuccessful bids for the White House, Senator Bernie Sanders" (D-VT) "made no secret of his disdain for billionaires." And now "in what could be his final act in Washington, he has the power to summon them to testify before Congress – and he has a few corporate executives in his sights." The list includes Moderna CEO Stéphane Bancel, Amazon founder Jeff Bezos, and Starbucks CEO Howard Schultz. Sanders "views them as union busters whose companies have resorted to 'really vicious and illegal' tactics to keep workers from organizing." As the "new chairman of the Senate Committee on Health, Education, Labor and Pensions," Sanders has "sweeping jurisdiction over issues that have animated his rise in politics, such as access to health care, the high cost of prescription drugs and workers' rights."

Rolling Stone (2/11, Voght, 12.39M) reported that as chairman, "Bernie Sanders is living, as he puts it, in a 'two-fold world.'" Sanders explains, "On the one hand, I'm trying to do what I can in a bipartisan way," referring to "a list of the cascading crises in health care, education, and labor Sanders thinks he could recruit some Republican allies to help solve." But Sanders adds, "I'm also going to continue to fight for a vision, which is not going to be passed in this Congress." Sander's wishlist includes "Medicare for All, tuition-free college, federal protections for workers to unionize – the familiar planks of his two insurgent runs for the presidency." Sanders said, "I'm not going to give up on those things."

FDA Places Partial Hold On Blueprint Medicines Cancer Drug Trial. Reuters (2/10, Jain) reported, "Blueprint Medicines Corp said on Friday the U.S. drug regulator had put on partial hold an early-stage trial testing its experimental cancer drug due to safety concerns." Blueprint said that "some patients faced episodes of light sensitivity and blurred vision." Blueprint Medicines' Chief Medical Officer Becker Hewes "said the company was working with the Food and Drug Administration to investigate the adverse events and amend the trial protocol to enable investigators to monitor and manage the events should they occur."

Endpoints News (2/12, Patchen) reports, "On Friday, the Massachusetts-based biotech said the FDA informed Blueprint two days ago that it is placing a partial hold on a Phase I/II study, also known as the VELA trial, looking at BLU-222 in advanced solid tumors." The FDA's "partial hold was due to adverse events being observed in a 'limited number' of patients, Blueprint said." Blueprint's "release said patients that are enrolled will continue with the study, but no more will be added until the hold is resolved."

Study Finds Minnesotans Experiencing Homelessness Have Three-Times Higher Death Rate. The Minneapolis Star Tribune (2/11, Serres, 855K) reported, "A major new study shows that Minnesotans experiencing homelessness die at three times the rate of other Minnesotans, and substance abuse accounts for about a third of their deaths." The Minnesota Department of Health released the study in January, and "found that deaths from substance use are 10 times higher among homeless Minnesotans than the overall state population." Hennepin Healthcare Research Institute researchers, who prepared the report, "found that 20-year-olds experiencing homelessness in Minnesota have the same likelihood of dying as 50-year-olds in the general population." The report "calls for a coordinated effort to elevate housing as a 'life-saving strategy,'

though it stops short of analyzing current methods for combating homelessness."

Scientists Frustrated With Chinese Biophysicist's Refusal To Discuss Research On Heritable Genome-Editing Technology. Nature (2/12, Mallapaty, 194K) reports, "He Jiankui, the Chinese biophysicist who shocked the world by creating the first children with edited genomes" as a treatment for HIV, "says research must accept moral and ethical constraints, but is otherwise refusing to speak about the work that landed him in jail for three years." His "silence is frustrating some scientists, who say he should answer questions about his past research before publicizing his latest plans to use genome-editing technology in people" as a treatment for Duchenne muscular dystrophy (DMD). And "some researchers worry that interest in He Jiankui is diverting attention away from more important ethical issues around heritable genome editing."

Analysis Identifies Highly-Cited Cancer-Genetics Papers With DNA, RNA Sequence Errors. Nature (2/10, Kwon, 194K) reported, "The prevalence of mistakes in published gene research could be more widespread than previously thought, according to an analysis of cancer-genetics papers in two high-impact journals." A team led by Australia's University of Sydney cancer researcher Jennifer Byrne "has identified some highly cited studies that contain errors in the DNA or RNA sequences of reagents." Reagents are used in science "for various reasons...and if the sequences are wrongly reported it could affect the reproducibility of the research." Currently "it is unclear whether the errors are accidental or indicate misconduct," and scientists agree" that the presence of such mistakes in the scientific literature is worrying." The study has not yet been peer reviewed and was "published on the preprint server bioRxiv on 3 February."

Scientists To Publish Entire Genome Of One Human Before End Of 2023. BBC News (2/10, Marshall, 876K) reported that "before the end of 2023," there "will be a seminal moment – the publication online of the entire genome of" Leon Peshkin, a single "human being, end to end with no gaps." Although the "first draft of the human genome was released in 2001," the composite sequence from several peoples' DNA "had major gaps and errors." Only now "in the last few years has technology advanced to the point that it is possible to read the entire human genome, without gaps and with minimal errors." And "the geneticists involved" in the Human Genome Project (HGP) "now want to sequence the genomes of people from around the world" to explore genetic diversity, what DNA does, and to "help doctors diagnose and treat us when we get sick."

Financial Filings Reveal Hospital Oligarchy In Orlando, Florida. STAT (2/10, Herman, 262K) reported, "A recent financial filing from a large, tax-exempt hospital system in Orlando provides a glimpse, and serves as a reminder, of just how concentrated America's hospital markets are." In Orlando, Florida, "just two giants run the show," with Orlando Health and AdventHealth together controlling "77% of the entire inpatient hospital market in the four-county Orlando metro area, according to Orlando Health's bond filing." Both "not-for-profit systems also own two-thirds of the pediatric hospital market," and according to older filings, they also "control closer to 90% of inpatient services in a narrower three-county slice of Orlando." But even as a "highly concentrated oligopoly," the "numbers didn't surprise experts who have spent decades studying hospital consolidation."

Transgender Advocacy Group Sues SD Governor, Alleging Contract With State Government Was Terminated Due To Discrimination. The AP (2/10, Biraben) reported, "A transgender advocacy group in South Dakota sued Republican Gov. Kristi Noem and the head of the state's Department of Health on Friday over the state's decision to terminate a contract with the group last December." The group, called the Transformation Project, "filed a lawsuit Friday that alleges that the decision to terminate the contract – which resulted in the group losing a nearly $136,000 grant from the U.S. Centers for Disease Control and Prevention – was discrimination." A representative for the governor "said last December that the contract had been signed without Noem's knowledge or consent. Noem's office has also said that the organization did not meet all of the terms of its contract, such as providing quarterly

reports." The group denied the latter claim in a statement to the AP.

Fox News (2/12, Chasmar, 23.99M) also reports.

Opinion: CVS, Walgreens Ventures Into Primary Care Will Not Fix Broken US Healthcare System. CEO of Hint Health Zak Holdsworth wrote in an op-ed for STAT (2/10, Holdsworth, 262K), "CVS Health's acquisition of Oak Street Health, a Medicare-focused primary care provider, for $10.6 billion is just the latest in a string of primary care clinic buyouts by other retailers and insurance companies," including Walgreens Boots Alliance. However, Holdsworth said, "while these moves could help address the severely broken U.S. healthcare system, their motives and the solutions they offer are Band-Aids at best. Companies like Amazon, Walgreens, CVS, and others aren't capable of solving the healthcare crisis, as they are so closely tied to the fundamentally flawed insurance fee-for-service infrastructure, which I believe has played a significant role in breaking the healthcare system to begin with."

Sanford, Fairview Agree To Delay Merger Until May 31 Amid Pressure Campaign. The Minneapolis Star Tribune (2/11, Snowbeck, 855K) reported, "Sanford and Fairview have agreed to push back the closing on their mega-merger until May 31, a two-month delay that comes after weeks of pressure by lawmakers, the University of Minnesota and Attorney General Keith Ellison." Ellison's office has alleged the health systems have failed to comply with his office's requests for information. Additionally, hours before announcement, the University of Minnesota's "Board of Regents blasted the timeline and process for the proposed merger during a meeting in Minneapolis." Of particular concern to Regents Board chair Ken Powell is the systems' "stated intent to combine systems 'with or without the University of Minnesota.'"

Kentucky Receives First "Baby Box" Drop Off. The AP (2/11) reported, "Kentucky has seen its first infant anonymously dropped off at one of its 'baby box' safe surrender locations." Safe Haven Baby Boxes Founder and CEO Monica Kelsey "said fire department staff was able to tend to the child in less than 90 seconds." This marks the 24th child "in the country to be surrendered at one of more than 130 baby boxes and drawers the organization has established across nine states."

CNN (2/12, Riess, 89.21M) reports, "Kentucky Gov. Andy Beshear in 2021 signed a law allowing the use of a 'newborn safety device' for the anonymous surrendering of infants less than 30 days old at a participating staffed police station, staffed fire station, or a staffed hospital." The purpose of Safe Haven Baby Boxes is "to give distressed parents a safe place to drop off their newborns while remaining anonymous, preventing the illegal abandonment of newborns."

Lawsuit Seeks Health Monitoring For Residents Potentially Affected By Toxic Train Derailment. The AP (2/10) reported, "Residents who filed a federal lawsuit in the fiery derailment of a train carrying toxic chemicals along the Ohio-Pennsylvania line are seeking to force Norfolk Southern to set up health monitoring for residents in both states." In addition to damages, the plaintiffs call "for the rail operator to pay for medical screenings and related care for anyone living within a 30-mile (48-kilometer) radius of the derailment to determine who was affected by toxic substances released after the derailment."

DOT Investigating Neuralink Over Shipping Methods Of "Contaminated" Devices. The AP (2/10) reported the US Department of Transportation is investigating Elon Musk's brain-implant company Neuralink "over its shipping methods after an animal rights group contacted the" DOT. According to the Physicians Committee for Responsible Medicine, "public records show untrained Neuralink employees transported 'contaminated' devices that were removed from the brains of 'infected' monkeys without safely packaging them." The alleged "incidents are said to have taken place in 2019 at the University of California, Davis."

CNBC (2/11, Capoot, 7.34M) reported the devices "may have been contaminated with viruses like Herpes B and antibiotic-resistant bacteria like Staphylococcus and Klebsiella, according to" PCRM.

Women Fear Seeking Treatment For Cervical, Breast Cancer In Kenya Because Of Stigma, Physician Says.

Reuters (2/10, Aruya, Hlatshwayo) said, "As in much of Africa, most cancer cases in Kenya are diagnosed at an advanced stage, when treatment options are limited and families make huge sacrifices by selling assets or borrowing money, according to a World Bank report." According to Nairobi Radiotherapy and Cancer Centre Physician Bridget Nyabuto, "stigma makes the problem worse," causing women to "fear seeking diagnosis for some of the most common and deadly cancers in Kenya such as cervical and breast cancer." She said, "Any topics to do with sex, the female reproductive system, are a bit taboo."

Highest-Income Black Families At Greater Risk For Maternal, Infant Mortality, Than White Families, Study Finds. The New York Times (2/12, Cain Miller, Kliff, Buchanan, 20.6M) reports, "In the United States, the richest mothers and their newborns are the most likely to survive the year after childbirth – except when the family is Black, according to a groundbreaking new study of two million California births" that showed "the richest Black mothers and their babies are twice as likely to die as the richest white mothers and their babies." Researchers also "found that maternal mortality rates were just as high among the highest-income Black women as among low-income white women," and "infant mortality rates between the two groups were...similar."

Opinion: Higher Education Needs To Retire "Weed-Out" Mentality In STEM Fields. In an op-ed for STAT (2/10, 262K), Wellesley College President Paula A. Johnson wrote, "Because the nation's increasingly diverse students come to college with vastly different high school experiences, it's time to retire the traditional 'weed-out' mentality in STEM teaching, which is as likely to reward privilege as ability." She added, "The onus should be on schools to help all of their students succeed." Johnson explained how "Wellesley has created multiple pathways into STEM majors." She concluded, "Higher education can make a real difference simply by meeting women, first-generation, and underrepresented students where they are and, rather than teaching to exclude, teaching to inspire."

Opinion: Pregnancy Represents Unique Opportunity To Increase Funding For Women's Health. In an op-ed for STAT (2/10, 262K), UCSF Pregnancy and Cardiac Treatment Program Cardiologist Nisha Parikh and OB/GYN Hospitalist Alison Cowan wrote, "While heart disease deaths are at a historic high, so too are disorders arising from high blood pressure (hypertension) during pregnancy." They added, "In addition to being a leading cause of pregnancy-related illness and death, there is now compelling evidence that preeclampsia and other complications of pregnancy increase an individual's future risk of heart disease." The experts said it is "time to address the disproportionately low funding for women's health, and the accompanying underwhelming investment, research, and progress for women's health in general, including women's cardiovascular health." They concluded, "Pregnancy is a window to the future and represents a unique opportunity to start reversing these unequal risks."

Wildfire Smoke Exposure During Pregnancy Tied To Increased Risk Of Preterm Birth, Study Finds. NBC News (2/11, Bendix, 4.91M) reported, "A study of more than 2.5 million pregnant people in California found that those exposed to wildfire smoke for at least one day faced a higher risk of giving birth prematurely." The findings "suggested that just one day of smoke exposure slightly raised the risk of spontaneous preterm birth – defined as before the 37th week of pregnancy." However, "the odds of preterm birth increased by 0.3% with each additional day of smoke exposure."

Analysis Identifies Factors That May Explain Differences In Cognitive Ability Among Older Adults. NBC News (2/11, Carroll, 4.91M) reported "a handful of factors, such as education, income and job type, may increase the likelihood that people in their mid-50s will still be mentally sharp," according to "an analysis of data from more than 7,000 U.S. adults" who "were 54 to 65 years old in 1996 and then 20 years later." The results "showed that these factors could explain nearly 40% of the differences in the amount of cognitive ability people had lost by age 54." According to researchers, "education, in particular whether a

person had finished college, made the biggest difference in cognitive abilities such as memory, judgment and focus."

Montana Weighs Proposal Allowing Physician Assistants To Practice Unsupervised. Kaiser Health News (2/10, Larson) reported, "As Montana grapples with a health care provider shortage, state lawmakers are trying to find ways to increase access to care." And one proposal currently "up for debate is to give physician assistants...more independence to practice unsupervised." House Bill 313 "would let physician assistants practice without a supervision agreement."

Louisiana Accidentally Legalized Recreational THC. The New Orleans Times-Picayune (2/12, Karlin, 691K) reports, "In November, John Williams, the top beer lobbyist in Louisiana, sent out a mass email to legislators with an alarming subject line: 'Recreational THC is now legal in Louisiana.'" He sent "pictures of gas stations and smoke shops advertising products full of THC...many of which hit the shelves after House Speaker Clay Schexnayder ushered through legislation to set up a legal hemp industry in the state." Schexnayder's 2022 bill to loosen the rules on hemp "set up an 'adult-use' market for consumable products made from hemp." He "assured fellow legislators...that his legislation wouldn't give people access to products that get them high." However, it is clear "that it hasn't worked out the way Schexnayder promised it would." Regulators and legislators are now "trying to unring the bell and crack down on a massive proliferation of THC-laden products that have become widely and legally available."

Weak Grip Could Indicate Risk Of Early Death, Study Suggests. The New York Post (2/10, Herz, 7.45M) reported, "having a weak grip could be a harbinger of early death, according to a new study." The researchers "followed 1,275 men and women over the course of 8 to 10 years, who were aged around 70 years old during that period." They used "a Smedley spring dynamometer – a device that measures grip strength – to test the participants every two years." They also took a blood sample "to study DNA methylation levels in each participant." According to the NCI, "DNA methylation can be defined as a kind of chemical reaction in your body where a 'small molecule' called a methyl group can enter your DNA. ... Having an increase in your DNA methylation or having too much of it can affect your risk of developing illnesses like cancer and other cardiovascular diseases." Researchers found "a correlation between normalized grip strength and DNAm age acceleration in both men and women."

Federal Government Awards Medical Schools Funding To Integrate Behavioral Health, Primary Care. The Washington Post (2/10, Johnson, 10.52M) reported, "A growing number of providers...are integrating behavioral health and primary care to improve the continuity of treatment and lower barriers to access." The federal government is now "awarding 24 medical schools and hospitals a total of $60 million to train the next generation of primary care physicians – family medicine doctors, pediatricians, internists – to address behavioral health needs."

Use Of Telehealth Among Clinicians Treating Patients With OUD Dropped 15%, Survey Finds. mHealth Intelligence (2/10, Vaidya) reported, "Telehealth use among clinicians who treat patients with opioid use disorder (OUD) dropped from 56.7 percent in December 2020 to 41.5 percent in March 2022, according to a recent survey." Additionally, "the use of audio-only visits declined from 20.2 percent of all OUD visits to 11.6 percent in the same period." Meanwhile, "clinicians' attitudes toward video and audio-only telehealth also changed over time." The survey found "the proportion of respondents saying that patients received higher-quality care via video rather than audio-only visits increased from 63.5 percent in December 2020 to 69.7 percent in March 2022."

Editorial: New Mexico Legislators Need To Take Action To Prevent Physicians From Fleeing To Other States. In an editorial, the Albuquerque (NM) Journal (2/11, 188K) wrote about New Mexico's shortage of physicians and its impact on healthcare. Local physicians "say unless changes are made, the situation will become much more dire." The Journal said, "Doctors are fleeing or passing us by because of our high costs of maintaining a private practice. ... Lawmakers need to act, STAT!"

Florida Nursing Homes See Surge In Citations. The Tampa Bay (FL) Times (2/10, Critchfield, 762K) reported, "Last year, Florida nursing homes were cited 83 times for putting their older adult residents at risk of immediate danger." According to records obtained by the Times, "since 2019, violations have nearly doubled compared to the previous six years." Meanwhile, "elder care advocates, nursing home industry leaders and long-term care researchers offered theories for the increase." They included "changes in how violations are measured to staff shortages to recent legislation that critics say weakened nursing home care standards."

Approximately 383K Illinoisans Struggle With Sports Gambling Addiction, Department Of Human Services Says. The Chicago Tribune (2/12, Sheridan, 2.03M) reports, "An estimated 383,000 Illinoisans have a gambling problem, while an additional 761,000 are estimated to be at risk of developing one, according to a study published in 2022 by the Illinois Department of Human Services." In 2022, "wagers placed with the state's sports gambling industry soared...with gamblers betting nearly $10 billion and casinos raking in $800 million in revenue from gamblers' aggregate losses."

Residents Not Convinced It Is Safe To Return Home After Toxic Train Derailment. The Washington Post (2/12, Salcedo, McDaniel, 10.52M) reports, "Days after a train carrying hazardous materials went off the tracks in northeastern Ohio, burst into flames and stoked fears of a 'potential explosion,' authorities assured evacuated residents that it was safe to return to town." However, residents are not convinced. A list of "chemicals that were aboard the train when it lost its course" has yet to be released. Experts and residents "told The Post that they question whether it's safe to return to their homes a week after contaminants flowed into local streams and spewed into the air" without this information.

Exposure To Traffic Noise At Home May Cause Tinnitus, Study Suggests. The Washington Post (2/11, Blakemore, 10.52M) reported a new study suggests "exposure to road traffic noise at home" may be linked to tinnitus. Researchers analyzed "data on 3.5 million Danish residents who were 30 and older between 2000 and 2017." During that time period, "40,692 were diagnosed with tinnitus." The investigators discovered "people's risk rose 6 percent with every 10-decibel increase in road traffic noise compared with controls."

Anti-Tobacco Advocates Support New York Governor's Effort To Ban Flavored Cigarettes. NY1-TV New York (2/10, Reisman, 13K) reported, "Anti-tobacco advocates in New York are cheering the effort to ban flavored cigarettes in the state and increase taxes on cigarette purchases, calling the move key for limiting tobacco use among young people." They are calling "the governor's tax and ban plan the right move to further reduce teen smoking." However, the proposed ban "is being opposed by tobacco groups as well as convenience store organizations, who argue the measure would simply encourage illicit sales of cigarettes, including menthol."

Anti-Smoking Advocate Raises Awareness About Risks Of Teen Vaping. The Sun (UK) (2/11, Einstein, Rollings, 561K) reported on an anti-smoking advocate who started vaping at 11. He was attracted by the bright colors and flavors of the vape cartridges. He managed to quit vaping when he was 17, after he developed a smoker's cough. He is now working to raise awareness about the risks of teen vaping.

New Mexico Considers Proposals To Make It Harder To Access Vape, Tobacco Products. KOB-TV Albuquerque, NM (2/10, Rushton, 69K) reported, "A new batch of bills at the New Mexico Roundhouse aim to make it harder to buy and use vape and tobacco products." The state lawmakers hope the legislation will chip away at the "many barriers to" enacting "a statewide vaping ban." The proposals "include raising tobacco taxes, banning flavored products, and allowing local governments to enact tougher restrictions against smoking," as well as "proposals to prohibit smoking in racinos and fund prevention programs."

Connecticut Considers Permitting Cigar Lounges To Sell Liquor. The Connecticut Post (2/12, Moritz, 310K) reports, "Connecticut's cigar lounges would be allowed to

seek liquor licenses for the first time in nearly twenty years under new legislation promoted by lawmakers who say that the state's strict anti-smoking laws are simply driving customers – and their money – over state lines." The proposed legislation "would require that any new tobacco bars exist in a stand-alone building or have their own heating, ventilating and air conditioning system to prevent air from co-mingling with adjacent businesses and homes." However, health advocates "have come out in opposition to plans to loosen the state's indoor smoking ban, citing a range of concerns over second-hand smoke."

City In Tennessee Restricts Smoke, Vape, CBD Shops To Manufacturing Districts. The Daily Memphian (TN) (2/10, Waddell) reported, "On Thursday, Feb. 9," Lakeland's "Board of Commissioners dealt with an agenda that included revising zoning for future smoke, vape and CBD shops." The city's "board unanimously approved a second and final reading of an ordinance to restrict smoke, vape and CBD shops and similar businesses to the city's manufacturing districts."

North Dakota Refuses To Raise Cigarette Taxes. The Grand Forks (ND) Herald (2/11, Klinski, 96K) reported North Dakota legislators have voted against raising cigarette taxes three times since 2013. A supporter of increasing the cigarette taxes "said other opponents have been worried about how raising the tax would lead to lower revenues and business on border towns where neighboring states have a significantly higher cigarette tax rate." He also "said he doesn't think taxes will be raised unless the state encounters a budget crunch in the future."

Youth Vaping Increases As Youth Smoking Decreases. The Grand Forks (ND) Herald (2/11, Otto, 96K) reported, "While youth smoking has decreased over the years, youth vaping has 'exploded over time,' according to Neil Charvat, director of the North Dakota Department of Health & Human Services' tobacco prevention and control program." Data from the North Dakota Department of Health & Human Services' tobacco surveillance found that "21.2% of high school students, as of 2021, have used electronic nicotine delivery systems" The data also showed that 5.9% of high school students have smoked cigarettes.

Wild Ducks Found Dead In Maine Test Positive For Type Of Bird Flu. The AP (2/12) reports that six wild ducks "found dead in a stream in Winthrop," Maine "have tested positive for bird flu," according to wildlife authorities. The hooded mergansers "were found dead in Mill Stream and tested positive for a highly pathogenic avian influenza, the Maine Department of Inland Fisheries and Wildlife said Friday."

Suburban Detroit Schools Shuts Down After Norovirus Outbreak Sickens Students, Staff. The AP (2/10) reported that classes "at a suburban Detroit school have been cancelled due to an outbreak of the norovirus among students and staff." The AP says "St. Michael the Archangel Catholic School in Livonia shut down Wednesday, WXYZ-TV reported Friday." As of Friday afternoon, "about 100 students and 15 staffers at the school had developed symptoms, according to the Wayne County Public Health Division."

ABC World News Tonight (2/12, 6:45 p.m. EST, story 6, 0:25, Johnson, 3.85M) also broadcasts the story.

"Canadian Horse Disease" Crippled US Cities 150 Years Ago. The Washington Post (2/12, Tillman, 10.52M) reports that a virus known as "Canadian horse disease" sickened some 600 horses near Toronto in the late 1800s. The Post says the disease "spread quickly, following rail lines into bustling cities and knocking out the workhorses that had powered the United States into a new era." According to the Post, the "the outbreak of what was later determined to be the equine flu hit the vast majority of the country's horses between October 1872 and March 1873, temporarily paralyzing cities in a crisis 'comparable to what would happen today if gas pumps ran dry or the electric grid went down,' University of Tennessee historian Ernest Freeberg wrote."

Number Of Mississippi Babies Being Treated For Congenital Syphilis Spikes By 900%. NBC News (2/11, Harris, 4.91M) reported that the "number of babies in Mississippi being treated for congenital syphilis has jumped by more than 900% over five years,

uprooting the progress the nation's poorest state had made in nearly quashing what experts say is an avoidable public health crisis." NBC says "the rise in cases has placed newborns at further risk of life-threatening harm in a state that's already home to the nation's worst infant mortality rate." In 2021, "102 newborns in Mississippi were treated for the sexually transmitted disease, up from 10 in 2016, according to an analysis of hospital billing data shared by Dr. Thomas Dobbs, the medical director for the Mississippi State Department of Health's Crossroads Clinic in Jackson, which focuses on sexually transmitted infections."

Scientists Monitor Possible Danger To Humans As Bird Flu Makes Leap To Mammals. NBC News (2/11, 4.91M) reported that scientists monitoring the leap of avian influenza to mammals such as wild sea lions and minks say such infections "are spooky reminders that a widespread outbreak in animals has potential consequences for humans." In the US, NBC says, "the most recent wave of bird flu has struck in 17 mammals and more than 160 birds." Richard Webby, "an infectious disease researcher at St. Jude Children's Research Hospital in Memphis and the director of the World Health Organization Collaborating Centre for Studies on the Ecology of Influenza in Animals and Birds, said: 'This is the number one potential pandemic virus everyone has been interested in for a long time.'"

Also reporting the story was USA Today (2/10, Rodriguez, 12.7M).

CDC: Pediatric Flu Deaths Top 100 For First Time Since Beginning Of Pandemic. The Hill (2/10, Choi, 5.69M) reported that the "number of pediatric flu deaths during the current season has officially gone over 100, according to the Centers for Disease Control and Prevention (CDC) – more than twice the number of the pediatric deaths confirmed in the last flu season." The Hill says the CDC "reported nine pediatric flu deaths this week, bringing the total for the season up to 106." The agency "also noted that it is the highest pediatric death rate for flu since the start of the COVID-19 pandemic."

Some Regions Of US Hit Harder By Norovirus Outbreaks. The Hill (2/10, Bartiromo, 5.69M) reported that some areas of the US are being harder hit from the "uptick in outbreaks of norovirus," according to data from the CDC. The Hill says "some parts of the country have noted especially high positivity rates slightly earlier than in previous years, mirroring an overall national trend." Participating laboratories "in the Midwest, for instance, had observed a 19.4% positivity rate among patients who took polymerase chain reaction (PCR) tests as of Feb. 4 – topping the previous year's high of 16.1%, recorded in April 2, 2022." And the Western region "also appears on track to exceed last year's top positivity rate of 13.49% (observed at the end of April) with recent positivity rates at 13.42%, and likely rising, as of Feb. 4."

Milwaukee County Identifies Chronic Wasting Disease In Wild Deer. The Milwaukee Journal Sentinel (2/12, Smith, 844K) reports that the state Department of Natural Resources "last Wednesday announced the detection of chronic wasting disease in a wild deer in Langlade County." The discovery is "the latest in a spate of initial CWD discoveries in recent months in wild deer in Wisconsin and follows similar announcements in Buffalo and Waupaca counties."

Michigan School Shut Down After Students, Staff After Suspected Norovirus Outbreak. The Detroit Free Press (2/10, Jordan Shamus, 2.16M) reported that "at least 115 students and staff at St. Michael the Archangel Catholic School in Livonia have been sickened by a suspected norovirus outbreak that has shut down the school." Co-principal Kathy Nold said, "We closed school the following day and spoke to the Wayne County Health Department." Also reporting the story was the Detroit News (2/11, Mackay, 1.16M).

Pittsburgh-Area Physicians Worried About Effect Of Measles Outbreak In Columbus, Ohio. The Pittsburgh Post-Gazette (2/12, Webster, 426K) reports that some physicians in the Pittsburgh area "expressed concern" that a November measles outbreak in Columbus, Ohio "could travel eastward" and "said a changing vaccine landscape post-pandemic could put children at risk." The Columbus Public Health Department "announced on Monday that the outbreak had ended." Mark Roberts, "a distinguished professor of health policy and management and the director of the Public Health

Dynamics Lab at the University of Pittsburgh School of Public Health, said: 'People also don't remember that measles is not just getting a rash. In other parts of the world, it kills 1 in 1,000 kids.'"

Florida Woman Files Suit Against Maker Of Eyedrops Allegedly Linked To Infections. NBC News (2/10, Lovelace, 4.91M) reported that a Florida woman "filed a lawsuit late Thursday against the maker of EzriCare artificial tears and Walmart after suffering a bacterial infection that she said was caused by the eyedrops." NBC said "Houston-based Lange Law Firm, which is representing the woman, Teresa Phillips, 60, of Bradford County, said the lawsuit is the first nationwide over injuries related to eyedrops linked to a drug-resistant bacterial infection called Pseudomonas aeruginosa." The lawsuit alleges "Phillips purchased EzriCare artificial tears in the weeks before her infection."

Meanwhile, Bloomberg Law (2/10, Subscription Publication, 4K) reported behind a paywall that "clusters of infections linked to the use of eye drops have been found in four states, according to US health officials tracking the outbreak that's already led to the death of one person." Bloomberg says "at least 35 of 56 cases related to the recalled eye drops have been reported from California, Connecticut, Florida and Utah, according to US Centers for Disease Control and Prevention spokesperson."

Research Shows Telehealth Improved Equitable Cancer Care Access, Delivery Before COVID-19 Pandemic. mHealth Intelligence (2/10, Melchionna) reported, "Recent research shows that equitable cancer care access and delivery benefited highly from telehealth before the COVID-19 pandemic." The research "notes that there is limited evidence regarding the use of telehealth to support equitable cancer care," and in order to "gain insight into pre-pandemic hospital efforts of providing telehealth and oncologic services, researchers conducted a retrospective cross-sectional analysis that considered geographic and sociodemographic statistics." The use of telehealth "to deliver cancer care is becoming more common." In fact, "funding from the National Cancer Institute in August 2022 led to the creation of the Northwestern Program for Scalable Telehealth Cancer Care, which aims to track smoking, obesity, and inactivity among cancer patients."

Study Finds Restrictive Calorie Diet May Extend Life Span. CNN (2/10, LaMotte, 89.21M) reported, "People of normal weight may be able to extend their life span by restricting calories, according to a new study that attempted to measure the pace of aging in people asked to cut their calorie intake by 25% over two years." Published Thursday in the journal Nature Aging, the new study "culled DNA sequences from white blood cells taken at 12-month intervals from participants in CALERIE." The research team "then analyzed methylation marks – signs of epigenetic changes – on the DNA, looking for symptoms of aging." According to the National Human Genome Research Institute, "epigenes are proteins and chemicals that sit like freckles on each gene, waiting to tell the gene 'what to do, where to do it, and when to do it.'"

Fox News (2/10, Rudy, 23.99M) reported, "The study included 200 men and women between the ages of 21 and 50." It was "funded by the U.S. National Institute on Aging," and "was the first-ever research to measure the impact of prolonged calorie restriction in healthy people without obesity."

Billionaire Bill Ackman Announces Foundation Funding For Controversial Biologist Ousted For Alleged Sexual Misconduct. CNN (2/12, del Valle, 89.21M) reports that Dr. David Sabatini, "a decorated but controversial biologist ousted for alleged sexual misconduct from the MIT-affiliated Whitehead Institute," is now "getting new funding with help from billionaire hedge fund manager Bill Ackman." The recent "funding announcement unfolded publicly on the heels of a Boston Globe Spotlight two-part report detailing a monthslong investigation into the allegations against Sabatini published in late January." During Sabatini's tenure at Whitehead, there was "a focus on improving workplace environments and weeding out sexual harassment...at institutions around the country...after a mandate from a major government grant source, the National Institutes of Health (NIH), to 'develop and implement policies and practices that foster a harassment-free environment' or risk losing funding."

Casino Workers Eagerly Await Hearing On Legislation That Could Prohibit Smoking In Nine Atlantic City Casinos. The AP (2/13, Parry) reports, Atlantic City "dealers, cocktail servers and other casino workers – some of them with breathing ailments and other health problems they suspect are related to secondhand smoke from casino patrons – are eagerly awaiting Monday's hearing before a New Jersey Senate committee on legislation that would prohibit smoking in Atlantic City's nine casinos." The new bill "would close a loophole in the state's 2006 indoor smoking law written specifically to exempt casinos from bans on smoking indoors. Currently, smoking is permitted on 25% of a casino floor in Atlantic City."

New York Governor's Proposed Menthol Ban, Cigarette Tax Receives Mixed Reactions. The New York Daily News (2/13, Slattery, 2.51M) reports that New York Gov. Hochul's "proposed plan to ban the sale of menthol cigarettes and hit smokers with an additional dollar-per-pack tax is sparking a heated debate over revenue and the black market sales of cigs." Hochul is "hoping to drive down tobacco use among younger New Yorkers and lower smoking levels in minority communities" through "legislative changes banning flavored cigarettes and increasing taxes on cigarette purchases in her $227 billion budget proposal earlier this month." While "anti-smoking groups and health officials have applauded the proposal," some convenience store owners and others "say the ban on flavored tobacco products would be an unenforceable mandate that could leave a hole in state coffers and be a boon to the already thriving black market."

VA Urges Camp Lejeune Veterans To Apply For Disability, Lawsuits Despite Possible Legal Complications. The Hill (2/13, Udasin, 5.69M) reports, "The Department of Veterans Affairs (VA) is urging former service members whose illnesses may be linked to contamination at Camp Lejeune in North Carolina to seek disability benefits – even if doing so might complicate future quests for legal recourse." The issue "for veterans who were exposed and have yet to submit claims" is that the "decision is complicated by the Honoring Our PACT Act." PACT "seeks to make significant improvements to health care for veterans who were exposed to toxins during their service," and permits lawsuits for Camp Lejeune. But with PACT, "any legal compensation awarded in court must be 'offset' by disability claims related to Camp Lejeune exposures that the individual is already receiving." This applies "to any program administered by the secretary of Veterans Affairs, Medicare or Medicaid."

Experts Seek Out Internal, External Cause Behind "TikTok Tics" Phenomenon. The New York Times (2/13, Ghorayshi, Bracken, 20.6M) reports during the pandemic, physicians "across the world treated thousands of young people for sudden, explosive tics. Many of the patients had watched popular TikTok videos of teenagers claiming to have Tourette's syndrome. A spate of alarming headlines about 'TikTok tics' followed." However, "similar outbreaks have happened for centuries. Mysterious symptoms can spread rapidly in a close-knit community, especially one that has endured a shared stress." The phenomenon known as "TikTok tics" came "at a unique moment in history, when a once-in-a-century pandemic spurred pervasive anxiety and isolation, and social media was at times the only way to connect and commiserate." As a result, "experts are trying to tease apart the many possible factors – internal and external – that made these teenagers so sensitive to what they watched online."

Opinion: Americans Need To Have More, Pleasurable Sex To Offset Loneliness. Contributing writer Magdalene J. Taylor writes for the New York Times (2/13, 20.6M), "Americans, in the midst of a loneliness epidemic, are not having enough sex." While "sex isn't the sole form of fulfilling human interaction and certainly isn't a salve for loneliness," it "should be seen as a critical part of our social well-being, not an indulgence or an afterthought." The "rise in loneliness closely parallels a decline in sex," along with a drop in "partnership and cohabitation." Isolation "is demolishing Americans' social lives, love lives and happiness," and it started before the COVID-19 pandemic. Almost "every group of Americans is experiencing the absence of sex – and the consequences are profound. ... A lack of sex can easily translate into less socialization, fewer families and a sicker population." Taylor concludes, "So, anyone capable should have sex

– as much as they can, as pleasurably as they can, as often as they can."

GLOBAL HEALTH

Chinese Health, Family Planning Experts Call For Government Action To Reduce Financial Burden Of Raising Children. Reuters (2/10, Master, Zhang) reported China's National Health Commission Population Monitoring and Family Development Department Director Yang Wen Zhuang "has urged local governments to take 'bold' steps to lower the cost of having babies and raising children to reduce the burden on families and boost fertility." He "said that worries about money and career development among women were the main factors for people opting not to have babies, adding that precise policies were needed to improve the fertility level."

In a separate article, Reuters (2/12, Wang, Orr) reports, "China should enhance incentives for people to build families and boost the birth rate as the country's now-falling population could threaten the world's second-biggest economy, a Chinese family planning expert said." China Family Planning Association Deputy Director Wang Pei'an "called for more incentives around employment, medical care, social security and housing that could encourage people to build families."

Over-Priced Child Care Costs Becoming Top UK Political Issue. Behind a paywall, Bloomberg (2/13, Konotey-Ahulu, 3.57M) reports, "Of the multitude of problems plaguing the UK, one issue is rising toward the top of the pile --" the exorbitant cost of early-years child care. Calls to tackle the issue "are growing louder ahead of the next general election, due within two years." But "there's no easy fix for a system that's become dominated by private interests, and any meaningful reform would likely require an injection of public funds at a time when Prime Minister Rishi Sunak is focused on tightening spending to bring down inflation."

EMA Begins Review Of Decongestant Medicines With Pseudoephedrine Over Safety Concerns. Reuters (2/10, Roy) reported, "A European Medicines Agency (EMA) committee said on Friday it has started a review of decongestant medicines for cold and flu that contain the ingredient pseudoephedrine following safety concerns." EMA "said the review was due to reports of conditions affecting blood vessels in the brain in some patients who took pseudoephedrine-containing medicines."

WHO Discussing Ending Mpox Global Public-Health Emergency. Nature (2/10, Kozlov, 194K) reported, "A World Health Organization (WHO) committee met earlier this week to decide whether the mpox outbreak...is still a global public-health emergency, and the agency could soon declare it over." So far "the outbreak has subsided in countries including the United Kingdom and the United States, thanks to the deployment of vaccines and therapeutics, as well as changes in awareness and social behaviour." However, "the same is not true in some nations in West and Central Africa, which have been battling the monkeypox virus for decades, and where the disease's toll has been historically highest."

US, South Korea Warn Of New Ransomware Tactics From North Korea Targeting Critical Infrastructure. Healthcare IT News (2/10, Fox, 2K) reported, "Government agencies from the United States and the Republic of Korea are highlighting new ransomware tactics they've seen, which they say are used to conceal the affiliation of Democratic People's Republic of Korea hackers working to stage attacks against U.S. and South Korean healthcare organizations and critical infrastructure." This "new cybersecurity advisory, Ransomware Attacks on Critical Infrastructure Fund DPRK Malicious Cyber Activities, details both North Korea's historically and recently observed tactics, techniques and procedures and indicators of compromise."

Brazil's Yanomami Health Crisis Drawing People Out Of Isolation. The AP (2/11, Maisonnave, Barros) reported on the health crisis plaguing Brazil's Yanomami people. Hundreds of homeless Yanomami, "who traditionally live in relative isolation" in the Amazon rainforest, are spread throughout Boa Vista seeking help. Many Yanomami arrived in the area to seek shelter at "the Indigenous Health House known as Casai, a federal facility on the outskirts of Boa Vista." The facility "was built to host

Yanomami under treatment and their relatives," but it only has a capacity of 200 people. Currently, "it harbors many as 700, representing 2% of the Yanomami population."

More Than 250K Spaniards Protest Healthcare Services In Madrid. The AP (2/12) reports that on Sunday, more than 250,000 "Spaniards flooded the streets of Madrid...for the largest protest yet against the regional government's management of the capital city's health care services." The demonstration was led by health worker associations and "was backed by left-wing parties, unions and normal citizens concerned with what they see as the dismantling of the public health care system by the Madrid region's conservative-led government."

Reuters (2/12, Rodriguez, Gore) reports protestors said the Madrid government "is dismantling public health services and favouring private health providers."

UK Anti-Smoking Organization Calls For Excise Tax On Disposable Vapes. The Telegraph (UK) (2/11, 249K) reported, "Action on Smoking and Health (ASH) are calling for an excise tax on disposable vapes to stop children from being able to buy them for less than £5" in the UK. ASH "said adding £4 to each single-use vape, which currently cost around £4.99, would make them significantly less affordable for children while still less expensive than tobacco." Additionally, ASH "argued such a tax would also have an environmental benefit, with discarded single-use vapes equating to 10 tonnes of lithium being thrown away a year."

Among other news outlets covering the story were PA Media (UK) (2/10, Clarke), The Guardian (UK) (2/11, Hall, 5.53M), and The Sun (UK) (2/10, Davies, 561K).

UK Regulatory Body Finds Poisons In Some Fake Vapes. The Sun (UK) (2/10, Singh, 561K) reported that some fake vapes "were found to contain" poisons, which included "arsenic, lead and formaldehyde." The poisons were found in the fake vapes by Trading Standards officers, who "also found other substances that could damage your health while testing the fake vape in Derby." The regulatory body "also warned of a rapid increase of disposable fake vaping devices being sold to children."

Equatorial Guinea Places More Than 200 People In Quarantine After Deaths From Unknown Hemorrhagic Fever. Reuters (2/10, Atabong) reported that Equatorial Guinea "has quarantined more than 200 people and restricted movement after an unknown illness causing hemorrhagic fever killed at least eight people, Health Minister Mitoha Ondo'o Ayekaba said on Friday as the government races to test samples." Reuters says "the outbreak was reported on Feb. 7, and from preliminary investigations, the deaths were linked to people who all took part in a funeral ceremony, Ayekaba said, adding the government had sent samples to neighbouring Gabon and will send others to Dakar in Senegal for further testing." Authorities "have restricted movement around the two villages that are directly linked, he said, and contact tracing was ongoing."

Spain Detects Atypical Mad Cow Disease Case, WOAH Says. Reuters (2/10) reported that Spain "has detected atypical bovine spongiform encephalopathy (BSE) in a dead cow in the northwestern region of Galicia, the World Organisation for Animal Health (WOAH) said on Friday." Reuters says "the disease, commonly called mad cow disease, was found after a 22-year-old cow was euthanised due to signs of illness not related to BSE, Paris-based WOAH said, citing information from the Spanish authorities." The case, "which was isolated, 'didn't enter the food chain and so didn't represent any risk for public health or require any preventive health measure,' the Galicia's regional health service said on its website."

Professor Says "Mass Suicide" Of Japan's Elderly Comment "Taken Out Of Context." The New York Times (2/12, Rich, Hida, 20.6M) reports on Yale Economics Assistant Professor Dr. Yusuke Narita's response to "the question of how to deal with the burdens of Japan's rapidly aging society." He said, "I feel like the only solution is pretty clear. ... In the end, isn't it mass suicide and mass 'seppuku' of the elderly?" But "Dr. Narita, 37, said that his statements had been 'taken out of context,' and that he was mainly addressing a growing effort to push the most senior people out of leadership positions in business and politics – to make room for younger generations."

NATIONAL NEWS

US Military Shoots Down Unidentified Object Over Lake Huron. The Washington Post (2/12, A1, Marimow, Johnson, Horton, Brasch, 10.52M) reports the US military "shot down a fourth aerial 'object,' this time over Lake Huron on Sunday afternoon, according to the Defense Department, which described the object as 'unmanned' and not a military threat to anything on the ground." The Post adds that officials "said the object, initially detected Saturday night, was flying over Michigan's upper peninsula at about 20,000 feet – an altitude and path that raised concerns about potential interference with commercial aviation." Officials also "acknowledged that the Pentagon tried and failed to confront the object late Saturday afternoon, when radars detected something suspicious 70 miles north of the U.S. border in Canada."

Politico (2/12, Olander, Ward, 6.73M) reports the Defense Department issued a statement disclosing that President Biden "gave the order to take out the object based on the recommendations of Defense Secretary Lloyd Austin and military leadership," and USA Today (2/12, Brook, 12.7M) reports Pentagon Press Secretary Brig. Gen. Patrick Ryder revealed that an F-16 pilot "shot down the object at 2:42 p.m. ET Sunday" using "an AIM 9X sidewinder missile, the same weapon used in the previous instances."

Reuters (2/12, Stewart, Ali) reports Gen. Glen VanHerck, the Commander of North American Aerospace Defense Command (NORAD) and US Northern Command, "told reporters that the military has not been able to identify what the three most recent objects are, how they stay aloft, or where they are coming from." VanHerck explained, "We're calling them objects, not balloons, for a reason." VanHerck continued, "I'll let the intel community and the counterintelligence community figure that out." Reuters (2/13, Stewart, Ali) reports VanHerck "said...he would not rule out aliens or any other explanation yet, deferring to U.S. intelligence experts."

Meanwhile, Reuters (2/12) reports a White House National Security Council spokesperson said the objects "did not closely resemble and were much smaller than the PRC balloon and we will not definitively characterize them until we can recover the debris, which we are working on." Bloomberg (2/12, Leonard, 3.57M) states that the remarks came after Senate Majority Leader Schumer "said they are believed to have been high-altitude balloons."

The AP (2/12, Long, Baldor, Miller) highlights that the shootdown "was the fourth such downing in eight days and the latest military strike in an extraordinary chain of events over U.S. airspace that Pentagon officials believe has no peacetime precedent." According to the New York Times (2/12, Cooper, 20.6M), "There are two big questions around the episodes: What were the craft? And why does the United States appear to be seeing more suddenly, and shooting down more?" The Times adds that while there are currently "no answers to the first question," as "American officials do not know what the objects were, much less their purpose or who sent them," when it comes to the second question, "it is not clear if there are suddenly more objects. But what is certain is that in the wake of the recent incursion by a Chinese spy balloon, the U.S. and Canadian militaries are hypervigilant in flagging some objects that might previously have been allowed to pass."

On ABC World News Tonight (2/12, 6:32 p.m. EST, lead story, 5:45, Johnson, 3.85M), White House Correspondent Mary Alice Parks characterized Biden's decision to order the shootdown as "a clear sign the US government is dramatically ramping up how it polices the skies, a week after that Chinese spy balloon was taken down and put the White House on high alert." In addition, The Hill (2/12, Sforza, 5.69M) reports that Assistant Secretary of Defense for Homeland Defense and Hemispheric Affairs Melissa Dalton "said on Sunday that the stark increase in the military spotting and shooting down aerial objects in recent days may be due to enhancing radar systems." The Wall Street Journal (2/12, A1, Youssef, Vieira, Subscription Publication, 8.41M) provides similar coverage.

Lawmakers Call For Details About Latest Shootdowns. The Hill (2/12, Mueller, 5.69M) reports lawmakers of both parties "spent Sunday questioning the Biden administration over the takedowns of two unidentified aerial objects in recent days, with some criticizing the White House over a lack of transparency about what the objects were and where they came from." Likewise, Monica Alba reported on NBC Nightly News (2/12, 6:31 p.m. EST, lead story, 4:30, Snow, 3.37M) that the news of Sunday's shootdown comes as a "bipartisan call for transparency from the White House and Pentagon grows louder."

On the CBS Weekend News (2/12, 6:31 p.m. EST, lead story, 2:50, Duncan, 10.89M), Skyler Henry summed up the response of US lawmakers "critical over...Biden's timing of shooting down the Chinese spy balloon earlier this month" as "demanding details on who is behind the latest objects," while being "pleased" the President ordered the shootdowns.

Axios (2/12, Saric, 1.26M) reports Senate Majority Leader Schumer, on ABC's This Week "acknowledged it was 'wild' the U.S. didn't know about the Chinese government's use of balloons 'until a few months ago,'" but The Hill (2/12, Neukam, 5.69M) reports the Majority Leader "called the downing of last week's balloon a 'coup' for the U.S. in terms of intelligence gathering." In addition, The Hill (2/12, Neukam, 5.69M) reports Schumer "suggested the Chinese may have to do away with its balloon program over the ordeals of the past week."

On CBS' Face The Nation (2/12, 2.55M), Sen. Jon Tester (D-MT) said that the discovery of these unknown objects "has been nothing short of craziness." Tester continued, "I think we need to take these things seriously. I think the President and I think, more importantly, the military are taking it very seriously." However, The Hill (2/12, Neukam, 5.69M) reports Tester "admitted that he did not know whether the objects shot down in the last few days belonged to China."

Republicans were especially critical of the Administration's limited disclosures about the shootdowns. The Hill (2/12, Mueller, 5.69M) reports House Intelligence Chair Mike Turner on CNN's State Of The Union stated that the Administration "needs to stop briefing Congress through our television sets and actually come and sit down and brief us." However, CNN (2/12, LeBlanc, 89.21M) reports Turner "said...he prefers how the US shot down unidentified objects over North American airspace in recent days to allowing them to traverse the country." The Hill (2/12, Mueller, 5.69M) reports Turner "said he'd prefer the Biden administration be 'trigger happy' with suspected spy balloons than to be 'permissive' when objects enter U.S. airspace."

The Hill (2/12, Neukam, 5.69M) reports House Foreign Affairs Chair Michael McCaul on CBS' Face The Nation "split with defense and intelligence officials who have said the U.S. mitigated the amount of information that could have been picked up by the Chinese balloon," and he asserted it "did a lot of damage." On Fox News' Sunday Morning Futures (2/12, 1.39M), McCaul said, "These spy balloons have great capability to gather and collect intelligence. I would argue more so than even satellites in the sense that they're flying at, say, 40-60,000 feet above the earth. The imagery that they can capture and other intelligence data that I can't be specific about can be captured and then transmitted back to the mothership in Beijing. They have control over these balloons. This was an act of espionage in plain view of the American people. I know there have been reports of prior ones, but none quite like this."

Other Republicans called for the Administration to punish China. The Hill (2/12, Neukam, 5.69M) reports Sen. Ron Johnson (R-WI), on Fox News' Sunday Morning Futures "said...Biden is 'detached from reality' and 'delusional' about the threat posed by China," while Rep. Jim Banks (R-IN) on Fox News' Sunday Morning Futures (2/12, 1.45M) said, "It's long past time to begin treating the Chinese Communist Party as an enemy." The Hill (2/12, Gans, 5.69M) reports Rep. Mike Gallagher (R-WI) in a radio interview "said timing the balloon to cross into U.S. airspace around [Secretary of State Blinken's now-postponed trip to China] would be 'well within the Chinese Communist Party's playbook' of trying to 'humiliate' the U.S. on the world stage."

Fox News (2/12, Hagstrom, 23.99M) says House Oversight Chair James Comer on ABC's This Week "bashed" Biden for not shooting down China's spy balloon before it crossed the US, but he also "argued...that the problem of Chinese surveillance was 'a lot bigger' than spy balloons floating over the country," and "said the failure of the Biden administration to combat intellectual property theft was the true issue."

In addition, Fox News (2/12, Betz, 23.99M) reports Sen. Steve Daines (R-MT) "slammed the Biden administration for its 'lack of communication' regarding...the recent shoot-downs." In a statement, Daines said, "The top priority should be the safety and security of the people of the United States and keeping the American people informed is a key part of fulfilling that duty." He continued, "President Biden owes Montanans and the country an immediate and full explanation. Without information, the public and media are left to rely on leaks, speculation and[,] worst off all[,] disinformation from foreign governments." Fox News (2/12, Laco, 23.99M)

reports Sen. Marsha Blackburn (R-TN) "said the American people 'deserve transparency and accountability from the Biden administration,'" and The Hill (2/12, Mueller, 5.69M) reports Rep. Jim Himes (D-CT), the ranking member of the House Intelligence Committee, on NBC's Meet The Press also "said...he has 'real concerns' about the Biden administration not being 'more forthcoming' about the recent shoot-downs of objects flying over American airspace."

However, Reuters (2/12, Stewart, Ali) reports that "several Michigan lawmakers...applauded the military for downing the object." Politico (2/12, Olander, Ward, 6.73M) reports Sen. Gary Peters (D-MI) tweeted, "I'm glad the object was neutralized over Lake Huron and I'll continue pressing DoD for transparency." The Hill (2/12, Sforza, 5.69M) reports Rep. Dan Kildee (D-MI) thanked the military for its "immediate action" and said he would "keep seeking information about the incident in the coming days." But while the Detroit Free Press (2/12, Johnson, 2.16M) reports Rep. Jack Bergman (R-MI) similarly praised "the decisive action by our fighter pilots," CNBC (2/12, Capoot, 7.34M) reports that he added, "The American people deserve far more answers than we have."

In addition, the Detroit News (2/12, Nann Burke, Kozlowski, 1.16M) reports that Rep. Debbie Dingell (D-MI) "call[ed] the shootdown over Lake Huron disquieting." Reuters (2/12, Stewart, Ali) reports Dingell tweeted, "We need the facts about where they are originating from, what their purpose is, and why their frequency is increasing." Likewise, Bloomberg (2/12, Martin, Leonard, 3.57M) reports Rep. Elissa Slotkin (D-MI) said, "We're all interested in exactly what this object was."

A Wall Street Journal (2/12, Subscription Publication, 8.41M) editorial accuses the Administration of being "tight-lipped and dissembling" regarding the flying objects that are being shot down in US airspace. The Journal claims the lack of any consistent information or transparency from the White House is causing concern among Americans.

Trudeau Says Effort To Recover Object Shot Down Over Canada Continues. Reuters (2/12, Scherer) reports Canadian Prime Minister Justin Trudeau on Sunday "said teams are looking for the cylindrical object a U.S. fighter jet shot down over Yukon territory on his orders a day ago so that they can analyze it and learn more about its purpose." Axios (2/12, Habeshian, 1.26M) reports NORAD "added that its team would also 'work to recover the object in an effort to learn more.'"

Meanwhile, a senior US official told Fox News (2/12, Hagstrom, Tomlinson, 23.99M) that although "details regarding the object that was flying through Canadian airspace were scarce throughout the weekend," US officials "now describe it as a 'small metallic balloon with a tethered payload.'"

China Reportedly Plans To Shoot Down Unidentified Object Near Qingdao. Bloomberg (2/12, 3.57M) cites Chinese news outlet The Paper as reporting the Chinese military is preparing "to take down an unidentified object flying over waters near the port city of Qingdao, which is home to a major naval base for the People's Liberation Army." While Fox News (2/12, Betz, 23.99M) says that the report comes amid "increased tension between Beijing and Washington," Reuters (2/12, Brunnstrom, Martina) states that analysts "say [the US and China] have strong reasons to manage their disagreements. The question now is when, not whether, they find their way back to the negotiating table." However, Reuters adds resuming the talks "won't be easy." A Wall Street Journal (2/12, Wei, Youssef, Hutzler, Subscription Publication, 8.41M) article titled "How a Balloon Opened a New Flashpoint in U.S.-China Ties" provides similar coverage.

In his Los Angeles Times (2/12, 3.37M) column, Doyle McManus says the Chinese spy balloon "began its journey as a curiosity" before becoming "a symbol of U.S. weakness to Republicans [and] a sign of...Biden's prudence to Democrats. Now, a week after the U.S. Air Force shot it down, the errant balloon is gone, but its impact is still reverberating." McManus says while the Chinese balloon "may not have collected much useful intelligence," its discovery, "and the larger Chinese program it revealed," poses "a serious obstacle to one of Biden's top foreign policy goals: stabilizing the prickly U.S. relationship with Beijing." According to McManus, "it appears China has scored the espionage equivalent of an own goal." However, he adds that "the stakes are far greater than spy-versus-spy drama. The balloon episode is a reminder that, just as in the Cold War, detente between nuclear powers is harder to manage than it looks."

Comer Defends Oversight Probes As Partisanship Defines Current Congress. On ABC's This Week (2/12, 2.31M), House Oversight Chair James Comer said "everything's on the table" for his committee's investigations into President Biden, his family, and the Administration. According to the Wall Street Journal (2/12, Andrews, Subscription Publication, 8.41M), Comer has two primary jobs: managing the investigations into the President, his family, and the Administration while also ensuring conservative lawmakers do not derail the probes with their efforts to grab media attention via political stunts.

Axios (2/12, Solender, 1.26M) suggests, "Biden's baiting of Republican hecklers wasn't just a signature moment in his State of the Union speech – it was in line with a series of partisan stunts that have marked the new Congress." Lawmakers of both parties "have jumped on opportunities to score political points and try to make things awkward for the other side."

In her Washington Post (2/12, 10.52M) column, Jennifer Rubin asserts that the "MAGA Republicans in charge of House committees are having a difficult time conducting their inquests into made-up scandals" because "savvy Democrats are effectively turning the tables to use the committees against Republicans." Rubin cites last week's House Oversight Committee hearing featuring former Twitter executives and the hearing for the subcommittee on the weaponization of the federal government. She adds Democrats, who "came to these hearings prepared and focused," both "eviscerated GOP conspiracy theories" and "did a bang-up job exposing Republicans as the ones who have 'weaponized' the government."

Whitmer Says Democrats Will Support Biden's Reelection Bid. Axios (2/12, Kraushaar, 1.26M) reports that while President Biden "has all but erased internal Democratic Party criticism," there is "a gaping divide in the Democratic Party between institutional public opinion – party leaders, lawmakers, donors, consultants – and the actual voters who ultimately decide elections, recent polling shows." However, Politico (2/12, Olander, 6.73M) reports Michigan Gov. Gretchen Whitmer (D) on CNN's State Of The Union "dismissed concerns over an apparent lack of enthusiasm among Democratic voters for...Biden's possible reelection campaign." CNN (2/12, LeBlanc, Sarisohn, 89.21M) reports Whitmer on CNN's State Of The Union also "said...serving in her current role is '100% my focus' as the Democrat's national profile and speculation about a future White House bid continue to grow." A Wall Street Journal (2/12, Subscription Publication, 8.41M) article headlined "Biden Appears Set To Run In 2024, But Many Democratic Voters Have Doubts" provides similar coverage.

Christie Has "No Doubt" Biden Is Running For Reelection. The Hill (2/12, Neukam, 5.69M) reports as Biden, "the oldest president ever, gears up for a potential reelection campaign in 2024, former New Jersey Gov. Chris Christie (R) said on Sunday that Biden's age puts a spotlight on Vice President Harris." On ABC's "This Week," Christie "said...if Biden, 80, decides to run in 2024, voters would be paying sharper attention to Harris, and the possibility that she could become president." Christie added he has "no doubt" that Biden will seek reelection following the State of the Union address last week.

Sununu Says If He Decides To Run, 2024 Bid Would Focus On Bringing "Better Attitude" To Politics. The Hill (2/12, Mueller, 5.69M) reports New Hampshire Gov. Chris Sununu (R) on CBS' Face The Nation "said...a potential 2024 presidential run would be 'an opportunity to change things' and put 'a little better attitude' in Washington, D.C." Sununu "hasn't officially announced a 2024 campaign, but has taken recent steps that sparked speculation that he'll run, including setting up a political action committee, 'Live Free or Die,' with its name grabbed from New Hampshire's motto." Axios (2/12, Saric, 1.26M) reports Sununu "decried the prevalence of 'woke cancel culture,' which he claimed sowed 'divisiveness' in American schools and communities," although he "noted that the government was unlikely to be the one to fix a 'cultural problem.'"

Cox Says Republicans Should Nominate A Governor For President. Politico (2/12, Cohen, 6.73M) reports that during a joint interview with New Jersey Gov. Phil Murphy (D), Utah Gov. Spencer Cox (R) on NBC's Meet The Press "said...he'd prefer that Republicans pick a governor to be their presidential nominee in 2024." In particular, Cox said New Hampshire Gov. Chris Sununu (R), Florida Gov. Ron

DeSantis (R) and South Dakota Gov. Kristi Noem (R) as well as former Arkansas Gov. Asa Hutchinson (R) and former South Carolina Gov. Nikki Haley (R) were "all fantastic" choices, while Politico reports that "for his part, Murphy, who has been pushing for President Joe Biden to run for another term, did suggest that one Republican governor run for president: 'Spencer Cox.'" However, Politico adds Cox "said he was running for reelection as governor of Utah."

DeSantis Must Determine When, How Hard To Hit Back At Trump. The New York Times (2/12, Bender, Haberman, 20.6M) reports Florida Gov. Ron DeSantis (R) has, for months, "pursued a strategy of conflict avoidance" with former President Donald Trump, "his top rival in the shadow 2024 Republican presidential primary, delaying what is likely to be a hostile and divisive clash that forces the party's voters to pick sides. But now he faces the pressing question of how long this approach can work." Trump "has spent weeks trying to goad Mr. DeSantis into a fight" and is "stepping up his social media-fueled assault, even as polls and interviews show that Mr. DeSantis has become the leading alternative to the former president for many voters and donors." DeSantis "must also decide just how forcefully to counterattack once he engages with Mr. Trump, and whether he has left himself enough room to effectively parry the former president's taunts and smears without offending his loyal supporters."

Brazile: Trump May Regret Announcing 2024 Candidacy So Early. The Hill (2/12, Polus, 5.69M) reports former DNC Chair Donna Brazile on ABC's This Week "said...Trump, who kicked off his reelection campaign just one week after the midterms, may regret entering the 2024 race too soon as Republican Nikki Haley prepares her White House bid." Brazile said, "The big donors in the Republican Party, they're now showing him the cold shoulder. So this may be Donald Trump's week to regret that he put his hat in the ring so soon." Haley is expected to announce her candidacy on Feb. 15. Brazile said, "The interesting thing about Nikki Haley is she's going to make a generational argument, similar to what Sarah Huckabee Sanders made in her rebuttal to Joe Biden. I don't know if Donald Trump is going to attack her the day before, which is Valentine's Day, or the day after. But clearly he benefits from a large field."

All In Together CEO: Haley Faces "High Hurdle" To Securing GOP's 2024 Nomination. Lauren Leader, co-founder and CEO of All In Together, writes in an op-ed for Politico Magazine (2/12, 6.68M) that 10 years ago, Nikki Haley "would be a candidate with enviable advantages, having served as a South Carolina governor and United Nations ambassador," but "given the reality of Republican Party politics today, her presidential dream could become a nightmare." Haley "could very likely have it worse than the candidates did in 2016, encountering a veritable buzz saw of sexist and racist attacks from the moment she declares her presidential run" because "the base of the Republican Party, the most rabid and committed primary voters, has become more male and more far-right since Trump became the party standard bearer." Leader warns Haley "faces a high hurdle in even convincing Republican voters that a woman can be president."

California Senate Race Taking Shape While Feinstein Has Not Made Her Intentions Known. The AP (2/12, Blood) reports the California Senate race "is unfolding at a furious pace." The contest "is shaping up as a marquee match-up between nationally known rivals and is likely to become one of the most expensive Senate races in the country next year." On Saturday, Rep. Adam Schiff (D) "gathered hundreds of supporters in a union hall parking lot for a rally in his hometown of Burbank, California," and the day before, Rep. Katie Porter (S) "brought her Senate campaign to Los Angeles, where she met with local leaders to discuss pollution in lower-income neighborhoods." Meanwhile, Sen. Dianne Feinstein (D) "has yet to say if she will seek a seventh term" and "her reticence about her future has created a publicly awkward dynamic – the race to replace her is rapidly taking shape, even as the senator remains unclear about her intentions."

Barnes Reelected As Michigan Democratic Party Chair. The AP (2/11, Cappelletti) reports Michigan Democratic Party Chair Lavora Barnes has been reelected for a third two-year term "after she helped lead the party to historic wins in the battleground state in

the 2022 midterms." Barnes, who ran unopposed, was reelected Saturday during the Michigan Democratic Party's spring convention in Detroit.

Kansas Republicans Choose Election Conspiracy Promoter To Lead State Party. The AP (2/11) reports Kansas Republicans on Saturday "narrowly picked an activist who has promoted unfounded election conspiracies and promised a shakeup" to lead the state party for the next two years. The committee elected Mike Brown, "who has long been active in the GOP in the Kansas City area, as its new chair through the 2024 elections." Retiring chair, Mike Kuckelman, and the Kansas party's "two other Republican National Committee members supported RNC Chair Ronna McDaniel when she won reelection last month. But Brown called on McDaniel to resign in December, and he said Saturday that the national GOP is seeing an internal 'uprising' from members still upset over COVID-19 pandemic restrictions."

Lake Delivers Election Denial Message During Visit To Iowa. The Washington Post (2/12, 10.52M) reports Kari Lake (R-AZ) delivered "a clear message" as she visited Iowa over the weekend. Lake "falsely claimed the 2020 election was stolen from Donald Trump. She baselessly insisted that votes were rigged against her in her run for Arizona governor last year. And she warned without evidence that future races will be compromised." Lake "is traveling the country as one of the most vocal standard-bearers of an animated if wounded election denialism movement as she weighs a run for U.S. Senate and hears encouragement from some to set her sights on national office." Lake "drew enthusiastic crowds" in Iowa but "others in the party have been sharply critical of her rhetoric, seeing her as a part of a Trump-era scourge at the ballot box that cost the GOP winnable races last fall and could doom its chances in 2024."

Black Voters In Wisconsin Not Surprised By Revelations Of GOP Election Tactics. The AP (2/12, Venhuizen) reports, "A Wisconsin election commissioner bragged about low turnout in predominantly Black and Latino neighborhoods during last year's elections," and weeks later, "an audio recording surfaced that showed then-President Donald Trump's Wisconsin campaign team laughing behind closed doors about efforts to reach Black voters in 2020." But the revelations "about Republican election strategies targeting minority communities...came as no surprise to many Black voters." Many "said they had long felt targeted by Republicans. The difference now is the public display of strategies that at best ignore the priorities of Black voters and at worst actively look to keep them from voting." Black voters "said they are tired of the countless hurdles that disproportionately try to keep them from being heard at the ballot box. Voters said their experiences with the GOP have been as voices to silence, not to win over."

Kansas City Chiefs Defeat Philadelphia Eagles In Close Super Bowl. The Washington Post (2/12, 10.52M) reports that "the Kansas City Chiefs won another Super Bowl, elevated the statures of quarterback Patrick Mahomes and Coach Andy Reid among the all-time greats and secured major bragging rights within the Kelce family." In a Super Bowl LVII "filled with connections between competitors and carrying historical significance, the Chiefs used a big fourth quarter to beat the Philadelphia Eagles, 38-35, on Sunday at State Farm Stadium." Kicker Harrison Butker's "27-yard field goal with eight seconds left won it." Mahomes "had a 26-yard run to set up the winning kick." The Eagles "had a key defensive holding penalty, and Chiefs tailback Jerick McKinnon slid down at the 2-yard line when the Philadelphia defense appeared to be trying to allow him to score." Butker's kick "came after two kneel-downs by Mahomes."

All-Female Piloted Flyover Makes Super Bowl History. The Hill (2/12, 5.69M) reports that "the first all-female piloted military flyover, commemorating 50 years of women flying in the U.S. Navy, flies over State Farm Stadium before the NFL Super Bowl 57 football game between the Kansas City Chiefs and the Philadelphia Eagles, Sunday, Feb. 12, 2023, in Glendale, Ariz." The group "of seven female aviators flew in a diamond formation over the State Farm Stadium in Glendale, Arizona, where the Kansas City Chiefs are facing off against the Philadelphia Eagles."

Black National Anthem Performed At Super Bowl For First Time. The Hill (2/12, 5.69M) reports that "the performance of "Lift Every Voice and Sing" at Sunday's Super Bowl marks

the first time the so-called Black National Anthem has been performed on-field at the NFL's championship game." Actress "and singer Sheryl Lee Ralph belted out the song prior to kickoff on Sunday." The historic performance "was the first time the song has been performed in an official capacity on a Super Bowl game field."

Celia Cruz To Be First Afro-Latina Depicted On US Quarter. The New York Times (2/12, Simonetti, 20.6M) reports that "Celia Cruz, a Cuban American singer who was known as the Queen of Salsa, will be the first Afro-Latina woman to appear on American quarters as part of a U.S. Mint initiative." The mint "said in a news release on Feb. 1 that Ms. Cruz would be featured as a 2024 honoree of the American Women Quarters Program, which portrays prominent women throughout history on the quarter."

Jackson Appoints New Public Works Director Amid Ongoing Water Crisis. The AP (2/12, Long) reports that "as the most populous city in Mississippi attempts to improve its troubled water system, it has appointed a new interim director to lead the agency that runs local infrastructure." City Engineer Robert Lee "was named interim director of the Jackson Public Works Department Friday as Jackson begins a nationwide search to find a permanent candidate to fill the position." Over "the past few years, repeated breakdowns have upended consistent access to safe running water in Jackson, which is also the state capital." The crisis "culminated in late Augustand early September when the system came to near collapse and most people in the city of 150,000 went several days without running water."

Advocates Call For Republicans To Become "Aspirational Conservatives." Stephen Goldsmith, the Derek Bok Professor of the Practice of Urban Policy at Harvard University's Kennedy School of Government, and Ryan Streeter, the Director of Domestic Policy Studies at the American Enterprise Institute, write in a Politico Magazine (2/12, 6.68M) op-ed that the Republican Party "has been adrift and lacking a coherent agenda for several years now." They advocate for an "aspirational conservatism," and argue Republicans "should create a clear set of policy objectives to support opportunity, individual initiative and hope," while being "the voice of reason on crime and justice." They also say "aspirational conservatives should break from a growing preference on the right for wielding federal power in pursuit of moral goals." Aspirational conservatives, they write, "have a chance to show they are on the side of the majority of Americans who care most about a good quality of life, ample opportunity and a government that works for them."

Joint Center Board Chair Laments Insufficient Diversity Among Senate Staff Leadership. In an op-ed for the Washington Post (2/12, 10.52M), Paul N.D. Thornell, a principal at Mehlman Consulting and board chair of the Joint Center for Political and Economic Studies, writes inadequate diversity "in leadership roles is common in workplaces across the country, including, arguably, one of the most important locations: the U.S. Senate." Among Senate workers, "there is only one Black chief of staff, four Black legislative directors and one Black communications director. On the Senate committees where legislation takes shape, there are zero Black people in top committee staff director positions." Thornell argues there is "value in having some top Black Senate staff 'at the table' to help develop measures based on their personal insights, experiences or those of family and communities [and this] could be said of virtually any other federal policy issue, from health care to education to housing to transportation issues. But with the makeup of top Senate staff, that perspective is missing."

EDITORIAL WRAP-UP

Wall Street Journal. ***"The University Of North Carolina Fight Escalates."*** In an editorial, the Wall Street Journal (2/12, Subscription Publication, 8.41M) argues that the creation of a new school for free expression at the University of North Carolina is becoming more complicated, with opponents of the plan now claiming that UNC's accreditation could be jeopardized by its board's support for the school. The Journal urges the board of UNC to remain steadfast, even in the face of what they describe as politically-motivated threats.

"Watch Out, Gigi Sohn Is Back." A Wall Street Journal (2/12, Subscription Publication, 8.41M) editorial argues that the Administration is making another mistake by re-nominating Gigi

Sohn for the top position at the FCC, due to her ideological positions as well as support for what they consider "dangerous rule-making." The Journal says that Sohn's organization, Public Knowledge, which she co-founded, supports a very broad mandate for the FCC to micromanage content, competition, and development. The Journal criticizes President Biden for nominating a progressive activist to the position instead of a more moderate alternative.

"What's Going On Up There, Mr. President?" A Wall Street Journal (2/12, Subscription Publication, 8.41M) editorial accuses the Administration of being "tight-lipped and dissembling" regarding the flying objects that are being shot down in US airspace. The Journal claims the lack of any consistent information or transparency from the White House is causing concern among Americans.

"Overruling The District Of Crazy." A Wall Street Journal (2/12, Subscription Publication, 8.41M) editorial supports a decision by the House to overturn a pair of District of Columbia laws. One of the laws would have eased sentences for carjacking, burglary and other felonies. The other would have granted noncitizens the right to vote in local elections. The Journal says the fate of the House bills in the Senate is uncertain, but predicts that Majority Leader Schumer will allow some Democrats facing reelection in 2024 to vote with the House, but not enough to provide enough votes to break a filibuster.

Washington Post. ***"In A Hong Kong Courtroom, Freedom Itself Is On Trial."*** The Washington Post (2/12, 10.52M) editorializes the 16 democracy activists being put on trial in Hong Kong beginning last week "had done one thing that truly frightens China's leaders: They held a vote." The activists are charged with "subverting state power," which carries a "carries a maximum sentence of life in prison, and 31 others who have already pleaded guilty will be sentenced at the trial's conclusion." The Post says that China's Communist Party and its "minions who run Hong Kong cannot stand the sight of people expressing their preferences for who should lead them." The Post adds, "Freedom itself is now on trial."

"A Shakeup In Ukraine Masks Deeper Problems." In an editorial, the Washington Post (2/12, 10.52M) writes Zelensky's administration faces "the threat posed by scandal or misuse of funds...to what has been solid U.S. and European support of Kyiv" following "recent reports that officials in his government were profiteering from wildly inflated prices" on certain goods. The Post adds Zelensky would be "shrewd not to ignore graft, sweetheart deals and the vestiges of oligarch capitalism that were a stain on the country's reputation long before Moscow launched its full-scale invasion," as "Ukraine's day of reckoning cannot be delayed indefinitely," and "Kyiv's own aspirations depend on establishing the rule of law."

New York Times. ***"India's Proud Tradition Of A Free Press Is At Risk."*** A New York Times (2/12, 20.6M) editorial says efforts to "intimidate, censor, silence or punish independent news media" are "an alarming hallmark of populist and authoritarian leaders," and warns Modi is on this path. The Times says Modi's actions to "suppress freedom of the press are undermining India's proud status as 'the world's largest democracy,'" while adding that since Modi took office in 2014, journalists have "increasingly risked their careers, and their lives, to report what the government doesn't want them to." The Times says that what began as a "potential embarrassment" for Modi has "thus escalated into a furor over press freedoms – and into a test for the rest of the world."

THE BIG PICTURE

Headlines From Today's Front Pages.

WALL STREET JOURNAL:

Investors Are Exiting US Stock Funds During 2023 Rally
US Military Shoots Down Fourth High-Altitude Object Over North America
From Apple To VW, CEOs Gradually Returning To China After Its Reopening
Hard Or Soft Landing? Some Economists See Neither If Growth Accelerates
Couples Who Stay Together Don't Ski Together
Blackstone's Big New Idea Leaves It Bruised

WASHINGTON POST:

A Fourth Aerial 'Object' Is Shot Down Over Lake Huron
Women Returning Faster To Workforce Than Men
Rescues Continue As Hopes Wane
Ukraine Readies Its Defenses On Every Front

FINANCIAL TIMES:

Taiwan Reveals Chinese Military Balloons Fly 'Very Frequently' Into Its Airspace
Erdoğan Targets Construction Firms As Earthquake Death Toll Tops 33,000
Goldman Chief Tells Partners He Should Have Cut Jobs Earlier

STORY LINEUP FROM LAST NIGHT'S NETWORK NEWS:

ABC: Unidentified Object Shot Down Over Great Lakes; New Mexico State University Suspends Men's Basketball Program; Aftermath Of Earthquake In Turkey And Syria; US Severe Weather; War In Ukraine; Rise In Norovirus Cases; Super Bowl; Search For Missing Woman In Houston; Engine On Delta Flight Catches Fire; Interview With Damar Hamlin; Woman Receives Liver Donation From Her Husband.
CBS: Unidentified Object Shot Down Over Great Lakes; Aftermath Of Earthquake In Turkey And Syria; War In Ukraine; NYC Terrorist Could Receive Death Penalty; Super Bowl; Florida Education Reforms; Rickie Fowler Shoots A Hole In One; Lebron James Surprises Young Fan At NBA Game; Mother And Daughter Hike The Appalachian Trail.
NBC: Unidentified Object Shot Down Over Great Lakes; Aftermath Of Earthquake In Turkey And Syria; War In Ukraine; Engine On Delta Flight Catches Fire; New Mexico State University Suspends Men's Basketball Program; Fallout After New Jersey Student Commits Suicide; US Coast Guard Operations To Intercept Migrants; Teenage Volunteer Gets To Go To The Super Bowl.

NETWORK TV AT A GLANCE:

Unidentified Object Shot Down Over Great Lakes – 13 minutes, 5 seconds
Aftermath Of Earthquake In Turkey And Syria – 9 minutes
Super Bowl – 7 minutes, 25 seconds
War In Ukraine – 6 minutes, 20 seconds
New Mexico State University Suspends Men's Basketball Program – 3 minutes, 40 seconds
Florida Education Reforms – 2 minutes, 50 seconds

LAST LAUGHS

Late Night Political Humor.

Last Week Tonight With John Oliver did not air on February 12, 2023.

From: Bulletin Intelligence
Sent: 29 Mar 2022 07:28:38 -0400
To: HHS@bulletinintelligence.com
Subject: HHS News Briefing for Tuesday, March 29, 2022
Attachments: HHSNewsBriefing220329.doc

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HHS.gov News Briefing

TO: THE SECRETARY AND SENIOR STAFF

DATE: TUESDAY, MARCH 29, 2022 7:30 AM EDT

Today's Table of Contents

Leading the News

The Secretary in the News

Coronavirus

Other Coronavirus News

• COVID-19 Positive Tests Trending Up In Colorado.
• New Jersey Reports One COVID-19 Death, 617 Positive Coronavirus Tests.
• Michigan Records 1,258 New COVID-19 Cases, Six Deaths Over Three-Day Period.
• WHO Examines Auditory Issues Potentially Linked To COVID-19 Vaccines.
• Nebraska Lawmakers Approve $1B Pandemic Recovery Bill.
• Nebraska Reports Continued Decrease In COVID-19 Cases, Hospitalizations.
• OHCA Warns 200K Oklahomans May Lose Medicaid Coverage When Public Health Emergency Ends.
• Brazil's Health Regulator Recommends Easing COVID-19 Travel Restrictions.
• Hong Kong Faces Coffin Shortage After COVID-19 Outbreak.
• Medicago's COVID-19 Vaccine Facing Limited Growth After WHO Refuses To Review It Due To Philip Morris Ties.
• UK Study To Test Pfizer's COVID-19 Pill In Hospitalized Patients.
• German Chancellor Says He Disagrees With Planned IP Waiver For COVID-19 Vaccines.
• FDA Pauses Distribution Of GSK, Vir's COVID-19 Antibody Drug In The Northeast.
• Therapeutic Antivirals Nirmatrelvir/Ritonavir And Molnupiravir Reportedly Have Potential To Change COVID-19 Pandemic.
• Shanghai Goes Into COVID-19 Lockdown, Reversing Weeks Of Denying It Would Impose Blanket Restrictions.
• South Korea's Daily New COVID-19 Case Average Declined Last Week For First Time In Two Months, Officials Say.
• G20 Chair Indonesia Starts Talks With Members On Standardizing Health Protocols For Travel, Health Minister Says.
• Commentary: Global Vaccination Against COVID-19 Almost Certain Not To Reach President Biden's Goal.
• CDC Eases COVID-19 Travel Ratings For India.
• Global COVID-19 Vaccines Face Waning Demand.
• Latina Health Access Promotores Work To Convince People To Get COVID-19 Vaccine.
• Number Of Cases Of Early Puberty Among Girls Has Surged During Pandemic, Physicians Say.
• White House Spokesperson Tests Positive For COVID-19 After Trip To Europe With Biden.
• Fauci Discusses Necessity Of Fourth COVID-19 Vaccine Dose.

• Biden Administration Stresses Importance Of Mitigating Indoor Aerosol Transmission Amid New COVID-19 Phase.
• Biden Administration May Have Difficulty Convincing People To Get Second COVID-19 Booster Shot.
• Former FDA Chief Predicts Federal Public Transportation Mask Mandates Will End Next Month.
• FDA May Soon Approve Second COVID-19 Booster Shot For Those 50 And Older.
• Flight Attendants Sue CDC Over Federal Mask Mandate On Public Transportation.
• Op-Ed: Dysfunction Affects Health Providers, Patients Every Day.
• Hundreds Of Billions In Pandemic Assistance Dollars "Lost To Fraud."
• People's Convoy Set To Leave DC To Protest COVID-19 Bills In California.
• Michigan To Reduce COVID-19 Data Reporting Frequency.
• Minnesota Launches Online Program Providing Free At-Home COVID-19 Tests.
• Only 30% Of Los Angeles County Children Aged Five To 11 Fully Vaccinated Against COVID-19.
• Omaha Revises Ordinance Stripping Health Director's Powers During A Pandemic.
• Columnist: Rural Texas Hospitals Still Looking For "Real Remedies" To Prevent Closures.
• Idaho Governor Vetoes Bill Banning Businesses From Requiring COVID-19 Vaccine.
• Saliva-Based COVID-19 Tests May Be More Sensitive Than Nasal-Swab Tests, Expert Says.
• Some People With Long COVID Not Ready To Go Back To The Office.
• MIT Reinstates Standardized Testing Requirements For Applicants.
• Op-Ed: Fourth COVID-19 Vaccine Dose Not Necessary For Everyone.
• Commentary Warns US Will Be In "Far Weaker Position" Against COVID-19 If Congress Does Not Approve Additional Funds.
• Racial, Ethnic Disparities In COVID-19's Toll "Likely To Worsen" Without New Pandemic Funds.
• Analysis: Russian Invasion Of Ukraine Has Doomed Sputnik V.

Unaccompanied Migrant Children

• Biden Administration To Require COVID-19 Vaccine For Some Undocumented Immigrants.

HHS in the News

• HHS Resolves Four Enforcement Cases Over Providers' Disclosure Of Heath Data.
• Ten-Year Health Spending Estimates Expected To Increase Despite Drop In 2021, CMS Says.
• Fauci To Serve As Keynote Speaker At Roger Williams University Commencement.
• Scientist Explains Natural Human Tendency To See Faces Everywhere.
• Clinical Sequencing May Lead To Diagnoses In Significant Subset Of Immune Conditions, NIAID Program Finds.
• FDA Oncology Chief Defends Rejection Of Eli Lilly, Innovent Cancer Drug.
• Judge Orders Animal Food Company Bravo Packing To Halt Production Until It Meets FDA Safety Standards.
• FDA Issues Review Raising Concerns Over Experimental Drug For ALS Treatment.
• Commentary Says Pandemic Exposed Issues In FDA, Industry Supply Chain For Blood Collection Tubes.
• Analysis Examines Claims Of One-Sided Censorship By Social Media Platforms.

Overdose Prevention

• Record Fentanyl Deaths Impact Local Families In California.

Mental Illness

• New Studies Examine Mental Health Toll Of Cancer.
• Georgia Senate Advances Updated Version Of Mental Healthcare Bill.
• Investigation Examines Former New York Governor's "Transformation Plan" For Children's Mental Healthcare.
• Article Examines Financial Toll Of Becoming Mental Healthcare Clinician.
• State Task Force Tells Connecticut Lawmakers Psychiatric Hospital Still Needs "Significant Improvements."

Prescription Drug Pricing

• Kentucky Bill To Curb PBMS Arrives At Likely Dead End.

Health Care & Insurance Reform

• State-Based Marketplace Enrollees To Face Higher Premiums Without Extension Of Subsidies Under ARPA.

• More Than 40 Percent Of US Hospital ERs Overseen By For-Profit Healthcare Staffing Companies Owned By Private-Equity Firms.
• Op-Ed: Overregulating Pay Of Nurses Would Be A Mistake.
• While Democrat-Led States Are Proposing Laws To Shore Up Abortion Rights, 41 States Have Introduced 519 Abortion Restrictions This Year.
• Colorado Braces For Increasing Number Of Out-Of-State Residents Seeking Abortions If Roe V. Wade Overturned, Weakened.

Health Information Technology

• Female Physicians Spend More Time On EHR Clinical Documentation Than Male Counterparts, Study Indicates.

Human Services News

• New York City Mayor Calls For Increasing Investment In State Budget For Child Care, Early Childhood Education.
• New AI-Using Tools Assist Students With Autism, Dyslexia And Address Accessibility For Blind, Deaf.
• Disability Services Providers Struggle With Ongoing Labor Shortage.
• Nursing Home Spending To Reach $273B In 2030, CMS Estimates.
• CODA, Film Starring Actors With Disabilities, Wins Best Picture.
• Editorial: Getting Federal Court-Appointed Monitor To Oversee Reform Usually Best Possible Outcome.

Food & Import Safety

• Consumer Reports Shares "Reassuring" Results From Frozen Vegetable Safety Tests.
• Dried Sweetened Strawberries Snack Recalled From Target For Undeclared Sulfites.

Health & Medical News

• Patients, Particularly Women And People Of Color, Calling Attention To "Medical Gaslighting."
• Prediabetes Prevalence More Than Doubled Among US Youth From 1999 To 2018, Data Indicate.
• Billionaire Former CEO Of Google Plays "Extraordinary" Role Shaping White House Office Of Science And Technology Policy.
• First Lady Visits St. Jude To Promote Cancer Moonshot Initiative.
• Oregon Ends Residency Requirement For Medically Assisted Suicide.

• Fresenius Files Federal Complaint Over Patent Infringement For Rare Thyroid Disease Drug.
• Rural Hospitals Face Obstacles Providing Prenatal Care, Obstetricians For Pregnant Women.
• Study Identifies Two Periods Of Adolescence When Heavy Social Media Use May Spur Lower Ratings Of "Life Satisfaction."
• Scientists Expect West Nile Virus Transmission To Increase Across US Due To Climate Change.
• "Fragmented" Regulatory Framework Complicating Sodium Chloride Shortage, Experts Say.
• Milk Of Magnesia, Generic Tylenol Sent To Nursing Homes Recalled Due To Contamination.
• Florida Lacks Enough Geriatricians To Handle Increasing Number Of Alzheimer's Cases, Report Finds.
• New Colorado Law Aims To Protect Healthcare, Child Protection, Code Enforcement Workers From Harassment.
• Avian Flu Detected In Flocks In Iowa, Nebraska, And Minnesota.
• Research Highlights Lack Of Racial, Ethnic, Language Concordance Between Patients And Physicians.
• North Carolina Lawmakers To Discuss Expanding Nurse Practitioner Duties.
• Walmart Ending Cigarette Sales In Some US Stores, Sources Say.
• RJ Reynolds To Increase Prices On Friday.
• Smoking Cessation Study Enrollment Opens In Nashville.
• Recovery Experts See Increased Demand For Their Services As Americans Turn To Drinking During Pandemic.
• Recent NIDA Data Suggest Medical Marijuana Can Lead To Cannabis Use Disorder.
• FDA Approves Fenfluramine For Treatment Of Seizures Tied To Rare Form Of Childhood Epilepsy.
• Sen. Tim Scott Top Recipient Of Drug Industry Cash During Second Half Of 2021.
• Men Taking Metformin Vs. Insulin More Likely To Have Offspring With Birth Defects, Study Suggests.
• FDA Approves Higher Dosage Of Novo Nordisk's Diabetes Drug.
• STAT Interviews UHG's Chief Medical Officer.
• CQMC Identifies Quality Measurement Gaps, Recommends New Digital Quality, Health Equity Quality Measures.

• Hospitals Stay At Operating Loss In Early 2022.

Global Health

• Unintended Pregnancies Reach 30-Year Low, But Abortions Have Risen Globally, Study Finds.
• Article Examines Efforts To Keep Science Education, Research Alive In Ukraine.

National News

• Judiciary Committee's Jackson Confirmation Vote Set For April 4.
• LATimes Report: Harris Keeping Tighter Circle Of Confidants.
• Dunn's Lobbying Firm "Straddling The Line Between The Private Sector And The Administration."
• Pelosi Extends Proxy Voting In House Until At Least May 14.
• Supreme Court To Hear Arguments Over Law Giving Employment Protections To Military Personnel.
• Supreme Court Agrees To Hear Challenge To California Law On Pig Protections.
• Justice Thomas Joins Arguments Remotely After Being Discharged From Hospital.
• New York State Judge Sets End Of April Deadline For Trump Organization To Comply With NY Attorney General's Subpoena.
• Poll Shows Hochul Up 8 Points Over Cuomo In Hypothetical Primary Matchup.
• Progressive, Environmental Groups Release "Green New Deal Pledge" For Candidates.
• Georgia Election Workers Argue Against New GOP Elections Bill.
• WSJournal Criticizes Will Smith For Incident At Academy Awards.

Editorial Wrap-Up

• Wall Street Journal.
• Washington Post.

The Big Picture

• Headlines From Today's Front Pages.

Last Laughs

• Late Night Political Humor.

Leading the News

Biden's Proposed 2023 Budget Includes More Funding For Pandemic Preparedness, Mental Health, IHS.

The Washington Post (3/28, Stein, 10.52M) reports on Monday, President Biden put forward "a $5.8 trillion budget plan...that reflects a major administration pivot to rein in future borrowing, introducing a proposal that would reduce the national deficit by roughly $1 trillion over 10 years." It "calls for substantial funding increases for the military and police, more money for a slew of domestic programs and a 'Bipartisan Unity Agenda' focused on cancer prevention, mental health care and veterans services." The budget includes $82 billion to allow HHS "to prepare for pandemics and 'other biological threats,'" $200 million for the CDC to upgrade the quality of public health data and $748 million for global health activities, as well as "$5 billion for an Advanced Research Projects Agency for Health that Biden proposed last year as a new engine for biomedical research," although it is unclear whether it will placed under the NIH or HHS.

The New York Times (3/28, A1, Kanno-Youngs, Rappeport, Cochrane, 20.6M) reports Biden "proposed a $5.8 trillion budget that includes significant increases in funding for the military and police departments, along with higher taxes on corporations and the wealthiest Americans." This request "reflects growing security and economic concerns at home and overseas, with Mr. Biden proposing a 7 percent increase in domestic spending that includes priorities like anti-gun violence initiatives, affordable housing and manufacturing investments to address supply chain issues that have helped fuel rapid inflation. The White House also for the first time proposed a discrete stream of funding for Veterans Affairs medical care."

In a separate article, the New York Times (3/28, Walker, 20.6M) reports there is "a significant proposed shift in the way the Indian Health Service was funded as part of" the 2023 budget. Biden is "proposing the health care agency move from discretionary to mandatory funding." He is seeking $9.1 billion, which represents an increase of more than 20% over the current funding level.

The Wall Street Journal (3/28, A1, Omeokwe, Duehren, Subscription Publication, 8.41M) reports the budget is seeking a record level of military spending and additional funding for law enforcement. Under the proposal, the CDC would receive $9.9 billion in discretionary funds to help increase capacity at the state and local levels. This amount represents an increase of $2.8 billion over the 2021 budget.

The AP (3/28, Boak) reports the budget includes more "funding for education, public health and housing." It "essentially tries to tell voters what a diverse and at times fractured Democratic Party stands for ahead of the midterm elections that could decide whether Congress remains under the party's control." The budget calls for "$795 billion for defense, $915 billion for domestic programs, and the remaining balance would go to mandatory spending such as Social Security, Medicare, Medicaid and net interest on the national debt."

Reuters (3/28, Shalal, Hunnicutt) reports the proposal "lays out Biden's priorities, including campaign promises to make the wealthy and companies pay more tax. It is merely a wish list as lawmakers on Capitol Hill make the final decisions on budget matters." In response, "House Speaker Nancy Pelosi said Congress looked forward to working on Biden's 'bold fiscal blueprint.'" However, "some fellow Democrats chafed at Biden's pledge to boost military spending. Biden's plan drew immediate criticism from Republicans, who together with moderate Democrats, killed similar tax proposals in the 2022 budget."

Bloomberg Law (3/28, Ruoff, Reed, Subscription Publication, 4K) reports the "administration's plan for fighting future pandemics comes even as it's asking Congress for funds to combat the current one. The White House asked lawmakers for more than $22 billion in March to replenish Covid-19 response programs, and health officials warned they might need more than that soon." In spite of "White House pleas, lawmakers have been at a stalemate over approving more funds." HHS Secretary Xavier Becerra said on Monday, "We're going to stretch where we can, but there's no question – if we don't have the resources, we're just going to fall behind. ... What we need to finish the job on Covid, we need immediately."

The Washington Times (3/28, Howell, 626K) reports Becerra added, "We can't afford to have bad inputs. We need not only good inputs, we need more inputs. ... We need better coordination with our state and local partners. We can't have some states giving us great data on where we are with COVID or on the public health crisis that we're facing and have other states fall behind. We need to coordinate."

Bloomberg Law (3/28, Baumann, Subscription Publication, 4K) reports the NIH's "total budget would grow to about $62 billion in fiscal 2023 under the president's request released Monday, about $20 billion more than it's had over the last few years." But "$12 billion of that money is designated for part of a larger mandatory pandemic preparedness package."

Bloomberg Law (3/28, Ruoff, Subscription Publication, 4K) reports, "Federal regulators would get the power to levy fines against insurers that violate mental

health parity rules and states would get an injection of $125 million to enforce parity laws under President Joe Biden's proposed fiscal 2023 budget." The President "has promised to build on consumer protections meant to ensure that people with insurance can get access to mental health care with the same kind of coverage they have for physical care." Becerra also said on Monday, "The president gave us a charge: let's stop treating mental health as a stepchild in the health care sector."

The Hill (3/28, Sullivan, 5.69M) reports under the proposal, the NIH "would get $12.1 billion for research on vaccines and other measures, while the Food and Drug Administration would get $1.6 billion for its labs and information technology."

Bloomberg Law (3/28, Baumann, Subscription Publication, 4K) reports, "The Biden administration's biomedical innovation budget proposal offers largely flat funding for basic research in favor of a big-ticket new agency focused on medical breakthroughs."

FierceBiotech (3/28, Armstrong, 4K) reports the budget includes "a $2.1 billion boost in funding for the FDA in 2023 to support the Cancer Moonshot program and pandemic preparedness." Overall, "the FDA could be up for $8.39 billion, a 34% increase over the $6.25 billion enacted for 2022." FDA Commissioner Dr. Robert Califf, who was confirmed last month, said, "The funding outlined in this year's FDA budget request is critical to fulfilling the agency's mission as we continue our work on a wide range of COVID-19 and non-COVID priorities."

In a separate article, The Hill (3/28, Bernal, Beitsch, 5.69M) reports, "The budget at both DOJ and the Department of Health and Human Services also sets aside funding legal aid for an immigration court system that, unlike the U.S. criminal court system, provides no guarantee of counsel."

Among other news outlets covering the story are Bloomberg (3/28, Sink, Wasson, 3.57M), NBC News (3/28, Finn, 4.91M), CNBC (3/28, Wilkie, 7.34M), Fox News (3/28, Singman, 23.99M), Politico (3/28, Scholtes, 6.73M), The Hill (3/28, Chalfant, Folley, 5.69M), Forbes (3/28, Ponciano, 10.33M), the New York Daily News (3/28, Goldiner, 2.51M), the New York Post (3/28, Nelson, 7.45M), NPR (3/28, Keith, 3.69M), Modern Healthcare (3/28, Goldman, Subscription Publication, 215K), FedScoop (3/28, Nyczepir), Government Executive (3/28, Bublé, 29K), NextGov (3/28, Kelley, Konkel), Inside Health Policy (3/28, Mills-Gregg, Subscription Publication), Inside Health Policy (3/28, Wang, Subscription Publication), Bloomberg Law (3/28, Castronuovo, Subscription Publication, 4K),

Nature (3/28, Tollefson, 194K), Inside Health Policy (3/28, Wilkerson, Subscription Publication), and Endpoints News (3/28, Brennan).

Analysis And Commentary. The New York Times (3/28, Weisman, 20.6M) reports the budget's "framing was a marked shift from the 2021 pitch for a fundamental transformation of an ailing American society." Rather, "Mr. Biden's plan was an appeal based on the reality of the moment, to both new dangers around the globe and at home, where inflation and crime are crushing the president's political standing."

A second New York Times (3/28, Sanger-Katz, 20.6M) analysis says while administrations "normally detail their biggest policy dreams in their annual budgets," the Biden Administration "tucked its into the footnotes instead. Months after congressional talks stalled on the president's expansive climate and social safety net bill known as Build Back Better, the White House simply declined to include its fine print in its annual budget proposal that was released on Monday." Although the budget "included a slew of smaller policy specifics," it "did not include the key provisions in Build Back Better – the legislation that President Biden has spent much of his time in office promoting."

The Washington Post (3/28, Demirjian, 10.52M) reports "Biden's defense spending proposal met an onslaught of criticism from congressional Republicans upon its release Monday for failing, they say, to adequately address escalating inflation and the West's standoff with Russia over Ukraine – growing crises that, officials acknowledged, did not factor into the Pentagon's request to Congress."

The Washington Post (3/28, Bump, 10.52M) reports in a separate article that Biden is seeking $5.8 trillion "for fiscal year 2023, which begins in October. It is likely to be significantly changed by Congress."

Bloomberg (3/28, Wasson, Dennis, 3.57M) reports "Biden's plan to tax unrealized capital gains ran into opposition from key Democratic Senator Joe Manchin, likely dooming it just hours after it was sent to Congress." The proposal seeks to "impose a 20% minimum tax on the unrealized capital gains for households worth at least $100 million."

Politico (3/28, Barron-Lopez, 6.73M) reports, "The White House is boasting that the president's budget contains major deficit reduction, a move that Democrats see as calculated to appeal to a handful of centrist lawmakers who hold the pre-midterms fate of the president's economic agenda in their hands." This "proposal comes as Biden seeks to revive talks with Senate Democratic moderates such as West Virginia's Manchin on central elements of his now-

defunct social spending bill. That includes universal pre-K, lowering prescription drug prices and combating climate change."

The Washington Post (3/28, 10.52M) editorializes that Biden's budget proposal "is more realistic about the nation's needs than many that have come before it. But it leaves out some of the most important details." In spite of the "shortcomings in the spending blueprint, if Mr. Biden persuades Congress to accept many of the proposals he outlined Monday and gets even a slimmed-down Build Back Better bill over the finish line, he could claim substantial victories for himself and for the Americans who elected him."

In an editorial, the Wall Street Journal (3/28, Subscription Publication, 8.41M) criticizes Biden's plan to tax the wealthy, saying that it goes against what the Constitution intended.

In another editorial, Wall Street Journal (3/28, Subscription Publication, 8.41M) also criticizes Biden's proposed budget, saying the plan to raise taxes on the wealthy would raise the tax portion of the GDP to record levels, which is not what the economy or taxpayers need.

In a Wall Street Journal (3/28, Subscription Publication, 8.41M) op-ed, Jason Furman lauds Biden's tax proposal, saying it is a good way to begin to raise taxes in a progressive manner.

HRSA COVID-19 Uninsured Program Stops Taking Claims Due To Lack Of Funding.

The Washington Post (3/28, Goldstein, 10.52M) reports, "The Biden administration has been trying to draw attention to the consequences if lawmakers continue bickering over whether to provide more coronavirus aid." As a result of the disputes, "the federal COVID-19 Uninsured Program," overseen by the Heath Resources and Services Administration (HRSA) refused to accept new "claims for testing and treating for the deadly virus on patients who had no way to pay their medical bills." The Post says according to "rules set by the Centers for Disease Control and Prevention, coronavirus vaccines must be given at no charge. The question of possibly charging for coronavirus tests is more ambiguous, and HHS Secretary Xavier Becerra has hinted at that in public."

The New York Times (3/28, Barry, 20.6M) reports that last week, Becerra warned "that reimbursements for testing were ending," and on Wednesday, HRSA "stopped accepting claims."

Fox News (3/28, Pergram, 23.99M) reports, "People will have to pony up the cash out of their own pocketbook to pay for vaccines and medicine" as

inflation continues to rise. The article adds, "So paying for a test becomes a de facto tax."

Fortune (3/28, 3.68M) and Bloomberg (3/28, Rutherford, 3.57M) also cover the story.

The Secretary in the News

Hospital Groups Want Becerra To Extend COVID-19 Public Health Emergency.

Fierce Healthcare (3/28, Muoio, 150K) reports hospital "groups are again asking Department of Health and Human Services (HHS) Secretary Xavier Becerra to extend the government's COVID-19 public health emergency, which is set to expire April 16." On Monday, 10 national hospital and health system organizations wrote to Becerra acknowledging "growing interest in ending the PHE due to the country's ongoing decline in cases and hospitalizations." But "the groups pointed to still-unvaccinated populations, such as the immunocompromised and children under five; potential future surges of COVID-19, potentially fueled by overseas increases due to an omicron subvariant; and lingering operational challenges including labor shortages and an influx of deferred care as reasons to maintain the declaration."

HealthLeaders Media (3/28, Ray, 118K) also covers the story.

HHS Proposes To Simplify Medicare Physician Pay System.

Inside Health Policy (3/28, Stein, Subscription Publication) reports behind a paywall, "HHS' fiscal 2023 Budget-in-Brief lays out a proposal to simplify the Medicare physician pay system by letting 5% bonus payments for clinicians in alternative payment models expire after 2022, but moving up the higher pay rates that those in such models will get compared to other clinicians participating in the Merit-based Incentive Payment System by a year to avoid any gaps in incentives." HHS Secretary Xavier Becerra is mentioned.

Coronavirus

Other Coronavirus News

Majority Of Americans Say They Have Contracted COVID-19, Monmouth University Poll Says.

The Washington Post (3/28, Blake, 10.52M) reports, "In a new Monmouth University poll, 52 percent of Americans say they've personally contracted the virus." The numbers are an increase "from 40 percent in late January, in the weeks following FDA acting commissioner Janet Woodcock's testimony" in which she warned that "most Americans were going to contract the coronavirus." As of now, "a little more than 4 in 10 say they've tested positive for or been diagnosed with COVID-19, while 10 percent say they haven't been diagnosed but know they've had the virus."

Political Polarization In US Was Evident Long Before Start Of Pandemic Two Years Ago.

ABC News (3/28, 2.44M) reports, "Political polarization in the US was evident and intensifying long before the onset of the COVID-19 pandemic, two years ago." Residents of the US "were already deeply divided about a multitude of issues, with differing opinions concerning healthcare, immigration, voting rights, gun reform and climate change, often leaving little room for collaboration across the aisle." Surveys show "that the emergence of the novel coronavirus in 2020 exacerbated the rift, pushing Americans further apart on key pandemic response efforts." CDC Director Dr. Rochelle Walensky and the National Library of Medicine are mentioned in this story.

Passengers, Crew On Cruise Ship Test Positive For COVID-19 On Return To San Francisco.

The Washington Post (3/28, Diller, 10.52M) reports, "Passengers and crew on a Princess Cruises ship that arrived in San Francisco on Sunday have tested positive for the coronavirus, the cruise line said." Princess Cruise's "Ruby Princess was returning from a 15-day trip to the Panama Canal." Princess Cruise "said in a statement that infected passengers and crew were asymptomatic or showed mild symptoms."

USA Today (3/28, Hines, 12.7M) reports, "The company did not specify the number of people on board who tested positive." COVID-19 vaccination rates for crew and passengers "were at '100%,' according to the cruise line." On the CDC's "'Cruise Ship Status Dashboard,' which provides info on COVID-19 levels present on ships and what kinds of precautions those vessels are taking, the ship is listed as 'under observation' by the health agency."

CBS News (3/28, Brooks, 5.39M) reports, "Those who tested positive for coronavirus did not spread it to others on the ship." Princess Cruise said in a

statement. The company "said some of the passengers who came down the virus didn't finish their quarantine while on board the ship."

COVID-19 Positive Tests Trending Up In Colorado.

The Denver Post (3/28, Wingerter, 660K) reports, "The percentage of COVID-19 tests coming back positive is trending up in Colorado, but it's not clear if that's a fluke or the start of a new wave of the virus." On Monday, "state epidemiologist Dr. Rachel Herlihy said the positivity rate trended up from about 2.5% on March 17 to about 3.3%." Though "that meets the state's goal of keeping the rate below 5%, it's something Herlihy said she'll be 'closely watching.'"

New Jersey Reports One COVID-19 Death, 617 Positive Coronavirus Tests.

New Jersey Star-Ledger (3/28, Rodas, 1.47M) reports, "New Jersey on Monday reported one more confirmed COVID-19 death and 617 positive tests, as New Jersey fell below West Virginia and Tennessee as the state with the seventh-most coronavirus deaths per capita in the US." The state's "seven-day average for confirmed cases was 841 on Monday, up 22% from a week ago, but still down 22% from a month ago." As of Sunday night, "there were 344 patients with confirmed or suspected coronavirus cases across 70 of the state's 71 hospitals."

Michigan Records 1,258 New COVID-19 Cases, Six Deaths Over Three-Day Period.

The Detroit Free Press (3/28, Stein, 2.16M) reports, "The Michigan health department on Monday reported 1,258 new confirmed COVID-19 cases and 6 deaths over a three-day period." The state "now has a total of 2,077,401 confirmed cases and 32,758 confirmed deaths since March 2020, when the pandemic began." On Sunday, Michigan had a test positivity rate of 4.46%, "reporting that 641 of 14,382 diagnostic test results were positive."

WHO Examines Auditory Issues Potentially Linked To COVID-19 Vaccines.

NBC News (3/28, Edwards, 4.91M) reports, "The World Health Organization is examining rare reports of hearing loss and other auditory issues following Covid-19 vaccinations." The agency "said that it has been made aware of sudden hearing problems, particularly tinnitus, or ringing of the ears, that may be associated with Covid vaccines." The WHO "reported 367 cases of tinnitus and 164 cases of hearing loss globally among people who had received a Covid-19 vaccine, usually within a day of the shot."

Nebraska Lawmakers Approve $1B Pandemic Recovery Bill.

The Omaha (NE) World-Herald (3/28, Stoddard, 509K) reports, "Disputes over tax cuts and criminal justice reform simmered in the background Monday as lawmakers gave second-round approval to a plan for using the state's $1.04 billion of federal pandemic recovery funds." The bill "advanced on a 33-7 vote," and "allocates money coming to the state through the American Rescue Plan Act."

Nebraska Reports Continued Decrease In COVID-19 Cases, Hospitalizations.

The Omaha (NE) World-Herald (3/28, Anderson, Cordes, 509K) reports, "Nebraska continued its two-month downward trend in COVID-19 cases and hospitalizations last week." While "exactly how many cases the state recorded last week...isn't entirely certain," the state "reported a negative number of cases for the week to the federal Centers for Disease Control and Prevention."

OHCA Warns 200K Oklahomans May Lose Medicaid Coverage When Public Health Emergency Ends.

The Tulsa (OK) World (3/28, Jones, 241K) reports, "The Oklahoma Health Care Authority (OHCA) warns that nearly one in five Oklahomans with SoonerCare might be removed from the program after the federal public health emergency ends." On Monday, OHCA Secretary Kevin Corbett "said 'all indications and signals' are that the public health emergency...will expire this year" which "means roughly 200,000 Oklahomans on Medicaid – called SoonerCare in Oklahoma – preliminarily appear to no longer qualify for the program, he said." OHCA "asks that all SoonerCare members update their contact information and documentation to help the agency better understand which members will be eligible to renew benefits when the U.S. Health and Human Services secretary announces the end of the federal health emergency."

Brazil's Health Regulator Recommends Easing COVID-19 Travel Restrictions.

Reuters (3/29) reports, "Brazilian health regulator Anvisa recommended on Monday that COVID-19 travel restrictions be eased due to a drop in cases and deaths, requiring only full vaccination and doing away with quarantine for unvaccinated travelers."

Hong Kong Faces Coffin Shortage After COVID-19 Outbreak.

The AP (3/29, Fung, Lo) reports, "Hong Kong's deadliest coronavirus outbreak has cost about 6,000 lives this year – and the city is now running out of coffins." Authorities are scrambling "to order more, with the government saying 1,200 coffins had reached the city last week with more to come." In the meantime, "some companies are offering alternatives such as an environmentally friendly cardboard coffin."

Medicago's COVID-19 Vaccine Facing Limited Growth After WHO Refuses To Review It Due To Philip Morris Ties.

Reuters (3/27, Khandekar, Roy) reported, "Canadian vaccine maker Medicago's COVID-19 vaccine, approved last month in Canada, is facing limited growth in the near-term after the World Health Organization said it would not review the vaccine because the company is partly owned by US-Swiss tobacco company Philip Morris, health experts say." Canada "defended its authorization of the vaccine, saying it needs a domestic bio-manufacturing industry to prepare for future pandemics."

Endpoints News (3/28, DeFeudis) also covers the story.

UK Study To Test Pfizer's COVID-19 Pill In Hospitalized Patients.

Reuters (3/28, A, Aripaka) reports that Pfizer's "oral COVID-19 therapy will be evaluated as a potential treatment for patients hospitalized with the illness in a major British trial, scientists said on Monday, as cases rise in some parts of the world." According to Reuters, "The world's largest randomized study of potential medicines for COVID-19, dubbed the RECOVERY trial, will assess Paxlovid [nirmatrelvir and ritonavir] across hospitals in Britain, which has already approved the drug for early-stage treatment."

German Chancellor Says He Disagrees With Planned IP Waiver For COVID-19 Vaccines.

Reuters (3/28, Szymanska) reports, "German Chancellor Olaf Scholz said on Monday he did not agree with a planned intellectual property waiver for COVID-19 vaccines as patents are a crucial way of encouraging companies to continue pushing ahead with new research." Scholz "said that a better way of making vaccines accessible in emerging economies would be to transfer vaccine production facilities to Africa."

FDA Pauses Distribution Of GSK, Vir's COVID-19 Antibody Drug In The Northeast.

FiercePharma (3/28, Dunleavy, 12K) reports that the FDA on Friday "paused the distribution of GlaxoSmithKline and Vir Biotechnology's antibody drug Xevudy [sotrovimab] in the northeast, where the omicron subvariant BA.2 now accounts for more than half of new infections." According to FiercePharma, "Lab testing shows that a 500-mg dose of Xevudy is not 'fully active' against the BA.2 variant, the FDA said." Vir responded that it is "preparing a package of data in support of a higher dose of sotrovimab for the omicron BA.2 variant and will be sharing these data with regulatory and health authorities around the world."

Also reporting are Endpoints News (3/28, Brennan) and BioPharma Dive (3/28, Fidler).

Therapeutic Antivirals Nirmatrelvir/Ritonavir And Molnupiravir Reportedly Have Potential To Change COVID-19 Pandemic.

Vox (3/28, Courage, 1.88M) reported that New York City in January "launched a program to provide COVID-19 treatments to residents at high risk of being hospitalized or killed by the virus – delivered free, to their door." The launch "was a potentially revolutionary moment in the pandemic's trajectory, possible only because, at the close of 2021, the US Food and Drug Administration granted emergency authorization to the first two oral antiviral drugs people can take, at home upon COVID-19 diagnosis, before they get sick enough to be hospitalized." Vox adds, "Paxlovid [nirmatrelvir and ritonavir] and molnupiravir, two therapeutic antivirals shown in studies to have varying levels of effectiveness in stunting COVID-19's dangers for those most at risk, represent a new weapon against" COVID-19. Vox adds, "The new oral antivirals...have the potential to reshape the contours of the pandemic going forward – not just for those at high risk, but also in surprising ways for those who aren't."

Shanghai Goes Into COVID-19 Lockdown, Reversing Weeks Of Denying It Would Impose Blanket Restrictions.

The Washington Post (3/28, Shepherd, Chiang, 10.52M) reports, "Late on Sunday evening, the Chinese financial hub of Shanghai announced it was going into lockdown, one half at a time, reversing weeks of denying it would impose blanket restrictions on the city's 25 million residents." The arrival of the highly infections omicron coronavirus variant, for much of the world, "has cemented acceptance

that the virus is here to stay and should be mitigated but tolerated." But in China, "rising case numbers appear to be reinforcing policies to smother the virus rather than accelerating plans to gradually ease restrictions."

The Wall Street Journal (3/28, Khan, Fan, Subscription Publication, 8.41M) reports that after announcing the COVID-19 lockdown, Shanghai reported a record 3,500 coronavirus cases as infections have doubled every few days. On Monday, numerous bus lines and metro services were halted and barricades were erected splitting up the city.

The AP (3/28) reports that Shanghai's lockdown "will be China's most extensive since the central city of Wuhan, where the virus was first detected in late 2019, confined its 11 million people to their homes for 76 days in early 2020." The Pudong financial district in Shanghai and "nearby areas will be locked down from Monday to Friday as mass testing gets underway, the local government said." On Friday, the second phase of the lockdown is scheduled to begin with "the vast downtown area west of the Huangpu River that divides the city."

Reuters (3/29, Shen, Stanway) reports, "China's financial hub of Shanghai reported a record 4,381 asymptomatic COVID-19 cases and 96 symptomatic cases for March 28, the city government said on its official WeChat account on Tuesday."

Bloomberg (3/29, 3.57M) reports, "All residents in the Pudong District, home to many elite financial institutions and the Shanghai Stock Exchange, will be confined to their homes and allowed out only to get a COVID test, according to a statement issued by the area's residential compounds reviewed by Bloomberg News."

The Christian Science Monitor (3/28, Tyson, 234K) reports that some residents are criticizing the lockdown, saying it is not necessary. One resident said, "Omicron has limited harm to our health. Our megacity should not come to a standstill!"

The Hill (3/28, Choi, 5.69M) also covers the story.

South Korea's Daily New COVID-19 Case Average Declined Last Week For First Time In Two Months, Officials Say.

The AP (3/28, Wilner) reports, "South Korea's daily average of new COVID-19 cases declined last week for the first time in more than two months, but the number of critically ill patients and deaths will likely continue to rise amid the omicron-driven outbreak, officials said Monday." The country "reported an

average of about 350,000 new cases last week, the Korea Disease Control and Prevention Agency said Monday." KDCA Commissioner Jeong Eun-kyeong said the numbers were "the first drop in the weekly average in 11 weeks." Citing expert studies, Jeong said that "the current outbreak has likely peaked and is expected to trend downward."

G20 Chair Indonesia Starts Talks With Members On Standardizing Health Protocols For Travel, Health Minister Says.

Reuters (3/28, Widianto) reports, "Group of 20 major economies (G20) chair Indonesia has started talks with members on standardizing health protocols for travel, its health minister said on Monday, stressing the importance of harmonizing rules and technology as global travel resumes." Budi Gunadi Sadikin told a news conference at a G20 health meeting in Yogyakarta, "Every person on this earth who travels... can do so more efficiently." Setiaji, an aide to Indonesia's health minister, "said countries were getting ready to roll out a global website to scan and verify travelers' vaccination status."

Commentary: Global Vaccination Against COVID-19 Almost Certain Not To Reach President Biden's Goal.

In a commentary for Nature (3/28, 194K), Thomas J. Bollyky, Jennifer Nuzzo, Noelle Huhn, Samantha Kiernan and Emily Pond write, "Last September, more than 100 governments attending US President Joe Biden's virtual Global COVID-19 Summit committed to vaccinating at least 70% of the population in every country by September 2022." The writers say, "Using national vaccination rates from mid-February, we estimate that nearly 100 countries will fall short of that objective." The writers continue, "Those missing the target include four out of five African nations, and most countries in Central America and the Middle East." The writers say, "In fact, at current vaccination rates, it will take until 15 July for 75% of high-income nations to fully vaccinate 70% of their populations." The FDA is mentioned in this story.

CDC Eases COVID-19 Travel Ratings For India.

Reuters (3/28, Shepardson) reports, "The US Centers for Disease Control and Prevention (CDC) and State Department eased government COVID-19 travel ratings for India and some other countries on Monday." It "had changed its COVID-19 travel recommendation for India to 'Level 1: Low' from 'Level 3: High,'

which urges unvaccinated Americans to avoid travel to those locations." The agency "also lowered Chad, Guinea and Namibia to 'Level 1.'"

The Hill (3/28, Rai, 5.69M) reports, "Despite easing the travel warning, the CDC recommends that travelers be up to date on their COVID-19 vaccines before traveling to India." The agency "classifies someone as 'up to date' if they have completed their primary series and received their booster dose."

Global COVID-19 Vaccines Face Waning Demand.

Bloomberg (3/28, Kay, Makol, 3.57M) reports, "After racing to build capacity and meet once seemingly insatiable orders for COVID-19 shots, the global vaccine industry is facing waning demand as many late-to-market producers fight over a slowing market." The waning demand "is poised to rein in the blockbuster sales that global pharmaceutical giants from Pfizer Inc. to AstraZeneca Plc saw at the peak of the pandemic." The situation "also stands to create new problems for local manufacturers from India to Indonesia that built mammoth capacity to make shots but are now grappling with excess supply."

Latina Health Access Promotores Work To Convince People To Get COVID-19 Vaccine.

The Los Angeles Times (3/28, 3.37M) reports that Socorro Juarez has promoted getting the COVID-19 vaccine as one "of nearly 100 promotores – Spanish-speaking community health workers – who operate in predominantly Latino neighborhoods in Orange County." The promotores "have earned the trust of many Spanish-speaking communities in the county by going directly to people – oftentimes walking door-to-door – to offer health services to low-income residents in some of Santa Ana's densest areas." Juarez was unable to convince her sister to get vaccinated before her sister got COVID-19, and now works to convince others to get vaccinated.

Number Of Cases Of Early Puberty Among Girls Has Surged During Pandemic, Physicians Say.

The Washington Post (3/28, Changoiwala, 10.52M) reports that the rate of children having early puberty has increased during the COVID-19 pandemic, especially among young girls. The phenomenon has been seen globally and experts have "pointed to two pandemic-related factors that could have led to the increased incidence of precocious puberty among girls: obesity resulting from

decreased physical activity during the lockdowns and increased exposure to endocrine-disrupting chemicals (EDCs) at home."

White House Spokesperson Tests Positive For COVID-19 After Trip To Europe With Biden.

The AP (3/28) reports, "White House spokeswoman Karine Jean-Pierre said she tested positive for COVID-19 on Sunday after returning from Europe with President Joe Biden, in the latest infiltration of the coronavirus into the West Wing's protective bubble around Biden." However, "the White House said Biden, 79, last tested negative for COVID-19 before returning to the U.S. from the trip as part of required pre-arrival testing."

NPR (3/28, Archie, 3.69M) reports, "Jean-Pierre said she saw Biden at a meeting Saturday, but they were socially distanced, and he would not be considered a close contact by the Centers of Disease Control and Prevention." Jean-Pierre also "said she will be working from home and isolated for a minimum of five days, per CDC recommendations, and return to the White House when she receives a negative coronavirus test."

Fauci Discusses Necessity Of Fourth COVID-19 Vaccine Dose.

During an interview with WUSA-TV Washington (3/28, Arnold, 502K), NIAID Director Dr. Anthony Fauci discusses whether "everyone will need a fourth COVID vaccine dose to protect themselves." He said, "I don't think we're going to see a recommendation for everybody I'm talking about in the immediate future." However, Fauci "added that there is 'no doubt' that those who are immunocompromised should get a fourth dose at some point."

Biden Administration Stresses Importance Of Mitigating Indoor Aerosol Transmission Amid New COVID-19 Phase.

The New York Times (3/28, Hassan, 20.6M) reports, "With the pandemic entering a new phase in the United States marked by fewer precautions and the rise of the even more transmissible Omicron subvariant BA.2, the Biden administration has begun stressing the importance of mitigating the risk of indoor aerosol transmission, the primary driver of the pandemic." Recently, the Environmental Protection Agency "issued expert guidance to building managers, contractors and business owners, with two pages of recommendations that codify the best practices on ventilation, air filtration and air disinfection from academic experts and federal agencies of the last two years."

Biden Administration May Have Difficulty Convincing People To Get Second COVID-19 Booster Shot.

The Hill (3/28, Weixel, 5.69M) reports, "The expected green light for a second coronavirus booster shot poses a challenge to the Biden administration, which will need to work overtime to convince a public that has largely decided to move on from the COVID-19 pandemic." Issues the Administration faced "during the first booster campaign loom large, and officials are likely eager to avoid the same pitfalls." However, "the underlying disagreement about the goal of booster shots has not changed." This may complicate recommendations, "which experts said helped depress enthusiasm" during the first round of boosters.

Former FDA Chief Predicts Federal Public Transportation Mask Mandates Will End Next Month.

The New York Post (3/28, Miller, 7.45M) reports that on Wednesday, former FDA Chief Dr. Scott Gottlieb predicted "that the federal mask mandate for airplanes and other public transportation will be lifted next month if the US isn't battling a COVID-19 surge fueled by the highly contagious Omicron subvariant BA.2."

FDA May Soon Approve Second COVID-19 Booster Shot For Those 50 And Older.

USA Today (3/28, Rodriguez, Weintraub, 12.7M) reports, "Everyone 50 and older could soon be eligible for an additional COVID-19 vaccine at least four months after their booster shot." Multiple reports say the FDA "is likely to approve that extra shot as soon as Tuesday." However, "some health experts questioned the focus on a fourth dose when many people still haven't had earlier doses, when cases are near historic lows and before there's solid data supporting the need for another shot and for whom."

ABC World News Tonight (3/28, 6:43 p.m. EST, story 4, 2:00, Muir, 7.25M) reported that "next Wednesday, the FDA will weigh a second booster shot for the rest of Americans, along with the need for a variant-specific booster."

US News & World Report (3/28, Smith-Schoenwalder, 1.91M) also covers the story.

Flight Attendants Sue CDC Over Federal Mask Mandate On Public Transportation.

The Washington Times (3/28, Howell, 626K) reports, "Nine flight attendants from six states said Monday they are suing the Centers for Disease Control and Prevention over the federal mask mandate on public transportation, arguing the COVID-19 rule obstructs their normal breathing over many hours and threatens aviation security because passengers refuse to comply." The plaintiffs "want a judge to vacate the rule...and prevent the CDC and the Department of Health and Human Services from issuing such a mandate again."

Op-Ed: Dysfunction Affects Health Providers, Patients Every Day.

In an op-ed for the Washington Post (3/28, Ranney, 10.52M), Brown University School of Public Health Academic Dean Megan Ranney writes, "In reality, our health-care system is in no better shape today than it was two years ago – and, in fact, it might be in worse condition. ... But never, in my 20 years of practice, have I seen the kind of dysfunction – day in and day out – currently afflicting providers and patients." She adds, "We must not forget the lessons from the early days of the pandemic." Ranney concludes, "Let's invest in health care and public health, now."

Hundreds Of Billions In Pandemic Assistance Dollars "Lost To Fraud."

NBC Nightly News (3/28, 6:45 p.m. EST, story 6, 3:45, Holt, 5.85M) reported, "Over the last two years, the federal government approved a historic $5 trillion in pandemic assistance for struggling Americans, small businesses and healthcare providers." However, "investigators say hundreds of billions have been lost to fraud."

People's Convoy Set To Leave DC To Protest COVID-19 Bills In California.

The AP (3/28, Boak) reports, "A group of truck drivers protesting COVID-19 mandates on roads and highways around the Washington, D.C., area in recent weeks will head to California next" to protest upcoming COVID-19-related bills. In an announcement, the People's Convoy said, "If passed, these bills set the stage for other states to introduce similar laws. ... This affects everyone!"

Michigan To Reduce COVID-19 Data Reporting Frequency.

The Detroit News (3/28, Rahal, 1.16M) reports that on Monday, Michigan's health department announced "it will scale back the frequency of COVID-19 data reporting as cases continue to decline." Beginning April 4, DHHS "will update its COVID-19 dashboard on Wednesdays, rather than three times a week."

The Detroit Free Press (3/28, Shamus, 2.16M) reports, "The change in the way the state will report cases and deaths going forward adheres to a national surveillance strategy created by the U.S. Centers for Disease Control and Prevention."

MLive (MI) (3/28, Salisbury, 828K) also covers the story.

Minnesota Launches Online Program Providing Free At-Home COVID-19 Tests.

The AP (3/28) reports that on Tuesday, "Minnesota is launching a new online program to provide free at-home rapid COVID-19 tests." Residents "can order two test kits per home for a total of four tests."

The Minneapolis Star Tribune (3/28, Olson, 855K) also covers the story.

Only 30% Of Los Angeles County Children Aged Five To 11 Fully Vaccinated Against COVID-19.

The Los Angeles Times (3/28, Do, 3.37M) reports that as of mid-March, "only 30% of children age[d] 5 to 11 were fully vaccinated" against COVID-19 in Los Angeles County. Meanwhile, "nearly 80% of teens and adults" are vaccinated – "a gap that echoes the national trend."

Omaha Revises Ordinance Stripping Health Director's Powers During A Pandemic.

The Omaha (NE) World-Herald (3/28, Wade, Anderson, 509K) reports, "A proposed Omaha city ordinance that would have stripped decision-making powers from the Douglas County health director during a pandemic has been revised, shifting authority back to the health director while keeping veto powers with the mayor and Omaha City Council as outlined earlier."

Columnist: Rural Texas Hospitals Still Looking For "Real Remedies" To Prevent Closures.

In his column for the Texas Tribune (3/28, 258K), Ross Ramsey writes, "From 2010-20, 26 hospitals in 22 Texas communities in rural Texas closed, according to the Texas Organization of Rural and Community Hospitals." He adds that "the persistent problems in rural health care in Texas return to legislative attention every two years, sometimes holding their ground but somehow never resulting in real remedies." However, Ramsey concludes, "Legislators are listening, even if they haven't figured it out."

Idaho Governor Vetoes Bill Banning Businesses From Requiring COVID-19 Vaccine.

The AP (3/28, Boone) reports, "Idaho Gov. Brad Little has vetoed legislation that would make it illegal for most businesses to require the coronavirus vaccine." The "'Coronavirus Pause Act' would have subjected public and private employers to a misdemeanor charge punishable by a $1,000 fine if they require vaccines as a condition of employment or service."

Saliva-Based COVID-19 Tests May Be More Sensitive Than Nasal-Swab Tests, Expert Says.

Scientific American (3/28, Warmack, 3.1M) reports, "COVID testing has advanced rapidly since early in the pandemic, when people had to get deep 'brain tickling' nasal swabs at a doctor's office and wait days for results." There is now "an array of saliva-based tests," which "are less invasive, can be processed faster and, in some cases, are more sensitive than nasal-based assays." University of Illinois Infectious Disease Epidemiologist Rebecca Lee Smith said, "Saliva-based PCR tests are very sensitive, and they can actually pick up infections before you're infectious." These tests "are as sensitive or even more sensitive than nasal-swab PCR assays."

Some People With Long COVID Not Ready To Go Back To The Office.

TIME (3/28, Ducharme, 18.1M) chronicles the stories of multiple Americans suffering from Long COVID and their thoughts on returning to the office. Many of these individuals are not ready to go back and feel pressured to do so. The article also discusses the millions of people across the US with "chronic illnesses or physical disabilities," and how "advocates have been calling for better workplace accommodations and federal disability policies since well before the pandemic."

MIT Reinstates Standardized Testing Requirements For Applicants.

Bloomberg (3/28, Lorin, 3.57M) reports, "The Massachusetts Institute of Technology is reinstating its standardized testing requirements, citing that most students are now able to access the exams safely." According to MIT, COVID-19 "vaccine availability and an increase in students taking tests at school have alleviated challenges that had made it especially difficult for high-schoolers to sit for the SAT and ACT during the pandemic."

Op-Ed: Fourth COVID-19 Vaccine Dose Not Necessary For Everyone.

In an op-ed for the Wall Street Journal (3/28, Subscription Publication, 8.41M), WHO Consultant Philip Krause and Council on Foreign Relations Global Health Senior Fellow Luciana Borio discuss the proposed fourth dose of COVID-19 vaccines. They suggest it is not necessary for people with healthy immune systems.

Commentary Warns US Will Be In "Far Weaker Position" Against COVID-19 If Congress Does Not Approve Additional Funds.

US Surgeon General Dr. Vivek Murthy and Dr. David A Kessler, chief science officer for the US COVID-19 Response Team and former FDA commissioner, write in a guest essay for the New York Times (3/29, 20.6M), "Over the last two years, the United States has made extraordinary progress in the fight against Covid-19," but "that progress is now threatened by Congress's failure to fund the continuing Covid-19 response effort." The government is "is running out of funds to provide Americans, especially those who are uninsured, with Covid-19 vaccines, tests and treatments," and "our efforts to sustain other critical elements of the public health response, from Covid-19 surveillance to the global vaccination campaign, are also now at risk." Murthy and Kessler say, "If adequate funding is provided, our country will be in a position of strength, well situated to manage Covid-19 and to adapt our response as future variants emerge." However, "if the funding does not materialize, we will find ourselves in a far weaker position, struggling to keep up with a constantly evolving virus that will continue to threaten our health, our economy and our peace of mind."

Racial, Ethnic Disparities In COVID-19's Toll "Likely To Worsen" Without New Pandemic Funds.

Politico (3/29, Messerly, Ollstein, 6.73M) reports, "Racial and ethnic disparities in Covid-19 infections, hospitalizations and deaths are likely to worsen if Congress does not soon approve billions in new pandemic funding." Public health experts, lawmakers and health officials all "say the White House's decision to scale back or suspend programs that provide free testing, treatments and vaccinations will disproportionately affect the tens of millions of uninsured Americans – a majority of whom are people of color."

Analysis: Russian Invasion Of Ukraine Has Doomed Sputnik V.

In an analysis for the Washington Post (3/29, 10.52M), columnist Adam Taylor writes, "Just a year ago, Moscow's quickly approved coronavirus vaccine, Sputnik V, looked to be in ascendance, casting off initial Western skepticism," after "the respected British medical journal the Lancet published a peer-reviewed paper that found the vaccine had high efficacy." Soon after, "dozens of countries would go on to grant emergency approval to Sputnik V." However, the vaccine was also "a vital tool for the Kremlin's geopolitical ambition," and "now looks like another victim of it." Emergency authorizations from the WHO and EU appear "as distant as ever," and China and India – which could "still work with Russia" – are likely to favor their own vaccines as sanctions impact the manufacturing and distribution of Sputnik V.

Unaccompanied Migrant Children

Biden Administration To Require COVID-19 Vaccine For Some Undocumented Immigrants.

The New York Times (3/28, Sullivan, 20.6M) reports, "The Biden administration is requiring coronavirus vaccines for some undocumented [im]migrants at the southwest border." Officials will vaccinate "undocumented [im]migrants without proof of vaccination who are apprehended by border officials." Meanwhile, "if single adults refuse to be vaccinated, they will be detained and put into deportation proceedings." Families that refuse vaccination "will be released with a monitoring device 'with stringent conditions.'" The Times says, "The administration has been offering vaccinations to eligible [im]migrant children in government shelters for months."

CNN (3/28, Alvarez, 89.21M) reports the Department of Homeland Security says it "will be able to initially provide up to 2,700 vaccines per day," and by the end of May will be able to administer 6,000 shots daily.

The Wall Street Journal (3/28, Hackman, Subscription Publication, 8.41M), CBS News (3/28, Montoya, 5.39M) and WTOP-FM Washington (3/29, 164K) also cover the story.

HHS in the News

HHS Resolves Four Enforcement Cases Over Providers' Disclosure Of Heath Data.

Bloomberg Law (3/28, Brown, Subscription Publication, 4K) reports, "The Department of Health and Human Services resolved four enforcement cases stemming from providers' disclosure of protected health data and failure to give patients timely access to their records, the agency announced Monday." Two of the cases "were part of the Office for Civil Rights' right-to-access initiative under the Health Insurance Portability and Accountability Act privacy rule, which seeks to guarantee patients' right to promptly see their records at a reasonable cost." The other two "cases involved health-care providers accused of improperly sharing patient information with third parties."

Healthcare IT News (3/28, Miliard, 2K) also covers the story.

Ten-Year Health Spending Estimates Expected To Increase Despite Drop In 2021, CMS Says.

The Wall Street Journal (3/28, Armour, Subscription Publication, 8.41M) reports US healthcare spending decreased to 4.2% in 2021 from 9.7% in 2020, according to the Centers for Medicare and Medicaid Services. The decline is due to less healthcare use and federal stimulus funds.

Bloomberg Law (3/28, Pugh, Subscription Publication, 4K) reports, "New 10-year health spending estimates released Monday by the Centers for Medicare and Medicaid Services expect national health spending to grow by nearly 5% a year through 2024 and by 5.3% annually from 2025 to 2030 as use of health services continues to normalize after the pandemic."

Fauci To Serve As Keynote Speaker At Roger Williams University Commencement.

The AP (3/28) reports, "Dr. Anthony Fauci, the face of the federal response to the coronavirus pandemic, will deliver the keynote address at Roger Williams University's commencement ceremony, the Rhode Island school announced Monday." The NIAID Director "will also receive an honorary degree at the May 20 exercise."

The Boston Globe (3/28, Fitzpatrick, 1.04M) reports Roger Williams President Ioannis N. Miaoulis said, "The ability to synthesize vast amounts of information and to make decisions that consider health, science, cultural, legal and political implications, is the type of education we strive to offer our students. ... Dr. Fauci's experience throughout his career, but especially over the last two years, has modeled how to do this exceptionally well and provides a real-world example to our students as they enter a complex world."

The Providence (RI) Journal (3/28, Perry, 376K), WLNE-TV Providence, RI (3/28, Dubois), and The Hill (3/28, Oshin, 5.69M) also cover the story.

Scientist Explains Natural Human Tendency To See Faces Everywhere.

The New York Times (3/29, Wollan, 20.6M) reports that Susan Wardle, a scientist at the Laboratory of Brain and Cognition at the National Institute of Mental Health, says that it is a natural tendency for humans to "see faces everywhere." Wardle "studies how and why people see illusory faces in objects, a phenomenon known as 'face pareidolia.'" According to Wardle, "You only need this minimal information to see a face because it's more adaptive to make a mistake and see a funny face in a cloud than to miss a real human face."

Clinical Sequencing May Lead To Diagnoses In Significant Subset Of Immune Conditions, NIAID Program Finds.

GenomeWeb (3/28, Anderson) reports, "Clinical sequencing may lead to molecular diagnoses in around one-third of families affected by undiagnosed immune conditions, new research suggests." NIAID Lead Genetic Counselor Morgan Similuk, on Friday, "presented findings from the first 1,000 immune disease-affected families participating in a clinical sequencing program at a[n] NIAID tertiary care center." The researchers concluded that "these genomic data will enrich our understanding of basic immunity, molecular diagnostics, and clinical care both for the 1,000 families included here, as well as many of the families who will be evaluated in the coming years."

FDA Oncology Chief Defends Rejection Of Eli Lilly, Innovent Cancer Drug.

FiercePharma (3/28, Liu, 12K) reports that the FDA has "declined to approve Eli Lilly and Innovent Biologics' China-developed immunotherapy sintilimab for certain lung cancer patients." According to FiercePharma, "Critics blame the FDA and its oncology chief Richard Pazdur, M.D., for closing the door to meaningful price reductions in the widely used PD-1 drug class, and some suspect that the agency is playing to the growing geopolitical tension between the US and China." Pazdur told FiercePharma that he is "not against China, that was not the implication here. ... It was a future-directing approach to what drug development should be."

Judge Orders Animal Food Company Bravo Packing To Halt Production Until It Meets FDA Safety Standards.

The Burlington County (NJ) Times (3/28, Walsh, 56K) reports, "A federal judge has ordered a South Jersey animal-food company to stop production until it makes sanitation improvements demanded by the U.S. Food and Drug Administration." Bravo Packing Inc. "must remove from the marketplace all products made since May 2021, a consent decree says." It also "must destroy 'under FDA supervision, all in-process and finished articles of pet food currently in their custody, control or possession,' it requires." The lawsuit "alleged samples collected by FDA inspectors in July 2019 and April 2021 contained salmonella and listeria monocytogenes, types of bacteria that can cause sometimes-deadly illnesses for animals and people." Steven Solomon, director of the FDA's Center for Veterinary Medicine, said Monday in a statement, "The food we give our pets should be safe for them to eat and safe for people to handle."

FDA Issues Review Raising Concerns Over Experimental Drug For ALS Treatment.

The AP (3/28, Perrone) reports the Food and Drug Administration "issued a negative review Monday of" Amylyx Pharmaceuticals' drug sodium phenylbutyrate/taurursodiol (AMX0035) for the treatment of amyotrophic lateral sclerosis (ALS), "after months of lobbying by patient advocates urging approval." The agency "said...that the company's small study was 'not persuasive,' due to missing data, errors in enrolling patients and other problems." The AP adds, "On Wednesday, a panel of FDA advisers will take a non-binding vote on whether the drug warrants approval."

Also reporting are FierceBiotech (3/28, Armstrong, 4K), Endpoints News (3/28), and STAT (3/28, Feuerstein, 262K).

Commentary Says Pandemic Exposed Issues In FDA, Industry Supply Chain For Blood Collection Tubes.

Senior contributor Jude Stone writes for Forbes (3/28, Stone, 10.33M), "Covid has again brought attention to supply chain issues, this time regarding shortages of blood collection tubes." She says, "It's surprising how something so seemingly mundane can have an outsized impact – and how difficult it is to get answers about from both industry and the FDA." The shortages are "widespread" and "affecting all types of tubes." Stone says, "This issue of vacutainer shortages is but one example of the problems of just-in-time inventories, short staffing as much as possible, and reliance on overseas production. We also need to do a better job educating the public and physicians about such shortages."

Analysis Examines Claims Of One-Sided Censorship By Social Media Platforms.

Fox News (3/29, Lanum, 23.99M) reports, "The Babylon Bee, a satirical conservative website, was locked out of its Twitter account last week after the tech company accused the Bee of violating its rules against 'hateful content' for a post jokingly naming Biden administration official Dr. Rachel Levine," a transgender woman, "the Bee's 2022 'Man of the Year.'" The next day, a New York Times podcast host "asserted there was 'no evidence' of political bias against conservatives occurring on social media platforms, a claim reiterated frequently by Democratic lawmakers and liberal media personalities." However, "speaking with Fox News Digital, Fox News contributor and 'The Federalist' editor-in-chief Mollie Hemingway said the notion that censorship hits both political parties equally simply because a few conservative outlets are allowed to exist on social media platforms is 'gaslighting in the extreme.'"

Overdose Prevention

Record Fentanyl Deaths Impact Local Families In California.

KNBC-TV Los Angeles (3/28, Lopez, Drechsler, 242K) reports, "Drug overdose deaths top 100,000 annually for the first time, driven by fentanyl, according to" provisional CDC data. While celebrities who died after overdosing on the powerful and synthetic drug fentanyl "make headlines, across Southern California similar tragedies are unfolding – sons and daughters – deaths rising at an alarming rate." According to the article, "The NBC4 I-Team analyzed data from the Centers for Disease Control and found since 2019 the number of overdose deaths caused by synthetic drugs in California is dramatically higher than cocaine and heroin. Nearly two thirds of annual overdose deaths [are] now connected to synthetic opioids, according to the CDC."

Mental Illness

New Studies Examine Mental Health Toll Of Cancer.

The New York Times (3/28, Wapner, 20.6M) reports on two new studies "that quantify the psychological burden of cancer in fine detail, pulling from much larger data sets than previous research." The findings, published Monday, "make a compelling case for oncologists to have more discussions with their patients

about mental health struggles." One "analysis showed that the suicide rate was 85 percent higher for people with cancer than the general population." The other study "yielded some surprising findings. For example, testicular cancer carried a higher risk of depression than any other cancer type, affecting 98 of every 100 patients." Dr. Alan Valentine, chair of the psychiatry department at M.D. Anderson Cancer Center in Houston, said, "That's slightly counterintuitive – it's one of the better prognosis forms of cancer." Furthermore, "because studies assessing mental health are typically based on questionnaires that rely on self-reporting, the data probably underrepresents reality, noted Wendy Balliet, a clinical psychologist at the Hollings Cancer Center at the Medical University of South Carolina in Charleston."

Georgia Senate Advances Updated Version Of Mental Healthcare Bill.

The AP (3/28) reports, "A state Senate committee on Monday advanced a version of a sweeping bill that aims to improve Georgia's dismal mental health care system." The bill "seeks to ensure that insurers provide the same level of benefits for mental health disorders as they do for physical illness." It also would "provide forgivable loans for people who become mental health workers." The committee "on Monday approved changes to a section that tries to make sure insurers provide the same level of benefits for depression, anxiety and other mental disorders as they do for other medical conditions." It also "changed a section aimed at forcing people into treatment."

The Atlanta Journal-Constitution (3/28, Prabhu, 1.46M) also reports.

Investigation Examines Former New York Governor's "Transformation Plan" For Children's Mental Healthcare.

ProPublica (3/28, Kramer, Blesener, 235K) reports, "Unlike private hospitals, where clinicians say the length of a standard psychiatric stay has shrunk in recent decades to not much more than a week, New York's state-run hospitals are designed to provide longer-term, high-level care to people who are experiencing a mental health crisis." However, "under a 'Transformation Plan' launched in 2014 by then-Gov. Andrew Cuomo, the state of New York has cut nearly a third of state psychiatric hospital beds reserved for children." The plan "shifted the savings into community-based and outpatient mental health programs that were supposed to prevent kids from needing to be hospitalized in the first place," but "eight years later, children...who are experiencing mental health emergencies find it harder to

get hospital care when they need it, an investigation by THE CITY and ProPublica has found."

Article Examines Financial Toll Of Becoming Mental Healthcare Clinician.

The Boston Globe (3/28, Freyer, 1.04M) reports, "At a time when people wait weeks or months for mental health treatment, when emergency rooms are filling with youngsters in psychiatric crises that might have been averted by outpatient care, when officials everywhere lament the rising tide of post-pandemic mental illness, the people training to be therapists confront one hurdle after another." Though "psychiatrists and psychologists play critical roles, social workers and mental health counselors provide most of the one-on-one therapy." Their coursework "differs somewhat, but the clinical training is similar. Both have to work hundreds of hours at internships, almost always unpaid, while attending school." The article further examines the financial toll required to become a mental healthcare clinician, as well as the low pay often found in the sector.

State Task Force Tells Connecticut Lawmakers Psychiatric Hospital Still Needs "Significant Improvements."

The AP (3/28, Collins) reports, "Five years after a patient abuse scandal, Connecticut's only maximum-security psychiatric hospital still needs significant improvements to its treatment programs, staff behaviors and oversight, members of a state task force told lawmakers Monday." Panel members "also told the Public Health Committee that Whiting Forensic Hospital in Middletown needs to be moved into an entirely new building because the current hospital is inadequately designed for psychiatric care and is in disrepair." The majority of the task force also "called for the elimination of the Psychiatric Security Review Board, which decides when Whiting patients can be released or transferred to other facilities, and allowing hospital staff to make some of those decisions."

Prescription Drug Pricing

Kentucky Bill To Curb PBMS Arrives At Likely Dead End.

The Louisville (KY) Courier-Journal (3/28, Yetter, 554K) reports a bill supported by Kentucky pharmacists that would seek to curb the powers of pharmacy benefit managers (PBMs) "has been consigned to the Senate Appropriations and Revenue Committee – often a dead-end for legislation." According to the Journal, "It follows a law the legislature enacted in 2020 cutting PBMs out of the state's $1.7

billion-a-year Medicaid prescription drug program amid complaints from pharmacists that PBMs were profiting at their expense."

Health Care & Insurance Reform

State-Based Marketplace Enrollees To Face Higher Premiums Without Extension Of Subsidies Under ARPA.

HealthPayerIntelligence (3/28, Bailey) reports, "If federal officials do not extend the enhanced premium subsidies under the American Rescue Plan Act (ARPA), state-based marketplace enrollees will face higher premiums and may lose coverage in 2023, according to data from the National Academy for State Health Policy (NASHP)." In March 2021, the Biden Administration passed the American Rescue Plan Act, "which increased premium tax credits for individuals receiving healthcare coverage on the Affordable Care Act marketplace." ARPA "also expanded tax credit eligibility to more middle-income individuals." But "the ARPA subsidies currently expire on December 31, 2022."

More Than 40 Percent Of US Hospital ERs Overseen By For-Profit Healthcare Staffing Companies Owned By Private-Equity Firms.

NBC News (3/28, Morgenson, 4.91M) reports, "Today, an estimated 40-plus percent of the nation's hospital emergency departments are overseen by for-profit health care staffing companies owned by private-equity firms, academic research, regulatory filings and internal documents show." According to their websites and press releases, two of the largest "are Envision Healthcare, owned by KKR, and TeamHealth, of the Blackstone Group. EmCare, the health care staffing company that managed Brovont, is part of Envision." In recent years, "private-equity firms have taken over a broad swath of health care entities in recent years." The firms "use large amounts of debt to acquire companies, aiming to increase their profits quickly so they can resell them at a gain in a few years." HHS is mentioned in this story.

Op-Ed: Overregulating Pay Of Nurses Would Be A Mistake.

In an op-ed for The Hill (3/28, 5.69M), Hadley Health Manning, policy director at Independent Women's Forum, writes, "The main lesson we should be learning about nursing" in response to the ACA passed 12 years ago and the COVID-19 pandemic – "a critical part of any hospital's labor supply – is that the market can work both to reward nurses for their heroic work and to keep patients safe."

Manning writes, "Sadly, there are efforts afoot to overregulate nurse pay and working conditions." Manning concludes, "This would be a mistake."

While Democrat-Led States Are Proposing Laws To Shore Up Abortion Rights, 41 States Have Introduced 519 Abortion Restrictions This Year.

NPR (3/28, Diaz, 3.69M) reports, "As the country awaits the US Supreme Court's decision on a case that could overturn Roe v. Wade, Democrat-led states are proposing laws to shore up abortion rights at the local level." The efforts of the Democrat-led states "is in direct response to the organized campaign to make abortion illegal." On the other hand, according to the Guttmacher Institute, a supporter of abortion rights, 41 states have introduced 519 abortion restrictions in 2022 "as the country awaits the Supreme Court's decision."

Colorado Braces For Increasing Number Of Out-Of-State Residents Seeking Abortions If Roe V. Wade Overturned, Weakened.

Kaiser Health News (3/29, Bichell) reports, "With the Supreme Court expected to overturn or severely weaken its landmark Roe v. Wade decision, clinics in Colorado are preparing for an increase in the number of out-of-state residents seeking abortions, and lawmakers are cementing abortion access protections in state law." Colorado is one of a few US states "without any restrictions on when in pregnancy an abortion can occur and is one of the few states in the region without a mandatory waiting period of up to 72 hours after required abortion counseling." If the Supreme Court overturns "the 49-year-old decision that protects the right to an abortion, the expectation is that the demand for abortions in Colorado from people who live in those nearby states where abortion is being restricted will rise."

Health Information Technology

Female Physicians Spend More Time On EHR Clinical Documentation Than Male Counterparts, Study Indicates.

EHR Intelligence (3/28, Nelson) reports "female physicians spent more time on EHR clinical documentation compared to their male counterparts, according to" findings of a "cross-sectional study in a large ambulatory practice network." The findings published in JAMA Network Open revealed "that clinical documentation is the primary activity driving gender differences in EHR time."

Human Services News

New York City Mayor Calls For Increasing Investment In State Budget For Child Care, Early Childhood Education.

The New York Post (3/28, Bamberger, 7.45M) reports that New York City "Mayor Eric Adams took up what he called 'a real battle' on Monday to increase access to quality child care." The mayor also "echoed calls for increased investment in the state budget for early childhood education." Taking these actions "would help women in particular, who are disproportionately impacted when child-care issues arise and they're faced with either staying home or leaving their jobs, according to the mayor."

New AI-Using Tools Assist Students With Autism, Dyslexia And Address Accessibility For Blind, Deaf.

The New York Times (3/29, Tugend, 20.6M) reports on new tools, which all incorporate artificial intelligence, that "assist students with autism and dyslexia and address accessibility for those who are blind or deaf." These tools, including social robots, "aim to find better ways to detect, teach and assist those with learning disabilities. Some are already in classrooms; others are still in the research phase." According to the Times, "The robots come in a variety of designs, including a small boy, a classic sci-fi machine and a furry snowman, and they go by peppy names such as Kaspar, Nao and Zeno."

Disability Services Providers Struggle With Ongoing Labor Shortage.

The Houston Chronicle (3/28, Carballo, 982K) reports a "shortage of personal aides to care for people with intellectual and developmental disabilities" is causing providers "to stop taking referrals, delay the implementation of new programs, and in some instances, halt services altogether." Turnover was 46% in Texas in 2020, "compared to 43.6 nationally," and vacancy rates for the positions rose to 12%. Industry experts cite pay as a common factor for the shortage. The Texas "Medicaid program provides enough for a base pay of about $8 an hour," while "restaurants paying as much as $15 an hour."

Nursing Home Spending To Reach $273B In 2030, CMS Estimates.

Skilled Nursing News (3/28, Stulick) reports nursing home spending will "experience an increase in expenditures from $174.2 billion in 2019 to $273 billion in 2030," according to the CMS Office of the Actuary, as federal aid

declines from pandemic highs. John Poisal, deputy director of the National Health Statistics Group, explained that the agency's "expectation is that other federal programs and public health activity begin to normalize and decline from these all time highs that were reached in 2020." At the same time, the industry will "transition back to the traditional drivers of health spending, we get back to economic, demographic and health-specific factors."

CODA, Film Starring Actors With Disabilities, Wins Best Picture.

Disability Scoop (3/29) reports CODA, "a film predominantly featuring people with disabilities," made history at the Oscars over the weekend, winning the award for Best Picture. Advocates are calling the recognition "a major win for disability representation in Hollywood." Troy Kotsur "became the first deaf male actor to receive an Academy Award," joining CODA co-star Marlee Matlin, who was also "the first deaf performer to win an Academy Award in 1987."

The Los Angeles Times (3/28, 3.37M) reports Matlin said "the recognition that Troy got last night is long overdue – that people recognize his work, our work." While "people are much more aware of Deaf culture and sign language" as a result of the film's success, Matlin added that it "doesn't mean you're going to blow open the doors. It's up to us to keep making it happen. We have to put the welcome mat out there and work."

Editorial: Getting Federal Court-Appointed Monitor To Oversee Reform Usually Best Possible Outcome.

The Newark (NJ) Star-Ledger (3/28, 1.89M) editorializes, "When states mess up badly, the most constructive road forward is often a federal lawsuit, as we saw with efforts to end the racial profiling of motorists by the New Jersey State Police, abuses by Newark cops and rampant sexual violence at Edna Mahan prison." The board says, "In almost every case, the state fights in court, whether out of pride or political damage control." The board concludes, "But getting a federal court-appointed monitor to oversee reform is usually the best possible outcome, as we see once again with the incredible progress of New Jersey's child welfare agency."

Food & Import Safety

Consumer Reports Shares "Reassuring" Results From Frozen Vegetable Safety Tests.

Consumer Reports (CR) writes in the Washington Post (3/28, 10.52M) about food safety and frozen vegetables. The organization says "though frozen produce is convenient and generally safe, it may still harbor bacteria that cause foodborne illness such as Listeria monocytogenes or salmonella." In 2016, "more than 450 frozen produce items from at least 42 brands" were recalled "because they were linked to a multistate outbreak of listeriosis, the disease caused by Listeria monocytogenes. Since then, frozen fruits and vegetables have been recalled at least 20 times because of possible contamination with listeria, hepatitis A or norovirus, according to data from the Food and Drug Administration." With "this history in mind," CR's scientists conducted tests "included 369 items from big brands, private label and store brands," and the "results were reassuring" as they "didn't find any harmful bacteria."

Dried Sweetened Strawberries Snack Recalled From Target For Undeclared Sulfites.

The Miami Herald (3/28, Neal, 647K) reports, "Two lots of Target's store brand of dried sweetened strawberries, Good & Gather, got recalled for having sulfites that aren't declared on the packaging." Manufacturer SunTree Snack Foods said, "People who have an allergy or severe sensitivity to sulfites run the risk of serious or life-threatening allergic reaction if they consume these products."

Health & Medical News

Patients, Particularly Women And People Of Color, Calling Attention To "Medical Gaslighting."

The New York Times (3/28, Moyer, 20.6M) reports "research suggests that diagnostic errors occur in up to one out of every seven encounters between a" physician and patient, and "women are more likely to be misdiagnosed than men in a variety of situations." Now, "patients who have felt that their symptoms were inappropriately dismissed as minor or primarily psychological by" physicians "are using the term 'medical gaslighting' to describe their experiences and" share their stories across platforms. The article adds, "Today – thanks in large part to a law passed in 1993 that mandated that women and minorities be included in medical research funded by the National Institutes of Health – women are more systematically included in studies, yet there are still huge knowledge gaps."

Prediabetes Prevalence More Than Doubled Among US Youth From 1999 To 2018, Data Indicate.

CNN (3/28, Holcombe, 89.21M) reports rates of prediabetes among US "children have more than doubled in about 20 years, according to" data from the "Centers for Disease Control and Prevention's National Health and Nutrition Examination Survey from 1999 to 2018." During that timeframe, "the rate of prediabetes in adolescents went from 11.6% to 28.2%." This "increase was seen over almost all subpopulations of young Americans, regardless of income, ethnicity and education, said" one study author. The data were published in JAMA Pediatrics.

Billionaire Former CEO Of Google Plays "Extraordinary" Role Shaping White House Office Of Science And Technology Policy.

Politico (3/28, Thompson, 6.73M) reports, "A foundation controlled by Eric Schmidt, the multi-billionaire former CEO of Google, has played an extraordinary, albeit private, role in shaping the White House Office of Science and Technology Policy over the past year." No fewer "than a dozen officials in the 140-person White House office have been associates of Schmidt's, including some current and former Schmidt employees, according to interviews with current and former staff members and internal emails obtained by POLITICO." He "maintained a close relationship with the president's former science adviser, Eric Lander, and other Biden appointees." Schmidt's "charity arm, Schmidt Futures, indirectly paid the salaries of two science-office employees, including, for six weeks, that of the current chief of staff, Marc Aidinoff, who is now one of the most senior officials in the office following Lander's resignation in February."

First Lady Visits St. Jude To Promote Cancer Moonshot Initiative.

The Memphis (TN) Business Journal (3/28, Airy, Subscription Publication, 855K) reports "one of the big reasons behind" First Lady Jill Biden's visit to St. Jude Children's Research Hospital in "Memphis was to promote the Biden administration's Cancer Moonshot initiative." According to St. Jude's Comprehensive Cancer Center Director Dr. Charles Roberts, "there is significant research at St. Jude that is either stimulated, funded, or aligned with the principles of the Cancer Moonshot initiative." He added, "We launched a program a year ago that has rapidly become one of the largest academic endeavors in HPV cancer prevention," and "this year, [St. Jude] led all 71 NCI cancer centers and

seven other groups in an HPV prevention initiative, helping doctors get back on their feet with vaccinations because of the impact of the pandemic."

Oregon Ends Residency Requirement For Medically Assisted Suicide.

The AP (3/29, Johnson) reports, "Oregon will no longer require people to be residents of the state to use its law allowing terminally ill people to receive lethal medication, after a lawsuit challenged the requirement as unconstitutional." In a settlement filed Monday, "the Oregon Health Authority and the Oregon Medical Board agreed to stop enforcing the residency requirement and to ask the Legislature to remove it from the law." Advocates "said they would use the settlement to press the eight other states and Washington, D.C., with medically assisted suicide laws to drop their residency requirements as well."

Fresenius Files Federal Complaint Over Patent Infringement For Rare Thyroid Disease Drug.

Bloomberg Law (3/28, Subscription Publication, 4K) reports behind a paywall, "Fresenius SE & Co. filed a new federal complaint alleging Zydus Lifesciences Ltd.'s proposed generic version of an injectable treatment for myxedema coma, a rare and life-threatening condition in patients with chronic severe untreated hypothyroidism, infringes three Fresenius patents for its levothyroxine sodium powder for injection." Fresenius "received a letter from Zydus saying the generic-drug maker had amended its application for U.S. Food and Drug Administration approval of its copycat to add a dosage that wasn't among the strengths included in Zydus' first notice on Feb. 7, according to a complaint."

Rural Hospitals Face Obstacles Providing Prenatal Care, Obstetricians For Pregnant Women.

The CBS Evening News (3/28, 6:43 p.m. EST, story 8, 2:00, O'Donnell, 4.28M) reported, "More than 2 million pregnant women live in the US in counties with no access to prenatal care or obstetricians." Correspondent Janet Shamlian reported on Kaylie Samuelwitz who "lives in Pampa, Texas, a rural city of 17,000, where the local hospital closed its labor and delivery unit." Shamlian said, "Fewer than half of rural Texas hospitals now deliver babies, creating what's called maternity deserts. One of the biggest factors: a shortage of nurses heightened by the pandemic. Cost is also an issue."

Study Identifies Two Periods Of Adolescence When Heavy Social Media Use May Spur Lower Ratings Of "Life Satisfaction."

The New York Times (3/28, Hughes, 20.6M) reports, "Analyzing survey responses of more than 84,000 people of all ages in Britain," investigators have "identified two distinct periods of adolescence when heavy use of social media spurred lower ratings of 'life satisfaction': first around puberty – ages 11 to 13 for girls, and 14 to 15 for boys – and then again for both sexes around age 19." The findings were published online March 28 in the journal Nature.

Scientists Expect West Nile Virus Transmission To Increase Across US Due To Climate Change.

Kaiser Health News (3/28, Bailey) reports the rise in cases of the West Nile virus in Colorado last year "may be a sign of what's to come: As climate change brings more drought and pushes temperatures toward what is termed the 'Goldilocks zone' for mosquitoes...scientists expect West Nile transmission to increase across the country." According to a United Nations climate report, "changes in climate have already been identified as drivers of West Nile infections in southeastern Europe." Though "most West Nile infections are mild, the virus is neuroinvasive in about 1 in 150 cases, causing serious illness that can lead to swelling in the brain or spinal cord, paralysis, or death, according to the Centers for Disease Control and Prevention."

"Fragmented" Regulatory Framework Complicating Sodium Chloride Shortage, Experts Say.

Modern Healthcare (3/28, Kacik, Subscription Publication, 215K) reports, "Different regulations for pharmaceuticals and medical devices are complicating the sodium chloride shortage." Nearly "60% of hospitals' requests for sodium chloride were not being filled as of Thursday, according to the group purchasing and consulting organization Premier." The vials and syringes hospitals "use to administer saline are classified as medical devices while the bags and solution are regulated as drugs." The FDA "has more authority over the pharmaceutical supply chain than the medical device sector." This "fragmented regulatory framework has made it harder to collect data, implement workarounds and guide conservation strategies, supply chain experts said."

Milk Of Magnesia, Generic Tylenol Sent To Nursing Homes Recalled Due To Contamination.

The Miami Herald (3/28, Neal, 647K) reports, "Ten lots of three oral drugs shipped to hospitals, nursing home and clinics nationwide have been recalled for 'microbial contamination and failure to properly investigate failed microbial testing.'" That information is "in the FDA-posted recall alert from Plastikon Healthcare, manufacturer of the medications for the Major Pharmaceuticals brand."

Florida Lacks Enough Geriatricians To Handle Increasing Number Of Alzheimer's Cases, Report Finds.

The Orlando (FL) Sentinel (3/28, Catherman, 599K) reports, "Florida has the second-highest number of Alzheimer's patients over 65 after California: 580,000." Furthermore, "by 2025, the number of Florida residents with Alzheimer's is expected to increase by about 24%, according to the Alzheimer's Association 2022 Alzheimer's Disease Facts and Figures report, released March 15." Florida has 362 geriatricians, "which is not enough to treat the current number of patients, according to the report. By 2050, the number of geriatricians needs to nearly quadruple in order to serve just 10% of the state's Alzheimer's patients."

New Colorado Law Aims To Protect Healthcare, Child Protection, Code Enforcement Workers From Harassment.

The Denver Post (3/28, Coltrain, 660K) reports, "Health care workers, child protection workers, code enforcement officers and other public-facing, but unelected, workers can now get another layer of protection under a new law signed by Gov. Jared Polis last week." The law "allows those workers to withhold their full name and home address from the internet if they attest to being at risk of imminent and serious threats." This law "started with concerns from Larimer County officials that code enforcement officers specifically were facing disgruntled people tracking them down at their homes."

Avian Flu Detected In Flocks In Iowa, Nebraska, And Minnesota.

Fox Business (3/28, Genovese, 3.06M) reports, "Highly pathogenic avian influenza was detected in multiple flocks across Minnesota, Iowa and Nebraska over the weekend, according to state and federal officials." Now, "tens of thousands of birds will be killed in order to prevent the virus – otherwise known

as bird flu – from spreading." The CDC "said these detections don't pose an 'immediate public health concern' and confirmed that no human cases of these avian influenza viruses have been detected in the United States."

Research Highlights Lack Of Racial, Ethnic, Language Concordance Between Patients And Physicians.

PatientEngagementHIT (3/28, Heath) reports that "about three-quarters of White patients have access to a" physician "of the same race, but only one in five Black patients can say the same, a medical workforce diversity trend that researchers from the Urban Institute said is hampering health equity efforts." Furthermore, among "Latino patients, having a provider who's both the same race and speaks the same language is also a rarity."

North Carolina Lawmakers To Discuss Expanding Nurse Practitioner Duties.

The Winston-Salem (NC) Journal (3/28, Craver, 226K) reports North Carolina "state lawmakers on Tuesday will discuss expanding nurse practitioners' duties during a joint legislative oversight committee on Medicaid expansion." The committee's agenda "lists eight topics that branch out from the overarching subject of advanced practice nursing and full practice authority."

Walmart Ending Cigarette Sales In Some US Stores, Sources Say.

Reuters (3/28, Paramasivam) reports, "Walmart Inc...will stop sales of tobacco products in some of its more than 5,000 stores across the United States, the world's largest retailer said on Monday." The company did not specify how many of its more than 5,000 U.S. stores would be affected, but "said it would not be exiting the category entirely."

Bloomberg (3/28, Mulier, 3.57M) reports that the decision "follows an internal debate at Walmart." Bloomberg adds that Walmart "has no plans to stop all cigarette sales, and the moves are being made to use space more efficiently," according to the company. In a statement, Walmart said that "As a result of our ongoing focus on the tobacco category, we have made the business decision to discontinue the sale of tobacco in select stores."

The AP (3/28, D'Innocenzio) reports Target stopped selling cigarettes in 1996, and CVS Health ended cigarette sales in 2014, but Walmart is the largest retailer to do so. However, CNN (3/28, Meyersohn, 89.21M) reports that in 2019, the company "raised the minimum age to buy tobacco to 21 and stopped selling

e-cigarettes," and Walmart-owned Sam's Club "has also stopped selling cigarettes at most of its stores in recent years."

Also reporting are Fox Business (3/28, 3.06M), Fortune (3/28, Morris, 3.68M), The Hill (3/28, Choi, 5.69M), the New York Post (3/28, Fickenscher, 7.45M), and the Winston-Salem (NC) Journal (3/28, Craver, 226K).

RJ Reynolds To Increase Prices On Friday.

The Winston-Salem (NC) Journal (3/28, Craver, 226K) reports that R.J. Reynolds Tobacco Co. will enact a 12-cent price increase for most of its cigarette and e-cigarette brands on Friday, according to Goldman Sachs Analyst Bonnie Herzog. She said her report was based on "industry trade contacts" that typically are accurate.

Smoking Cessation Study Enrollment Opens In Nashville.

WTVF-TV Nashville, TN (3/29, Luxen, 182K) reports Clinical Research Associates has opened enrollment for a smoking cessation study in Nashville, Tennessee. Researchers will evaluate the efficacy of a "plant-based, naturally occurring compound called Cytisinicline," a smoking cessation treatment that "is already on the market in other countries."

Recovery Experts See Increased Demand For Their Services As Americans Turn To Drinking During Pandemic.

WFYI-FM Indianapolis (3/28, Legan, 3K) reports that the many Americans turned to alcohol to cope with the stresses of the COVID-19 pandemic. According to the article, "Studies reported a 50 percent spike in drinking initially, with levels remaining elevated throughout 2020." The number of people referred to IU Health Virtual Care lead peer recovery coach Spencer "Medcalf's services has jumped 65 percent from pre-pandemic levels – the program saw 560 patients in 2019, when it was first implemented," which "ballooned to 925 in 2021."

Recent NIDA Data Suggest Medical Marijuana Can Lead To Cannabis Use Disorder.

WDVM-TV Washington (3/28, Newton) reports, "Recent data from the National Institute on Drug Abuse suggests that 30% of those who use marijuana may have some degree of marijuana use disorder." Green Health Docs Medical Cannabis Educator Remy Alvarez "says it all comes down to the patient, for example, if they are a first-time user or using it correctly." According to the

article, "In 2015, the same group found about 4 million people in the United States met the diagnostic criteria for a marijuana use disorder."

FDA Approves Fenfluramine For Treatment Of Seizures Tied To Rare Form Of Childhood Epilepsy.

Reuters (3/28, Satija, Maddipatla, Shibu) reports, "Belgian biotech firm UCB SA said on Monday the US Food and Drug Administration (FDA) approved its drug to treat seizures associated with Lennox-Gastaut Syndrome...a rare form of childhood epilepsy." The drug Fintepla (fenfluramine), "already has the US approval to treat another form of childhood-onset epilepsy, Davet Syndrome...in patients aged two years and older."

Sen. Tim Scott Top Recipient Of Drug Industry Cash During Second Half Of 2021.

Kaiser Health News (3/28, Pradhan, Knight) reports that Sen. Tim Scott (R-SC) "is getting showered with drug industry money before facing voters this fall." According to KHN, "Scott was the top recipient of pharma campaign cash in Congress during the second half of 2021, receiving $99,000, KHN's Pharma Cash to Congress database shows, emerging as a new favorite of the industry." Scott "is someone widely viewed as destined for greater things during his political career. And this is an existential moment for the American pharmaceutical industry when securing allies is critical."

Men Taking Metformin Vs. Insulin More Likely To Have Offspring With Birth Defects, Study Suggests.

Reuters (3/28, Rigby) reports, "Metformin, among the most common and often initially prescribed treatments for type 2 diabetes, was associated with a 1.4 times greater risk of birth defects in boys whose fathers were taking the drug compared with those born to fathers who were not, researchers from the University of Southern Denmark and Stanford University in the United States found" in a study published Monday in the Annals of Internal Medicine.

CNN (3/28, Ahmed, 89.21M) also covers the story.

FDA Approves Higher Dosage Of Novo Nordisk's Diabetes Drug.

Reuters (3/28, Leo) reports, "Novo Nordisk...said on Monday the US Food and Drug Administration has approved a higher dosage of 2 mg of Ozempic [semaglutide] for the treatment of adults with type 2 diabetes."

STAT Interviews UHG's Chief Medical Officer.

STAT Plus (3/28, McFarling, Subscription Publication, 262K) publishes an interview with UnitedHealth Group executive Margaret-Mary Wilson who details her "path into medicine" and her focus on health equity. According to STAT, "Long before she became a top executive at UnitedHealth Group, back in her native Nigeria, Margaret-Mary Wilson was discouraged from her dreams of becoming a doctor because 'girls don't do that.'" However, she "persisted, attending medical school in Nigeria, then receiving specialty training in the UK and US." She details her "path into medicine" and her focus on health equity, explaining, "We've tried the hammer approach, we've tried the carrot approach, and we see that doesn't get us where we need to get. What gets us there is aligning around common purposes. Our approach is to think about how we can all drive collectively towards value. That's part of our health equity work."

CQMC Identifies Quality Measurement Gaps, Recommends New Digital Quality, Health Equity Quality Measures.

HealthPayerIntelligence (3/28, Waddill) reports, "Members of the Core Quality Measures Collaborative (CQMC), including AHIP, have identified multiple quality measurement gaps and recommended new digital quality measures and health equity quality measures." In all, "the report found seven quality measurement gaps." The collaborative "is a partnership between AHIP and the Centers for Medicare & Medicaid Services (CMS) with involvement from the National Quality Forum (NQF)."

Hospitals Stay At Operating Loss In Early 2022.

Modern Healthcare (3/28, Devereaux, Subscription Publication, 215K) reports, "Hospitals saw a median operating margin decline of 11.8% between January and February, as healthcare providers dealt with lower inpatient and outpatient volumes, higher resource costs and the omicron surge's effects." They "saw a median operating margin index in February of -3.45%, up from -4.52% in January, Kaufman Hall," a healthcare consultancy "which reports monthly on the finances of more than 900 mostly not-for-profit hospitals," found. However, "they were still below sustainable operating margins."

Global Health

Unintended Pregnancies Reach 30-Year Low, But Abortions Have Risen Globally, Study Finds.

US News & World Report (3/28, Navarre, 1.91M) reports, "Unintended pregnancies are at a 30-year low, while abortions have risen globally, according to a study by the World Health Organization, the U.N.'s Human Reproduction Program, and the Guttmacher Institute, which is a research and policy organization committed to furthering reproductive rights." The study authors "say it's the first study of its kind to measure unintended pregnancy and abortion rates on the country level." The study "analyzed available data on abortion and unintended pregnancy rates for 150 countries from 2015 to 2019."

Article Examines Efforts To Keep Science Education, Research Alive In Ukraine.

The Scientist (3/28, 157K) reports, "As Russia's war on Ukraine enters its second month, the country's scientific community is among those suffering dramatic effects." Many scientists and students "have scattered, fleeing to safer regions of Ukraine or joining the nearly 4 million refugees leaving the country," while "others are helping to defend the country or distributing necessities to people in need." However, "there are many efforts to keep both education and research afloat, in academia and in industry." Around the world, scientists "have responded to the war by opening their labs to offer work for refugee scientists," and "at many Ukrainian universities, professors are preparing to resume teaching suspended classes remotely, while striving to keep their research going." The NIH is mentioned.

National News

Judiciary Committee's Jackson Confirmation Vote Set For April 4.

The Washington Post (3/28, Wang, Min Kim, 10.52M) reports that the Senate Judiciary Committee "met briefly Monday afternoon to review the candidacy of Judge Ketanji Brown Jackson, President Biden's Supreme Court nominee, for the first time since her confirmation hearings concluded." According to the Post, "Republicans requested to delay the committee's confirmation vote by one week – a move that is not unusual for the minority party – pushing it until April 4." The Post says that "if her confirmation is reported out of committee then, the full Senate would vote on Jackson's nomination later next week."

CNN (3/28, Foran, Hunt, 89.21M) reports Sen. Mitt Romney (R-UT) on Monday said he has not yet made up his mind on how he will vote on the nomination "as he undertakes an in-depth review of her record." Romney told CNN, "I'll complete that analysis and then reach a decision, but I've not reached my decision."

LATimes Report: Harris Keeping Tighter Circle Of Confidants.

The Los Angeles Times (3/28, Bierman, 3.37M) reports, "Since taking office, the roster of confidants [Vice President Harris] relies on for advice and support has contracted and tilted away from her long-time home base of California." The change "has left close friends saying they are satisfied and pleasantly surprised by her efforts to stay in touch." But "some of her earliest backers warn that her outreach has been insufficient to maintain a loyal base of support and could hamper her ability to make another run at the presidency. They also worry that Harris...lacks a full stable of trusted and tested allies to guide her through a vice presidency that has proved to be as daunting as it is historic." The "drift away from California could hamper Harris' prospects of running for president."

Dunn's Lobbying Firm "Straddling The Line Between The Private Sector And The Administration."

The Washington Post (3/28, Pager, Sullivan, Scherer, 10.52M) reports Anita Dunn, "a top architect of President Biden's 2020 victory who followed him into the White House before returning to her company," SKDK, "a powerful public relations and political strategy firm," last summer, and SKDK "are a unique force in Biden's Washington – straddling the line between the private sector and the administration to quietly staff the government, steer the presidency and remake the Democratic Party in Biden's image." According to the Post, "One of Biden's promises on taking office was to cleanse Washington from the taint of a Trump presidency with a reputation for self-dealing, as President Donald Trump and his relatives and associates benefited from their ties to the government. Many have applauded Biden's efforts, but SKDK's role shows that Washington still features well-connected operatives moving smoothly between public service and the private sector."

Pelosi Extends Proxy Voting In House Until At Least May 14.

The Hill (3/28, Marcos, 5.69M) reports House Speaker Pelosi "announced Monday that proxy voting," which was set to end at the conclusion of this month, "will

remain available to House members through at least May 14 even as Capitol officials lift other pandemic precautions." The Hill adds that lawmakers "have ultimately embraced proxy voting beyond the original intent of allowing them to cast votes if they were sick with COVID-19 or had to quarantine." Members of both parties "have used proxy voting as a scheduling convenience."

Supreme Court To Hear Arguments Over Law Giving Employment Protections To Military Personnel.

Roll Call (3/28, Ruger, 130K) reports that on Tuesday, the Supreme Court will hear arguments over "a federal law that gives employment protections for military servicemembers who return from duty, and lawmakers have warned the justices that they are critical for recruiting and retaining armed forces." The Uniformed Services Employment and Reemployment Rights Act was designed to give "uniform rights for all servicemembers when they return to the civilian workforce, the bipartisan group of six lawmakers wrote in a brief in the case," but a number of state courts have ruled the law "doesn't provide servicemembers the right to file civil lawsuits against a state when it hasn't given its permission to be sued."

Supreme Court Agrees To Hear Challenge To California Law On Pig Protections.

The Los Angeles Times (3/28, Savage, 3.37M) reports that on Monday, the Supreme Court "agreed to hear a constitutional challenge to a California ballot measure that would force pork producers across the country to end 'extreme methods' of confining breeding pigs." The justices will "decide whether out-of-state producers may be required to change their practices if they want to sell their products in California," and the decision to take the case "casts some doubt on the future of the state measure."

Justice Thomas Joins Arguments Remotely After Being Discharged From Hospital.

The AP (3/28) reports Supreme Court Justice Clarence Thomas "participated in arguments at the Supreme Court via telephone rather than in person on Monday following a hospital stay of nearly a week." However, the AP adds "Thomas' voice was clear when he asked several questions during arguments over a federal law meant to protect railroad workers, at one point making an analogy to when he drives his 40-foot long motor coach."

New York State Judge Sets End Of April Deadline For Trump Organization To Comply With NY Attorney General's Subpoena.

CNN (3/28, Scannell, 89.21M) reports New York state Judge Arthur Engoron on Monday "ordered the Trump Organization to comply by the end of April with a subpoena from the New York attorney general as part of its long-running civil investigation into the former president and his real estate company." CNN adds Engoron "ordered an e-discovery firm hired to audit Trump's compliance with the subpoena issued over two years ago to produce weekly reports identifying specific information about whose devices have been searched and what hasn't been searched. The Trump Organization must also respond in weekly reports over any differences discovered by the firm."

Poll Shows Hochul Up 8 Points Over Cuomo In Hypothetical Primary Matchup.

Politico (3/28, Mahoney, 6.73M) reports a Siena poll released Monday showed New York Gov. Kathy Hochul leading the state's Democratic gubernatorial primary with 38%, followed by former Gov. Andrew Cuomo, who is mulling the race, at 30%, Rep. Tom Suozzi at 10%, and New York City Public Advocate Jumaane Williams at 7%. In "a question asking only about the candidates who have actually entered the race, Hochul received 52 percent of the vote to Williams' 12 percent and Suozzi's 11 percent." The poll surveyed 369 registered Democrats from March 20-24, with a margin of error of 5.5 percent.

Progressive, Environmental Groups Release "Green New Deal Pledge" For Candidates.

The Hill (3/28, Budryk, 5.69M) reports a "coalition of progressive and environmental organizations on Monday introduced a pledge for candidates indicating plans to co-sponsor a handful of bills associated with Green New Deal policies." The pledge requires signers to "commit to rejecting any donations of more than $200 from fossil fuel lobbyists, companies or executives and commit to co-sponsoring 10 pieces of Green New Deal-related legislation within six months of taking office."

Georgia Election Workers Argue Against New GOP Elections Bill.

The New York Times (3/28, King, Corasaniti, 20.6M) reports a "bipartisan coalition of county-level election administrators" in Georgia "is speaking out

against" a new Republican voter bill. At "a legislative hearing on Monday, they warned that the proposal would create additional burdens on a dwindling force of election workers and that the provisions could lead to more voter intimidation." Among its provision, the legislation "would expand the reach of the Georgia Bureau of Investigation over election crimes; limit private funding of elections; empower partisan poll watchers; and establish new requirements for tracking absentee ballots as they are verified and counted."

WSJournal Criticizes Will Smith For Incident At Academy Awards.

The Wall Street Journal (3/28, Subscription Publication, 8.41M), in an editorial, takes issue with actor Will Smith's altercation with comedian Chris Rock at the Academy Awards, and takes particular umbrage with the willingness of the event to then applaud Smith when he received the Oscar for best actor.

Editorial Wrap-Up

Wall Street Journal.

"Biden's Big New Wealth Tax." A Wall Street Journal (3/28, Subscription Publication, 8.41M) editorial questions the constitutionality of President Biden's new proposal to tax the wealthy, adding that Democrats will have to own any damage caused if the tax is enacted.

"Washington's Record Tax Windfall." In an editorial, the Wall Street Journal (3/28, Subscription Publication, 8.41M) says that in the first five months of fiscal 2022, federal receipts increased 26% from a year earlier and in fiscal 2021, federal receipts were a record $4.05 trillion, which is an 18% increase over fiscal 2020. But, the Administration is proposing $2.5 trillion in tax increases over 10 years.

"Will Smith Wins The Oscar For Battery." The Wall Street Journal (3/28, Subscription Publication, 8.41M), in an editorial, takes issue with actor Will Smith's altercation with comedian Chris Rock at the Academy Awards, and takes particular umbrage with the willingness of the event to then applaud Smith when he received the Oscar for best actor.

"Breaking Down California's 'Mystery' High Gas Prices." A Wall Street Journal (3/28, Finley, Subscription Publication, 8.41M) editorial carries an info graphic examining why California's gasoline prices are higher than in the rest of the US. The Journal says the prices are the result of the high costs California's special gasoline blend and the state's environmental regulations.

Washington Post.

"Biden's New Agenda: Insufficient, Incomplete … And Pretty Good." A Washington Post (3/28, 10.52M) editorial says Biden's proposal "is incomplete, devoting scant space to Mr. Biden's stalled Build Back Better agenda. Its provisions, unaddressed in the Biden budget, include boosting anti-poverty programs such as the child tax credit and the earned-income tax credit, bolstering Obamacare and pouring money into clean energy." But, "if Mr. Biden persuades Congress to accept many of the proposals he outlined Monday and gets even a slimmed-down Build Back Better bill over the finish line, he could claim substantial victories for himself and for the Americans who elected him."

"Biden Told The Truth About Putin. But Regime Change Is Not A Policy Option." In an editorial, the Washington Post (3/28, 10.52M) says that it is "not usually a good idea for a president even to imply a foreign policy objective that he or she does not actually have the intention or capability to achieve. And so it was necessary and appropriate that President Biden's aides quickly told the world that his unscripted remark...did not mean that regime change in Moscow is on the U.S. policy agenda." Still, the Post says, it "can be a good idea...for presidents to speak in a clear moral voice about world affairs. On that score, Mr. Biden's remark had something going for it: truth."

"No College? No Problem. Maryland Might Hire You." The Washington Post (3/28, 10.52M) says in an editorial that Maryland Gov. Larry Hogan (R) "has taken a page from the private sector and announced that thousands of state jobs would no longer require applicants to have a four-year college degree as long as they can show they have the skills to do the job." Hogan "has launched a first-in-the-nation initiative that, if properly implemented, will help address the state's labor shortage and open up needed opportunities." Critics "raised concerns that the effort will lead to a lower-quality state workforce and...will devalue the college education many worked so hard to earn, while often going into debt." But "increasing numbers of businesses...have removed the requirement of a college degree from their job descriptions."

The Big Picture

Headlines From Today's Front Pages.

Wall Street Journal:

Ukraine And Russia Prepare For Talks In Turkey As Russian Missiles Hit Cities
Secret World Of Pro-Russia Hacking Group Exposed In Leak
Roman Abramovich And Ukrainian Peace Negotiators Suffer Suspected Poisoning
Biden's Budget Calls For Increase In Defense Spending, Including Funds For Ukraine
Ancient Pottery Inspires A Town's Tourist Attraction—Anatomically Explicit Statues

New York Times:
Ukraine Claims Some Battle Successes As Russia Focuses On Another Front
'I Make No Apologies': Biden Says His Putin Comments Were An Expression Of Moral Outrage
Federal Judge Finds Trump Most Likely Committed Crimes Over 2020 Election
Biden's $5.8 Trillion Budget Pivots Toward Economic And Security Concerns
'High-Rise Hell': NYC Skyscraper's Elevator Breakdowns Strand Tenants

Washington Post:
Cruz's Last-Ditch Battle To Keep Trump In Power
Historic Synagogue And Its Rabbi Help Tens Of Thousands Find Safety In Kyiv
Ukraine Claws Back Territory In North
Trump Probably Broke Law, Judge Finds
Russian Gas Still Flows In The Pipes Of War-torn Areas
Academy Launches 'Formal Review' Of Smith Slap

Financial Times:
Russia No Longer Demanding Ukraine Be 'Denazified' In Ceasefire Talks
Biden Insists US Has Not Altered Policy On Russia Regime Change
Abramovich Suffered Suspected Poisoning After Peace Talks In Kyiv

Story Lineup From Last Night's Network News:
ABC: Ukrainian Resistance Efforts Against Russia; President Biden Not Walking Back Comments About Vladimir Putin; Fallout After The Oscars; US COVID/FDA Expected Approve A Second Booster Shot; January 6 Investigation; Florida Governor Signs Don't Say Gay Bill; Deadly Vehicle Pile Up In Pennsylvania; The US Capitol Open Again To Tourists; CODA Wins Best Picture At Oscars.
CBS: President Biden Not Walking Back Comments About Vladimir Putin; Russian Assaults Continue In Ukraine; Deadly Vehicle Pile Up In Pennsylvania; US Weather; Fallout After The Oscars; January 6 Investigation; Florida Governor

Signs Don't Say Gay Bill; Maternity Health In The US; Dollywood Temporarily Closed; Wal-Mart Pulls Cigarettes From Some Stores; Investigation Into Death Of Taylor Hawkins; Photojournalist On Covering The Ukraine Crisis.
NBC: Ukrainian Resistance Efforts Against Russia; President Biden Not Walking Back Comments About Vladimir Putin; Inside Odesa, Ukraine; Fallout After The Oscars; Florida Governor Signs Don't Say Gay Bill; Pandemic Assistance Fraud; Deadly Vehicle Pile Up In Pennsylvania; January 6 Investigation; American Pastor Detained By Russians In Ukraine Is Freed; CODA Wins Best Picture At Oscars.

Network TV At A Glance:
Ukrainian Resistance Efforts Against Russia – 10 minutes, 5 seconds
Fallout After The Oscars – 10 minutes, 5 seconds
President Biden Not Walking Back Comments About Vladimir Putin – 7 minutes, 20 seconds
CODA Wins Best Picture At Oscars – 4 minutes, 15 seconds
Florida Governor Signs Don't Say Gay Bill – 4 minutes, 5 seconds
Pandemic Assistance Fraud – 3 minutes, 45 seconds

Last Laughs

Late Night Political Humor.

Stephen Colbert: [discussing the Russian invasion of Ukraine] "Instead of toppling Kyiv, experts believe that Russia's new objective is to split the country between regions it controls and regions it does not. You know you're starting to scare the school bully when he goes from 'Give me your lunch money' to 'I'll tell you what, you keep your lunch money, I'll keep my lunch money, and I'll limit my wedgies to your butt's eastern regions.'"

Stephen Colbert: "Over the past few weeks, Russian forces have suffered heavy losses and have been thwarted in their primary objective to control the country's main cities, including Kyiv. So, the Russian military has now announced a change of strategy. Over the weekend, Russia said the first phase of the war is over. Yes! Over! Everything's going according to plan. That plan? 'Phase one: We lose. Phase two: War is over. We win!'"

Jimmy Fallon: "During a speech in Poland this weekend, President Biden went off script and said that Putin cannot remain in power. However, the White House

quickly walked it back and said Biden wasn't calling for his removal. That's like if Reagan's staff said, 'He actually meant to say, "Mr. Gorbachev, tear down this wallpaper."'"

Seth Meyers: "During his speech on Saturday in Poland, President Biden spoke directly to the Russian people and said that President Vladimir Putin was to blame for Western economic sanctions. Because if there's one thing Biden loves, it's pointing fingers."

Seth Meyers: "According to a new report, Supreme Court Justice Clarence Thomas' wife Ginni discussed ways to overturn the 2020 election with then-White House Chief of Staff Mark Meadows. But don't worry, she'll get her comeuppance when she's eliminated first on 'Dancing With the Stars.'"

HHS News Briefing

Produced By Bulletin Intelligence www.bulletinintelligence.com/hhs

TO: **THE SECRETARY AND SENIOR STAFF**

DATE: **TUESDAY, MARCH 29, 2022 7:30 AM EDT**

Today's Edition

Unaccompanied Migrant Children

HHS in the News

Overdose Prevention

Mental Illness

Prescription Drug Pricing

Health Care & Insurance Reform

Health Information Technology

Human Services News

Food & Import Safety

Health & Medical News

Global Health

National News

LEADING THE NEWS

Biden's Proposed 2023 Budget Includes More Funding For Pandemic Preparedness, Mental Health, IHS. The Washington Post (3/28, Stein, 10.52M) reports on Monday, President Biden put forward "a $5.8 trillion budget plan...that reflects a major administration pivot to rein in future borrowing, introducing a proposal that would reduce the national deficit by roughly $1 trillion over 10 years." It "calls for substantial funding increases for the military and police, more money for a slew of domestic programs and a 'Bipartisan Unity Agenda' focused on cancer prevention, mental health care and veterans services." The budget includes $82 billion to allow HHS "to prepare for pandemics and 'other biological threats,'" $200 million for the CDC to upgrade the quality of public health data and $748 million for global health activities, as well as "$5 billion for an Advanced Research Projects Agency for Health that Biden proposed last year as a new engine for biomedical research," although it is unclear whether it will placed under the NIH or HHS.

The New York Times (3/28, A1, Kanno-Youngs, Rappeport, Cochrane, 20.6M) reports Biden "proposed a $5.8 trillion budget that includes significant increases in funding for the military and police departments, along with higher taxes on corporations and the wealthiest Americans." This request "reflects growing security and economic concerns at home and overseas, with Mr. Biden proposing a 7 percent increase in domestic spending that includes priorities like anti-gun violence initiatives, affordable housing and manufacturing investments to address supply chain issues that have helped fuel rapid inflation. The White House also for the first time proposed a discrete stream of funding for Veterans Affairs medical care."

In a separate article, the New York Times (3/28, Walker, 20.6M) reports there is "a significant proposed shift in the way the Indian Health Service was funded as part of" the 2023 budget. Biden is "proposing the health care agency move from discretionary to mandatory funding." He is seeking $9.1 billion, which represents an increase of more than 20% over the current funding level.

The Wall Street Journal (3/28, A1, Omeokwe, Duehren, Subscription Publication, 8.41M) reports the budget is seeking a record level of military spending and additional funding for law enforcement. Under the proposal, the CDC would receive $9.9 billion in discretionary funds to help increase capacity at the state and local levels. This amount represents an increase of $2.8 billion over the 2021 budget.

The AP (3/28, Boak) reports the budget includes more "funding for education, public health and housing." It "essentially tries to tell voters what a diverse and at times fractured Democratic Party stands for ahead of the midterm elections that could decide whether Congress remains under the party's control." The budget calls for "$795 billion for defense, $915 billion for domestic programs, and the remaining balance would go to mandatory spending such as Social Security, Medicare, Medicaid and net interest on the national debt."

Reuters (3/28, Shalal, Hunnicutt) reports the proposal "lays out Biden's priorities, including campaign promises to make the wealthy and companies pay more tax. It is merely a wish list as lawmakers on Capitol Hill make the final decisions on budget matters." In response, "House Speaker Nancy Pelosi said Congress looked forward to working on Biden's 'bold fiscal blueprint.'" However, "some fellow Democrats chafed at Biden's pledge to boost military spending. Biden's plan drew immediate criticism from Republicans, who together with moderate Democrats, killed similar tax proposals in the 2022 budget."

Bloomberg Law (3/28, Ruoff, Reed, Subscription Publication, 4K) reports the "administration's plan for fighting future pandemics comes even as it's asking Congress for funds to combat the current one. The White House asked lawmakers for more than $22 billion in March to replenish Covid-19 response programs, and health officials warned they might need more than that soon." In spite of "White House pleas, lawmakers have been at a stalemate over approving more funds." HHS Secretary Xavier Becerra said on Monday, "We're going to stretch where we can, but there's no question – if we don't have the resources, we're just going to fall behind. ... What we need to finish the job on Covid, we need immediately."

The Washington Times (3/28, Howell, 626K) reports Becerra added, "We can't afford to have bad inputs. We need not only good inputs, we need more inputs. ... We need better coordination with our state and local partners. We can't have some states giving us great data on where we are with COVID or on the public health crisis that we're facing and have other states fall behind. We need to coordinate."

Bloomberg Law (3/28, Baumann, Subscription Publication, 4K) reports the NIH's "total budget would grow to about $62 billion in fiscal 2023 under the president's request released Monday, about $20 billion more than it's had over the last few years." But "$12 billion of that money is designated for part of a larger mandatory pandemic preparedness package."

Bloomberg Law (3/28, Ruoff, Subscription Publication, 4K) reports, "Federal regulators would get the power to levy fines against insurers that violate mental health parity rules and states would get an injection of $125 million to enforce parity laws under President Joe Biden's proposed fiscal 2023 budget." The President "has promised to build on consumer protections meant to ensure that people with insurance can get access to mental health care with the same kind of coverage they have for physical care." Becerra also said on Monday, "The president gave us a charge: let's stop treating mental health as a stepchild in the health care sector."

The Hill (3/28, Sullivan, 5.69M) reports under the proposal, the NIH "would get $12.1 billion for research on vaccines and other measures, while the Food and Drug Administration would get $1.6 billion for its labs and information technology."

Bloomberg Law (3/28, Baumann, Subscription Publication, 4K) reports, "The Biden administration's biomedical innovation budget proposal offers largely flat funding for basic research in favor of a big-ticket new agency focused on medical breakthroughs."

FierceBiotech (3/28, Armstrong, 4K) reports the budget includes "a $2.1 billion boost in funding for the FDA in 2023 to support the Cancer Moonshot program and pandemic preparedness." Overall, "the FDA could be up for $8.39 billion, a 34% increase over the $6.25 billion enacted for 2022." FDA Commissioner Dr. Robert Califf, who was confirmed last month, said, "The funding outlined in this year's FDA budget request is critical to fulfilling the agency's mission as we continue our work on a wide range of COVID-19 and non-COVID priorities."

In a separate article, The Hill (3/28, Bernal, Beitsch, 5.69M) reports, "The budget at both DOJ and the Department of Health and Human Services also sets aside funding legal aid for an immigration court system that, unlike the U.S. criminal court system, provides no guarantee of counsel."

Among other news outlets covering the story are Bloomberg (3/28, Sink, Wasson, 3.57M), NBC News (3/28, Finn, 4.91M), CNBC (3/28, Wilkie, 7.34M), Fox News (3/28, Singman, 23.99M), Politico (3/28, Scholtes, 6.73M), The Hill (3/28, Chalfant, Folley, 5.69M), Forbes (3/28, Ponciano, 10.33M), the New York Daily News (3/28, Goldiner, 2.51M), the New York Post (3/28, Nelson, 7.45M), NPR (3/28, Keith, 3.69M), Modern Healthcare (3/28, Goldman, Subscription Publication, 215K), FedScoop (3/28, Nyczepir), Government Executive (3/28, Bublé, 29K), NextGov (3/28, Kelley, Konkel), Inside Health Policy (3/28, Mills-Gregg, Subscription Publication), Inside Health Policy (3/28, Wang, Subscription Publication), Bloomberg Law (3/28, Castronuovo, Subscription Publication, 4K), Nature (3/28, Tollefson, 194K), Inside Health Policy (3/28, Wilkerson, Subscription Publication), and Endpoints News (3/28, Brennan).

Analysis And Commentary. The New York Times (3/28, Weisman, 20.6M) reports the budget's "framing was a marked shift from the 2021 pitch for a fundamental transformation of an ailing American society." Rather, "Mr. Biden's plan was an appeal based on the reality of the moment, to both new dangers around the globe

and at home, where inflation and crime are crushing the president's political standing."

A second New York Times (3/28, Sanger-Katz, 20.6M) analysis says while administrations "normally detail their biggest policy dreams in their annual budgets," the Biden Administration "tucked its into the footnotes instead. Months after congressional talks stalled on the president's expansive climate and social safety net bill known as Build Back Better, the White House simply declined to include its fine print in its annual budget proposal that was released on Monday." Although the budget "included a slew of smaller policy specifics," it "did not include the key provisions in Build Back Better – the legislation that President Biden has spent much of his time in office promoting."

The Washington Post (3/28, Demirjian, 10.52M) reports "Biden's defense spending proposal met an onslaught of criticism from congressional Republicans upon its release Monday for failing, they say, to adequately address escalating inflation and the West's standoff with Russia over Ukraine – growing crises that, officials acknowledged, did not factor into the Pentagon's request to Congress."

The Washington Post (3/28, Bump, 10.52M) reports in a separate article that Biden is seeking $5.8 trillion "for fiscal year 2023, which begins in October. It is likely to be significantly changed by Congress."

Bloomberg (3/28, Wasson, Dennis, 3.57M) reports "Biden's plan to tax unrealized capital gains ran into opposition from key Democratic Senator Joe Manchin, likely dooming it just hours after it was sent to Congress." The proposal seeks to "impose a 20% minimum tax on the unrealized capital gains for households worth at least $100 million."

Politico (3/28, Barron-Lopez, 6.73M) reports, "The White House is boasting that the president's budget contains major deficit reduction, a move that Democrats see as calculated to appeal to a handful of centrist lawmakers who hold the pre-midterms fate of the president's economic agenda in their hands." This "proposal comes as Biden seeks to revive talks with Senate Democratic moderates such as West Virginia's Manchin on central elements of his now-defunct social spending bill. That includes universal pre-K, lowering prescription drug prices and combating climate change."

The Washington Post (3/28, 10.52M) editorializes that Biden's budget proposal "is more realistic about the nation's needs than many that have come before it. But it leaves out some of the most important details." In spite of the "shortcomings in the spending blueprint, if Mr. Biden persuades Congress to accept many of the proposals he outlined Monday and gets even a slimmed-down Build Back Better bill over the finish line, he could claim substantial victories for himself and for the Americans who elected him."

In an editorial, the Wall Street Journal (3/28, Subscription Publication, 8.41M) criticizes Biden's plan to tax the wealthy, saying that it goes against what the Constitution intended.

In another editorial, Wall Street Journal (3/28, Subscription Publication, 8.41M) also criticizes Biden's proposed budget, saying the plan to raise taxes on the wealthy would raise the tax portion of the GDP to record levels, which is not what the economy or taxpayers need.

In a Wall Street Journal (3/28, Subscription Publication, 8.41M) op-ed, Jason Furman lauds Biden's tax proposal, saying it is a good way to begin to raise taxes in a progressive manner.

HRSA COVID-19 Uninsured Program Stops Taking Claims Due To Lack Of Funding. The Washington Post (3/28, Goldstein, 10.52M) reports, "The Biden administration has been trying to draw attention to the consequences if lawmakers continue bickering over whether to provide more coronavirus aid." As a result of the disputes, "the federal COVID-19 Uninsured Program," overseen by the Heath Resources and Services Administration (HRSA) refused to accept new "claims for testing and treating for the deadly virus on patients who had no way to pay their medical bills." The Post says according to "rules set by the Centers for Disease Control and Prevention, coronavirus vaccines must be given at no charge. The question of possibly charging for coronavirus tests is more ambiguous, and HHS Secretary Xavier Becerra has hinted at that in public."

The New York Times (3/28, Barry, 20.6M) reports that last week, Becerra warned "that reimbursements for testing were ending," and on Wednesday, HRSA "stopped accepting claims."

Fox News (3/28, Pergram, 23.99M) reports, "People will have to pony up the cash out of their own pocketbook to pay for vaccines and medicine" as inflation continues to rise. The article

adds, "So paying for a test becomes a de facto tax."

Fortune (3/28, 3.68M) and Bloomberg (3/28, Rutherford, 3.57M) also cover the story.

THE SECRETARY IN THE NEWS

Hospital Groups Want Becerra To Extend COVID-19 Public Health Emergency. Fierce Healthcare (3/28, Muoio, 150K) reports hospital "groups are again asking Department of Health and Human Services (HHS) Secretary Xavier Becerra to extend the government's COVID-19 public health emergency, which is set to expire April 16." On Monday, 10 national hospital and health system organizations wrote to Becerra acknowledging "growing interest in ending the PHE due to the country's ongoing decline in cases and hospitalizations." But "the groups pointed to still-unvaccinated populations, such as the immunocompromised and children under five; potential future surges of COVID-19, potentially fueled by overseas increases due to an omicron subvariant; and lingering operational challenges including labor shortages and an influx of deferred care as reasons to maintain the declaration."

HealthLeaders Media (3/28, Ray, 118K) also covers the story.

HHS Proposes To Simplify Medicare Physician Pay System. Inside Health Policy (3/28, Stein, Subscription Publication) reports behind a paywall, "HHS' fiscal 2023 Budget-in-Brief lays out a proposal to simplify the Medicare physician pay system by letting 5% bonus payments for clinicians in alternative payment models expire after 2022, but moving up the higher pay rates that those in such models will get compared to other clinicians participating in the Merit-based Incentive Payment System by a year to avoid any gaps in incentives." HHS Secretary Xavier Becerra is mentioned.

CORONAVIRUS

OTHER CORONAVIRUS NEWS

Majority Of Americans Say They Have Contracted COVID-19, Monmouth University Poll Says. The Washington Post (3/28, Blake, 10.52M) reports, "In a new Monmouth University poll, 52 percent of Americans say they've personally contracted the virus." The numbers are an increase "from 40 percent in late January, in the weeks following FDA acting commissioner Janet Woodcock's testimony" in which she warned that "most Americans were going to contract the coronavirus." As of now, "a little more than 4 in 10 say they've tested positive for or been diagnosed with COVID-19, while 10 percent say they haven't been diagnosed but know they've had the virus."

Political Polarization In US Was Evident Long Before Start Of Pandemic Two Years Ago. ABC News (3/28, 2.44M) reports, "Political polarization in the US was evident and intensifying long before the onset of the COVID-19 pandemic, two years ago." Residents of the US "were already deeply divided about a multitude of issues, with differing opinions concerning healthcare, immigration, voting rights, gun reform and climate change, often leaving little room for collaboration across the aisle." Surveys show "that the emergence of the novel coronavirus in 2020 exacerbated the rift, pushing Americans further apart on key pandemic response efforts." CDC Director Dr. Rochelle Walensky and the National Library of Medicine are mentioned in this story.

Passengers, Crew On Cruise Ship Test Positive For COVID-19 On Return To San Francisco. The Washington Post (3/28, Diller, 10.52M) reports, "Passengers and crew on a Princess Cruises ship that arrived in San Francisco on Sunday have tested positive for the coronavirus, the cruise line said." Princess Cruise's "Ruby Princess was returning from a 15-day trip to the Panama Canal." Princess Cruise "said in a statement that infected passengers and crew were asymptomatic or showed mild symptoms."

USA Today (3/28, Hines, 12.7M) reports, "The company did not specify the number of people on board who tested positive." COVID-19 vaccination rates for crew and passengers "were at '100%,' according to the cruise line." On the CDC's "'Cruise Ship Status Dashboard,' which provides info on COVID-19 levels present on ships and what kinds of precautions those vessels are taking, the ship is listed as 'under observation' by the health agency."

CBS News (3/28, Brooks, 5.39M) reports, "Those who tested positive for coronavirus did not spread it to others on the ship." Princess Cruise said in a statement. The company "said some of the passengers who came down the virus didn't finish their quarantine while on board the ship."

COVID-19 Positive Tests Trending Up In Colorado. The Denver Post (3/28, Wingerter, 660K) reports, "The percentage of COVID-19 tests coming back positive is trending up in Colorado, but it's not clear if that's a fluke or the start of a new wave of the virus." On Monday, "state epidemiologist Dr. Rachel Herlihy said the positivity rate trended up from about 2.5% on March 17 to about 3.3%." Though "that meets the state's goal of keeping the rate below 5%, it's something Herlihy said she'll be 'closely watching.'"

New Jersey Reports One COVID-19 Death, 617 Positive Coronavirus Tests. New Jersey Star-Ledger (3/28, Rodas, 1.47M) reports, "New Jersey on Monday reported one more confirmed COVID-19 death and 617 positive tests, as New Jersey fell below West Virginia and Tennessee as the state with the seventh-most coronavirus deaths per capita in the US." The state's "seven-day average for confirmed cases was 841 on Monday, up 22% from a week ago, but still down 22% from a month ago." As of Sunday night, "there were 344 patients with confirmed or suspected coronavirus cases across 70 of the state's 71 hospitals."

Michigan Records 1,258 New COVID-19 Cases, Six Deaths Over Three-Day Period. The Detroit Free Press (3/28, Stein, 2.16M) reports, "The Michigan health department on Monday reported 1,258 new confirmed COVID-19 cases and 6 deaths over a three-day period." The state "now has a total of 2,077,401 confirmed cases and 32,758 confirmed deaths since March 2020, when the pandemic began." On Sunday, Michigan had a test positivity rate of 4.46%, "reporting that 641 of 14,382 diagnostic test results were positive."

WHO Examines Auditory Issues Potentially Linked To COVID-19 Vaccines. NBC News (3/28, Edwards, 4.91M) reports, "The World Health Organization is examining rare reports of hearing loss and other auditory issues following Covid-19 vaccinations." The agency "said that it has been made aware of sudden hearing problems, particularly tinnitus, or ringing of the ears, that may be associated with Covid vaccines." The WHO "reported 367 cases of tinnitus and 164 cases of hearing loss globally among people who had received a Covid-19 vaccine, usually within a day of the shot."

Nebraska Lawmakers Approve $1B Pandemic Recovery Bill. The Omaha (NE) World-Herald (3/28, Stoddard, 509K) reports, "Disputes over tax cuts and criminal justice reform simmered in the background Monday as lawmakers gave second-round approval to a plan for using the state's $1.04 billion of federal pandemic recovery funds." The bill "advanced on a 33-7 vote," and "allocates money coming to the state through the American Rescue Plan Act."

Nebraska Reports Continued Decrease In COVID-19 Cases, Hospitalizations. The Omaha (NE) World-Herald (3/28, Anderson, Cordes, 509K) reports, "Nebraska continued its two-month downward trend in COVID-19 cases and hospitalizations last week." While "exactly how many cases the state recorded last week...isn't entirely certain," the state "reported a negative number of cases for the week to the federal Centers for Disease Control and Prevention."

OHCA Warns 200K Oklahomans May Lose Medicaid Coverage When Public Health Emergency Ends. The Tulsa (OK) World (3/28, Jones, 241K) reports, "The Oklahoma Health Care Authority (OHCA) warns that nearly one in five Oklahomans with SoonerCare might be removed from the program after the federal public health emergency ends." On Monday, OHCA Secretary Kevin Corbett "said 'all indications and signals' are that the public health emergency...will expire this year" which "means roughly 200,000 Oklahomans on Medicaid – called SoonerCare in Oklahoma – preliminarily appear to no longer qualify for the program, he said." OHCA "asks that all SoonerCare members update their contact information and documentation to help the agency better understand which members will be eligible to renew benefits when the U.S. Health and Human Services secretary announces the end of the federal health emergency."

Brazil's Health Regulator Recommends Easing COVID-19 Travel Restrictions. Reuters (3/29) reports, "Brazilian health regulator Anvisa recommended on Monday that COVID-19 travel restrictions be eased due to a drop in cases and deaths, requiring only full vaccination and doing away with quarantine for unvaccinated travelers."

Hong Kong Faces Coffin Shortage After COVID-19 Outbreak. The AP (3/29, Fung, Lo) reports, "Hong Kong's deadliest coronavirus outbreak has cost about 6,000 lives this year – and the city is now running out of coffins." Authorities are scrambling "to order more, with the government saying 1,200 coffins had reached the city last week with more to come." In the meantime, "some companies are offering alternatives such as an environmentally friendly cardboard coffin."

Medicago's COVID-19 Vaccine Facing Limited Growth After WHO Refuses To Review It Due To Philip Morris Ties. Reuters (3/27, Khandekar, Roy) reported, "Canadian vaccine maker Medicago's COVID-19 vaccine, approved last month in Canada, is facing limited growth in the near-term after the World Health Organization said it would not review the vaccine because the company is partly owned by US-Swiss tobacco company Philip Morris, health experts say." Canada "defended its authorization of the vaccine, saying it needs a domestic bio-manufacturing industry to prepare for future pandemics."

Endpoints News (3/28, DeFeudis) also covers the story.

UK Study To Test Pfizer's COVID-19 Pill In Hospitalized Patients. Reuters (3/28, A, Aripaka) reports that Pfizer's "oral COVID-19 therapy will be evaluated as a potential treatment for patients hospitalized with the illness in a major British trial, scientists said on Monday, as cases rise in some parts of the world." According to Reuters, "The world's largest randomized study of potential medicines for COVID-19, dubbed the RECOVERY trial, will assess Paxlovid [nirmatrelvir and ritonavir] across hospitals in Britain, which has already approved the drug for early-stage treatment."

German Chancellor Says He Disagrees With Planned IP Waiver For COVID-19 Vaccines. Reuters (3/28, Szymanska) reports, "German Chancellor Olaf Scholz said on Monday he did not agree with a planned intellectual property waiver for COVID-19 vaccines as patents are a crucial way of encouraging companies to continue pushing ahead with new research." Scholz "said that a better way of making vaccines accessible in emerging economies would be to transfer vaccine production facilities to Africa."

FDA Pauses Distribution Of GSK, Vir's COVID-19 Antibody Drug In The Northeast. FiercePharma (3/28, Dunleavy, 12K) reports that the FDA on Friday "paused the distribution of GlaxoSmithKline and Vir Biotechnology's antibody drug Xevudy [sotrovimab] in the northeast, where the omicron subvariant BA.2 now accounts for more than half of new infections." According to FiercePharma, "Lab testing shows that a 500-mg dose of Xevudy is not 'fully active' against the BA.2 variant, the FDA said." Vir responded that it is "preparing a package of data in support of a higher dose of sotrovimab for the omicron BA.2 variant and will be sharing these data with regulatory and health authorities around the world."

Also reporting are Endpoints News (3/28, Brennan) and BioPharma Dive (3/28, Fidler).

Therapeutic Antivirals Nirmatrelvir/Ritonavir And Molnupiravir Reportedly Have Potential To Change COVID-19 Pandemic. Vox (3/28, Courage, 1.88M) reported that New York City in January "launched a program to provide COVID-19 treatments to residents at high risk of being hospitalized or killed by the virus – delivered free, to their door." The launch "was a potentially revolutionary moment in the pandemic's trajectory, possible only because, at the close of 2021, the US Food and Drug Administration granted emergency authorization to the first two oral antiviral drugs people can take, at home upon COVID-19 diagnosis, before they get sick enough to be hospitalized." Vox adds, "Paxlovid [nirmatrelvir and ritonavir] and molnupiravir, two therapeutic antivirals shown in studies to have varying levels of effectiveness in stunting COVID-19's dangers for those most at

risk, represent a new weapon against" COVID-19. Vox adds, "The new oral antivirals...have the potential to reshape the contours of the pandemic going forward – not just for those at high risk, but also in surprising ways for those who aren't."

Shanghai Goes Into COVID-19 Lockdown, Reversing Weeks Of Denying It Would Impose Blanket Restrictions. The Washington Post (3/28, Shepherd, Chiang, 10.52M) reports, "Late on Sunday evening, the Chinese financial hub of Shanghai announced it was going into lockdown, one half at a time, reversing weeks of denying it would impose blanket restrictions on the city's 25 million residents." The arrival of the highly infections omicron coronavirus variant, for much of the world, "has cemented acceptance that the virus is here to stay and should be mitigated but tolerated." But in China, "rising case numbers appear to be reinforcing policies to smother the virus rather than accelerating plans to gradually ease restrictions."

The Wall Street Journal (3/28, Khan, Fan, Subscription Publication, 8.41M) reports that after announcing the COVID-19 lockdown, Shanghai reported a record 3,500 coronavirus cases as infections have doubled every few days. On Monday, numerous bus lines and metro services were halted and barricades were erected splitting up the city.

The AP (3/28) reports that Shanghai's lockdown "will be China's most extensive since the central city of Wuhan, where the virus was first detected in late 2019, confined its 11 million people to their homes for 76 days in early 2020." The Pudong financial district in Shanghai and "nearby areas will be locked down from Monday to Friday as mass testing gets underway, the local government said." On Friday, the second phase of the lockdown is scheduled to begin with "the vast downtown area west of the Huangpu River that divides the city."

Reuters (3/29, Shen, Stanway) reports, "China's financial hub of Shanghai reported a record 4,381 asymptomatic COVID-19 cases and 96 symptomatic cases for March 28, the city government said on its official WeChat account on Tuesday."

Bloomberg (3/29, 3.57M) reports, "All residents in the Pudong District, home to many elite financial institutions and the Shanghai Stock Exchange, will be confined to their homes and allowed out only to get a COVID test, according to a statement issued by the area's residential compounds reviewed by Bloomberg News."

The Christian Science Monitor (3/28, Tyson, 234K) reports that some residents are criticizing the lockdown, saying it is not necessary. One resident said, "Omicron has limited harm to our health. Our megacity should not come to a standstill!"

The Hill (3/28, Choi, 5.69M) also covers the story.

South Korea's Daily New COVID-19 Case Average Declined Last Week For First Time In Two Months, Officials Say. The AP (3/28, Wilner) reports, "South Korea's daily average of new COVID-19 cases declined last week for the first time in more than two months, but the number of critically ill patients and deaths will likely continue to rise amid the omicron-driven outbreak, officials said Monday." The country "reported an average of about 350,000 new cases last week, the Korea Disease Control and Prevention Agency said Monday." KDCA Commissioner Jeong Eun-kyeong said the numbers were "the first drop in the weekly average in 11 weeks." Citing expert studies, Jeong said that "the current outbreak has likely peaked and is expected to trend downward."

G20 Chair Indonesia Starts Talks With Members On Standardizing Health Protocols For Travel, Health Minister Says. Reuters (3/28, Widianto) reports, "Group of 20 major economies (G20) chair Indonesia has started talks with members on standardizing health protocols for travel, its health minister said on Monday, stressing the importance of harmonizing rules and technology as global travel resumes." Budi Gunadi Sadikin told a news conference at a G20 health meeting in Yogyakarta, "Every person on this earth who travels... can do so more efficiently." Setiaji, an aide to Indonesia's health minister, "said countries were getting ready to roll out a global website to scan and verify travelers' vaccination status."

Commentary: Global Vaccination Against COVID-19 Almost Certain Not To Reach President Biden's Goal. In a commentary for Nature (3/28, 194K), Thomas J. Bollyky, Jennifer Nuzzo, Noelle Huhn, Samantha

Kiernan and Emily Pond write, "Last September, more than 100 governments attending US President Joe Biden's virtual Global COVID-19 Summit committed to vaccinating at least 70% of the population in every country by September 2022." The writers say, "Using national vaccination rates from mid-February, we estimate that nearly 100 countries will fall short of that objective." The writers continue, "Those missing the target include four out of five African nations, and most countries in Central America and the Middle East." The writers say, "In fact, at current vaccination rates, it will take until 15 July for 75% of high-income nations to fully vaccinate 70% of their populations." The FDA is mentioned in this story.

CDC Eases COVID-19 Travel Ratings For India. Reuters (3/28, Shepardson) reports, "The US Centers for Disease Control and Prevention (CDC) and State Department eased government COVID-19 travel ratings for India and some other countries on Monday." It "had changed its COVID-19 travel recommendation for India to 'Level 1: Low' from 'Level 3: High,' which urges unvaccinated Americans to avoid travel to those locations." The agency "also lowered Chad, Guinea and Namibia to 'Level 1.'"

The Hill (3/28, Rai, 5.69M) reports, "Despite easing the travel warning, the CDC recommends that travelers be up to date on their COVID-19 vaccines before traveling to India." The agency "classifies someone as 'up to date' if they have completed their primary series and received their booster dose."

Global COVID-19 Vaccines Face Waning Demand. Bloomberg (3/28, Kay, Makol, 3.57M) reports, "After racing to build capacity and meet once seemingly insatiable orders for COVID-19 shots, the global vaccine industry is facing waning demand as many late-to-market producers fight over a slowing market." The waning demand "is poised to rein in the blockbuster sales that global pharmaceutical giants from Pfizer Inc. to AstraZeneca Plc saw at the peak of the pandemic." The situation "also stands to create new problems for local manufacturers from India to Indonesia that built mammoth capacity to make shots but are now grappling with excess supply."

Latina Health Access Promotores Work To Convince People To Get COVID-19 Vaccine. The Los Angeles Times (3/28, 3.37M) reports that Socorro Juarez has promoted getting the COVID-19 vaccine as one "of nearly 100 promotores – Spanish-speaking community health workers – who operate in predominantly Latino neighborhoods in Orange County." The promotores "have earned the trust of many Spanish-speaking communities in the county by going directly to people – oftentimes walking door-to-door – to offer health services to low-income residents in some of Santa Ana's densest areas." Juarez was unable to convince her sister to get vaccinated before her sister got COVID-19, and now works to convince others to get vaccinated.

Number Of Cases Of Early Puberty Among Girls Has Surged During Pandemic, Physicians Say. The Washington Post (3/28, Changoiwala, 10.52M) reports that the rate of children having early puberty has increased during the COVID-19 pandemic, especially among young girls. The phenomenon has been seen globally and experts have "pointed to two pandemic-related factors that could have led to the increased incidence of precocious puberty among girls: obesity resulting from decreased physical activity during the lockdowns and increased exposure to endocrine-disrupting chemicals (EDCs) at home."

White House Spokesperson Tests Positive For COVID-19 After Trip To Europe With Biden. The AP (3/28) reports, "White House spokeswoman Karine Jean-Pierre said she tested positive for COVID-19 on Sunday after returning from Europe with President Joe Biden, in the latest infiltration of the coronavirus into the West Wing's protective bubble around Biden." However, "the White House said Biden, 79, last tested negative for COVID-19 before returning to the U.S. from the trip as part of required pre-arrival testing."

NPR (3/28, Archie, 3.69M) reports, "Jean-Pierre said she saw Biden at a meeting Saturday, but they were socially distanced, and he would not be considered a close contact by the Centers of Disease Control and Prevention." Jean-Pierre also "said she will be working from home and isolated for a minimum of five days, per CDC

recommendations, and return to the White House when she receives a negative coronavirus test."

Fauci Discusses Necessity Of Fourth COVID-19 Vaccine Dose. During an interview with WUSA-TV Washington (3/28, Arnold, 502K), NIAID Director Dr. Anthony Fauci discusses whether "everyone will need a fourth COVID vaccine dose to protect themselves." He said, "I don't think we're going to see a recommendation for everybody I'm talking about in the immediate future." However, Fauci "added that there is 'no doubt' that those who are immunocompromised should get a fourth dose at some point."

Biden Administration Stresses Importance Of Mitigating Indoor Aerosol Transmission Amid New COVID-19 Phase. The New York Times (3/28, Hassan, 20.6M) reports, "With the pandemic entering a new phase in the United States marked by fewer precautions and the rise of the even more transmissible Omicron subvariant BA.2, the Biden administration has begun stressing the importance of mitigating the risk of indoor aerosol transmission, the primary driver of the pandemic." Recently, the Environmental Protection Agency "issued expert guidance to building managers, contractors and business owners, with two pages of recommendations that codify the best practices on ventilation, air filtration and air disinfection from academic experts and federal agencies of the last two years."

Biden Administration May Have Difficulty Convincing People To Get Second COVID-19 Booster Shot. The Hill (3/28, Weixel, 5.69M) reports, "The expected green light for a second coronavirus booster shot poses a challenge to the Biden administration, which will need to work overtime to convince a public that has largely decided to move on from the COVID-19 pandemic." Issues the Administration faced "during the first booster campaign loom large, and officials are likely eager to avoid the same pitfalls." However, "the underlying disagreement about the goal of booster shots has not changed." This may complicate recommendations, "which experts said helped depress enthusiasm" during the first round of boosters.

Former FDA Chief Predicts Federal Public Transportation Mask Mandates Will End Next Month. The New York Post (3/28, Miller, 7.45M) reports that on Wednesday, former FDA Chief Dr. Scott Gottlieb predicted "that the federal mask mandate for airplanes and other public transportation will be lifted next month if the US isn't battling a COVID-19 surge fueled by the highly contagious Omicron subvariant BA.2."

FDA May Soon Approve Second COVID-19 Booster Shot For Those 50 And Older. USA Today (3/28, Rodriguez, Weintraub, 12.7M) reports, "Everyone 50 and older could soon be eligible for an additional COVID-19 vaccine at least four months after their booster shot." Multiple reports say the FDA "is likely to approve that extra shot as soon as Tuesday." However, "some health experts questioned the focus on a fourth dose when many people still haven't had earlier doses, when cases are near historic lows and before there's solid data supporting the need for another shot and for whom."

ABC World News Tonight (3/28, 6:43 p.m. EST, story 4, 2:00, Muir, 7.25M) reported that "next Wednesday, the FDA will weigh a second booster shot for the rest of Americans, along with the need for a variant-specific booster."

US News & World Report (3/28, Smith-Schoenwalder, 1.91M) also covers the story.

Flight Attendants Sue CDC Over Federal Mask Mandate On Public Transportation. The Washington Times (3/28, Howell, 626K) reports, "Nine flight attendants from six states said Monday they are suing the Centers for Disease Control and Prevention over the federal mask mandate on public transportation, arguing the COVID-19 rule obstructs their normal breathing over many hours and threatens aviation security because passengers refuse to comply." The plaintiffs "want a judge to vacate the rule...and prevent the CDC and the Department of Health and Human Services from issuing such a mandate again."

Op-Ed: Dysfunction Affects Health Providers, Patients Every Day. In an op-ed for the Washington Post (3/28, Ranney, 10.52M), Brown University School of Public Health Academic Dean Megan Ranney writes, "In

reality, our health-care system is in no better shape today than it was two years ago – and, in fact, it might be in worse condition. ... But never, in my 20 years of practice, have I seen the kind of dysfunction – day in and day out – currently afflicting providers and patients." She adds, "We must not forget the lessons from the early days of the pandemic." Ranney concludes, "Let's invest in health care and public health, now."

Hundreds Of Billions In Pandemic Assistance Dollars "Lost To Fraud." NBC Nightly News (3/28, 6:45 p.m. EST, story 6, 3:45, Holt, 5.85M) reported, "Over the last two years, the federal government approved a historic $5 trillion in pandemic assistance for struggling Americans, small businesses and healthcare providers." However, "investigators say hundreds of billions have been lost to fraud."

People's Convoy Set To Leave DC To Protest COVID-19 Bills In California. The AP (3/28, Boak) reports, "A group of truck drivers protesting COVID-19 mandates on roads and highways around the Washington, D.C., area in recent weeks will head to California next" to protest upcoming COVID-19-related bills. In an announcement, the People's Convoy said, "If passed, these bills set the stage for other states to introduce similar laws. ... This affects everyone!"

Michigan To Reduce COVID-19 Data Reporting Frequency. The Detroit News (3/28, Rahal, 1.16M) reports that on Monday, Michigan's health department announced "it will scale back the frequency of COVID-19 data reporting as cases continue to decline." Beginning April 4, DHHS "will update its COVID-19 dashboard on Wednesdays, rather than three times a week."

The Detroit Free Press (3/28, Shamus, 2.16M) reports, "The change in the way the state will report cases and deaths going forward adheres to a national surveillance strategy created by the U.S. Centers for Disease Control and Prevention."

MLive (MI) (3/28, Salisbury, 828K) also covers the story.

Minnesota Launches Online Program Providing Free At-Home COVID-19 Tests. The AP (3/28) reports that on Tuesday, "Minnesota is launching a new online program to provide free at-home rapid COVID-19 tests." Residents "can order two test kits per home for a total of four tests."

The Minneapolis Star Tribune (3/28, Olson, 855K) also covers the story.

Only 30% Of Los Angeles County Children Aged Five To 11 Fully Vaccinated Against COVID-19. The Los Angeles Times (3/28, Do, 3.37M) reports that as of mid-March, "only 30% of children age[d] 5 to 11 were fully vaccinated" against COVID-19 in Los Angeles County. Meanwhile, "nearly 80% of teens and adults" are vaccinated – "a gap that echoes the national trend."

Omaha Revises Ordinance Stripping Health Director's Powers During A Pandemic. The Omaha (NE) World-Herald (3/28, Wade, Anderson, 509K) reports, "A proposed Omaha city ordinance that would have stripped decision-making powers from the Douglas County health director during a pandemic has been revised, shifting authority back to the health director while keeping veto powers with the mayor and Omaha City Council as outlined earlier."

Columnist: Rural Texas Hospitals Still Looking For "Real Remedies" To Prevent Closures. In his column for the Texas Tribune (3/28, 258K), Ross Ramsey writes, "From 2010-20, 26 hospitals in 22 Texas communities in rural Texas closed, according to the Texas Organization of Rural and Community Hospitals." He adds that "the persistent problems in rural health care in Texas return to legislative attention every two years, sometimes holding their ground but somehow never resulting in real remedies." However, Ramsey concludes, "Legislators are listening, even if they haven't figured it out."

Idaho Governor Vetoes Bill Banning Businesses From Requiring COVID-19 Vaccine. The AP (3/28, Boone) reports, "Idaho Gov. Brad Little has vetoed legislation that would make it illegal for most businesses to require the coronavirus vaccine." The "'Coronavirus Pause Act' would have subjected public and private employers to a misdemeanor charge punishable

by a $1,000 fine if they require vaccines as a condition of employment or service."

Saliva-Based COVID-19 Tests May Be More Sensitive Than Nasal-Swab Tests, Expert Says. Scientific American (3/28, Warmack, 3.1M) reports, "COVID testing has advanced rapidly since early in the pandemic, when people had to get deep 'brain tickling' nasal swabs at a doctor's office and wait days for results." There is now "an array of saliva-based tests," which "are less invasive, can be processed faster and, in some cases, are more sensitive than nasal-based assays." University of Illinois Infectious Disease Epidemiologist Rebecca Lee Smith said, "Saliva-based PCR tests are very sensitive, and they can actually pick up infections before you're infectious." These tests "are as sensitive or even more sensitive than nasal-swab PCR assays."

Some People With Long COVID Not Ready To Go Back To The Office. TIME (3/28, Ducharme, 18.1M) chronicles the stories of multiple Americans suffering from Long COVID and their thoughts on returning to the office. Many of these individuals are not ready to go back and feel pressured to do so. The article also discusses the millions of people across the US with "chronic illnesses or physical disabilities," and how "advocates have been calling for better workplace accommodations and federal disability policies since well before the pandemic."

MIT Reinstates Standardized Testing Requirements For Applicants. Bloomberg (3/28, Lorin, 3.57M) reports, "The Massachusetts Institute of Technology is reinstating its standardized testing requirements, citing that most students are now able to access the exams safely." According to MIT, COVID-19 "vaccine availability and an increase in students taking tests at school have alleviated challenges that had made it especially difficult for high-schoolers to sit for the SAT and ACT during the pandemic."

Op-Ed: Fourth COVID-19 Vaccine Dose Not Necessary For Everyone. In an op-ed for the Wall Street Journal (3/28, Subscription Publication, 8.41M), WHO Consultant Philip Krause and Council on Foreign Relations Global Health Senior Fellow Luciana Borio discuss the proposed fourth dose of COVID-19 vaccines. They suggest it is not necessary for people with healthy immune systems.

Commentary Warns US Will Be In "Far Weaker Position" Against COVID-19 If Congress Does Not Approve Additional Funds. US Surgeon General Dr. Vivek Murthy and Dr. David A Kessler, chief science officer for the US COVID-19 Response Team and former FDA commissioner, write in a guest essay for the New York Times (3/29, 20.6M), "Over the last two years, the United States has made extraordinary progress in the fight against Covid-19," but "that progress is now threatened by Congress's failure to fund the continuing Covid-19 response effort." The government is "is running out of funds to provide Americans, especially those who are uninsured, with Covid-19 vaccines, tests and treatments," and "our efforts to sustain other critical elements of the public health response, from Covid-19 surveillance to the global vaccination campaign, are also now at risk." Murthy and Kessler say, "If adequate funding is provided, our country will be in a position of strength, well situated to manage Covid-19 and to adapt our response as future variants emerge." However, "if the funding does not materialize, we will find ourselves in a far weaker position, struggling to keep up with a constantly evolving virus that will continue to threaten our health, our economy and our peace of mind."

Racial, Ethnic Disparities In COVID-19's Toll "Likely To Worsen" Without New Pandemic Funds. Politico (3/29, Messerly, Ollstein, 6.73M) reports, "Racial and ethnic disparities in Covid-19 infections, hospitalizations and deaths are likely to worsen if Congress does not soon approve billions in new pandemic funding." Public health experts, lawmakers and health officials all "say the White House's decision to scale back or suspend programs that provide free testing, treatments and vaccinations will disproportionately affect the tens of millions of uninsured Americans – a majority of whom are people of color."

Analysis: Russian Invasion Of Ukraine Has Doomed Sputnik V. In an analysis for the Washington Post (3/29, 10.52M), columnist Adam Taylor writes, "Just a year ago, Moscow's

quickly approved coronavirus vaccine, Sputnik V, looked to be in ascendance, casting off initial Western skepticism," after "the respected British medical journal the Lancet published a peer-reviewed paper that found the vaccine had high efficacy." Soon after, "dozens of countries would go on to grant emergency approval to Sputnik V." However, the vaccine was also "a vital tool for the Kremlin's geopolitical ambition," and "now looks like another victim of it." Emergency authorizations from the WHO and EU appear "as distant as ever," and China and India – which could "still work with Russia" – are likely to favor their own vaccines as sanctions impact the manufacturing and distribution of Sputnik V.

UNACCOMPANIED MIGRANT CHILDREN

Biden Administration To Require COVID-19 Vaccine For Some Undocumented Immigrants. The New York Times (3/28, Sullivan, 20.6M) reports, "The Biden administration is requiring coronavirus vaccines for some undocumented [im]migrants at the southwest border." Officials will vaccinate "undocumented [im]migrants without proof of vaccination who are apprehended by border officials." Meanwhile, "if single adults refuse to be vaccinated, they will be detained and put into deportation proceedings." Families that refuse vaccination "will be released with a monitoring device 'with stringent conditions.'" The Times says, "The administration has been offering vaccinations to eligible [im]migrant children in government shelters for months."

CNN (3/28, Alvarez, 89.21M) reports the Department of Homeland Security says it "will be able to initially provide up to 2,700 vaccines per day," and by the end of May will be able to administer 6,000 shots daily.

The Wall Street Journal (3/28, Hackman, Subscription Publication, 8.41M), CBS News (3/28, Montoya, 5.39M) and WTOP-FM Washington (3/29, 164K) also cover the story.

HHS IN THE NEWS

HHS Resolves Four Enforcement Cases Over Providers' Disclosure Of Heath Data. Bloomberg Law (3/28, Brown, Subscription Publication, 4K) reports, "The Department of Health and Human Services resolved four enforcement cases stemming from providers' disclosure of protected health data and failure to give patients timely access to their records, the agency announced Monday." Two of the cases "were part of the Office for Civil Rights' right-to-access initiative under the Health Insurance Portability and Accountability Act privacy rule, which seeks to guarantee patients' right to promptly see their records at a reasonable cost." The other two "cases involved health-care providers accused of improperly sharing patient information with third parties."

Healthcare IT News (3/28, Miliard, 2K) also covers the story.

Ten-Year Health Spending Estimates Expected To Increase Despite Drop In 2021, CMS Says. The Wall Street Journal (3/28, Armour, Subscription Publication, 8.41M) reports US healthcare spending decreased to 4.2% in 2021 from 9.7% in 2020, according to the Centers for Medicare and Medicaid Services. The decline is due to less healthcare use and federal stimulus funds.

Bloomberg Law (3/28, Pugh, Subscription Publication, 4K) reports, "New 10-year health spending estimates released Monday by the Centers for Medicare and Medicaid Services expect national health spending to grow by nearly 5% a year through 2024 and by 5.3% annually from 2025 to 2030 as use of health services continues to normalize after the pandemic."

Fauci To Serve As Keynote Speaker At Roger Williams University Commencement. The AP (3/28) reports, "Dr. Anthony Fauci, the face of the federal response to the coronavirus pandemic, will deliver the keynote address at Roger Williams University's commencement ceremony, the Rhode Island school announced Monday." The NIAID Director "will also receive an honorary degree at the May 20 exercise."

The Boston Globe (3/28, Fitzpatrick, 1.04M) reports Roger Williams President Ioannis N. Miaoulis said, "The ability to synthesize vast amounts of information and to make decisions that consider health, science, cultural, legal and political implications, is the type of education we strive to offer our students. ... Dr. Fauci's experience throughout his career, but especially

over the last two years, has modeled how to do this exceptionally well and provides a real-world example to our students as they enter a complex world."

The Providence (RI) Journal (3/28, Perry, 376K), WLNE-TV Providence, RI (3/28, Dubois), and The Hill (3/28, Oshin, 5.69M) also cover the story.

Scientist Explains Natural Human Tendency To See Faces Everywhere. The New York Times (3/29, Wollan, 20.6M) reports that Susan Wardle, a scientist at the Laboratory of Brain and Cognition at the National Institute of Mental Health, says that it is a natural tendency for humans to "see faces everywhere." Wardle "studies how and why people see illusory faces in objects, a phenomenon known as 'face pareidolia.'" According to Wardle, "You only need this minimal information to see a face because it's more adaptive to make a mistake and see a funny face in a cloud than to miss a real human face."

Clinical Sequencing May Lead To Diagnoses In Significant Subset Of Immune Conditions, NIAID Program Finds. GenomeWeb (3/28, Anderson) reports, "Clinical sequencing may lead to molecular diagnoses in around one-third of families affected by undiagnosed immune conditions, new research suggests." NIAID Lead Genetic Counselor Morgan Similuk, on Friday, "presented findings from the first 1,000 immune disease-affected families participating in a clinical sequencing program at a[n] NIAID tertiary care center." The researchers concluded that "these genomic data will enrich our understanding of basic immunity, molecular diagnostics, and clinical care both for the 1,000 families included here, as well as many of the families who will be evaluated in the coming years."

FDA Oncology Chief Defends Rejection Of Eli Lilly, Innovent Cancer Drug. FiercePharma (3/28, Liu, 12K) reports that the FDA has "declined to approve Eli Lilly and Innovent Biologics' China-developed immunotherapy sintilimab for certain lung cancer patients." According to FiercePharma, "Critics blame the FDA and its oncology chief Richard Pazdur, M.D., for closing the door to meaningful price reductions in the widely used PD-1 drug class, and some suspect that the agency is playing to the growing geopolitical tension between the US and China." Pazdur told FiercePharma that he is "not against China, that was not the implication here. ... It was a future-directing approach to what drug development should be."

Judge Orders Animal Food Company Bravo Packing To Halt Production Until It Meets FDA Safety Standards. The Burlington County (NJ) Times (3/28, Walsh, 56K) reports, "A federal judge has ordered a South Jersey animal-food company to stop production until it makes sanitation improvements demanded by the U.S. Food and Drug Administration." Bravo Packing Inc. "must remove from the marketplace all products made since May 2021, a consent decree says." It also "must destroy 'under FDA supervision, all in-process and finished articles of pet food currently in their custody, control or possession,' it requires." The lawsuit "alleged samples collected by FDA inspectors in July 2019 and April 2021 contained salmonella and listeria monocytogenes, types of bacteria that can cause sometimes-deadly illnesses for animals and people." Steven Solomon, director of the FDA's Center for Veterinary Medicine, said Monday in a statement, "The food we give our pets should be safe for them to eat and safe for people to handle."

FDA Issues Review Raising Concerns Over Experimental Drug For ALS Treatment. The AP (3/28, Perrone) reports the Food and Drug Administration "issued a negative review Monday of" Amylyx Pharmaceuticals' drug sodium phenylbutyrate/taurursodiol (AMX0035) for the treatment of amyotrophic lateral sclerosis (ALS), "after months of lobbying by patient advocates urging approval." The agency "said...that the company's small study was 'not persuasive,' due to missing data, errors in enrolling patients and other problems." The AP adds, "On Wednesday, a panel of FDA advisers will take a non-binding vote on whether the drug warrants approval."

Also reporting are FierceBiotech (3/28, Armstrong, 4K), Endpoints News (3/28), and STAT (3/28, Feuerstein, 262K).

Commentary Says Pandemic Exposed Issues In FDA, Industry Supply Chain For Blood Collection Tubes. Senior

contributor Jude Stone writes for Forbes (3/28, Stone, 10.33M), "Covid has again brought attention to supply chain issues, this time regarding shortages of blood collection tubes." She says, "It's surprising how something so seemingly mundane can have an outsized impact – and how difficult it is to get answers about from both industry and the FDA." The shortages are "widespread" and "affecting all types of tubes." Stone says, "This issue of vacutainer shortages is but one example of the problems of just-in-time inventories, short staffing as much as possible, and reliance on overseas production. We also need to do a better job educating the public and physicians about such shortages."

Analysis Examines Claims Of One-Sided Censorship By Social Media Platforms. Fox News (3/29, Lanum, 23.99M) reports, "The Babylon Bee, a satirical conservative website, was locked out of its Twitter account last week after the tech company accused the Bee of violating its rules against 'hateful content' for a post jokingly naming Biden administration official Dr. Rachel Levine," a transgender woman, "the Bee's 2022 'Man of the Year.'" The next day, a New York Times podcast host "asserted there was 'no evidence' of political bias against conservatives occurring on social media platforms, a claim reiterated frequently by Democratic lawmakers and liberal media personalities." However, "speaking with Fox News Digital, Fox News contributor and 'The Federalist' editor-in-chief Mollie Hemingway said the notion that censorship hits both political parties equally simply because a few conservative outlets are allowed to exist on social media platforms is 'gaslighting in the extreme.'"

OVERDOSE PREVENTION

Record Fentanyl Deaths Impact Local Families In California. KNBC-TV Los Angeles (3/28, Lopez, Drechsler, 242K) reports, "Drug overdose deaths top 100,000 annually for the first time, driven by fentanyl, according to" provisional CDC data. While celebrities who died after overdosing on the powerful and synthetic drug fentanyl "make headlines, across Southern California similar tragedies are unfolding – sons and daughters – deaths rising at an alarming rate." According to the article, "The NBC4 I-Team analyzed data from the Centers for Disease Control and found since 2019 the number of overdose deaths caused by synthetic drugs in California is dramatically higher than cocaine and heroin. Nearly two thirds of annual overdose deaths [are] now connected to synthetic opioids, according to the CDC."

MENTAL ILLNESS

New Studies Examine Mental Health Toll Of Cancer. The New York Times (3/28, Wapner, 20.6M) reports on two new studies "that quantify the psychological burden of cancer in fine detail, pulling from much larger data sets than previous research." The findings, published Monday, "make a compelling case for oncologists to have more discussions with their patients about mental health struggles." One "analysis showed that the suicide rate was 85 percent higher for people with cancer than the general population." The other study "yielded some surprising findings. For example, testicular cancer carried a higher risk of depression than any other cancer type, affecting 98 of every 100 patients." Dr. Alan Valentine, chair of the psychiatry department at M.D. Anderson Cancer Center in Houston, said, "That's slightly counterintuitive – it's one of the better prognosis forms of cancer." Furthermore, "because studies assessing mental health are typically based on questionnaires that rely on self-reporting, the data probably underrepresents reality, noted Wendy Balliet, a clinical psychologist at the Hollings Cancer Center at the Medical University of South Carolina in Charleston."

Georgia Senate Advances Updated Version Of Mental Healthcare Bill. The AP (3/28) reports, "A state Senate committee on Monday advanced a version of a sweeping bill that aims to improve Georgia's dismal mental health care system." The bill "seeks to ensure that insurers provide the same level of benefits for mental health disorders as they do for physical illness." It also would "provide forgivable loans for people who become mental health workers." The committee "on Monday approved changes to a section that tries to make sure insurers provide the same level of benefits for depression, anxiety and other mental disorders as they do for other medical conditions." It also "changed a section aimed at forcing people into treatment."

The Atlanta Journal-Constitution (3/28, Prabhu, 1.46M) also reports.

Investigation Examines Former New York Governor's "Transformation Plan" For Children's Mental Healthcare. ProPublica (3/28, Kramer, Blesener, 235K) reports, "Unlike private hospitals, where clinicians say the length of a standard psychiatric stay has shrunk in recent decades to not much more than a week, New York's state-run hospitals are designed to provide longer-term, high-level care to people who are experiencing a mental health crisis." However, "under a 'Transformation Plan' launched in 2014 by then-Gov. Andrew Cuomo, the state of New York has cut nearly a third of state psychiatric hospital beds reserved for children." The plan "shifted the savings into community-based and outpatient mental health programs that were supposed to prevent kids from needing to be hospitalized in the first place," but "eight years later, children...who are experiencing mental health emergencies find it harder to get hospital care when they need it, an investigation by THE CITY and ProPublica has found."

Article Examines Financial Toll Of Becoming Mental Healthcare Clinician. The Boston Globe (3/28, Freyer, 1.04M) reports, "At a time when people wait weeks or months for mental health treatment, when emergency rooms are filling with youngsters in psychiatric crises that might have been averted by outpatient care, when officials everywhere lament the rising tide of post-pandemic mental illness, the people training to be therapists confront one hurdle after another." Though "psychiatrists and psychologists play critical roles, social workers and mental health counselors provide most of the one-on-one therapy." Their coursework "differs somewhat, but the clinical training is similar. Both have to work hundreds of hours at internships, almost always unpaid, while attending school." The article further examines the financial toll required to become a mental healthcare clinician, as well as the low pay often found in the sector.

State Task Force Tells Connecticut Lawmakers Psychiatric Hospital Still Needs "Significant Improvements." The AP (3/28, Collins) reports, "Five years after a patient abuse scandal, Connecticut's only maximum-security psychiatric hospital still needs significant improvements to its treatment programs, staff behaviors and oversight, members of a state task force told lawmakers Monday." Panel members "also told the Public Health Committee that Whiting Forensic Hospital in Middletown needs to be moved into an entirely new building because the current hospital is inadequately designed for psychiatric care and is in disrepair." The majority of the task force also "called for the elimination of the Psychiatric Security Review Board, which decides when Whiting patients can be released or transferred to other facilities, and allowing hospital staff to make some of those decisions."

PRESCRIPTION DRUG PRICING

Kentucky Bill To Curb PBMS Arrives At Likely Dead End. The Louisville (KY) Courier-Journal (3/28, Yetter, 554K) reports a bill supported by Kentucky pharmacists that would seek to curb the powers of pharmacy benefit managers (PBMs) "has been consigned to the Senate Appropriations and Revenue Committee – often a dead-end for legislation." According to the Journal, "It follows a law the legislature enacted in 2020 cutting PBMs out of the state's $1.7 billion-a-year Medicaid prescription drug program amid complaints from pharmacists that PBMs were profiting at their expense."

HEALTH CARE & INSURANCE REFORM

State-Based Marketplace Enrollees To Face Higher Premiums Without Extension Of Subsidies Under ARPA. HealthPayerIntelligence (3/28, Bailey) reports, "If federal officials do not extend the enhanced premium subsidies under the American Rescue Plan Act (ARPA), state-based marketplace enrollees will face higher premiums and may lose coverage in 2023, according to data from the National Academy for State Health Policy (NASHP)." In March 2021, the Biden Administration passed the American Rescue Plan Act, "which increased premium tax credits for individuals receiving healthcare coverage on the Affordable Care Act marketplace." ARPA "also expanded tax credit eligibility to more middle-income individuals." But "the ARPA subsidies currently expire on December 31, 2022."

More Than 40 Percent Of US Hospital ERs Overseen By For-Profit Healthcare Staffing Companies Owned By Private-Equity Firms. NBC News (3/28, Morgenson, 4.91M) reports, "Today, an estimated 40-plus percent of the nation's hospital emergency departments are overseen by for-profit health care staffing companies owned by private-equity firms, academic research, regulatory filings and internal documents show." According to their websites and press releases, two of the largest "are Envision Healthcare, owned by KKR, and TeamHealth, of the Blackstone Group. EmCare, the health care staffing company that managed Brovont, is part of Envision." In recent years, "private-equity firms have taken over a broad swath of health care entities in recent years." The firms "use large amounts of debt to acquire companies, aiming to increase their profits quickly so they can resell them at a gain in a few years." HHS is mentioned in this story.

Op-Ed: Overregulating Pay Of Nurses Would Be A Mistake. In an op-ed for The Hill (3/28, 5.69M), Hadley Health Manning, policy director at Independent Women's Forum, writes, "The main lesson we should be learning about nursing" in response to the ACA passed 12 years ago and the COVID-19 pandemic – "a critical part of any hospital's labor supply – is that the market can work both to reward nurses for their heroic work and to keep patients safe." Manning writes, "Sadly, there are efforts afoot to overregulate nurse pay and working conditions." Manning concludes, "This would be a mistake."

While Democrat-Led States Are Proposing Laws To Shore Up Abortion Rights, 41 States Have Introduced 519 Abortion Restrictions This Year. NPR (3/28, Diaz, 3.69M) reports, "As the country awaits the US Supreme Court's decision on a case that could overturn Roe v. Wade, Democrat-led states are proposing laws to shore up abortion rights at the local level." The efforts of the Democrat-led states "is in direct response to the organized campaign to make abortion illegal." On the other hand, according to the Guttmacher Institute, a supporter of abortion rights, 41 states have introduced 519 abortion restrictions in 2022 "as the country awaits the Supreme Court's decision."

Colorado Braces For Increasing Number Of Out-Of-State Residents Seeking Abortions If Roe V. Wade Overturned, Weakened. Kaiser Health News (3/29, Bichell) reports, "With the Supreme Court expected to overturn or severely weaken its landmark Roe v. Wade decision, clinics in Colorado are preparing for an increase in the number of out-of-state residents seeking abortions, and lawmakers are cementing abortion access protections in state law." Colorado is one of a few US states "without any restrictions on when in pregnancy an abortion can occur and is one of the few states in the region without a mandatory waiting period of up to 72 hours after required abortion counseling." If the Supreme Court overturns "the 49-year-old decision that protects the right to an abortion, the expectation is that the demand for abortions in Colorado from people who live in those nearby states where abortion is being restricted will rise."

HEALTH INFORMATION TECHNOLOGY

Female Physicians Spend More Time On EHR Clinical Documentation Than Male Counterparts, Study Indicates. EHR Intelligence (3/28, Nelson) reports "female physicians spent more time on EHR clinical documentation compared to their male counterparts, according to" findings of a "cross-sectional study in a large ambulatory practice network." The findings published in JAMA Network Open revealed "that clinical documentation is the primary activity driving gender differences in EHR time."

HUMAN SERVICES NEWS

New York City Mayor Calls For Increasing Investment In State Budget For Child Care, Early Childhood Education. The New York Post (3/28, Bamberger, 7.45M) reports that New York City "Mayor Eric Adams took up what he called 'a real battle' on Monday to increase access to quality child care." The mayor also "echoed calls for increased investment in the state budget for early childhood education." Taking these actions "would

help women in particular, who are disproportionately impacted when child-care issues arise and they're faced with either staying home or leaving their jobs, according to the mayor."

New AI-Using Tools Assist Students With Autism, Dyslexia And Address Accessibility For Blind, Deaf. The New York Times (3/29, Tugend, 20.6M) reports on new tools, which all incorporate artificial intelligence, that "assist students with autism and dyslexia and address accessibility for those who are blind or deaf." These tools, including social robots, "aim to find better ways to detect, teach and assist those with learning disabilities. Some are already in classrooms; others are still in the research phase." According to the Times, "The robots come in a variety of designs, including a small boy, a classic sci-fi machine and a furry snowman, and they go by peppy names such as Kaspar, Nao and Zeno."

Disability Services Providers Struggle With Ongoing Labor Shortage. The Houston Chronicle (3/28, Carballo, 982K) reports a "shortage of personal aides to care for people with intellectual and developmental disabilities" is causing providers "to stop taking referrals, delay the implementation of new programs, and in some instances, halt services altogether." Turnover was 46% in Texas in 2020, "compared to 43.6 nationally," and vacancy rates for the positions rose to 12%. Industry experts cite pay as a common factor for the shortage. The Texas "Medicaid program provides enough for a base pay of about $8 an hour," while "restaurants paying as much as $15 an hour."

Nursing Home Spending To Reach $273B In 2030, CMS Estimates. Skilled Nursing News (3/28, Stulick) reports nursing home spending will "experience an increase in expenditures from $174.2 billion in 2019 to $273 billion in 2030," according to the CMS Office of the Actuary, as federal aid declines from pandemic highs. John Poisal, deputy director of the National Health Statistics Group, explained that the agency's "expectation is that other federal programs and public health activity begin to normalize and decline from these all time highs that were reached in 2020." At the same time, the industry will "transition back to the traditional drivers of health spending, we get back to economic, demographic and health-specific factors."

CODA, Film Starring Actors With Disabilities, Wins Best Picture. Disability Scoop (3/29) reports CODA, "a film predominantly featuring people with disabilities," made history at the Oscars over the weekend, winning the award for Best Picture. Advocates are calling the recognition "a major win for disability representation in Hollywood." Troy Kotsur "became the first deaf male actor to receive an Academy Award," joining CODA co-star Marlee Matlin, who was also "the first deaf performer to win an Academy Award in 1987."

The Los Angeles Times (3/28, 3.37M) reports Matlin said "the recognition that Troy got last night is long overdue – that people recognize his work, our work." While "people are much more aware of Deaf culture and sign language" as a result of the film's success, Matlin added that it "doesn't mean you're going to blow open the doors. It's up to us to keep making it happen. We have to put the welcome mat out there and work."

Editorial: Getting Federal Court-Appointed Monitor To Oversee Reform Usually Best Possible Outcome. The Newark (NJ) Star-Ledger (3/28, 1.89M) editorializes, "When states mess up badly, the most constructive road forward is often a federal lawsuit, as we saw with efforts to end the racial profiling of motorists by the New Jersey State Police, abuses by Newark cops and rampant sexual violence at Edna Mahan prison." The board says, "In almost every case, the state fights in court, whether out of pride or political damage control." The board concludes, "But getting a federal court-appointed monitor to oversee reform is usually the best possible outcome, as we see once again with the incredible progress of New Jersey's child welfare agency."

FOOD & IMPORT SAFETY

Consumer Reports Shares "Reassuring" Results From Frozen Vegetable Safety Tests. Consumer Reports (CR) writes in the Washington Post (3/28, 10.52M) about food safety and frozen vegetables. The organization says "though frozen produce is

convenient and generally safe, it may still harbor bacteria that cause foodborne illness such as Listeria monocytogenes or salmonella." In 2016, "more than 450 frozen produce items from at least 42 brands" were recalled "because they were linked to a multistate outbreak of listeriosis, the disease caused by Listeria monocytogenes. Since then, frozen fruits and vegetables have been recalled at least 20 times because of possible contamination with listeria, hepatitis A or norovirus, according to data from the Food and Drug Administration." With "this history in mind," CR's scientists conducted tests "included 369 items from big brands, private label and store brands," and the "results were reassuring" as they "didn't find any harmful bacteria."

Dried Sweetened Strawberries Snack Recalled From Target For Undeclared Sulfites. The Miami Herald (3/28, Neal, 647K) reports, "Two lots of Target's store brand of dried sweetened strawberries, Good & Gather, got recalled for having sulfites that aren't declared on the packaging." Manufacturer SunTree Snack Foods said, "People who have an allergy or severe sensitivity to sulfites run the risk of serious or life-threatening allergic reaction if they consume these products."

HEALTH & MEDICAL NEWS

Patients, Particularly Women And People Of Color, Calling Attention To "Medical Gaslighting." The New York Times (3/28, Moyer, 20.6M) reports "research suggests that diagnostic errors occur in up to one out of every seven encounters between a" physician and patient, and "women are more likely to be misdiagnosed than men in a variety of situations." Now, "patients who have felt that their symptoms were inappropriately dismissed as minor or primarily psychological by" physicians "are using the term 'medical gaslighting' to describe their experiences and" share their stories across platforms. The article adds, "Today – thanks in large part to a law passed in 1993 that mandated that women and minorities be included in medical research funded by the National Institutes of Health – women are more systematically included in studies, yet there are still huge knowledge gaps."

Prediabetes Prevalence More Than Doubled Among US Youth From 1999 To 2018, Data Indicate. CNN (3/28, Holcombe, 89.21M) reports rates of prediabetes among US "children have more than doubled in about 20 years, according to" data from the "Centers for Disease Control and Prevention's National Health and Nutrition Examination Survey from 1999 to 2018." During that timeframe, "the rate of prediabetes in adolescents went from 11.6% to 28.2%." This "increase was seen over almost all subpopulations of young Americans, regardless of income, ethnicity and education, said" one study author. The data were published in JAMA Pediatrics.

Billionaire Former CEO Of Google Plays "Extraordinary" Role Shaping White House Office Of Science And Technology Policy. Politico (3/28, Thompson, 6.73M) reports, "A foundation controlled by Eric Schmidt, the multi-billionaire former CEO of Google, has played an extraordinary, albeit private, role in shaping the White House Office of Science and Technology Policy over the past year." No fewer "than a dozen officials in the 140-person White House office have been associates of Schmidt's, including some current and former Schmidt employees, according to interviews with current and former staff members and internal emails obtained by POLITICO." He "maintained a close relationship with the president's former science adviser, Eric Lander, and other Biden appointees." Schmidt's "charity arm, Schmidt Futures, indirectly paid the salaries of two science-office employees, including, for six weeks, that of the current chief of staff, Marc Aidinoff, who is now one of the most senior officials in the office following Lander's resignation in February."

First Lady Visits St. Jude To Promote Cancer Moonshot Initiative. The Memphis (TN) Business Journal (3/28, Airy, Subscription Publication, 855K) reports "one of the big reasons behind" First Lady Jill Biden's visit to St. Jude Children's Research Hospital in "Memphis was to promote the Biden administration's Cancer Moonshot initiative." According to St. Jude's Comprehensive Cancer Center Director Dr. Charles Roberts, "there is significant research at St. Jude that is either

stimulated, funded, or aligned with the principles of the Cancer Moonshot initiative." He added, "We launched a program a year ago that has rapidly become one of the largest academic endeavors in HPV cancer prevention," and "this year, [St. Jude] led all 71 NCI cancer centers and seven other groups in an HPV prevention initiative, helping doctors get back on their feet with vaccinations because of the impact of the pandemic."

Oregon Ends Residency Requirement For Medically Assisted Suicide. The AP (3/29, Johnson) reports, "Oregon will no longer require people to be residents of the state to use its law allowing terminally ill people to receive lethal medication, after a lawsuit challenged the requirement as unconstitutional." In a settlement filed Monday, "the Oregon Health Authority and the Oregon Medical Board agreed to stop enforcing the residency requirement and to ask the Legislature to remove it from the law." Advocates "said they would use the settlement to press the eight other states and Washington, D.C., with medically assisted suicide laws to drop their residency requirements as well."

Fresenius Files Federal Complaint Over Patent Infringement For Rare Thyroid Disease Drug. Bloomberg Law (3/28, Subscription Publication, 4K) reports behind a paywall, "Fresenius SE & Co. filed a new federal complaint alleging Zydus Lifesciences Ltd.'s proposed generic version of an injectable treatment for myxedema coma, a rare and life-threatening condition in patients with chronic severe untreated hypothyroidism, infringes three Fresenius patents for its levothyroxine sodium powder for injection." Fresenius "received a letter from Zydus saying the generic-drug maker had amended its application for U.S. Food and Drug Administration approval of its copycat to add a dosage that wasn't among the strengths included in Zydus' first notice on Feb. 7, according to a complaint."

Rural Hospitals Face Obstacles Providing Prenatal Care, Obstetricians For Pregnant Women. The CBS Evening News (3/28, 6:43 p.m. EST, story 8, 2:00, O'Donnell, 4.28M) reported, "More than 2 million pregnant women live in the US in counties with no access to prenatal care or obstetricians." Correspondent Janet Shamlian reported on Kaylie Samuelwitz who "lives in Pampa, Texas, a rural city of 17,000, where the local hospital closed its labor and delivery unit." Shamlian said, "Fewer than half of rural Texas hospitals now deliver babies, creating what's called maternity deserts. One of the biggest factors: a shortage of nurses heightened by the pandemic. Cost is also an issue."

Study Identifies Two Periods Of Adolescence When Heavy Social Media Use May Spur Lower Ratings Of "Life Satisfaction." The New York Times (3/28, Hughes, 20.6M) reports, "Analyzing survey responses of more than 84,000 people of all ages in Britain," investigators have "identified two distinct periods of adolescence when heavy use of social media spurred lower ratings of 'life satisfaction': first around puberty – ages 11 to 13 for girls, and 14 to 15 for boys – and then again for both sexes around age 19." The findings were published online March 28 in the journal Nature.

Scientists Expect West Nile Virus Transmission To Increase Across US Due To Climate Change. Kaiser Health News (3/28, Bailey) reports the rise in cases of the West Nile virus in Colorado last year "may be a sign of what's to come: As climate change brings more drought and pushes temperatures toward what is termed the 'Goldilocks zone' for mosquitoes...scientists expect West Nile transmission to increase across the country." According to a United Nations climate report, "changes in climate have already been identified as drivers of West Nile infections in southeastern Europe." Though "most West Nile infections are mild, the virus is neuroinvasive in about 1 in 150 cases, causing serious illness that can lead to swelling in the brain or spinal cord, paralysis, or death, according to the Centers for Disease Control and Prevention."

"Fragmented" Regulatory Framework Complicating Sodium Chloride Shortage, Experts Say. Modern Healthcare (3/28, Kacik, Subscription Publication, 215K) reports, "Different regulations for pharmaceuticals and medical devices are complicating the sodium chloride shortage." Nearly "60% of hospitals' requests for sodium chloride were not being filled as of Thursday, according to the group purchasing and consulting organization Premier." The vials

and syringes hospitals "use to administer saline are classified as medical devices while the bags and solution are regulated as drugs." The FDA "has more authority over the pharmaceutical supply chain than the medical device sector." This "fragmented regulatory framework has made it harder to collect data, implement workarounds and guide conservation strategies, supply chain experts said."

Milk Of Magnesia, Generic Tylenol Sent To Nursing Homes Recalled Due To Contamination. The Miami Herald (3/28, Neal, 647K) reports, "Ten lots of three oral drugs shipped to hospitals, nursing home and clinics nationwide have been recalled for 'microbial contamination and failure to properly investigate failed microbial testing.'" That information is "in the FDA-posted recall alert from Plastikon Healthcare, manufacturer of the medications for the Major Pharmaceuticals brand."

Florida Lacks Enough Geriatricians To Handle Increasing Number Of Alzheimer's Cases, Report Finds. The Orlando (FL) Sentinel (3/28, Catherman, 599K) reports, "Florida has the second-highest number of Alzheimer's patients over 65 after California: 580,000." Furthermore, "by 2025, the number of Florida residents with Alzheimer's is expected to increase by about 24%, according to the Alzheimer's Association 2022 Alzheimer's Disease Facts and Figures report, released March 15." Florida has 362 geriatricians, "which is not enough to treat the current number of patients, according to the report. By 2050, the number of geriatricians needs to nearly quadruple in order to serve just 10% of the state's Alzheimer's patients."

New Colorado Law Aims To Protect Healthcare, Child Protection, Code Enforcement Workers From Harassment. The Denver Post (3/28, Coltrain, 660K) reports, "Health care workers, child protection workers, code enforcement officers and other public-facing, but unelected, workers can now get another layer of protection under a new law signed by Gov. Jared Polis last week." The law "allows those workers to withhold their full name and home address from the internet if they attest to being at risk of imminent and serious threats." This law "started with concerns from Larimer County officials that code enforcement officers specifically were facing disgruntled people tracking them down at their homes."

Avian Flu Detected In Flocks In Iowa, Nebraska, And Minnesota. Fox Business (3/28, Genovese, 3.06M) reports, "Highly pathogenic avian influenza was detected in multiple flocks across Minnesota, Iowa and Nebraska over the weekend, according to state and federal officials." Now, "tens of thousands of birds will be killed in order to prevent the virus – otherwise known as bird flu – from spreading." The CDC "said these detections don't pose an 'immediate public health concern' and confirmed that no human cases of these avian influenza viruses have been detected in the United States."

Research Highlights Lack Of Racial, Ethnic, Language Concordance Between Patients And Physicians. PatientEngagementHIT (3/28, Heath) reports that "about three-quarters of White patients have access to a" physician "of the same race, but only one in five Black patients can say the same, a medical workforce diversity trend that researchers from the Urban Institute said is hampering health equity efforts." Furthermore, among "Latino patients, having a provider who's both the same race and speaks the same language is also a rarity."

North Carolina Lawmakers To Discuss Expanding Nurse Practitioner Duties. The Winston-Salem (NC) Journal (3/28, Craver, 226K) reports North Carolina "state lawmakers on Tuesday will discuss expanding nurse practitioners' duties during a joint legislative oversight committee on Medicaid expansion." The committee's agenda "lists eight topics that branch out from the overarching subject of advanced practice nursing and full practice authority."

Walmart Ending Cigarette Sales In Some US Stores, Sources Say. Reuters (3/28, Paramasivam) reports, "Walmart Inc...will stop sales of tobacco products in some of its more than 5,000 stores across the United States, the world's largest retailer said on Monday." The company did not specify how many of its more than 5,000 U.S. stores would be affected, but "said it would not be exiting the category entirely."

Bloomberg (3/28, Mulier, 3.57M) reports that the decision "follows an internal debate at

Walmart." Bloomberg adds that Walmart "has no plans to stop all cigarette sales, and the moves are being made to use space more efficiently," according to the company. In a statement, Walmart said that "As a result of our ongoing focus on the tobacco category, we have made the business decision to discontinue the sale of tobacco in select stores."

The AP (3/28, D'Innocenzio) reports Target stopped selling cigarettes in 1996, and CVS Health ended cigarette sales in 2014, but Walmart is the largest retailer to do so. However, CNN (3/28, Meyersohn, 89.21M) reports that in 2019, the company "raised the minimum age to buy tobacco to 21 and stopped selling e-cigarettes," and Walmart-owned Sam's Club "has also stopped selling cigarettes at most of its stores in recent years."

Also reporting are Fox Business (3/28, 3.06M), Fortune (3/28, Morris, 3.68M), The Hill (3/28, Choi, 5.69M), the New York Post (3/28, Fickenscher, 7.45M), and the Winston-Salem (NC) Journal (3/28, Craver, 226K).

RJ Reynolds To Increase Prices On Friday. The Winston-Salem (NC) Journal (3/28, Craver, 226K) reports that R.J. Reynolds Tobacco Co. will enact a 12-cent price increase for most of its cigarette and e-cigarette brands on Friday, according to Goldman Sachs Analyst Bonnie Herzog. She said her report was based on "industry trade contacts" that typically are accurate.

Smoking Cessation Study Enrollment Opens In Nashville. WTVF-TV Nashville, TN (3/29, Luxen, 182K) reports Clinical Research Associates has opened enrollment for a smoking cessation study in Nashville, Tennessee. Researchers will evaluate the efficacy of a "plant-based, naturally occurring compound called Cytisinicline," a smoking cessation treatment that "is already on the market in other countries."

Recovery Experts See Increased Demand For Their Services As Americans Turn To Drinking During Pandemic. WFYI-FM Indianapolis (3/28, Legan, 3K) reports that the many Americans turned to alcohol to cope with the stresses of the COVID-19 pandemic. According to the article, "Studies reported a 50 percent spike in drinking initially, with levels remaining elevated throughout 2020." The number of people referred to IU Health Virtual Care lead peer recovery coach Spencer "Medcalf's services has jumped 65 percent from pre-pandemic levels – the program saw 560 patients in 2019, when it was first implemented," which "ballooned to 925 in 2021."

Recent NIDA Data Suggest Medical Marijuana Can Lead To Cannabis Use Disorder. WDVM-TV Washington (3/28, Newton) reports, "Recent data from the National Institute on Drug Abuse suggests that 30% of those who use marijuana may have some degree of marijuana use disorder." Green Health Docs Medical Cannabis Educator Remy Alvarez "says it all comes down to the patient, for example, if they are a first-time user or using it correctly." According to the article, "In 2015, the same group found about 4 million people in the United States met the diagnostic criteria for a marijuana use disorder."

FDA Approves Fenfluramine For Treatment Of Seizures Tied To Rare Form Of Childhood Epilepsy. Reuters (3/28, Satija, Maddipatla, Shibu) reports, "Belgian biotech firm UCB SA said on Monday the US Food and Drug Administration (FDA) approved its drug to treat seizures associated with Lennox-Gastaut Syndrome...a rare form of childhood epilepsy." The drug Fintepla (fenfluramine), "already has the US approval to treat another form of childhood-onset epilepsy, Davet Syndrome...in patients aged two years and older."

Sen. Tim Scott Top Recipient Of Drug Industry Cash During Second Half Of 2021. Kaiser Health News (3/28, Pradhan, Knight) reports that Sen. Tim Scott (R-SC) "is getting showered with drug industry money before facing voters this fall." According to KHN, "Scott was the top recipient of pharma campaign cash in Congress during the second half of 2021, receiving $99,000, KHN's Pharma Cash to Congress database shows, emerging as a new favorite of the industry." Scott "is someone widely viewed as destined for greater things during his political career. And this is an existential moment for the American pharmaceutical industry when securing allies is critical."

Men Taking Metformin Vs. Insulin More Likely To Have Offspring With

Birth Defects, Study Suggests. Reuters (3/28, Rigby) reports, "Metformin, among the most common and often initially prescribed treatments for type 2 diabetes, was associated with a 1.4 times greater risk of birth defects in boys whose fathers were taking the drug compared with those born to fathers who were not, researchers from the University of Southern Denmark and Stanford University in the United States found" in a study published Monday in the Annals of Internal Medicine.

CNN (3/28, Ahmed, 89.21M) also covers the story.

FDA Approves Higher Dosage Of Novo Nordisk's Diabetes Drug. Reuters (3/28, Leo) reports, "Novo Nordisk...said on Monday the US Food and Drug Administration has approved a higher dosage of 2 mg of Ozempic [semaglutide] for the treatment of adults with type 2 diabetes."

STAT Interviews UHG's Chief Medical Officer. STAT Plus (3/28, McFarling, Subscription Publication, 262K) publishes an interview with UnitedHealth Group executive Margaret-Mary Wilson who details her "path into medicine" and her focus on health equity. According to STAT, "Long before she became a top executive at UnitedHealth Group, back in her native Nigeria, Margaret-Mary Wilson was discouraged from her dreams of becoming a doctor because 'girls don't do that.'" However, she "persisted, attending medical school in Nigeria, then receiving specialty training in the UK and US." She details her "path into medicine" and her focus on health equity, explaining, "We've tried the hammer approach, we've tried the carrot approach, and we see that doesn't get us where we need to get. What gets us there is aligning around common purposes. Our approach is to think about how we can all drive collectively towards value. That's part of our health equity work."

CQMC Identifies Quality Measurement Gaps, Recommends New Digital Quality, Health Equity Quality Measures. HealthPayerIntelligence (3/28, Waddill) reports, "Members of the Core Quality Measures Collaborative (CQMC), including AHIP, have identified multiple quality measurement gaps and recommended new digital quality measures and health equity quality measures." In all, "the report found seven quality measurement gaps." The collaborative "is a partnership between AHIP and the Centers for Medicare & Medicaid Services (CMS) with involvement from the National Quality Forum (NQF)."

Hospitals Stay At Operating Loss In Early 2022. Modern Healthcare (3/28, Devereaux, Subscription Publication, 215K) reports, "Hospitals saw a median operating margin decline of 11.8% between January and February, as healthcare providers dealt with lower inpatient and outpatient volumes, higher resource costs and the omicron surge's effects." They "saw a median operating margin index in February of -3.45%, up from -4.52% in January, Kaufman Hall," a healthcare consultancy "which reports monthly on the finances of more than 900 mostly not-for-profit hospitals," found. However, "they were still below sustainable operating margins."

GLOBAL HEALTH

Unintended Pregnancies Reach 30-Year Low, But Abortions Have Risen Globally, Study Finds. US News & World Report (3/28, Navarre, 1.91M) reports, "Unintended pregnancies are at a 30-year low, while abortions have risen globally, according to a study by the World Health Organization, the U.N.'s Human Reproduction Program, and the Guttmacher Institute, which is a research and policy organization committed to furthering reproductive rights." The study authors "say it's the first study of its kind to measure unintended pregnancy and abortion rates on the country level." The study "analyzed available data on abortion and unintended pregnancy rates for 150 countries from 2015 to 2019."

Article Examines Efforts To Keep Science Education, Research Alive In Ukraine. The Scientist (3/28, 157K) reports, "As Russia's war on Ukraine enters its second month, the country's scientific community is among those suffering dramatic effects." Many scientists and students "have scattered, fleeing to safer regions of Ukraine or joining the nearly 4 million refugees leaving the country," while "others are helping to defend the country or distributing necessities to people in need." However, "there are many efforts

to keep both education and research afloat, in academia and in industry." Around the world, scientists "have responded to the war by opening their labs to offer work for refugee scientists," and "at many Ukrainian universities, professors are preparing to resume teaching suspended classes remotely, while striving to keep their research going." The NIH is mentioned.

NATIONAL NEWS

Judiciary Committee's Jackson Confirmation Vote Set For April 4. The Washington Post (3/28, Wang, Min Kim, 10.52M) reports that the Senate Judiciary Committee "met briefly Monday afternoon to review the candidacy of Judge Ketanji Brown Jackson, President Biden's Supreme Court nominee, for the first time since her confirmation hearings concluded." According to the Post, "Republicans requested to delay the committee's confirmation vote by one week – a move that is not unusual for the minority party – pushing it until April 4." The Post says that "if her confirmation is reported out of committee then, the full Senate would vote on Jackson's nomination later next week."

CNN (3/28, Foran, Hunt, 89.21M) reports Sen. Mitt Romney (R-UT) on Monday said he has not yet made up his mind on how he will vote on the nomination "as he undertakes an in-depth review of her record." Romney told CNN, "I'll complete that analysis and then reach a decision, but I've not reached my decision."

LATimes Report: Harris Keeping Tighter Circle Of Confidants. The Los Angeles Times (3/28, Bierman, 3.37M) reports, "Since taking office, the roster of confidants [Vice President Harris] relies on for advice and support has contracted and tilted away from her long-time home base of California." The change "has left close friends saying they are satisfied and pleasantly surprised by her efforts to stay in touch." But "some of her earliest backers warn that her outreach has been insufficient to maintain a loyal base of support and could hamper her ability to make another run at the presidency. They also worry that Harris...lacks a full stable of trusted and tested allies to guide her through a vice presidency that has proved to be as daunting as it is historic." The "drift away from California could hamper Harris' prospects of running for president."

Dunn's Lobbying Firm "Straddling The Line Between The Private Sector And The Administration." The Washington Post (3/28, Pager, Sullivan, Scherer, 10.52M) reports Anita Dunn, "a top architect of President Biden's 2020 victory who followed him into the White House before returning to her company," SKDK, "a powerful public relations and political strategy firm," last summer, and SKDK "are a unique force in Biden's Washington – straddling the line between the private sector and the administration to quietly staff the government, steer the presidency and remake the Democratic Party in Biden's image." According to the Post, "One of Biden's promises on taking office was to cleanse Washington from the taint of a Trump presidency with a reputation for self-dealing, as President Donald Trump and his relatives and associates benefited from their ties to the government. Many have applauded Biden's efforts, but SKDK's role shows that Washington still features well-connected operatives moving smoothly between public service and the private sector."

Pelosi Extends Proxy Voting In House Until At Least May 14. The Hill (3/28, Marcos, 5.69M) reports House Speaker Pelosi "announced Monday that proxy voting," which was set to end at the conclusion of this month, "will remain available to House members through at least May 14 even as Capitol officials lift other pandemic precautions." The Hill adds that lawmakers "have ultimately embraced proxy voting beyond the original intent of allowing them to cast votes if they were sick with COVID-19 or had to quarantine." Members of both parties "have used proxy voting as a scheduling convenience."

Supreme Court To Hear Arguments Over Law Giving Employment Protections To Military Personnel. Roll Call (3/28, Ruger, 130K) reports that on Tuesday, the Supreme Court will hear arguments over "a federal law that gives employment protections for military servicemembers who return from duty, and lawmakers have warned the justices that they are critical for recruiting and retaining armed forces." The Uniformed Services Employment and Reemployment Rights Act was designed to give "uniform rights for all servicemembers when they return to the civilian workforce, the bipartisan group of six lawmakers wrote in a brief in the

case," but a number of state courts have ruled the law "doesn't provide servicemembers the right to file civil lawsuits against a state when it hasn't given its permission to be sued."

Supreme Court Agrees To Hear Challenge To California Law On Pig Protections. The Los Angeles Times (3/28, Savage, 3.37M) reports that on Monday, the Supreme Court "agreed to hear a constitutional challenge to a California ballot measure that would force pork producers across the country to end 'extreme methods' of confining breeding pigs." The justices will "decide whether out-of-state producers may be required to change their practices if they want to sell their products in California," and the decision to take the case "casts some doubt on the future of the state measure."

Justice Thomas Joins Arguments Remotely After Being Discharged From Hospital. The AP (3/28) reports Supreme Court Justice Clarence Thomas "participated in arguments at the Supreme Court via telephone rather than in person on Monday following a hospital stay of nearly a week." However, the AP adds "Thomas' voice was clear when he asked several questions during arguments over a federal law meant to protect railroad workers, at one point making an analogy to when he drives his 40-foot long motor coach."

New York State Judge Sets End Of April Deadline For Trump Organization To Comply With NY Attorney General's Subpoena. CNN (3/28, Scannell, 89.21M) reports New York state Judge Arthur Engoron on Monday "ordered the Trump Organization to comply by the end of April with a subpoena from the New York attorney general as part of its long-running civil investigation into the former president and his real estate company." CNN adds Engoron "ordered an e-discovery firm hired to audit Trump's compliance with the subpoena issued over two years ago to produce weekly reports identifying specific information about whose devices have been searched and what hasn't been searched. The Trump Organization must also respond in weekly reports over any differences discovered by the firm."

Poll Shows Hochul Up 8 Points Over Cuomo In Hypothetical Primary Matchup. Politico (3/28, Mahoney, 6.73M) reports a Siena poll released Monday showed New York Gov. Kathy Hochul leading the state's Democratic gubernatorial primary with 38%, followed by former Gov. Andrew Cuomo, who is mulling the race, at 30%, Rep. Tom Suozzi at 10%, and New York City Public Advocate Jumaane Williams at 7%. In "a question asking only about the candidates who have actually entered the race, Hochul received 52 percent of the vote to Williams' 12 percent and Suozzi's 11 percent." The poll surveyed 369 registered Democrats from March 20-24, with a margin of error of 5.5 percent.

Progressive, Environmental Groups Release "Green New Deal Pledge" For Candidates. The Hill (3/28, Budryk, 5.69M) reports a "coalition of progressive and environmental organizations on Monday introduced a pledge for candidates indicating plans to co-sponsor a handful of bills associated with Green New Deal policies." The pledge requires signers to "commit to rejecting any donations of more than $200 from fossil fuel lobbyists, companies or executives and commit to co-sponsoring 10 pieces of Green New Deal-related legislation within six months of taking office."

Georgia Election Workers Argue Against New GOP Elections Bill. The New York Times (3/28, King, Corasaniti, 20.6M) reports a "bipartisan coalition of county-level election administrators" in Georgia "is speaking out against" a new Republican voter bill. At "a legislative hearing on Monday, they warned that the proposal would create additional burdens on a dwindling force of election workers and that the provisions could lead to more voter intimidation." Among its provision, the legislation "would expand the reach of the Georgia Bureau of Investigation over election crimes; limit private funding of elections; empower partisan poll watchers; and establish new requirements for tracking absentee ballots as they are verified and counted."

WSJournal Criticizes Will Smith For Incident At Academy Awards. The Wall Street Journal (3/28, Subscription Publication, 8.41M), in an editorial, takes issue with actor Will

Smith's altercation with comedian Chris Rock at the Academy Awards, and takes particular umbrage with the willingness of the event to then applaud Smith when he received the Oscar for best actor.

EDITORIAL WRAP-UP

Wall Street Journal. ***"Biden's Big New Wealth Tax."*** A Wall Street Journal (3/28, Subscription Publication, 8.41M) editorial questions the constitutionality of President Biden's new proposal to tax the wealthy, adding that Democrats will have to own any damage caused if the tax is enacted.

"Washington's Record Tax Windfall." In an editorial, the Wall Street Journal (3/28, Subscription Publication, 8.41M) says that in the first five months of fiscal 2022, federal receipts increased 26% from a year earlier and in fiscal 2021, federal receipts were a record $4.05 trillion, which is an 18% increase over fiscal 2020. But, the Administration is proposing $2.5 trillion in tax increases over 10 years.

"Will Smith Wins The Oscar For Battery." The Wall Street Journal (3/28, Subscription Publication, 8.41M), in an editorial, takes issue with actor Will Smith's altercation with comedian Chris Rock at the Academy Awards, and takes particular umbrage with the willingness of the event to then applaud Smith when he received the Oscar for best actor.

"Breaking Down California's 'Mystery' High Gas Prices." A Wall Street Journal (3/28, Finley, Subscription Publication, 8.41M) editorial carries an info graphic examining why California's gasoline prices are higher than in the rest of the US. The Journal says the prices are the result of the high costs California's special gasoline blend and the state's environmental regulations.

Washington Post. ***"Biden's New Agenda: Insufficient, Incomplete … And Pretty Good."*** A Washington Post (3/28, 10.52M) editorial says Biden's proposal "is incomplete, devoting scant space to Mr. Biden's stalled Build Back Better agenda. Its provisions, unaddressed in the Biden budget, include boosting anti-poverty programs such as the child tax credit and the earned-income tax credit, bolstering Obamacare and pouring money into clean energy." But, "if Mr. Biden persuades Congress to accept many of the proposals he outlined Monday and gets even a slimmed-down Build Back Better bill over the finish line, he could claim substantial victories for himself and for the Americans who elected him."

"Biden Told The Truth About Putin. But Regime Change Is Not A Policy Option." In an editorial, the Washington Post (3/28, 10.52M) says that it is "not usually a good idea for a president even to imply a foreign policy objective that he or she does not actually have the intention or capability to achieve. And so it was necessary and appropriate that President Biden's aides quickly told the world that his unscripted remark...did not mean that regime change in Moscow is on the U.S. policy agenda." Still, the Post says, it "can be a good idea...for presidents to speak in a clear moral voice about world affairs. On that score, Mr. Biden's remark had something going for it: truth."

"No College? No Problem. Maryland Might Hire You." The Washington Post (3/28, 10.52M) says in an editorial that Maryland Gov. Larry Hogan (R) "has taken a page from the private sector and announced that thousands of state jobs would no longer require applicants to have a four-year college degree as long as they can show they have the skills to do the job." Hogan "has launched a first-in-the-nation initiative that, if properly implemented, will help address the state's labor shortage and open up needed opportunities." Critics "raised concerns that the effort will lead to a lower-quality state workforce and...will devalue the college education many worked so hard to earn, while often going into debt." But "increasing numbers of businesses...have removed the requirement of a college degree from their job descriptions."

THE BIG PICTURE

Headlines From Today's Front Pages.

WALL STREET JOURNAL:

Ukraine And Russia Prepare For Talks In Turkey As Russian Missiles Hit Cities

Secret World Of Pro-Russia Hacking Group Exposed In Leak

Roman Abramovich And Ukrainian Peace Negotiators Suffer Suspected Poisoning

Biden's Budget Calls For Increase In Defense Spending, Including Funds For Ukraine

Ancient Pottery Inspires A Town's Tourist Attraction—Anatomically Explicit Statues

NEW YORK TIMES:

Ukraine Claims Some Battle Successes As Russia Focuses On Another Front
'I Make No Apologies': Biden Says His Putin Comments Were An Expression Of Moral Outrage
Federal Judge Finds Trump Most Likely Committed Crimes Over 2020 Election
Biden's $5.8 Trillion Budget Pivots Toward Economic And Security Concerns
'High-Rise Hell': NYC Skyscraper's Elevator Breakdowns Strand Tenants

WASHINGTON POST:

Cruz's Last-Ditch Battle To Keep Trump In Power
Historic Synagogue And Its Rabbi Help Tens Of Thousands Find Safety In Kyiv
Ukraine Claws Back Territory In North
Trump Probably Broke Law, Judge Finds
Russian Gas Still Flows In The Pipes Of War-torn Areas
Academy Launches 'Formal Review' Of Smith Slap

FINANCIAL TIMES:

Russia No Longer Demanding Ukraine Be 'Denazified' In Ceasefire Talks
Biden Insists US Has Not Altered Policy On Russia Regime Change
Abramovich Suffered Suspected Poisoning After Peace Talks In Kyiv

STORY LINEUP FROM LAST NIGHT'S NETWORK NEWS:

ABC: Ukrainian Resistance Efforts Against Russia; President Biden Not Walking Back Comments About Vladimir Putin; Fallout After The Oscars; US COVID/FDA Expected Approve A Second Booster Shot; January 6 Investigation; Florida Governor Signs Don't Say Gay Bill; Deadly Vehicle Pile Up In Pennsylvania; The US Capitol Open Again To Tourists; CODA Wins Best Picture At Oscars.

CBS: President Biden Not Walking Back Comments About Vladimir Putin; Russian Assaults Continue In Ukraine; Deadly Vehicle Pile Up In Pennsylvania; US Weather; Fallout After The Oscars; January 6 Investigation; Florida Governor Signs Don't Say Gay Bill; Maternity Health In The US; Dollywood Temporarily Closed; Wal-Mart Pulls Cigarettes From Some Stores; Investigation Into Death Of Taylor Hawkins; Photojournalist On Covering The Ukraine Crisis.

NBC: Ukrainian Resistance Efforts Against Russia; President Biden Not Walking Back Comments About Vladimir Putin; Inside Odesa, Ukraine; Fallout After The Oscars; Florida Governor Signs Don't Say Gay Bill; Pandemic Assistance Fraud; Deadly Vehicle Pile Up In Pennsylvania; January 6 Investigation; American Pastor Detained By Russians In Ukraine Is Freed; CODA Wins Best Picture At Oscars.

NETWORK TV AT A GLANCE:

Ukrainian Resistance Efforts Against Russia – 10 minutes, 5 seconds
Fallout After The Oscars – 10 minutes, 5 seconds
President Biden Not Walking Back Comments About Vladimir Putin – 7 minutes, 20 seconds
CODA Wins Best Picture At Oscars – 4 minutes, 15 seconds
Florida Governor Signs Don't Say Gay Bill – 4 minutes, 5 seconds
Pandemic Assistance Fraud – 3 minutes, 45 seconds

LAST LAUGHS

Late Night Political Humor.

Stephen Colbert: [discussing the Russian invasion of Ukraine] "Instead of toppling Kyiv, experts believe that Russia's new objective is to split the country between regions it controls and regions it does not. You know you're starting to scare the school bully when he goes from 'Give me your lunch money' to 'I'll tell you what, you keep your lunch money, I'll keep my lunch money, and I'll limit my wedgies to your butt's eastern regions.'"

Stephen Colbert: "Over the past few weeks, Russian forces have suffered heavy losses and have been thwarted in their primary objective to control the country's main cities, including Kyiv. So, the Russian military has now announced a change of strategy. Over the weekend, Russia said the first phase of the war is over. Yes! Over! Everything's going according to plan. That plan? 'Phase one: We lose. Phase two: War is over. We win!'"

Jimmy Fallon: "During a speech in Poland this weekend, President Biden went off script and said that Putin cannot remain in power. However, the White House quickly walked it back and said Biden wasn't calling for his removal. That's like if Reagan's staff said, 'He actually meant to say, "Mr. Gorbachev, tear down this wallpaper."'"

Seth Meyers: "During his speech on Saturday in Poland, President Biden spoke directly to the Russian people and said that President Vladimir Putin was to blame for Western economic sanctions. Because if there's one thing Biden loves, it's pointing fingers."

Seth Meyers: "According to a new report, Supreme Court Justice Clarence Thomas' wife Ginni discussed ways to overturn the 2020 election with then-White House Chief of Staff Mark Meadows. But don't worry, she'll get her comeuppance when she's eliminated first on 'Dancing With the Stars.'"

From: Epoch Health
Sent: Sat, 24 Dec 2022 11:02:54 +0000
To: Sharan, Martha (CDC/DDID/NCEZID/DHQP)
Subject: How Cancer Deaths From the COVID Jabs Are Being Hidden

RISE & SHINE

by EPOCH HEALTH

December 24, 2022

Daily Health Fact

Cardio exercise before breakfast can burn more fat. [1]

What's New

How Cancer Deaths From the COVID Jabs Are Being Hidden

By Joseph Mercola

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VACCINES & SAFETY

Vaccinated at Higher Risk of COVID-19 Infection: Studies

By Zachary Stieber

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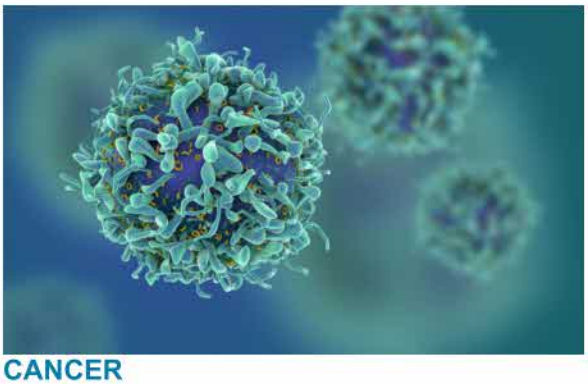

CANCER

50 Percent of Cancers May Be Preventable, Avoid These Carcinogens to Stay Healthy

By Flora Zhao

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COVID-19

Is the White House's Push for Paxlovid Evidence-Based?

By Christy Prais

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No Studies Showing 'Masks Work That Well' Against COVID-19: White House Health Official

By Zachary Stieber

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VITAL SIGNS

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By Brendon Fallon

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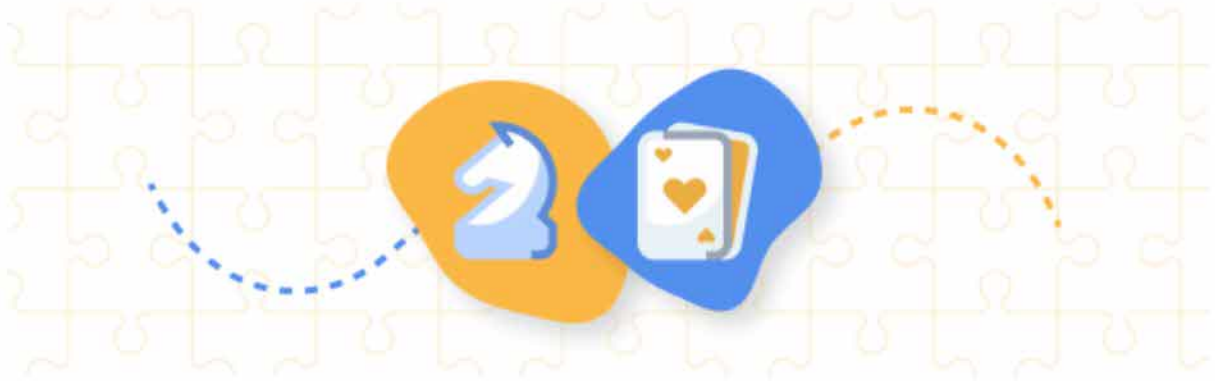
Brain Games



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[1] Source for Daily Health Fact: Epcoh Health Article

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From: Epoch Health
Sent: Mon, 26 Dec 2022 11:03:05 +0000
To: Sharan, Martha (CDC/DDID/NCEZID/DHQP)
Subject: Ivermectin Is Safe and Effective: The Evidence

RISE & SHINE

by EPOCH HEALTH

December 25, 2022

Daily Health Fact

The nose knows: it can remember 50,000 different scents. [1]

What's New

Ivermectin Is Safe and Effective: The Evidence

By Colleen Huber

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COVID VACCINE INJURIES

McCullough and Malhotra: More Doses of mRNA Vaccines, More Likelihood of Cardiac Harm

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WEF Begins Preparations for Next Pandemic; Pastor Brian Gibson on 'Respect for Marriage Act'

By Joshua Philipp

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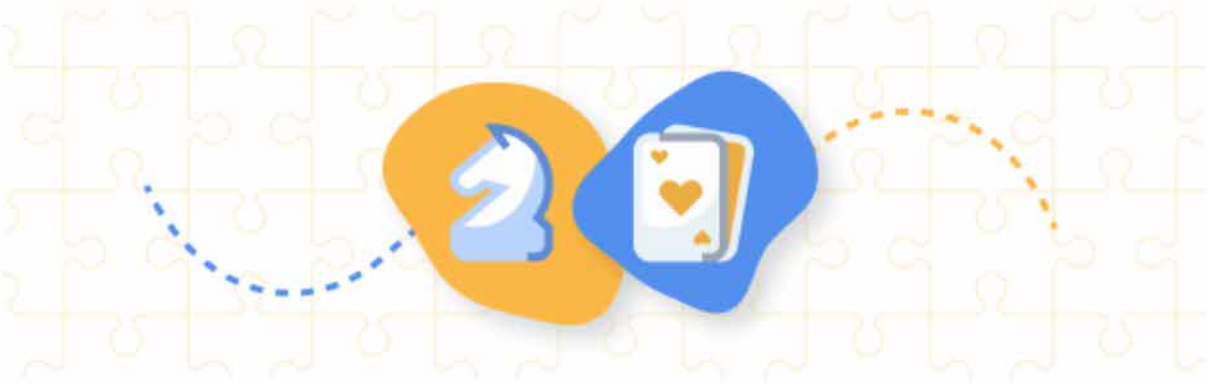
Brain Games



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[1] Source for Daily Health Fact: HowStuffWorks.

*The information in this newsletter is not intended to replace a one-on-one relationship with a qualified health care professional and is not intended as medical advice. It is intended as a sharing of knowledge and information from the research and experience of many experts and journalists. The Epoch Times encourages you to make your own health care decisions based upon your research and in partnership with a qualified health care professional.
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From: Yih, Katherine
Sent: Mon, 19 Dec 2022 14:57:04 +0000
To: Jazwa, Amelia (CDC/DDID/NCEZID/DHQP); Duffy, Jonathan M. (CDC/DDID/NCEZID/DHQP); McNeil, Michael (CDC/DDID/NCEZID/DHQP); Weintraub, Eric (CDC/DDID/NCEZID/DHQP); Schembri, Christopher P. (CDC/DDID/NCEZID/DHQP); Maro, Judy; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); rrosofsky@healthinfosys.net; LeBlanc, Jessica
Subject: outline of tinnitus exploration
Attachments: Notes for a report on tinnitus after COVID vaccination 2022-12-19.docx

Hi all,

At Jonathan's request, we developed an outline for a possible report on COVID vaccination and tinnitus, attached. (b)(5)

(b)(5)

I see that Jonathan is (b)(6), but we'd be interested in your comments at any point.

Thank you and best wishes,

Katherine

(b)(5)

(b)(5)

Sent: Mon, 6 Feb 2023 12:50:41 +0000
To: Sharan, Martha (CDC/DDID/NCEZID/DHQP)
Subject: RE: CDC Response - National Geographic interview request - AEs from COVID vaccines
Attachments: Dorney et al._2022.pdf

Here is my suggested response (b)(5)

(b)(5)

(b)(5)

From: Tara Haelle (b)(6)
Sent: Monday, February 6, 2023 2:12 AM
To: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Subject: Re: CDC Response - National Geographic interview request - AEs from COVID vaccines

Hi Martha and Dr. Shimabukuro,
We are looking to publish the article at National Geographic on tinnitus as a possible/presumptive adverse event of COVID vaccines this week. The story was put on hold while (b)(6). I wanted to check in to see if you had any additional information for me regarding CDC's progress on investigating this issue since we last corresponded. If it's at all possible to speak with Shimabukuro in the next few days before it's published, please let me know.

Thank you,
Tara Haelle

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Journalist, author, public speaker & AHCJ Medical Studies Core Topic Leader
Books: Vaccination Investigation, The Informed Parent, various children's titles

On Mon, Nov 14, 2022 at 9:11 AM Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov> wrote:
Hi Tara – unfortunately I don't have any more information to share at this time.

Martha Sharan
Public Affairs
CDC/Division of Healthcare Quality Promotion
Off.: 404-639-2683
Cell: 404-998-1787

From: Tara Haelle (b)(6)
Sent: Thursday, November 10, 2022 11:22 PM
To: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Subject: Re: CDC Response - National Geographic interview request - AEs from COVID vaccines

Thank you! Do you know if it's possible to find out the precise methodology that the ISO is using for the VSD analysis?

Thanks,
Tara

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On Thu, Nov 10, 2022 at 9:31 AM Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov> wrote:
Hi Tara:

Here's what the Immunization Safety Office is telling me:

> At this time, vaccine safety monitoring efforts in CDC have identified no evidence of a causal association between COVID-19 vaccination and tinnitus or other hearing loss.

The VSD analysis is in progress but the Immunization Safety Office can't discuss preliminary findings.

No target date for completion has been given.
Thanks,
Martha

Martha Sharan
Public Affairs
CDC/Division of Healthcare Quality Promotion
Off.: 404-639-2683
Cell: 404-998-1787

From: Sharan, Martha (CDC/DDID/NCEZID/DHQP)
Sent: Thursday, November 10, 2022 9:51 AM
To: Tara Haelle <(b)(6)
Subject: RE: CDC Response - National Geographic interview request - AEs from COVID vaccines

Checking on this for you!

Martha Sharan
Public Affairs
CDC/Division of Healthcare Quality Promotion
Off.: 404-639-2683
Cell: 404-998-1787

From: Tara Haelle (b)(6)
Sent: Thursday, November 10, 2022 7:40 AM
To: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Subject: Re: CDC Response - National Geographic interview request - AEs from COVID vaccines

Hi Martha,
I wanted to check back in to see if you had any update on the additional analysis that you mentioned using VSD. Do you know when it will be started, when it will be complete, or when results from it might be available? I need to file my story this week or next, so I'm wondering if I could still briefly speak with Dr. Shimabukuro, especially regarding the specific way CDC conducts its statistical analysis for associations.

Thank you,
Tara

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On Mon, Oct 3, 2022 at 7:56 AM Tara Haelle (b)(6) wrote:

Martha,
Thank you very much for the update. I look forward to hearing more when the analysis is complete.

Thanks,
Tara

—Sent from a buzzing brain probably clumsily dictating to a miniature magical box

****

www.tarahaelle.com
Mob 817.458.8133

On Oct 3, 2022, at 7:53 AM, Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov> wrote:

Hi Tara:
Received word from Dr. Shimabukuro that he would like to delay this interview due to an additional analyses that CDC is going to do in one of the safety monitoring systems known as the Vaccine Safety Datalink (VSD). We may have updated information on tinnitus and he would prefer to hold off until the analysis is completed to avoid giving you outdated information.

I don't have a target date for completion at this time. Dr. Shimabukuro indicated that it would be "relatively soon."
I will try to keep you informed, however, please feel free to check back with me.
Thanks,
Martha

From: Tara Haelle (b)(6)
Sent: Friday, September 30, 2022 5:31 PM
To: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Subject: Re: CDC Response - National Geographic interview request - AEs from COVID vaccines

Martha,
A Monday interview would be fantastic. Thank you so much. Let me know what time works best. Thanks also for the note about CDC not commenting on non-CDC studies. I'll keep that in mind and adjust my questions accordingly.

Thank you,
Tara

– –

These are incredibly tough, strange times. Feeling awful and frustrated you can't "snap out of it?" Read this. If you're thinking of hurting yourself, please call the Suicide Hotline at 1-800-273-8255 or text 741741. You matter.

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Books: Vaccination Investigation, The Informed Parent, various children's titles

On Fri, Sep 30, 2022 at 7:39 AM Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov> wrote:
Hi Tara – I can try to arrange a short interview on Monday. Dr. Shimabukuro is (b)(6)
(b)(6) o his schedule will be impossible.

Please note, as a general rule, CDC does not comment on studies/findings that did not involve CDC experts and were conducted outside of the agency.

Thanks,
Martha

From: Tara Haelle (b)(6)
Sent: Friday, September 30, 2022 6:22 AM
To: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Subject: Re: CDC Response - National Geographic interview request - AEs from COVID vaccines

Martha,
Thank you very much for sending these along. In reading the responses, I notice that several of the responses explain things I'm already aware of, such as the difference between incidence and prevalence; the difference between VAERS and VSD; and the substantial limitations of a passive monitoring system like VAERS. (I've reported on vaccine safety for over a decade, so I'm very familiar with all these issues and the CDC's mechanisms.)

I'm not sure if my questions weren't worded well or there was a misunderstanding otherwise, but I have follow-up questions to try to get better clarification on what I was asking. Would it be possible to set up a brief phone call with Dr. Shimabukuro to discuss this issue? It doesn't seem as though email questions are adequate for the level of specificity and nuance I'm seeking for this story. I'm a little different than most reporters in writing about vaccine adverse events because I've reported on them for so long, and I'm very familiar with all the tropes and misconceptions promoted by those who are anti-vaccine or who otherwise are unfamiliar with the specifics of CDC vaccine safety surveillance and research.

Thank you,
Tara Haelle

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On Thu, Sep 29, 2022 at 7:07 AM Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov> wrote:
Hi Tara:
Yes, I have responses from Dr. Shimabukuro, Director, CDC's Immunization Safety Office. I will pass along your additional questions.

Please see below:

> **A recent paper by Harpaz et al (doi: 10.1007/s40264-022-01186-z) suggests a strong association exists in VAERS reports for tinnitus and each of the three COVID-19 vaccines initially authorized by the FDA, but that the association is masked because of the high number of overall reports. Is this something that the CDC safety researchers have considered and/or that they are looking into?**

CDC did not participate in this analysis and recommends that you contact the authors if you have questions about their analysis.

One of the challenges of considering tinnitus as a presumptive AE is that it is so common as a background condition in the general population. Does a condition's prevalence in the general population affect how CDC safety researchers consider potential associations from AEs reported in VAERS? Would shortening the time after vaccination that they looked for an association be likely to change any likelihood of finding an association?

> Per CDC (Principles of Epidemiology | Lesson 3 - Section 2 (cdc.gov)), "Prevalence refers to proportion of persons who have a condition at or during a particular time period, whereas incidence refers to the proportion or rate of persons who develop a condition during a particular time period. So prevalence and incidence are similar, but prevalence includes new and pre-existing cases whereas incidence includes new cases only." For vaccine safety monitoring, we are most concerned with incident cases, or new cases occurring following vaccination. Expected incidence (background incidence) is taken into consideration when conducting vaccine safety evaluations.
>
> A vaccine adverse event is an adverse health event or other outcome or event (e.g., a medical error) occurring in temporal association with a vaccination. CDC monitors all VAERS data and can take into consideration incident versus prevalent conditions when information is available in the report, as well as biologically plausible risk intervals for symptom onset of the adverse event following vaccination. VAERS is a spontaneous reporting (passive surveillance) system that accepts all reports regardless of the plausibility of the vaccine causing the event or the clinical

seriousness of the event. VAERS is a signal detection (hypothesis generating) system and is not designed to determine causality.

Many of the individuals I have spoken to have said that they either did not file a VAERS report because they were told it was pointless, or they asked their doctor to file one and the doctor refused or referred them to a different doctor to report it (who then refused or referred them back to the original doctor). I heard this frequently enough to wonder whether tinnitus was underreported in VAERS. How likely might it be that tinnitus is similarly underreported in the healthcare systems involved in VSD? Is there a way to take this into account in analyses of a potential association?

The Vaccine Safety Datalink (VSD) is an electronic health record (EHR)-based system that collects data (in the EHR) on patients with health insurance when they receive healthcare. This is one of the main differences between passive surveillance in VAERS and active surveillance in VSD; VAERS depends upon people filing reports, while in VSD, a diagnosis of tinnitus would be recorded in the EHR during a patient visit as part of standard healthcare practice.VSD data are not impacted by the types of reporting biases inherent to VAERS.

Is there any possibility that the CDC will initiate another study in the future, using VSD again or another data set, to investigate tinnitus as a potential AE correlated with any of the COVID-19 vaccines? Or is the matter considered settled? Why or why not?

CDC will continue to monitor COVID-19 vaccine safety in VAERS, VSD, and other systems. If we observe data that indicates a potential safety problem we will further investigate. Additional assessments of safety signals may include epidemiologic studies if appropriate.

It seems statistically possible that a condition that has a naturally high prevalence in the general population (as tinnitus does) but is very rare as a vaccine adverse event could easily be missed as a true signal by traditional VSD analysis methods. How, if at all, have CDC safety researchers accounted for this possibility. (I'd wager that tinnitus is likely the most common condition that's ever been considered as a serious AE, which would make it fairly unique among presumptive AEs.)

Please refer to our original response and the above response to your question on common conditions. Other relatively common conditions have been evaluated in vaccine safety research, such as febrile seizure and shoulder injury. While tinnitus prevalence in the general population is relatively high, the incidence of new onset tinnitus is a different concept.

VSD uses TreeScan data mining methods, which can detect pattens of clustering of diagnoses in a post-vaccination observation period, even if few diagnoses are made (because the diagnosis is rare). To date, VSD TreeScan data mining has not observed clustering of tinnitus in a post-vaccination observation period.

Thanks,
Martha

From: Tara Haelle <(b)(6)
Sent: Thursday, September 29, 2022 5:31 AM
To: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Subject: Re: FW: National Geographic interview request - AEs from COVID vaccines

Hi Martha,
I wanted to check in on the status of the questions I sent, and I had some additional questions that arose in the process of my reporting on this story. Those additional questions are below. I certainly realize this will extend the time Dr. Shimabukuro needs to respond to my questions.

6) The WHO identified tinnitus as having a signal with the adenovirus vector vaccines (see attached), and the European Medicines Agency listed tinnitus as a possible side effect from the adenovirus vector vaccine, but the CDC has not. Can you comment on why the CDC has not followed the WHO's and EMA's lead on this and why an association would be seen with adenovirus vector vaccines?

7) When the CDC did their investigation into any associations between tinnitus and vaccination, did that analysis only look at a binary association (tinnitus did/did not occur within 90 days after vaccination), or did the analysis look at temporal patterns within that 90-day period (ie, whether there was a clustering of tinnitus reports within a shorter time period post-vaccination vs tinnitus reporting that was consistently spread out across the 90 days)?

8A) Tinnitus in the general population nearly always follows the same pattern as gradual hearing loss, with an estimated 90% of people who have tinnitus also having hearing loss. When the CDC did their analysis of tinnitus and COVID-19 vaccines, did that analysis also look at whether the people who reported tinnitus also had concurrent hearing loss?
8B) In the WHO report, only 15% of those who reported tinnitus also had hearing loss, suggesting that their tinnitus was distinct from the "usual" tinnitus that develops in the general population. Another unpublished analysis of data looking at tinnitus and COVID-19 vaccines similarly found that a very low percentage of people who experienced tinnitus after the vaccination also had hearing loss. Can you comment on whether this information might strengthen the potential possibility of an association between tinnitus and COVID-19 vaccines?

Thank you,
Tara

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Books: Vaccination Investigation, The Informed Parent, various children's titles

On Thu, Sep 22, 2022 at 2:13 PM Tara Haelle <(b)(6)> wrote:
Thank you.

– –

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Books: Vaccination Investigation, The Informed Parent, various children's titles

On Thu, Sep 22, 2022 at 11:56 AM Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov> wrote:
Hi Tara:

Dr. Shimabukuro will look at these, but he will not have time to get back to you until next week.
Thanks for your patience,
Martha

Martha Sharan
Public Affairs
CDC/Division of Healthcare Quality Promotion
Off.: 404-639-2683
Cell: 404-998-1787

From: Tara Haelle <(b)(6)>
Sent: Thursday, September 22, 2022 2:31 AM
To: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Subject: Re: FW: National Geographic interview request - AEs from COVID vaccines

Martha,
Thank you for this. Is that VSD analysis published somewhere? If so, could you share the citation with me? Meanwhile, I've adjusted some of the questions below, including the order of them.

Thanks,

Tara

—A recent paper by Harpaz et al (doi: 10.1007/s40264-022-01186-z) suggests a strong association exists in VAERS reports for tinnitus and each of the three COVID-19 vaccines initially authorized by the FDA, but that the association is masked because of the high number of overall reports. Is this something that the CDC safety researchers have considered and/or that they are looking into?

—One of the challenges of considering tinnitus as a presumptive AE is that it is so common as a background condition in the general population. Does a condition's prevalence in the general population affect how CDC safety researchers consider potential associations from AEs reported in VAERS? Would shortening the time after vaccination that they looked for an association be likely to change any likelihood of finding an association?

—Many of the individuals I have spoken to have said that they either did not file a VAERS report because they were told it was pointless, or they asked their doctor to file one and the doctor refused or referred them to a different doctor to report it (who then refused or referred them back to the original doctor). I heard this frequently enough to wonder whether tinnitus was underreported in VAERS. How likely might it be that tinnitus is similarly underreported in the healthcare systems involved in VSD? Is there a way to take this into account in analyses of a potential association?

—Is there any possibility that the CDC will initiate another study study in the future, using VSD again or another data set, to investigate tinnitus as a potential AE correlated with any of the COVID-19 vaccines? Or is the matter considered settled? Why or why not?

—It seems statistically possible that a condition that has a naturally high prevalence in the general population (as tinnitus does) but is very rare as a vaccine adverse event could easily be missed as a true signal by traditional VSD analysis methods. How, if at all, have CDC safety researchers accounted for this possibility. (I'd wager that tinnitus is likely the most common condition that's ever been considered as a serious AE, which would make it fairly unique among presumptive AEs.)

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On Wed, Sep 21, 2022 at 2:52 PM Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov> wrote:
Hi Tara:
CDC now has a statement that I am including below – not sure if this will have an impact on your list of questions. Let me know if you need to adjust any of them:

> CDC is aware of reports to the Vaccine Adverse Event Reporting System (VAERS) of tinnitus occurring in temporal association with COVID-19 vaccination (i.e., following vaccination). Tinnitus is a common condition and heterogenous in clinical presentation and course. There are some established risk factors, such as exposure to loud noise; however, in many cases, no discernable cause for tinnitus is identified.
>
> Hundreds of millions of people have received COVID-19 vaccinations under the most intensive monitoring in U.S. history. Because so many people have been vaccinated and because tinnitus is so common in the population, temporally-associated cases are expected, with some expected to occur shortly after vaccination. To further evaluate concerns about reports of tinnitus following COVID-19 vaccination, CDC conducted an analysis in the Vaccine Safety Datalink (VSD). Unlike VAERS, which relies primarily on voluntary reports from healthcare providers, patients, and others, the VSD uses data from electronic health records. Consequently, the VSD data are less likely to be affected by the reporting biases and other biases that impact spontaneous reporting patterns to VAERS and data quality. The VSD looked for clustering of tinnitus diagnoses in COVID-19 vaccinated patients during a post-vaccination observation period out to 70 days after vaccination. In the VSD's patient population of approximately 12 million people with 6.6 million COVID-19 vaccine doses administered, to date no clustering of tinnitus diagnoses has been observed post-vaccination.
>
> Currently, the information from vaccine safety monitoring systems does not suggest a link between COVID-19 vaccination and tinnitus. CDC will continue to monitor the safety of COVID-19 vaccines and continue to evaluate the outcome of tinnitus as additional data are collected.

Thanks,
Martha

Martha Sharan
Public Affairs
CDC/Division of Healthcare Quality Promotion
Off.: 404-639-2683
Cell: 404-998-1787

From: Tara Haelle (b)(6)
Sent: Wednesday, September 21, 2022 3:27 PM
To: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Subject: Re: FW: National Geographic interview request - AEs from COVID vaccines

Hi Martha,
It took me a while to pull these questions together because most of my questions will depend on the answers he gives to the first questions. In other words, I'm almost certainly going to have follow-up questions in response to these because of the nature of the questions. I've tried to include that in these questions, but I wanted to give you a heads up about likely having follow-

up questions. If it's at all possible to set up a phone or Zoom interview, that would be far preferable given the challenging nature of discussing adverse effects and vaccines and nuance required in those discussions.

Please let me know when Dr. Shimabukuro will be able to respond to these. If it's possible by the end of this week, that would be particularly helpful.

Thank you,
Tara Haelle

—Has the CDC investigated the potential association between tinnitus and COVID-19 vaccines? If so, can you tell me what the CDC vaccine safety researchers have done and found? Or, if not, can explain the reasoning behind that decision?

—One of the challenges of considering tinnitus as a presumptive AE is that it is so common as a background condition in the general population. Does a condition's prevalence in the general population affect how CDC safety researchers consider potential associations from AEs reported in VAERS?

—Does the CDC have plans to initiate a case control or other epidemiological study, using VSD or another data set, to investigate tinnitus as a potential AE correlated with any of the COVID-19 vaccines? Why or why not?

—A recent paper by Harpaz et al (doi: 10.1007/s40264-022-01186-z) suggests a strong association exists in VAERS reports for tinnitus and each of the three COVID-19 vaccines initially authorized by the FDA, but that the association is masked because of the high number of overall reports. Is this something that the CDC safety researchers have considered and/or that they are looking into?

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Books: Vaccination Investigation, The Informed Parent, various children's titles

On Thu, Sep 1, 2022 at 7:24 AM Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov> wrote:
Hi Tara:
Your request was forwarded to me. I work closely with Dr. Shimabukuro on media inquiries.
Would it be possible for you to send us a list of questions that you would like him to address. It would be easier for him to respond in writing.

Thanks,
Martha

Martha Sharan
Public Affairs
CDC/Division of Healthcare Quality Promotion
Off.: 404-639-2683
Cell: 404-998-1787

From: Tara Haelle (b)(6)
Sent: Wednesday, August 31, 2022 6:32 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Subject: National Geographic interview request - AEs from COVID vaccines

Hello Dr. Shimabukuro,
I'm not sure if you remember me, but I believe we met while I was on a CDC fellowship for AHCJ a number of years ago. I've been writing about vaccines for more than a decade, and I'm now writing an article for National Geographic about whether there is adequate evidence to determine whether tinnitus could be a potential adverse event linked to any of the COVID-19 vaccines.

I spoke with Patsy Stinchfield, and she mentioned you would be a good source on this since I have questions about the CDC's process in going through VAERS reports and determining what to further investigate using VSD or other epi studies.

Would you have time for an interview this week or next to discuss this topic for my article?

Thank you,
Tara Haelle

P.S. I realize discussing vaccine AEs with a reporter can be a precarious decision, so please feel free to contact others who might vouch for my credibility and reliance on the evidence, such as Dan Salmon, Paul Offit, Patsy Stinchfield, Walter Orenstein, Bruce Gellin, or Saad Omer, all of whom are familiar with me and my work.

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The Laryngoscope

Prevalence of New-Onset Tinnitus after COVID-19 Vaccination with Comparison to Other Vaccinations

Ian Dorney, BS; Lukas Bobak, BS; Todd Otteson, MD, MPH; David C. Kaelber, MD, PhD, MPH

Objective: To investigate how often patients are diagnosed with new-onset tinnitus within 21 days after COVID-19 vaccination in comparison to after three other common vaccinations: influenza, Tdap (tetanus, diphtheria, and acellular pertussis), and polysaccharide pneumococcus.

Methods: The TriNetX Analytics Network, a federated health research network that aggregates the de-identified electronic health record (EHR) data of over 78 million patients, was queried for patients receiving each vaccination. Instances of new-onset tinnitus within 21 days of vaccination were recorded and reported.

Results: Out of 2,575,235 patients receiving a first dose of the mRNA COVID-19 vaccine without any prior tinnitus diagnosis, 0.038% (95% CI: 0.036%–0.041%) of patients had a new diagnosis of tinnitus within 21 days. There was a higher risk of a new tinnitus diagnosis after the influenza vaccine (RR: 1.95, 95% CI: 1.72–2.21), Tdap vaccine (RR: 2.36, 95% CI: 1.93–2.89), and pneumococcal vaccine (RR: 1.97, 95% CI: 1.48–2.64) than after the first dose of the COVID-19 vaccine. There was a lower risk of a new tinnitus diagnosis after the second dose of COVID-19 than after the first dose (RR: 0.80, 95% CI: 0.71–0.91).

Conclusion: The rate of newly diagnosed tinnitus acutely after the first dose of the COVID-19 vaccine is very low. There was a higher risk of newly diagnosed tinnitus after influenza, Tdap, and pneumococcal vaccinations than after the COVID-19 vaccine. The present findings can help to address COVID-19 vaccine hesitancy during the ongoing pandemic.

Key Words: COVID-19 Vaccine, Epidemiology, Tinnitus, Vaccine Adverse Effect.

Level of Evidence: Level 3

***Laryngoscope*, 00:1–4, 2022**

INTRODUCTION

Vaccine hesitancy and fear of adverse effects from the mRNA COVID-19 vaccine are becoming more widespread and represent a significant national health concern. Consequently, the sequelae of the COVID-19 vaccine have been the topic of significant research throughout the COVID-19 pandemic. In recent months, there has been growing interest in tinnitus as a potential adverse effect of the mRNA COVID-19 vaccination. Recent case reports[1–4] describe patients experiencing life-altering tinnitus within days of the COVID-19 vaccination that may be accompanied by impaired hearing, significantly affect a patient's quality of life, and last for months. Post-vaccination otologic symptoms observed within 30 days of COVID-19 vaccination included tinnitus, hearing loss, dizziness, or vertigo.[5,6] Earlier this year, 555 cases of sudden sensorineural hearing loss after COVID-19 vaccination were reported in the North American Vaccine Related Adverse Effects System (VAERS) were investigated and no association was found between sudden sensorineural hearing loss and vaccination.[7] Symptom patterns and potential pathophysiologic mechanisms for post-vaccine tinnitus were discussed in a recent review of over 12,000 cases of tinnitus post-COVID-19 vaccination, reported by the CDC.[8] A 2021 study of national vaccine adverse event databases in Italy and the United Kingdom examining audiovestibular pathologies related to COVID-19 vaccination investigated tinnitus as a possible adverse effect but was unable to control for timing of symptomatology or provide comparisons to other vaccinations.[6] To our knowledge, there has not been a large-scale investigation into the prevalence of new tinnitus diagnoses after the COVID-19 vaccination in comparison to other common vaccinations.

Using a sample size of over 2.5 million patients who received a COVID-19 vaccine, the present study aims to investigate how often episodes of new-onset tinnitus are diagnosed within 21 days after vaccination. The purpose of this investigation is to use population-level data to examine how frequently newly diagnosed tinnitus occurs after COVID-19 vaccination in comparison to other common vaccinations for influenza, Tdap (tetanus, diphtheria, and acellular pertussis), and polysaccharide pneumococcus. The large sample size provides a unique opportunity to

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Additional supporting information may be found in the online version of this article.

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acquire meaningful data for this likely rare adverse effect. To give a frame of reference for the number of diagnosed tinnitus cases observed after COVID-19 vaccination, large populations of patients receiving other common vaccinations were compared to the mRNA COVID-19 group. These three other vaccination groups were analyzed as secondary outcomes and served as a reference group for the first dose COVID-19 vaccinated group.

MATERIALS AND METHODS

A retrospective cohort design was implemented using the TriNetX Analytics Network, a federated health research network that aggregates the de-identified electronic health record (EHR) data of over 78 million patients across 45 health care organizations (HCOs) within the US. There were 78,058,186 patients with any EHR contained in the US Collaborative Network of the TriNetX platform that was queried for vaccination events. Five patient groups were identified (Supplementary Cohort Criteria):

1. Received First mRNA COVID-19 Vaccine from December 15, 2020 to March 1, 2022
2. Received Second mRNA COVID-19 Vaccine from December 15, 2020 to March 1, 2022
3. Received Influenza Vaccine from January 1, 2019 to December 1, 2019
4. Received Tdap Vaccine from January 1, 2019 to December 1, 2019
5. Received Pneumococcal Vaccine from January 1, 2019 to December 1, 2019

The dates for the COVID-19 vaccinated group span from the first day of vaccine administration in the US to an arbitrary date that gave over a three-week window before the data was collected. The three other common vaccination groups were examined throughout the 2019 year to eliminate the possibility of COVID-19 vaccination within these three groups. Patients with any history of tinnitus before each respective vaccination event were excluded from all groups to more precisely focus on vaccine-related tinnitus and have findings applicable to the vast majority of the population without a history of tinnitus. Notably, the vaccination event was defined as the first time that the patients met the criteria within the time window, meaning that the first dose of the COVID-19 vaccination series was analyzed in the first dose group. The second dose COVID-19 group underwent exactly two recorded vaccination procedures. Because patients in the second dose group were excluded if they had a previous history of tinnitus, patients experiencing diagnosed tinnitus after the first dose were excluded from this population. New-onset tinnitus was defined as an encounter with a diagnosis of tinnitus in patients with no prior history of tinnitus.

Each patient group was indexed to the event of receiving the respective vaccination, and any occurrence of an encounter diagnosis of tinnitus within 21 days of vaccination was recorded. The timeline of 21 days was arbitrarily decided based on the symptomatology described in existing case reports and reviews that suggested acute to subacute onset within hours to days of vaccination.[1–5,8] Because 21 days is the earliest recommended time frame to receive a second dose of the COVID-19 vaccine after receiving the first dose, this timeline also served to exclude tinnitus caused by the second dose while examining the first dose group. The three common vaccinations were selected arbitrarily based on the most common vaccinations administered in the US in an effort to provide applicable comparison groups to the COVID-19 vaccine.

After the total number of diagnosed tinnitus cases were recorded for each of the five vaccination groups, four separate 1:1 propensity score matching procedures were performed using TriNetX's built-in logistic regression model. Full data sets and results of each propensity score matching procedure are provided in the Data S1, including standardized mean differences for each ICD-10 variable before and after matching. Matching was performed between the following groups: second dose COVID-19 vaccine to first dose COVID-19 vaccine (Table S1); influenza vaccine to first dose COVID-19 vaccine (Table S2), Tdap vaccine to first dose COVID-19 vaccine (Table S3); and polysaccharide pneumococcal vaccine to first dose COVID-19 vaccine (Table S4). Matching was performed for each group relative to the first dose COVID-19 vaccine group because our primary outcome was exploring the risk of new-onset tinnitus after the first dose of the COVID-19 vaccination as compared to other common vaccinations. Patients were matched between these groups based on age at vaccination, sex, race, and ethnicity (Supplementary Matching Criteria).

RESULTS

Out of 2,575,235 patients receiving a first dose of the mRNA COVID-19 vaccine without any prior tinnitus diagnosis, 0.038% (95% CI: 0.036%–0.041%) of patients had a new diagnosis of tinnitus within 21 days. Out of 1,477,890 patients receiving a second dose of the mRNA COVID-19 vaccine without any prior tinnitus diagnosis, 0.031% (95% CI: 0.029%–0.034%) of patients had a new diagnosis of tinnitus within 21 days of the second dose. The numbers and percentages of patients in each vaccination group with a new diagnosis of tinnitus are shown in Table I.

After four separate 1:1 propensity score matching procedures based on age at vaccination, sex, race, and ethnicity between patients receiving the first dose of the

TABLE I.
Numbers and Percentages of Patients with a New Encounter Diagnoses of Tinnitus within 21 days After Vaccination.

Vaccination Received	Vaccinated Patients without Any History of Encounter Diagnoses of Tinnitus	Patients with New Encounter Diagnoses of Tinnitus within 21 Days after Vaccination	Proportion with a New Encounter Diagnoses of Tinnitus (%) (95% CI)
First Dose mRNA COVID-19	2,575,235	986	0.038 (0.036–0.041)
Second Dose mRNA COVID-19	1,477,890	465	0.031 (0.029–0.034)
Influenza	1,200,749	745	0.062 (0.058–0.067)
Tetanus and diphtheria (Tdap)	456,306	314	0.069 (0.061–0.077)
Polysaccharide Pneumococcus	153,522	135	0.088 (0.074–0.100)

TABLE II.
Relative Risks for Post Vaccination New Encounter Diagnoses of Tinnitus Compared to the First Dose of COVID-19 Vaccine.

Vaccination Received	Relative Risk for New Encounter Diagnoses of Tinnitus Compared to First Dose COVID-19 Vaccination (after propensity score matching)
First Dose mRNA COVID-19	1
Second Dose mRNA COVID-19	0.80 (95% CI: 0.71–0.91)
Influenza	1.95 (95% CI: 1.72–2.21)
Tetanus and diphtheria (Tdap)	2.36 (95% CI: 1.93–2.89)
Polysaccarhide Pneumococcus	1.97 (95% CI: 1.48–2.64)

COVID-19 vaccine and the four other selected vaccinations, there was a higher risk of a new-onset diagnosed tinnitus after influenza vaccination, Tdap vaccination, and pneumococcal vaccination than after the first dose of the COVID-19 vaccine (Table II). There was a lower risk of a new diagnosis of tinnitus after the second dose of the COVID-19 vaccination series than after the first dose (RR: 0.80, 95% CI: 0.71–0.91). In the comparison for the influenza group, there were 998,991 influenza vaccine patients compared to 1,009,935 first dose COVID-19 vaccine patients, with 720 cases of a new encounter diagnosis of tinnitus in the influenza group and 374 cases of a new encounter diagnosis of tinnitus in the first dose COVID-19 group (RR: 1.95, 95% CI: 1.72–2.21). In comparison to the Tdap group, there were 444,708 Tdap vaccine patients compared to 444,721 first dose COVID-19 vaccine patients, with 314 cases of a new encounter diagnosis of tinnitus in the Tdap group and 133 cases of a new encounter diagnosis of tinnitus in the first dose COVID-19 group (RR: 2.36, 95% CI: 1.93–2.89). In the comparison for the polysaccharide pneumococcal vaccine group, there were 153,344 pneumococcal vaccine patients compared to 154,825 patients who received first dose of COVID-19 vaccine, with 132 cases of a new encounter diagnosis of tinnitus in the pneumococcal group and 79 cases of a new encounter diagnosis of tinnitus in the first dose of COVID-19 group (RR: 1.97, 95% CI: 1.48–2.64). In the comparison for the second dose of COVID-19 group, there were 1,516,282 patients who received second dose of COVID-19 vaccine compared to 1,516,282 patients who received first dose COVID-19 vaccine, with 465 cases of a new encounter diagnosis of tinnitus in the second dose COVID-19 group and 577 cases of a new encounter diagnosis of tinnitus in the first dose of COVID-19 group (RR: 0.80, 95% CI: 0.71–0.91).

DISCUSSION

In this retrospective cohort study examining over 2.5 million patients receiving a first dose of the mRNA COVID-19 vaccine, there was a low rate (0.038%, 95% CI: 0.036%–0.041%) of a new encounter diagnosis of tinnitus within 21 days of vaccination. After matching similar patients between COVID-19 vaccination groups, the likelihood of having a new encounter diagnosis of tinnitus was lower after the second dose of the COVID-19 vaccine than after the first dose (RR = 0.80, 95% CI: 0.71–0.91). This finding may suggest that patients with a predisposition to vaccine-related tinnitus may be more vulnerable after the first dose than after the second dose, or that the first dose provokes an inflammatory response more likely to cause tinnitus. There was a higher risk of a new encounter diagnosis of tinnitus after the influenza vaccine, Tdap vaccine, and polysaccharide pneumococcal vaccine than after the first dose of COVID-19 vaccination. It is important to consider that while the risk of a new encounter diagnosis of tinnitus was higher after these three common vaccinations than after the first dose of COVID-19 vaccination, the rates of a new encounter diagnosis of tinnitus for each of these groups were extremely low (≤0.1% in each of these groups). With such low rates of a new encounter diagnosis of tinnitus after each vaccination, consideration should be given to the baseline risk of developing a new encounter diagnosis of tinnitus independent of any vaccine. However, the lower risk of a new encounter diagnosis of tinnitus after the COVID-19 vaccination than the other three common vaccinations is not obviously explained by a difference in baseline risk between patient groups. The differences in tinnitus based on vaccinations may be due to different patterns of inflammation invoked by each vaccine or may be explained by uncontrolled variables.

In the discussion of post-COVID-19 vaccination tinnitus, the risk of a new tinnitus encounter diagnosis following COVID-19 infection should be considered. COVID-19 infection, like many other viral infections, has been shown to be associated with audiological and vestibular pathologies.[9,10] A recent meta-analysis of COVID-19 infection symptomatology found tinnitus as a statistically significant side effect of infection.[11] Multiple case reports[12–14] and reviews[15,16] describe tinnitus as a direct symptom of COVID-19 infection, likely secondary to systemic inflammation. Pathophysiological explanations posit cochleovestibular inflammation, the cross-reaction of immune cells to inner ear antigens, and endothelial dysfunction leading to microvascular damage of the inner ear as explanations for the significant audiovestibular sequela of COVID-19 infection.[14] Given the current body of evidence, tinnitus is more clearly causally linked to COVID-19 infection than to COVID-19 vaccination, and the risk of developing tinnitus after the vaccine is likely lower than after the infection prevented by the vaccine.

The present findings should not be used to discourage the administration of common vaccinations but rather serve as an impetus for further exploration into mRNA vaccine side effects. When provided with evidence of low incidences of adverse effects of the vaccine, patients may be more likely to consider being vaccinated.[17] The present findings do not speak to the severity of tinnitus or the long-lasting effects of post-vaccination tinnitus, but provide important information on how often patients are diagnosed with tinnitus subacutely after vaccination on a large population level. With the advent of mRNA vaccination in humans occurring on such a widespread scale, the complications of the vaccine should be researched thoroughly and medical providers should be up to date on the prevalence of adverse events for patient

discussion and education. The rate of diagnosed new-onset tinnitus seen in this investigation provides valuable clinical information for medical providers talking to patients with fear of the vaccine or vaccine hesitancy. The present findings provide evidence for medical providers to answer patient questions about the risk of tinnitus after vaccination.

There are limitations to this population-level study with such a large EHR data set. Notably, undiagnosed or uncoded tinnitus is not included and may be better studied with a smaller cohort and direct researcher oversight. This study excluded patients with any encounter diagnosis history of tinnitus in an effort to focus on vaccine-related tinnitus, which excludes information about the reactivation of tinnitus symptoms by vaccination. Additionally, this study did not separate the specific formulations of the COVID-19 vaccine. The timeline of 21 days was arbitrarily decided based on preliminary research and case reports and could potentially miss late-onset cases of tinnitus if too short or include unrelated events if too long. The common vaccination groups were studied throughout 2019 as opposed to the COVID-19 group, which was examined from 2020 to 2022, and widespread hesitation to present to the hospital during the pandemic could have masked cases of tinnitus post-COVID-19 vaccination.[18] However, it has been posited that the emotional burden widely experienced during pandemic lockdowns increased the perceived loudness of tinnitus[19] and may have increased the perception of otherwise subclinical tinnitus symptoms. Hearing outcomes from episodes of tinnitus were not examined in this study as they are not easily quantifiable from our data set but serve as an important direction for further research.

CONCLUSION

The rate of newly diagnosed tinnitus within 3 weeks of the first dose of COVID-19 vaccination is very low. Patients are more likely to develop a new encounter diagnosis of tinnitus after the three other common vaccinations for influenza, Tdap, and pneumococcus than after the first dose of the COVID-19 vaccine. The results of this study will be valuable to medical providers providing patient education about the COVID-19 vaccine, addressing vaccine hesitancy in the ongoing pandemic, and researching the side effect profile of mRNA vaccinations.

BIBLIOGRAPHY

1. Canales Medina M, Ramirez GM. Tinnitus, sudden sensorineural hearing loss, and vestibular neuritis as complications of the Astra Zeneca COVID-19 vaccine. *Cureus*. 2022;14(1):e20906. https://doi.org/10.7759/cureus.20906.
2. Parrino D, Frosolini A, Gallo C, De Siati RD, Spinato G, de Filippis C. Tinnitus following COVID-19 vaccination: report of three cases. *Int J Audiol*. 2021;13:1-4. https://doi.org/10.1080/14992027.2021.1931969.
3. Tseng PT, Chen TY, Sun YS, Chen YW, Chen JJ. The reversible tinnitus and cochleopathy followed first-dose AstraZeneca COVID-19 vaccination. *QJM*. 2021;114(9):663-664. https://doi.org/10.1093/qjmed/hcab210.
4. Finsterer J, Edmonds R. Persisting, unilateral tinnitus 22 days after first dose of an mRNA-based SARS-CoV-2 vaccine. *J Family Med Prim Care*. 2022;11(6):3330-3332. https://doi.org/10.4103/jfmpc.jfmpc_1927_21.
5. Wichova H, Miller ME, Derebery MJ. Otologic manifestations after COVID-19 vaccination: the house ear clinic experience. *Otol Neurotol*. 2021;42(9):e1213-e1218. https://doi.org/10.1097/MAO.0000000000003275.
6. Ciorba A, Bianchini C, Caranti A, Skarżyński PH, Pelucchi S, Hatzopoulos S. Incidence of audiological adverse effects induced by COVID-19 vaccines: a preliminary study. *Ear Nose Throat J*. 2021;0145561321104898. https://doi.org/10.1177/01455613211048975.
7. Formeister EJ, Wu MJ, Chari DA, et al. Assessment of sudden sensorineural hearing loss after COVID-19 vaccination. *JAMA Otolaryngol Head Neck Surg*. 2022;148(4):307-315. https://doi.org/10.1001/jamaoto.2021.4414.
8. Ahmed SH, Waseem S, Shaikh TG, et al. SARS-CoV-2 vaccine-associated-tinnitus: a review. *Ann Med Surg*. 2022;75:103293. https://doi.org/10.1016/j.amsu.2022.103293.
9. Viola P, Ralli M, Pisani D, et al. Tinnitus and equilibrium disorders in COVID-19 patients: preliminary results. *Eur Arch Otorhinolaryngol*. 2021;278(10):3725-3730. https://doi.org/10.1007/s00405-020-06440-7.
10. Kaliyappan K, Chen YC, Krishnan Muthaiah VP. Vestibular Cochlear manifestations in COVID-19 cases. *Front Neurol*. 2022;18(13):850337. https://doi.org/10.3389/fneur.2022.850337.
11. Jafari Z, Kolb BE, Mohajerani MH. Hearing loss, tinnitus, and dizziness in COVID-19: a systematic review and meta-analysis. *Can J Neurol Sci*. 2022;49(2):184-195. https://doi.org/10.1017/cjn.2021.63.
12. Daher GS, Nassiri AM, Vanichkachorn G, Carlson ML, Neff BA, Driscoll CLW. New onset tinnitus in the absence of hearing changes following COVID-19 infection. *Am J Otolaryngol*. 2022;43(1):103208. https://doi.org/10.1016/j.amjoto.2021.103208.
13. Chirakkal P, Al Hail AN, Zada N, Vijayakumar DS. COVID-19 and tinnitus. *Ear Nose Throat J*. 2021;100(2_suppl):160S-162S. https://doi.org/10.1177/0145561320974849.
14. Di Mauro P, La Mantia I, Cocuzza S, et al. Acute vertigo after COVID-19 vaccination: case series and literature review. *Front Med*. 2022;6(8):790931. https://doi.org/10.3389/fmed.2021.790931.
15. Ong KMC, Cruz TLG. Otologic and vestibular symptoms in COVID-19: a scoping review. *World J Otorhinolaryngol Head Neck Surg*. 2022;1-10. https://doi.org/10.1002/wjo2.57.
16. Maharaj S, Bello Alvarez M, Mungul S, Hari K. Otologic dysfunction in patients with COVID-19: a systematic review. *Laryngoscope Investig Otolaryngol*. 2020;5(6):1192-1196. https://doi.org/10.1002/lio2.498.
17. Kreps S, Prasad S, Brownstein JS, et al. Factors associated with US Adults' likelihood of accepting COVID-19 vaccination. *JAMA Netw Open*. 2020;3(10):e2025594. https://doi.org/10.1001/jamanetworkopen.2020.25594.
18. Beukes EW, Onozuka J, Brazell TP, Manchaiah V. Coping with tinnitus during the COVID-19 pandemic. *Am J Audiol*. 2021;30(2):385-393. https://doi.org/10.1044/2021_AJA-20-00188.
19. Aydoğan Z, Çinar Satekin M, Ocak E, Tokgoz YS. Effects of the coronavirus disease 2019 pandemic on subjective tinnitus perception. *J Laryngol Otol*. 2022;136(5):410-413. https://doi.org/10.1017/S0022215122000640.

From: Sharan, Martha (CDC/DDID/NCEZID/DHQP)
Sent: Mon, 6 Feb 2023 15:42:45 +0000
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Subject: RE: CDC Response - National Geographic interview request - AEs from COVID vaccines

Understood – thanks Tom. I will pass along the study you attached.
Thanks.
Martha

Martha Sharan
Public Affairs
CDC/Division of Healthcare Quality Promotion
Off.: 404-639-2683
Cell: 404-998-1787

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Sent: Monday, February 6, 2023 7:56 AM
To: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Subject: RE: CDC Response - National Geographic interview request - AEs from COVID vaccines

Here is my suggested response (b)(5)

(b)(5)

From: Tara Haelle (b)(6)
Sent: Monday, February 6, 2023 2:12 AM
To: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Subject: Re: CDC Response - National Geographic interview request - AEs from COVID vaccines

Hi Martha and Dr. Shimabukuro,
We are looking to publish the article at National Geographic on tinnitus as a possible/presumptive adverse event of COVID vaccines this week. The story was put on hold while I was out of the country from the holidays through January. I wanted to check in to see if

you had any additional information for me regarding CDC's progress on investigating this issue since we last corresponded. If it's at all possible to speak with Shimabukuro in the next few days before it's published, please let me know.

Thank you,
Tara Haelle

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Journalist, author, public speaker & AHCJ Medical Studies Core Topic Leader
Books: Vaccination Investigation, The Informed Parent, various children's titles

On Mon, Nov 14, 2022 at 9:11 AM Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov> wrote:
Hi Tara – unfortunately I don't have any more information to share at this time.

Martha Sharan
Public Affairs
CDC/Division of Healthcare Quality Promotion
Off.: 404-639-2683
Cell: 404-998-1787

From: Tara Haelle [(b)(6)]
Sent: Thursday, November 10, 2022 11:22 PM
To: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Subject: Re: CDC Response - National Geographic interview request - AEs from COVID vaccines

Thank you! Do you know if it's possible to find out the precise methodology that the ISO is using for the VSD analysis?

Thanks,
Tara

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On Thu, Nov 10, 2022 at 9:31 AM Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov> wrote:
Hi Tara:

Here's what the Immunization Safety Office is telling me:

> At this time, vaccine safety monitoring efforts in CDC have identified no evidence of a causal association between COVID-19 vaccination and tinnitus or other hearing loss.

The VSD analysis is in progress but the Immunization Safety Office can't discuss preliminary findings.

No target date for completion has been given.
Thanks,
Martha

Martha Sharan
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Cell: (b)(6)

From: Sharan, Martha (CDC/DDID/NCEZID/DHQP)
Sent: Thursday, November 10, 2022 9:51 AM
To: Tara Haelle (b)(6)
Subject: RE: CDC Response - National Geographic interview request - AEs from COVID vaccines

Checking on this for you!

Martha Sharan
Public Affairs
CDC/Division of Healthcare Quality Promotion
Off.: 404-639-2683
Cell: (b)(6)

From: Tara Haelle (b)(6)
Sent: Thursday, November 10, 2022 7:40 AM
To: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Subject: Re: CDC Response - National Geographic interview request - AEs from COVID vaccines

Hi Martha,
I wanted to check back in to see if you had any update on the additional analysis that you mentioned using VSD. Do you know when it will be started, when it will be complete, or when results from it might be available? I need to file my story this week or next, so I'm wondering if I could still briefly speak with Dr. Shimabukuro, especially regarding the specific way CDC conducts its statistical analysis for associations.

Thank you,
Tara

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On Mon, Oct 3, 2022 at 7:56 AM Tara Haelle (b)(6) wrote:
Martha,
Thank you very much for the update. I look forward to hearing more when the analysis is complete.

Thanks,
Tara

—Sent from a buzzing brain probably clumsily dictating to a miniature magical box

****
www.tarahaelle.com
Mob 817.458.8133

On Oct 3, 2022, at 7:53 AM, Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov> wrote:

Hi Tara:
Received word from Dr. Shimabukuro that he would like to delay this interview due to an additional analyses that CDC is going to do in one of the safety monitoring systems known as the Vaccine Safety Datalink (VSD). We may have updated information on tinnitus and he would prefer to hold off until the analysis is completed to avoid giving you outdated information.

I don't have a target date for completion at this time. Dr. Shimabukuro indicated that it would be "relatively soon."
I will try to keep you informed, however, please feel free to check back with me.
Thanks,
Martha

From: Tara Haelle (b)(6)
Sent: Friday, September 30, 2022 5:31 PM

To: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Subject: Re: CDC Response - National Geographic interview request - AEs from COVID vaccines

Martha,
A Monday interview would be fantastic. Thank you so much. Let me know what time works best. Thanks also for the note about CDC not commenting on non-CDC studies. I'll keep that in mind and adjust my questions accordingly.

Thank you,
Tara

– –

These are incredibly tough, strange times. Feeling awful and frustrated you can't "snap out of it?" Read this. If you're thinking of hurting yourself, please call the Suicide Hotline at 1-800-273-8255 or text 741741. You matter.

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Books: Vaccination Investigation, The Informed Parent, various children's titles

On Fri, Sep 30, 2022 at 7:39 AM Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov> wrote:
Hi Tara – I can try to arrange a short interview on Monday. Dr. Shimabukuro is (b)(6) th (b)(6) so his schedule will be impossible.

Please note, as a general rule, CDC does not comment on studies/findings that did not involve CDC experts and were conducted outside of the agency.

Thanks,
Martha

From: Tara Haelle (b)(6)
Sent: Friday, September 30, 2022 6:22 AM
To: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Subject: Re: CDC Response - National Geographic interview request - AEs from COVID vaccines
Martha,
Thank you very much for sending these along. In reading the responses, I notice that several of the responses explain things I'm already aware of, such as the difference between incidence and prevalence; the difference between VAERS and VSD; and the substantial limitations of a passive monitoring system like VAERS. (I've reported on vaccine safety for over a decade, so I'm very familiar with all these issues and the CDC's mechanisms.)

I'm not sure if my questions weren't worded well or there was a misunderstanding otherwise, but I have follow-up questions to try to get better clarification on what I was asking. Would it be possible to set up a brief phone call with Dr. Shimabukuro to discuss this issue? It doesn't seem as though email questions are adequate for the level of specificity and nuance I'm seeking for this story. I'm a little different than most reporters in writing about vaccine adverse events because I've reported on them for so long, and I'm very familiar with all the tropes and misconceptions promoted by those who are anti-vaccine or who otherwise are unfamiliar with the specifics of CDC vaccine safety surveillance and research.

Thank you,
Tara Haelle

– –

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Journalist, author, public speaker & AHCJ Medical Studies Core Topic Leader
Books: Vaccination Investigation, The Informed Parent, various children's titles

On Thu, Sep 29, 2022 at 7:07 AM Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov> wrote:
Hi Tara:
Yes, I have responses from Dr. Shimabukuro, Director, CDC's Immunization Safety Office. I will pass along your additional questions.

Please see below:

> **A recent paper by Harpaz et al (doi: 10.1007/s40264-022-01186-z) suggests a strong association exists in VAERS reports for tinnitus and each of the three COVID-19 vaccines initially authorized by the FDA, but that the association is masked because of the high number of overall reports. Is this something that the CDC safety researchers have considered and/or that they are looking into?**

CDC did not participate in this analysis and recommends that you contact the authors if you have questions about their analysis.

One of the challenges of considering tinnitus as a presumptive AE is that it is so common as a background condition in the general population. Does a condition's prevalence in the general population affect how CDC safety researchers consider potential associations from AEs reported in VAERS? Would shortening the time after vaccination that they looked for an association be likely to change any likelihood of finding an association?

> Per CDC (Principles of Epidemiology | Lesson 3 - Section 2 (cdc.gov)), "Prevalence refers to proportion of persons who have a condition at or during a particular time period, whereas

incidence refers to the proportion or rate of persons who develop a condition during a particular time period. So prevalence and incidence are similar, but prevalence includes new and pre-existing cases whereas incidence includes new cases only." For vaccine safety monitoring, we are most concerned with incident cases, or new cases occurring following vaccination. Expected incidence (background incidence) is taken into consideration when conducting vaccine safety evaluations.

A vaccine adverse event is an adverse health event or other outcome or event (e.g., a medical error) occurring in temporal association with a vaccination. CDC monitors all VAERS data and can take into consideration incident versus prevalent conditions when information is available in the report, as well as biologically plausible risk intervals for symptom onset of the adverse event following vaccination. VAERS is a spontaneous reporting (passive surveillance) system that accepts all reports regardless of the plausibility of the vaccine causing the event or the clinical seriousness of the event. VAERS is a signal detection (hypothesis generating) system and is not designed to determine causality.

Many of the individuals I have spoken to have said that they either did not file a VAERS report because they were told it was pointless, or they asked their doctor to file one and the doctor refused or referred them to a different doctor to report it (who then refused or referred them back to the original doctor). I heard this frequently enough to wonder whether tinnitus was underreported in VAERS. How likely might it be that tinnitus is similarly underreported in the healthcare systems involved in VSD? Is there a way to take this into account in analyses of a potential association?

The Vaccine Safety Datalink (VSD) is an electronic health record (EHR)-based system that collects data (in the EHR) on patients with health insurance when they receive healthcare. This is one of the main differences between passive surveillance in VAERS and active surveillance in VSD; VAERS depends upon people filing reports, while in VSD, a diagnosis of tinnitus would be recorded in the EHR during a patient visit as part of standard healthcare practice.VSD data are not impacted by the types of reporting biases inherent to VAERS.

Is there any possibility that the CDC will initiate another study in the future, using VSD again or another data set, to investigate tinnitus as a potential AE correlated with any of the COVID-19 vaccines? Or is the matter considered settled? Why or why not?

CDC will continue to monitor COVID-19 vaccine safety in VAERS, VSD, and other systems. If we observe data that indicates a potential safety problem we will further investigate. Additional assessments of safety signals may include epidemiologic studies if appropriate.

It seems statistically possible that a condition that has a naturally high prevalence in the general population (as tinnitus does) but is very rare as a vaccine adverse event could easily be missed as a true signal by traditional VSD analysis methods. How, if at all, have CDC safety researchers accounted for this possibility. (I'd wager that tinnitus is likely the most common condition that's ever been considered as a serious AE, which would make it fairly unique among presumptive AEs.)

Please refer to our original response and the above response to your question on common conditions. Other relatively common conditions have been evaluated in vaccine safety research,

such as febrile seizure and shoulder injury. While tinnitus prevalence in the general population is relatively high, the incidence of new onset tinnitus is a different concept.

VSD uses TreeScan data mining methods, which can detect pattens of clustering of diagnoses in a post-vaccination observation period, even if few diagnoses are made (because the diagnosis is rare). To date, VSD TreeScan data mining has not observed clustering of tinnitus in a post-vaccination observation period.

Thanks,
Martha

From: Tara Haelle (b)(6)
Sent: Thursday, September 29, 2022 5:31 AM
To: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Subject: Re: FW: National Geographic interview request - AEs from COVID vaccines

Hi Martha,
I wanted to check in on the status of the questions I sent, and I had some additional questions that arose in the process of my reporting on this story. Those additional questions are below. I certainly realize this will extend the time Dr. Shimabukuro needs to respond to my questions.

6) The WHO identified tinnitus as having a signal with the adenovirus vector vaccines (see attached), and the European Medicines Agency listed tinnitus as a possible side effect from the adenovirus vector vaccine, but the CDC has not. Can you comment on why the CDC has not followed the WHO's and EMA's lead on this and why an association would be seen with adenovirus vector vaccines?

7) When the CDC did their investigation into any associations between tinnitus and vaccination, did that analysis only look at a binary association (tinnitus did/did not occur within 90 days after vaccination), or did the analysis look at temporal patterns within that 90-day period (ie, whether there was a clustering of tinnitus reports within a shorter time period post-vaccination vs tinnitus reporting that was consistently spread out across the 90 days)?

8A) Tinnitus in the general population nearly always follows the same pattern as gradual hearing loss, with an estimated 90% of people who have tinnitus also having hearing loss. When the CDC did their analysis of tinnitus and COVID-19 vaccines, did that analysis also look at whether the people who reported tinnitus also had concurrent hearing loss?
8B) In the WHO report, only 15% of those who reported tinnitus also had hearing loss, suggesting that their tinnitus was distinct from the "usual" tinnitus that develops in the general population. Another unpublished analysis of data looking at tinnitus and COVID-19 vaccines similarly found that a very low percentage of people who experienced tinnitus after the vaccination also had hearing loss. Can you comment on whether this information might strengthen the potential possibility of an association between tinnitus and COVID-19 vaccines?

Thank you,
Tara

These are incredibly tough, strange times. Feeling awful and frustrated you can't "snap out of it?" Read this. If you're thinking of hurting yourself, please call the Suicide Hotline at 1-800-273-8255 or text 741741. You matter.

Tara Haelle • @tarahaelle
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Journalist, author, public speaker & AHCJ Medical Studies Core Topic Leader
Books: Vaccination Investigation, The Informed Parent, various children's titles

On Thu, Sep 22, 2022 at 2:13 PM Tara Haelle (b)(6) wrote:
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On Thu, Sep 22, 2022 at 11:56 AM Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov> wrote:
Hi Tara:

Dr. Shimabukuro will look at these, but he will not have time to get back to you until next week.
Thanks for your patience,
Martha

Martha Sharan
Public Affairs
CDC/Division of Healthcare Quality Promotion
Off.: 404-639-2683
Cell: 404-998-1787

From: Tara Haelle (b)(6)
Sent: Thursday, September 22, 2022 2:31 AM
To: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Subject: Re: FW: National Geographic interview request - AEs from COVID vaccines

Martha,
Thank you for this. Is that VSD analysis published somewhere? If so, could you share the citation with me? Meanwhile, I've adjusted some of the questions below, including the order of them.

Thanks,
Tara

—A recent paper by Harpaz et al (doi: 10.1007/s40264-022-01186-z) suggests a strong association exists in VAERS reports for tinnitus and each of the three COVID-19 vaccines initially authorized by the FDA, but that the association is masked because of the high number of overall reports. Is this something that the CDC safety researchers have considered and/or that they are looking into?

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On Wed, Sep 21, 2022 at 2:52 PM Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov> wrote:
Hi Tara:
CDC now has a statement that I am including below – not sure if this will have an impact on your list of questions. Let me know if you need to adjust any of them:

> CDC is aware of reports to the Vaccine Adverse Event Reporting System (VAERS) of tinnitus occurring in temporal association with COVID-19 vaccination (i.e., following vaccination). Tinnitus is a common condition and heterogenous in clinical presentation and course. There are some established risk factors, such as exposure to loud noise; however, in many cases, no discernable cause for tinnitus is identified.
>
> Hundreds of millions of people have received COVID-19 vaccinations under the most intensive monitoring in U.S. history. Because so many people have been vaccinated and because tinnitus is so common in the population, temporally-associated cases are expected, with some expected to occur shortly after vaccination. To further evaluate concerns about reports of tinnitus following COVID-19 vaccination, CDC conducted an analysis in the Vaccine Safety Datalink (VSD). Unlike VAERS, which relies primarily on voluntary reports from healthcare providers, patients, and others, the VSD uses data from electronic health records. Consequently, the VSD data are less likely to be affected by the reporting biases and other biases that impact spontaneous reporting patterns to VAERS and data quality. The VSD looked for clustering of tinnitus diagnoses in COVID-19 vaccinated patients during a post-vaccination observation period out to 70 days after vaccination. In the VSD's patient population of approximately 12 million people with 6.6 million COVID-19 vaccine doses administered, to date no clustering of tinnitus diagnoses has been observed post-vaccination.
>
> Currently, the information from vaccine safety monitoring systems does not suggest a link between COVID-19 vaccination and tinnitus. CDC will continue to monitor the safety of COVID-19 vaccines and continue to evaluate the outcome of tinnitus as additional data are collected.

Thanks,
Martha

Martha Sharan
Public Affairs
CDC/Division of Healthcare Quality Promotion

Off.: 404-639-2683
Cell: 404-998-1787

From: Tara Haelle (b)(6)
Sent: Wednesday, September 21, 2022 3:27 PM
To: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Subject: Re: FW: National Geographic interview request - AEs from COVID vaccines

Hi Martha,
It took me a while to pull these questions together because most of my questions will depend on the answers he gives to the first questions. In other words, I'm almost certainly going to have follow-up questions in response to these because of the nature of the questions. I've tried to include that in these questions, but I wanted to give you a heads up about likely having follow-up questions. If it's at all possible to set up a phone or Zoom interview, that would be far preferable given the challenging nature of discussing adverse effects and vaccines and nuance required in those discussions.

Please let me know when Dr. Shimabukuro will be able to respond to these. If it's possible by the end of this week, that would be particularly helpful.

Thank you,
Tara Haelle

—Has the CDC investigated the potential association between tinnitus and COVID-19 vaccines? If so, can you tell me what the CDC vaccine safety researchers have done and found? Or, if not, can explain the reasoning behind that decision?

—One of the challenges of considering tinnitus as a presumptive AE is that it is so common as a background condition in the general population. Does a condition's prevalence in the general population affect how CDC safety researchers consider potential associations from AEs reported in VAERS?

—Does the CDC have plans to initiate a case control or other epidemiological study, using VSD or another data set, to investigate tinnitus as a potential AE correlated with any of the COVID-19 vaccines? Why or why not?

—A recent paper by Harpaz et al (doi: 10.1007/s40264-022-01186-z) suggests a strong association exists in VAERS reports for tinnitus and each of the three COVID-19 vaccines initially authorized by the FDA, but that the association is masked because of the high number of overall reports. Is this something that the CDC safety researchers have considered and/or that they are looking into?

– –

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On Thu, Sep 1, 2022 at 7:24 AM Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov> wrote:
Hi Tara:
Your request was forwarded to me. I work closely with Dr. Shimabukuro on media inquiries.
Would it be possible for you to send us a list of questions that you would like him to address. It would be easier for him to respond in writing.

Thanks,
Martha

Martha Sharan
Public Affairs
CDC/Division of Healthcare Quality Promotion
Off.: 404-639-2683
Cell: 404-998-1787

From: Tara Haelle (b)(6)
Sent: Wednesday, August 31, 2022 6:32 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Subject: National Geographic interview request - AEs from COVID vaccines

Hello Dr. Shimabukuro,
I'm not sure if you remember me, but I believe we met while I was on a CDC fellowship for AHCJ a number of years ago. I've been writing about vaccines for more than a decade, and I'm now writing an article for National Geographic about whether there is adequate evidence to determine whether tinnitus could be a potential adverse event linked to any of the COVID-19 vaccines.

I spoke with Patsy Stinchfield, and she mentioned you would be a good source on this since I have questions about the CDC's process in going through VAERS reports and determining what to further investigate using VSD or other epi studies.

Would you have time for an interview this week or next to discuss this topic for my article?

Thank you,

Tara Haelle

P.S. I realize discussing vaccine AEs with a reporter can be a precarious decision, so please feel free to contact others who might vouch for my credibility and reliance on the evidence, such as Dan Salmon, Paul Offit, Patsy Stinchfield, Walter Orenstein, Bruce Gellin, or Saad Omer, all of whom are familiar with me and my work.

– –

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From: Sharan, Martha (CDC/DDID/NCEZID/DHQP)
Sent: Mon, 14 Nov 2022 15:16:43 +0000
To: Avery, Lacey (CDC/DDID/NCEZID/DHQP)
Cc: Kraun, Sharon (CDC/DDID/NCEZID/DHQP) (CTR)
Subject: RE: DHQP Media Summary - week of 11-7-22

Sure – will do!

Martha Sharan
Public Affairs
CDC/Division of Healthcare Quality Promotion
Off.: 404-639-2683
Cell: 404-998-1787

From: Avery, Lacey (CDC/DDID/NCEZID/DHQP) <xmh2@cdc.gov>
Sent: Monday, November 14, 2022 10:16 AM
To: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Cc: Kraun, Sharon (CDC/DDID/NCEZID/DHQP) (CTR) <ubl2@cdc.gov>
Subject: FW: DHQP Media Summary - week of 11-7-22

Hey Martha!

Katy forwarded the below email. Can you add me and Sharon onto these emails? At least while I'm acting ARX ADC. Thank you!

And thank you to Curtis for his assistance with the Media Plant and Infection Control interviews.

:) Lacey

From: Capers, Catherine (Katy) (CDC/DDID/NCEZID/DHQP) <ybz5@cdc.gov>
Sent: Monday, November 14, 2022 10:13 AM
To: Avery, Lacey (CDC/DDID/NCEZID/DHQP) <xmh2@cdc.gov>; Kraun, Sharon (CDC/DDID/NCEZID/DHQP) (CTR) <ubl2@cdc.gov>
Subject: FW: DHQP Media Summary - week of 11-7-22

FYI

From: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Sent: Monday, November 14, 2022 10:03 AM
To: Cardo, Denise M. MD (CDC/DDID/NCEZID/DHQP) <dbc0@cdc.gov>; Bell, Michael MD (CDC/DDID/NCEZID/DHQP) <zzb8@cdc.gov>; Capers, Catherine (Katy) (CDC/DDID/NCEZID/DHQP) <ybz5@cdc.gov>; Craig, Michael R. (CDC/DDID/NCEZID/DHQP) <bez7@cdc.gov>; Coffin, Nicole (CDC/DDID/NCEZID/DHQP) <ndc3@cdc.gov>; Kroop, Seth (CDC/DDID/NCEZID/DHQP) <wpw7@cdc.gov>; McBride, Stefanie (CDC/DDID/NCEZID/DHQP) <wve1@cdc.gov>; McDonald, Clifford (CDC/DDID/NCEZID/DHQP) <ljm3@cdc.gov>; McClune, Elizabeth (CDC/DDID/NCEZID/DHQP)

<ymt0@cdc.gov>; Moran, Kerri (CDC/DDID/NCEZID/DHQP) <ytb5@cdc.gov>; Srinivasan, Arjun (CDC/DDID/NCEZID/DHQP) <beu8@cdc.gov>; Brinsley-Rainisch, Kristin (CDC/DDID/NCEZID/DHQP) <aof4@cdc.gov>
Cc: Gill, Curtis (CDC/DDID/NCEZID/DHQP) (CTR) <qsi3@cdc.gov>
Subject: DHQP Media Summary - week of 11-7-22

Everyone: Below, please find the media summary for the week of 11/07/22. Please let me know if you have any questions or would like any additional information.

3 media inquiries handled at the spokesperson level:

- **FactCheck.org –** fact checking claims that there has been an increase in stillbirths following COVID-19 vaccination
- **Lead Stories –** fact checking claims that there has been an increase in stillbirths following COVID-19 vaccination
- **National Geographic –** CDC findings on possible association of tinnitus and sudden and sensorineural hearing loss and COVID-19 vaccinations

2 media interviews:

- **Media Planet (written response)**
    - SME: Michael Craig – contributing to Media Planet's annual "Antimicrobial Resistance Campaign" with article highlighting U.S. data on antimicrobial resistance and prevention/action to combat the global health threat and raising awareness about antimicrobial resistance and the need for prevention to reverse current rise of AR; to be published this year in The Guardian Newspaper during World Antimicrobial Awareness Week (11/18-11/24/22)

- **Infection Control Today (written response)**
    - SME: Lauri Hicks on the AMR Exchange Webinar - Addressing Health Inequities by Strengthening Antibiotic Stewardship

Work in progress:

- Vital Signs – Disparities in Dialysis Treatment; press statement, telebriefing script, tough Q&A

Have a great week,
Martha

Martha Sharan
Public Affairs
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Cell: 404-998-1787

From: Tara Haelle
Sent: Thu, 29 Sep 2022 04:30:35 -0500
To: Sharan, Martha (CDC/DDID/NCEZID/DHQP)
Subject: Re: FW: National Geographic interview request - AEs from COVID vaccines
Attachments: 2-WHO tinnitus report.pdf

Hi Martha,
I wanted to check in on the status of the questions I sent, and I had some additional questions that arose in the process of my reporting on this story. Those additional questions are below. I certainly realize this will extend the time Dr. Shimabukuro needs to respond to my questions.

6) The WHO identified tinnitus as having a signal with the adenovirus vector vaccines (see attached), and the European Medicines Agency listed tinnitus as a possible side effect from the adenovirus vector vaccine, but the CDC has not. Can you comment on why the CDC has not followed the WHO's and EMA's lead on this and why an association would be seen with adenovirus vector vaccines?

7) When the CDC did their investigation into any associations between tinnitus and vaccination, did that analysis only look at a binary association (tinnitus did/did not occur within 90 days after vaccination), or did the analysis look at temporal patterns within that 90-day period (ie, whether there was a clustering of tinnitus reports within a shorter time period post-vaccination vs tinnitus reporting that was consistently spread out across the 90 days)?

8A) Tinnitus in the general population nearly always follows the same pattern as gradual hearing loss, with an estimated 90% of people who have tinnitus also having hearing loss. When the CDC did their analysis of tinnitus and COVID-19 vaccines, did that analysis also look at whether the people who reported tinnitus also had concurrent hearing loss?
8B) In the WHO report, only 15% of those who reported tinnitus also had hearing loss, suggesting that their tinnitus was distinct from the "usual" tinnitus that develops in the general population. Another unpublished analysis of data looking at tinnitus and COVID-19 vaccines similarly found that a very low percentage of people who experienced tinnitus after the vaccination also had hearing loss. Can you comment on whether this information might strengthen the potential possibility of an association between tinnitus and COVID-19 vaccines?

Thank you,
Tara

— —

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Public Affairs

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— —

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> Hundreds of millions of people have received COVID-19 vaccinations under the most intensive monitoring in U.S. history. Because so many people have been vaccinated and because tinnitus is so common in the population, temporally-associated cases are expected, with some expected to occur shortly after vaccination. To further evaluate concerns about reports of tinnitus following COVID-19 vaccination, CDC conducted an analysis in the Vaccine Safety Datalink (VSD). Unlike VAERS, which relies primarily on voluntary reports from healthcare providers, patients, and others, the VSD uses data from electronic health records. Consequently, the VSD data are less likely to be affected by the reporting biases and other biases that impact spontaneous reporting patterns to VAERS and data quality. The VSD looked for clustering of tinnitus diagnoses in COVID-19 vaccinated patients during a post-vaccination observation period out to 70 days after vaccination. In the VSD's patient population of approximately 12 million people with 6.6 million COVID-19 vaccine doses administered, to date no clustering of tinnitus diagnoses has been observed post-vaccination.
>
> Currently, the information from vaccine safety monitoring systems does not suggest a link between COVID-19 vaccination and tinnitus. CDC will continue to monitor the safety of COVID-19 vaccines and continue to evaluate the outcome of tinnitus as additional data are collected.

Thanks,
Martha

Martha Sharan

Public Affairs

CDC/Division of Healthcare Quality Promotion

Off.: 404-639-2683

Cell: 404-998-1787

From: Tara Haelle (b)(6)
Sent: Wednesday, September 21, 2022 3:27 PM
To: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Subject: Re: FW: National Geographic interview request - AEs from COVID vaccines

Hi Martha,

It took me a while to pull these questions together because most of my questions will depend on the answers he gives to the first questions. In other words, I'm almost certainly going to have follow-up questions in response to these because of the nature of the questions. I've tried to include that in these questions, but I wanted to give you a heads up about likely having follow-up questions. If it's at all possible to set up a phone or Zoom interview, that would be far preferable given the challenging nature of discussing adverse effects and vaccines and nuance required in those discussions.

Please let me know when Dr. Shimabukuro will be able to respond to these. If it's possible by the end of this week, that would be particularly helpful.

Thank you,

Tara Haelle

—Has the CDC investigated the potential association between tinnitus and COVID-19 vaccines? If so, can you tell me what the CDC vaccine safety researchers have done and found? Or, if not, can explain the reasoning behind that decision?

—One of the challenges of considering tinnitus as a presumptive AE is that it is so common as a background condition in the general population. Does a condition's prevalence in the general population affect how CDC safety researchers consider potential associations from AEs reported in VAERS?

—Does the CDC have plans to initiate a case control or other epidemiological study, using VSD or another data set, to investigate tinnitus as a potential AE correlated with any of the COVID-19 vaccines? Why or why not?

—A recent paper by Harpaz et al (doi: 10.1007/s40264-022-01186-z) suggests a strong association exists in VAERS reports for tinnitus and each of the three COVID-19 vaccines initially authorized by the FDA, but that the association is masked because of the high number of overall reports. Is this something that the CDC safety researchers have considered and/or that they are looking into?

— —

These are incredibly tough, strange times. Feeling awful and frustrated you can't "snap out of it?" Read this. If you're thinking of hurting yourself, please call the Suicide Hotline at 1-800-273-8255 or text 741741. You matter.

Tara Haelle • @tarahaelle

Pronouns: She/Her • 817.458.8133 CST (no PR calls please)

tarahaelle.net

Journalist, author, public speaker & AHCJ Medical Studies Core Topic Leader

Books: Vaccination Investigation, The Informed Parent, various children's titles

On Thu, Sep 1, 2022 at 7:24 AM Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov> wrote:

Hi Tara:
Your request was forwarded to me. I work closely with Dr. Shimabukuro on media inquiries.

Would it be possible for you to send us a list of questions that you would like him to address. It would be easier for him to respond in writing.

Thanks,

Martha

Martha Sharan

Public Affairs

CDC/Division of Healthcare Quality Promotion

Off.: 404-639-2683

Cell: 404-998-1787

From: Tara Haelle (b)(6)
Sent: Wednesday, August 31, 2022 6:32 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Subject: National Geographic interview request - AEs from COVID vaccines

Hello Dr. Shimabukuro,

I'm not sure if you remember me, but I believe we met while I was on a CDC fellowship for AHCJ a number of years ago. I've been writing about vaccines for more than a decade, and I'm now writing an article for National Geographic about whether there is

adequate evidence to determine whether tinnitus could be a potential adverse event linked to any of the COVID-19 vaccines.

I spoke with Patsy Stinchfield, and she mentioned you would be a good source on this since I have questions about the CDC's process in going through VAERS reports and determining what to further investigate using VSD or other epi studies.

Would you have time for an interview this week or next to discuss this topic for my article?

Thank you,

Tara Haelle

P.S. I realize discussing vaccine AEs with a reporter can be a precarious decision, so please feel free to contact others who might vouch for my credibility and reliance on the evidence, such as Dan Salmon, Paul Offit, Patsy Stinchfield, Walter Orenstein, Bruce Gellin, or Saad Omer, all of whom are familiar with me and my work.

— —

These are incredibly tough, strange times. Feeling awful and frustrated you can't "snap out of it?" Read this. If you're thinking of hurting yourself, please call the Suicide Hotline at 1-800-273-8255 or text 741741. You matter.

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World Health Organization

WHO Pharmaceuticals NEWSLETTER

2022
No. 1

WHO Vision for Safety of Medicinal Products
No country left behind: worldwide pharmacovigilance for safer medicinal products, safer patients

The aim of the Newsletter is to disseminate regulatory information on the safety of medicinal products, based on communications received from our network of national pharmacovigilance centres and other sources such as specialized bulletins and journals, as well as partners in WHO.

The information is produced in the form of résumés in English, full texts of which may be obtained on request from:

Pharmacovigilance,
MHP/RPQ,
World Health Organization,
1211 Geneva 27, Switzerland,
E-mail address:
pvsupport@who.int

This Newsletter is also available at:
https://www.who.int/teams/regulation-prequalification

The WHO Pharmaceuticals Newsletter provides you with the latest information on the safety of medicinal products and legal actions taken by regulatory authorities around the world. It also provides signals based on information from the WHO global database of individual case safety reports, VigiBase.

In addition, this edition of the Newsletter includes a short article on the recent Advisory Committee on Safety of Medicinal Products (ACSoMP) meeting.

Contents

WHO Pharmaceuticals Newsletter No. 1, 2022

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Table of Contents

Regulatory Matters

Safety of medicines

All the previous issues of the WHO Pharmaceuticals Newsletter can be accessed from our website at:

https://www.who.int/publications/i?healthtopics=c896df17-29f4-4e3a-b81f-302f999ed12d,9bc69cb6-e97e-4ae9-adf3-76d5b171ff08,5f7b6914-1953-48b6-aabe-9b997a16999e&publishingoffices=a511529e-adb5-49ea-bbde-546a3c26cba7&healthtopics-hidden=true&publishingoffices-hidden=true&regionscountries-hidden=true

Bisphosphonates, denosumab and romosozumab

Risk of atypical fracture in non-femur sites

Japan. The Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA) have announced that the product information for bisphosphonates, denosumab (Ranmark®) and romosozumab (Evenity®) should be revised to include the risk of atypical fracture in non-femur sites.

Bisphosphonates (including alendronate, ibandronate, etidronate, zoledronic, pamidronate, minodronic acid and risedronate), denosumab and romosozumab are indicated for the treatment of osteoporosis.

The MHLW and the PMDA reviewed reports of atypical fracture in non-femur sites (such as ulna or tibia) following administration of those products.

Reference:
Revision of Precautions, MHLW/PMDA, 20 June 2021 *(link to the source within www.pmda.go.jp/english/)*

(See WHO Pharmaceuticals Newsletter No.3, 2019: Risk of hypercalcaemia and multiple vertebral fractures for denosumab in UK)

Cefoperazone and sulbactam

Risk of acute coronary syndrome accompanying allergic reaction

Japan. The MHLW and the PMDA have announced that the product information for the products containing both cefoperazone and sulbactam (Sulperazon®) should be revised to include the risk of acute coronary syndrome accompanying allergic reaction.

Cefoperazone and sulbactam are indicated for the treatment of infectious diseases which are strains of genus susceptible to the substances.

The MHLW and the PMDA reviewed two cases of acute coronary syndrome accompanying allergic reaction in patients treated with the products reported in Japan.

Reference:
Revision of Precautions, MHLW/PMDA, 12 October 2021 *(link to the source within www.pmda.go.jp/english/)*

Chloral hydrate, cloral betaine

Restriction of paediatric indication

United Kingdom. The Medicines and Healthcare Products Regulatory Agency (MHRA) has announced that the paediatric indication for chloral hydrate (for children aged two years and older) and cloral betaine (children aged 12 years and older) has been restricted to short-term treatment (maximum two weeks) of severe insomnia only when the child or adolescent has a suspected or definite neurodevelopmental disorder and when the insomnia is interfering with normal daily life after treatment failure with other therapies (behavioural and pharmacological). The product information is being amended to clarify the restricted use.

Chloral hydrate (Welldorm Elixir®) and cloral betaine (Welldorm®) are indicated for severe insomnia that is interfering with normal daily life and where other therapies have failed, as an adjunct to non-pharmacological therapies. Chloral hydrate is licensed for use in adults and in children aged two years and older. Cloral betaine tablets are licensed for use in adults and adolescents aged 12 years and older.

The MHRA conducted a review of safety and efficacy data and sought independent expert advice including for paediatric sleep disorders. No new safety concerns were identified; however, in view of the carcinogenicity data in animals and the lack of long-term studies, a risk in humans for long-term use was not excluded. As such, the above restriction was recommended where the benefits of short-term use outweigh any potential risk, reflecting current clinical practice.

In addition, the maximum treatment period for these medicines in all patients has now been defined as two weeks in the product information because their prolonged use is associated with tolerance and the risks of dependence and abuse. Repeated courses are not recommended and can only be administered following medical specialist re-assessment. Following prolonged treatment, the dose should be slowly tapered before discontinuation

to avoid delirium.

Reference:
Drug Safety Update, MHRA, 6 October 2021 *(link to the source within www.gov.uk/mhra)*

COVID-19 vaccine NRVV Ad (ChAdOx1 nCoV-19)

Risk of immune thrombocytopenia (ITP)

Europe. The Pharmacovigilance Risk Assessment Committee (PRAC) has recommended a change to the product information for COVID-19 vaccine NRVV Ad (ChAdOx1 nCoV-19) (Vaxzevria®) to include a warning on immune thrombocytopenia (ITP) as an adverse reaction with an unknown frequency. ITP is a condition in which the immune system mistakenly targets platelets in blood.

COVID-19 vaccine NRVV Ad (ChAdOx1 nCoV-19) is a vaccine for preventing COVID-19.

The PRAC assessed cases of ITP reported following vaccination and evidence from the scientific literature.

Healthcare professionals should consider the risk of developing low platelet levels prior to administering the vaccine if an individual has a history of ITP and are recommended to monitor platelet levels following vaccination in individuals with a history of ITP.

Reference:
Patients and carers, EMA, 1 October 2021 *(link to the source within www.ema.europa.eu)*

COVID-19 vaccine NRVV Ad26 (JNJ 78436735)

1. Risk of venous thromboembolism (VTE)

Europe. The PRAC has recommended that thromboembolism (VTE) should be listed as a rare side effect in the product information for COVID-19 vaccine NRVV Ad26 (JNJ 78436735) (COVID-19 vaccine Janssen®). VTE is a condition in which a blood clot forms in a deep vein, usually in a leg, arm or groin, and may travel to the lungs causing a blockage of the blood supply, with possible life-threatening consequences.

COVID-19 vaccine NRVV Ad26 (JNJ 78436735) is indicated for preventing COVID-19.

The PRAC reviewed data form two large clinical studies and post marketing surveillance and concluded that there is a possible link to rare cases of VTE with COVID-19 vaccine NRVV Ad26 (JNJ 78436735).

The PRAC has also recommended to provide a warning to raise awareness among healthcare professionals and people taking the vaccine, especially those who may have an increased risk of VTE, and to assess a potential diagnosis of thrombosis with thrombocytopenia syndrome (TTS) when signs are present within three weeks after vaccination.

Reference:
Patients and carers, EMA, 1 October 2021 *(link to the source within www.ema.europa.eu)*

2. Risk of immune thrombocytopenia (ITP)

Europe. The PRAC has recommended a change to the product information for COVID-19 vaccine NRVV Ad26 (JNJ 78436735) (COVID-19 vaccine Janssen®) to include a warning on immune thrombocytopenia (ITP) as an adverse reaction with an unknown frequency. ITP is a condition in which the immune system mistakenly targets platelets in blood.

The PRAC assessed cases of ITP reported following vaccination and evidence from the scientific literature.

Healthcare professionals should consider the risk of developing low platelet levels prior to administering the vaccine if an individual has a history of ITP. They are recommended to monitor platelet levels following vaccination in individuals with a history of ITP.

Reference:
Patients and carers, EMA, 1 October 2021 *(link to the source within www.ema.europa.eu)*

3. Risk of dizziness and tinnitus

Europe. The PRAC has recommended that dizziness and tinnitus should be listed as adverse reactions in the product information of COVID-19 vaccine NRVV Ad26 (JNJ 78436735) (COVID-19 vaccine Janssen®). Tinnitus is ringing or other noises in one or both ears.

The PRAC assessed the available evidence including

cases of dizziness identified in spontaneous reports and cases of tinnitus identified in clinical trials and spontaneous reports and concluded that cases of dizziness and tinnitus are linked to the administration of COVID-19 vaccine NRVV Ad26 (JNJ 78436735).

Reference:
Patients and carers, EMA, 6 August 2021 *(link to the source within www.ema.europa.eu)*

Eperisone

Risk of Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN)

Republic of Korea. The Ministry of Food and Drug Safety (MFDS) has updated the product information for eperisone products (oral) to include the risk of Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN).

Eperisone is a centrally-acting muscle relaxant used for relieving painful muscle spasms or rigidity in musculoskeletal and neuromuscular disorders.

The Korea institute of Drug safety and Risk Management (KIDS) reviewed one report, which suggested a causal link between oral eperisone and SJS/TEN, and information from a foreign regulatory authority and a medical database.

Healthcare professionals should be aware of the signs and symptoms of SJS and TEN to allow early diagnosis and prompt treatment. Patients are advised to seek immediate medical attention if they experience these severe cutaneous symptoms.

Reference:
Based on the communication from MFDS and KIDS, November 2021

Erenumab

Risk of hypertension

Australia. The Therapeutic Goods Administration (TGA) has announced that the product information for erenumab (Aimovig®) has been updated with a warning statement about a potential causal relationship between the drug and hypertension.

Erenumab is indicated for prophylaxis of migraine in adults.

The TGA reviewed cases of the development of hypertension and worsening of pre-existing hypertension reported following use of the drug in the postmarketing setting internationally. Hypertension can occur at any time during treatment, but it was most frequently reported within seven days of dose administration. In the majority of cases, the onset or worsening of hypertension was reported after the first dose of erenumab.
Healthcare professionals should monitor patients treated with erenumab for new-onset hypertension or worsening of pre-existing hypertension. If hypertension is observed and evaluation fails to establish an alternative etiology, they should consider whether discontinuation of erenumab is warranted.

Reference:
Medicines Safety Update, TGA, 9 September 2021 *(link to the source within www.tga.gov.au)*

Fingolimod

Risk of liver injury

New Zealand. The Medsafe has announced that the product information for fingolimod (Gilenya®) has been updated to include the risk of liver injury, to require liver function monitoring during and after treatment, and to include criteria for stopping treatment to prevent serious drug-induced liver injury.

Fingolimod is an immunomodulating drug indicated for the treatment of relapsing multiple sclerosis.

Clinically significant liver injury and cases of acute liver failure requiring liver transplant have been reported in patients treated with fingolimod and the Centre for Adverse Reactions Monitoring (CARM) received four adverse reaction reports of increased hepatic enzymes where fingolimod was the suspected medicine.
Healthcare professionals are advised to check recent transaminase and bilirubin levels before initiation of treatment, to promptly measure transaminase and bilirubin levels if the patient treated with fingolimod reports signs and symptoms of liver injury, and not to resume the treatment unless a plausible alternative aetiology for the signs and symptoms of liver injury can be established.

Reference:
Prescriber Update, Medsafe, September 2021 *(link to the source within*

www.medsafe.govt.nz/)

(See WHO Pharmaceuticals Newsletter No.1, 2021: Risk of serious liver injury and herpes meningoencephalitis in UK)

Gadolinium-based contrast agents

Potential risk of stillbirth and neonatal death

Canada. Health Canada announced that it will work with the manufacturers of gadolinium-based contrast agents (GBCAs) to include the potential risks of stillbirth and neonatal death in their Canadian Product Monographs (CPMs) to raise awareness among healthcare professionals and encourage reporting of these potential safety issues.

GBCAs are used to make certain body tissues easier to see during a magnetic resonance imaging (MRI) or a magnetic resonance angiography (MRA) scan. Gadopentetate dimeglumine, gadobenate dimeglumine, gadodiamide, gadoxetate disodium, gadoterate meglumine, gadobutrol and gadoteridol are authorized as GBCAs.

Health Canada reviewed information from databases (Canada Vigilance database and VigiBase), where reports of stillbirths or neonatal deaths with the use of GBCAs during pregnancy are received, and literature and concluded that there is not enough information to rule out a link between the use of GBCAs during pregnancy and the risks of stillbirth and neonatal death. The measure will be taken as a precaution, given the potential for serious harm to fetuses and infants.

In the review process, case reports of congenital anomalies with the use of GBCAs were also assessed but no link was found between the use of GBCAs during pregnancy and the risk of congenital anomalies.

Reference:
Summary Safety Review, Health Canada, 22 September 2021 *(link to the source within www.hc-sc.gc.ca)*

Hydrocortisone

Risk of hypertrophic cardiomyopathy in neonates and infants

Japan. The MHLW and the PMDA have announced that the product information for hydrocortisone preparations (oral and injectable dosage forms) should be revised to include the risk of hypertrophic cardiomyopathy in neonates and infants.

Hydrocortisone preparations are used for various indications including endocrine and allergic diseases.

The MHLW and the PMDA reviewed cases of hypertrophic cardiomyopathy reported in neonates and infants treated with hydrocortisone preparations overseas.

Reference:
Revision of Precautions, MHLW/PMDA, 20 June 2021 *(link to the source within www.pmda.go.jp/english/)*

Ivermectin

1. Risk of disturbed consciousness

Japan. The MHLW and the PMDA have announced that the product information for ivermectin (Stromectol®) should be revised to include the risk of disturbed consciousness.

Ivermectin is indicated for the treatment of intestinal strongyloidiasis and scabies.

The MHLW and the PMDA reviewed four cases of disturbed consciousness reported in patients treated with ivermectin in Japan and other countries.

Reference:
Revision of Precautions, MHLW/PMDA, 12 October 2021 *(link to the source within www.pmda.go.jp/english/)*

2. Potential risk of encephalopathy

Saudi Arabia. The Saudi Food & Drug Authority (SFDA) has announced that healthcare professionals should be aware of the potential risk of encephalopathy associated with the use of ivermectin and to monitor any signs or symptoms in treated patients.

The SFDA reviewed eight case reports, of which two suggested possible association of encephalopathy with ivermectin and one case positive dechallenge reaction reported, as well as the literature.

Reference:
Safety Alerts, SFDA, 17 August 2021 *(link to the source within www.sfda.gov.sa)*

Magnesium sulfate

Risk of rickets-like bone lesion in neonates at birth

Japan. The MHLW and the PMDA have announced that the product information for magnesium sulfate (injection) indicated for eclampsia should be revised to include the risk of rickets-like bone lesion in neonates at birth with prolonged administration of this drug during pregnancy.

The MHLW and the PMDA reviewed cases of rickets-like bone lesion reported in neonates born to patients treated with magnesium sulfate in Japan and concluded that a causal relationship between the drug and event was reasonably possible in all the cases. The shortest duration of administration with magnesium sulfate (injections) to the mother was 18 days.

Reference:
Revision of Precautions, MHLW/PMDA, 20 June 2021 *(link to the source within www.pmda.go.jp/english/)*

(See WHO Pharmaceuticals Newsletter No.4, 2019: Risk of skeletal adverse effects in neonates in UK)

Methylphenidate

Potential risk of birth defects and malformations

Australia. The TGA has announced that the product information for methylphenidate products has been updated with new information about use in pregnancy. Updated safety information relating to birth defects and malformations is included and the pregnancy category has now been changed so that methylphenidate should not be prescribed for women of childbearing age unless, in the opinion of the physician, the potential benefits outweigh the possible risks.

Methylphenidate is a central nervous system stimulant. It is available in the forms of immediate-release tablets (Ritalin 10®), modified-release capsules (Ritalin LA®) and modified-release tablets (Concerta®) and is indicated for the treatment of ADHD.

The TGA reviewed large observational studies and observed a small increased occurrence of foetal cardiac malformations in women who received methylphenidate during the first trimester of pregnancy, compared with non-exposed pregnancies.

Reference:
Medicines Safety Update, TGA, 26 July 2021 (*link to the source within www.tga.gov.au*)

Minocycline

Risk of agranulocytosis

Australia. The TGA has announced that the product information for minocycline (Minomycin®, Akamin®) is in the process of being updated to include information about agranulocytosis, a rare but potentially life-threatening adverse event, where there is an extremely low number of granulocytes (a type of white blood cell) in the blood.

Minocycline is a tetracycline antibiotic used to treat bacterial infections.

The TGA reviewed four cases of agranulocytosis reported following treatment with minocycline. One case had a positive dechallenge while another was a fatal case reported as tetracycline-induced agranulocytosis. In the other two cases, minocycline-induced agranulocytosis could not be ruled out, as the cases were confounded by other medicines known to cause agranulocytosis.
Healthcare professionals should be aware of the potential risk of agranulocytosis associated with minocycline and the importance of early recognition and monitoring of full blood count and liver function tests during treatment. Prior to treatment with minocycline, patients should be made aware of the risk, including signs and symptoms, and what to do in the event of suspected agranulocytosis.

Reference:
Medicines Safety Update, TGA, 30 August 2021 *(link to the source within www.tga.gov.au)*

Nifedipine

Risk of pulmonary oedema when used in pregnancy

Australia. The TGA has announced that the product information for nifedipine products has been updated to provide new information about the risk of acute pulmonary oedema when used as a tocolytic agent (inhibiting myometrial smooth muscle contractions) for the treatment of preterm labor in pregnancy.

Nifedipine is a calcium channel blocker and indicated for the management of chronic stable angina pectoris and vasospastic

angina pectoris (Prinzmetal's angina, variant angina) due to coronary heart disease and the treatment of hypertension. Nifedipine is contraindicated in pregnancy and during lactation.

The TGA reviewed four adverse event reports involving off-label use of nifedipine in pregnancy. The risk was higher in cases of multiple pregnancy (twins or more), with an intravenous administration route or concomitant use of beta-2 agonists.

Reference:
Medicines Safety Update, TGA, 26 July 2021 *(link to the source within www.tga.gov.au)*

Ocrelizumab

Risk of late onset neutropenia

Australia. The TGA has announced that the product information for ocrelizumab (Ocrevus®) has been updated to include a warning and further information about late onset neutropenia.

Ocrelizumab is a recombinant humanised anti-CD20 monoclonal antibody (IgG1 subtype) that is indicated for patients with relapsing forms of multiple sclerosis and primary progressive multiple sclerosis.

The TGA reviewed four reported cases of neutropenia associated with ocrelizumab. Cases of late onset of neutropenia have been reported at least four weeks after the last Ocrevus infusion.

Healthcare professionals should be advised that late onset neutropenia is a serious safety concern and requires prompt recognition and treatment. Signs and symptoms of late onset neutropenia may not be apparent initially and can occur at least four weeks after the last administration of ocrelizumab.

Reference:
Medicines Safety Update, TGA, 26 July 2021 (*link to the source within www.tga.gov.au*)

Parenteral iron products

Risk of fetal bradycardia and Kounis syndrome

Australia. The TGA has announced that the product information for parenteral iron products has been updated class-wide to include information about fetal bradycardia and Kounis syndrome, which is the concurrence of acute coronary syndromes with conditions associated with mast cell activation. Both conditions can have serious clinical implications.

There are four parenteral iron products marketed in Australia: ferric carboxymaltose (Ferinject®) and ferric derisomaltose (Monofer®) are indicated for iron deficiency where oral administration is ineffective or contraindicated, or where there is a need to deliver iron rapidly; iron polymaltose (Ferrosig injection®) is for the treatment of iron deficiency anaemia when oral iron therapy is contraindicated, enteric absorption of iron is defective, or when patient non-compliance or persistent gastrointestinal intolerance makes oral therapy impractical; and iron sucrose (Venofer®) is for the treatment of iron deficiency anaemia in patients undergoing chronic haemodialysis and who are receiving supplemental erythropoietin therapy.

Hypersensitivity is a class effect that is well documented in the product information of all parenteral iron products. The TGA concluded that fetal bradycardia and Kounis syndrome are biologically plausible as a result of hypersensitivity reactions.

Reference:
Medicines Safety Update, TGA, 27 July 2021 *(link to the source within www.tga.gov.au)*

Pentosan polysulfate sodium

Potential risk of pigmentary maculopathy

Australia. The TGA has announced that the product information for pentosan polysulfate sodium (Elmiron®) has been updated with a warning about potential pigmentary maculopathy, especially after long-term use.

Pentosan polysulfate sodium is indicated for the treatment of bladder pain syndrome (interstitial cystitis).

The TGA reviewed rare cases of pigmentary maculopathy with the use of pentosan polysulfate sodium, especially after long-term use, reported in the literature. Visual symptoms could include complaints of difficulty to read and slow adjustment in low or reduced light environments.

Healthcare professionals should

be aware of this potential adverse event and advise patients receiving pentosan polysulfate sodium of the risks. All patients should have regular ophthalmic examinations for early detection of pigmentary maculopathy, particularly those on long-term use of pentosan polysulfate sodium.

Reference:
Medicines Safety Update, TGA, 11 October 2021 *(link to the source within www.tga.gov.au)*

(See WHO Pharmaceuticals Newsletter No.6, 2019: Rare risk of pigmentary maculopathy in UK)

Pregabalin

Risk of severe respiratory depression

Ireland. The Health Products Regulatory Authority (HPRA) has announced that the product information for pregabalin-containing medicinal products will be updated to include a warning on respiratory depression and to add it as a possible adverse reaction with unknown frequency, following the conclusions of the PRAC.

Pregabalin-containing medicinal products are indicated for the treatment of neuropathic pain in adults, as adjunctive therapy in adults for specific forms of epilepsy and for generalized anxiety disorder in adults.

The PRAC reviewed safety data and concluded that pregabalin is associated with reports of respiratory depression in the absence of concomitant therapy with opioids or other central nervous system (CNS) depressants, in patients with and without other risk factors for respiratory depression.

Healthcare professionals should be advised that patients with risk factors (compromised respiratory function, respiratory or neurological disease, renal impairment, concomitant use of CNS depressants and older age (> 65 years)) may be at higher risk of experiencing respiratory depression with pregabalin and dose adjustment may be necessary. Patients taking the medicine should be advised to contact their doctor if they experience trouble breathing or have shallow breaths and not to drink alcohol while taking pregabalin.

Reference:
Newsletters and Reports, HPRA, 16 September 2021 *(link to the source within www.hpra.ie)*

(See also WHO Pharmaceuticals Newsletter No.2, 2021: Risk of severe respiratory depression in UK)

Remdesivir

Potential risk of sinus bradycardia

Canada. Health Canada has announced that it will work with the manufacturer of remdesivir (Veklury®) to update the product information to include a warning on the potential risk of sinus bradycardia. Sinus bradycardia occurs when the heart beats slower than normal.

Remdesivir is indicated to treat COVID-19 in adults with pneumonia who require oxygen.

Health Canada assessed case reports of sinus bradycardia in patients receiving remdesivir in their database and in the literature and concluded that a link between the use of remdesivir and the risk of sinus bradycardia is possible.

Reference:
Summary Safety Review, Health Canada, 18 August 2021 *(link to the source within www.hc-sc.gc.ca)*

(See also WHO Pharmaceuticals Newsletter No.4, 2021: Risk of sinus bradycardia in Europe)

Sertraline

Potential risk of microscopic colitis

Singapore. The Health Sciences Authority (HSA) has announced that it is working with the manufacturers of sertraline-containing products to update the product information to include microscopic colitis as an adverse event. Microscopic colitis is a rare inflammatory disorder of the colon.

Sertraline is a selective serotonin reuptake inhibitor (SSRI) indicated for the treatment of depression, obsessive compulsive disorder, panic disorder, post-traumatic stress disorder, social phobia and pre-menstrual dysphoric disorder.

The HSA reviewed a case-control study, three case reports of microscopic colitis related to the use of sertraline and the decisions by other regulatory authorities.

Healthcare professionals should be advised to consider the possibility of microscopic colitis in patients on sertraline who

present with prolonged or severe diarrhoea. Diarrhoea is a common adverse drug reaction associated with the use of sertraline.

Reference:
Safety Alerts, HSA, 18 October 2021 *(link to the source within www.hsa.gov.sg)*

(See also WHO Pharmaceuticals Newsletter No.4, 2021: potential risk of microscopic colitis in Singapore)

Statins

Removal of contraindication for pregnant women

USA. The US Food and Drug Administration (FDA) has requested revisions to the information in the prescribing information for the entire class of statin medicines about use in pregnancy. These changes include removing the contraindication against using these medicines in all pregnant patients.

Statins are a class of medicines that have been used to lower low-density lipoprotein cholesterol (LDL-C) in the blood. Medicines in the statin class include atorvastatin, fluvastatin, lovastatin, pitavastatin, pravastatin, rosuvastatin, and simvastatin.

It was concluded that contraindicating these drugs in all pregnant women is not appropriate because the benefits of statins may include prevention of serious or potentially fatal events in a small group of very high-risk pregnant patients.

Healthcare professionals should discontinue statin therapy in most pregnant patients, or they can consider the ongoing therapeutic needs of the individual patient, particularly those at very high risk for cardiovascular events during pregnancy. Patients taking statins should notify their healthcare professionals if they become pregnant or suspect they are pregnant. Those who require statins after giving birth should not breastfeed and should use alternatives such as infant formula.

Reference:
MedWatch, US FDA, 20 July 2021 *(link to the source within www.fda.gov)*

Tetanus, diphtheria and pertussis (Tdap) vaccine

Risk of Guillain-Barré syndrome

Republic of Korea. The MFDS has updated the product information for tetanus, diphtheria and pertussis (Tdap) vaccine (Boostrix®) to include the risk of Guillain-Barré syndrome (GBS).

Tdap vaccine is indicated for booster immunization against tetanus, diphtheria and pertussis in individuals aged 10 years and older.

The KIDS reviewed one report, which suggested a causal link between Tdap vaccine administration and GBS, and other information from a foreign regulatory authority and a medical database.

Healthcare professionals should be aware of the signs and symptoms of GBS in patients with recent vaccination history.

Reference:
Based on the communication from MFDS and KIDS, November 2021

Tinidazole

Risk of fixed eruption

India. The National Coordination Centre – Pharmacovigilance Programme of India (NCC-PvPI), Indian Pharmacopoeia Commission (IPC) has advised the Central Drugs Standard Control Organization (CDSCO) to revise the prescribing information leaflet (PIL) for tinidazole to include fixed eruption as an adverse drug reaction.

Tinidazole is indicated for the treatment of intestinal amoebiasis, giardiasis, trichomoniasis and anaerobic infections.

NCC-PvPI, IPC reviewed 71 case reports of tinidazole associated fixed eruption and a strong causal relationship between them was found.

Reference:
Based on the communication from IPC, India, November 2021 *(ipc.gov.in)*

Tofacitinib, Baricitinib and Upadacitinib

Risk of serious heart-related events, cancer, blood clots, and death

1. USA. The US FDA has requested that the boxed warnings for tofacitinib (Xeljanz®/Xeljanz XR®),

baricitinib (Olumiant®) and upadacitinib (Rinvoq®), are updated to include the risk of serious heart-related events, cancer, blood clots, and death.

Tofacitinib, baricitinib and upadacitinib are janus kinase (JAK) inhibitors and are used to treat inflammatory conditions such as rheumatoid arthritis.

A review of safety data for tofacitinib was recently completed in USA. Based on this review increased risks of serious heart-related events, cancer, blood clots, and death were identified for tofacitinib compared with TNF blockers in the treatment of patients with rheumatoid arthritis.

Baricitinib and upadacitinib, also used for inflammatory conditions in the same class, are considered to have a risk similar to that of tofacitinib.

Healthcare professionals should consider the benefits and risks for individual patients prior to initiating or continuing therapy with these medicines. Patients should be advised to seek emergency medical attention if they experience signs and symptoms of a heart attack, stroke, or blood clot. Patients should tell their healthcare professional their history and risk factors for those events and seek emergency help immediately if they have any of those symptoms.

Reference:
MedWatch, US FDA, 1 September 2021 *(link to the source within www.fda.gov)*

2. United Kingdom. The MHRA has announced that the product information for tofacitinib will be updated with the information that tofacitinib should not be used in patients older than 65 years of age, people who are current or past smokers, or individuals with other cardiovascular (e.g., diabetes or coronary artery disease) or malignancy risk factors unless there are no suitable alternative treatments.

The MHRA reviewed the results of a clinical safety trial to evaluate the safety of tofacitinib compared with TNF blockers and identified these risk factors.

Reference:
Drug Safety Update, MHRA, 6 October 2021 *(link to the source within www.ema.europa.eu)*

3. Japan. The MHLW and the PMDA have announced that the package insert for tofacitinib should be revised to include the risk of cardiovascular events, such as myocardial infarction.

The MHLW and the PMDA reviewed the results of a clinical safety trial to evaluate the safety of tofacitinib compared with TNF blockers and identified these risk factors.

Reference:
Revision of Precautions, MHLW/PMDA, 12 October 2021 *(link to the source within www.pmda.go.jp/english/)*

(See also WHO Pharmaceuticals Newsletter No.4, 2021: Risk of cardiovascular events and cancer in Europe)

Topical corticosteroids

Risk of topical steroid withdrawal reactions

United Kingdom. The MHRA has warned that rare, severe adverse effects can occur on stopping treatment with topical corticosteroids, often after long-term continuous or inappropriate use of moderate to high potency products. Information about the risks and characteristics of topical steroid withdrawal reactions will be added to the product information for topical corticosteroid medicines.

Topical corticosteroids are used for treatments of skin conditions such as eczema, psoriasis, and atopic dermatitis. They are available in four different levels of potencies.

The MHRA reviewed 55 reports indicative of topical steroid withdrawal reactions, most of which were reported by patients, and information available in the literature and from other regulators and sought advice from clinical experts. Although it was not possible to estimate the frequency of these reactions, given the number of patients who use topical corticosteroids, it was understood that reports of severe withdrawal reactions were very infrequent.

To reduce the risks of these events, it is recommended that healthcare professionals should prescribe the lowest potency of topical corticosteroid needed and ensure patients know how to use it safely and effectively.

Reference:
Drug Safety Update, MHRA, 15 September 2021 *(link to the source within www.gov.uk/mhra)*

Tramadol

Risk of urinary retention

India. The NCC-PvPI, IPC has advised the CDSCO to revise the PIL for tramadol to include urinary retention as an adverse drug reaction.

Tramadol is indicated for the treatment of moderate to severe pain, diagnostic procedures and surgical pain.

NCC-PvPI, IPC reviewed seven reports of tramadol-associated urinary retention and a causal relationship between them was found.

Reference:
Based on the communication from IPC, India, November 2021 *(ipc.gov.in)*

Aflibercept

Potential risk of Fournier's gangrene

Saudi Arabia. The SFDA has released a potential safety signal concerning Fournier's gangrene associated with the use of aflibercept.

Aflibercept is indicated for the treatment of neovascular (wet) age-related macular degeneration and metastatic colorectal cancer.

The SFDA reviewed five case reports, two of which supported the association, and the literature.

Reference:
Safety Alerts, SFDA, 21 September 2021 *(link to the source within www.sfda.gov.sa)*

Atezolizumab

Potential risk of keratitis

Saudi Arabia. The SFDA has released a potential safety signal concerning keratitis associated with the use of atezolizumab.

Atezolizumab is a monoclonal antibody inhibiting PD-L1 and indicated for the treatment of locally advanced or metastatic urothelial carcinoma after prior chemotherapy or that are considered cisplatin ineligible.

The SFDA reviewed four case reports, one of which supported the association, and the literature.

Reference:
Safety Alerts, SFDA, 9 August 2021 *(link to the source within www.sfda.gov.sa)*

Bevacizumab

Potential risk of Fournier's gangrene

Saudi Arabia. The SFDA has released a potential safety signal concerning Fournier's gangrene associated with the use of bevacizumab.

Bevacizumab is a monoclonal antibody inhibiting VEGF-A and indicated for the treatment of non-small cell lung cancer and other cancers.

The SFDA reviewed 35 case reports, nine of which supported the association, and the literature.

Reference:
Safety Alerts, SFDA, 9 August 2021 *(link to the source within www.sfda.gov.sa)*

Cefuroxime

Potential risk of Kounis syndrome

Saudi Arabia. The SFDA has released a potential safety signal concerning Kounis syndrome associated with the use of cefuroxime.

Cefuroxime is cephalosporin antibacterial drug indicated for the treatment of infectious diseases caused by sensitive bacteria.

The SFDA reviewed 11 case reports, three of which supported the association, and the literature.

Reference:
Safety Alerts, SFDA, 21 June 2021 *(link to the source within www.sfda.gov.sa)*

Colchicine

Potential risk of pneumonia

Saudi Arabia. The SFDA has released a potential safety signal concerning pneumonia associated with the use of colchicine.

Colchicine is indicated for prophylaxis of gout flares in adults.

The SFDA reviewed 40 case reports, four of which supported the association, and the literature.

Reference:
Safety Alerts, SFDA, 9 August 2021 *(link to the source within www.sfda.gov.sa)*

Empagliflozin

Risk of ketoacidosis and Fournier's gangrene

New Zealand. The Medsafe has announced that empagliflozin is associated with the risk of ketoacidosis and Fournier's gangrene (necrotising fasciitis of the perineum).

Empagliflozin is a sodium glucose co-transporter 2 (SGLT2) inhibitors and is used for the treatment of type two diabetes mellitus.
The CARM received three reports of ketoacidosis and two reports of Fournier's gangrene following initiation of empagliflozin.

For the risk of ketoacidosis, healthcare professionals are advised to consider stopping empagliflozin temporarily during an acute illness, particularly if patients are unwell, febrile or vomiting and

not eating. Empagliflozin should also be temporarily stopped before undergoing medical procedures or surgery. For the risk of Fournier's gangrene, patients should be advised to seek immediate medical attention if they experience pain, tenderness, redness or swelling of the genital or perineal area, particularly with associated fever or malaise.

Reference:
Prescriber Update, Medsafe, September 2021 *(link to the source within www.medsafe.govt.nz/)*

(See WHO Pharmaceuticals Newsletter No.3, 2020: Risk of diabetic ketoacidosis for SGLT2 inhibitors in UK)

Finasteride

Potential risk of diabetes mellitus

Saudi Arabia. The SFDA has released a potential safety signal concerning diabetes mellitus associated with the use of finasteride.

Finasteride is a 5α-reductase inhibitor and indicated for the treatment of symptomatic benign prostatic hyperplasia (BPH) in men with an enlarged prostate.

The SFDA reviewed 62 case reports, two of which supported the association, and the literature.

Reference:
Safety Alerts, SFDA, 17 August 2021 *(link to the source within www.sfda.gov.sa)*

Infliximab

Potential risk of bursitis

Saudi Arabia. The SFDA has released a potential safety signal concerning bursitis associated with the use of infliximab.

Infliximab is a monoclonal antibody inhibiting the function of TNFα and indicated for the treatment of rheumatoid arthritis and other inflammatory diseases.

The SFDA reviewed 30 case reports, 18 of which supported the association and the literature.

Reference:
Safety Alerts, SFDA, 8 July 2021 *(link to the source within www.sfda.gov.sa)*

(See WHO Pharmaceuticals Newsletter No.4, 2018: Potential risk of linear IgA bullous dermatosis in Canada)

Octreotide

Risk of atrioventricular block

Australia. The TGA has announced that intravenous infusion of octreotide, which is used off-label in Australia, is linked to the risk of atrioventricular block.

Octreotide is an octapeptide that mimics natural somatostatin pharmacologically and is indicated for symptomatic control and reduction of growth hormone and IGF-1 plasma levels in patients with acromegaly etc. The approved route of administration for octreotide products is only subcutaneous injection for the registered indications, while one product (Sandostatin LAR®) may only be administered by deep intragluteal injection.

The TGA evaluated the risk of atrioventricular blocks associated with octreotide treatment using the product information in European Union and clinical guidelines in Australia.

Healthcare professionals should be advised of the identified risk of atrioventricular block in patients receiving off-label high doses of continuous infusion (100 micrograms/hour) of octreotide and in patients receiving bolus octreotide intravenously (50 micrograms bolus followed by 50 micrograms/hour continuous infusion).

Reference:
Medicines Safety Update, TGA, 25 October *2021 (link to the source within www.tga.gov.au)*

Propylthiouracil and carbimazole

Use in pregnancy

Australia. The TGA has announced that the pregnancy category for both propylthiouracil (PTU®) and carbimazole (Neo-Mercazole®) is being changed from being suspected of harmful effects on the human foetus by the pharmacological effects to the being associated with an increased incidence of human foetal malformations.

Propylthiouracil is an antithyroid drug indicated for the treatment of hyperthyroidism or prior to surgery or radioactive iodine therapy in these patients.

Carbimazole is also an antithyroid drug indicated for hyperthyroidism. It is used as a definitive therapy for the induction of a permanent remission in either primary or secondary thyrotoxicosis. It is also used in preparation for thyroidectomy before and after radioactive iodine treatment. The risks relating to congenital abnormalities in neonates are known for these medicines.

The TGA reviewed reported cases of congenital abnormalities for propylthiouracil and carbimazole in the postmarketing setting.

Healthcare professionals should be advised that propylthiouracil and carbimazole should not be prescribed for women of childbearing age unless, in the opinion of the physician, the potential benefits outweigh the possible risks.

Reference:
Medicines Safety Update, TGA, 15 September 2021 *(link to the source within www.tga.gov.au)*

(See WHO Pharmaceuticals Newsletter No.3, 2020: Potential risk of birth defects in Canada)

Selective serotonin reuptake inhibitors (SSRIs) and serotonin-noradrenaline reuptake inhibitors (SNRIs)

Increased risk of postpartum hemorrhage

Saudi Arabia. The SFDA has announced to healthcare professionals that there is a small increased risk of postpartum hemorrhage associated with use of selective serotonin reuptake inhibitors (SSRIs) and serotonin-noradrenaline reuptake inhibitors (SNRIs) antidepressants when used during the last month before delivery.

The SFDA reviewed the result from observational studies suggesting the risk.

Healthcare professionals are advised to carefully assess the safety of antidepressants use during pregnancy against the benefits, especially in later stages, and consider the patient's risk factors for bleeding or thrombotic events.

Reference:
Safety communication, SFDA, 29 July 2021 *(link to the source within www.sfda.gov.sa)*

(See also WHO Pharmaceuticals Newsletter No.4, 2021: Increased risk of postpartum haemorrhage in New Zealand)

A signal is defined by WHO as reported information on a possible causal relationship between an adverse event and a drug, the relationship being unknown or incompletely documented previously. Usually more than a single report is required to generate a signal, depending on the seriousness of the event and the quality of the information. A signal is a hypothesis together with data and arguments and it is important to note that a signal is not only uncertain but also preliminary in nature.

The signals in this Newsletter are based on information derived from reports of suspected adverse drug reactions available in the WHO global database of individual case safety reports (ICSRs), VigiBase. The database contains over 27 million reports of suspected adverse drug reactions, submitted by National Pharmacovigilance Centres participating in the WHO Programme for International Drug Monitoring. VigiBase is maintained by the Uppsala Monitoring Centre (UMC) on behalf of WHO and periodic analysis of VigiBase data is performed in accordance with UMC's current routine signal detection process. International pharmaceutical companies, when identified as uniquely responsible for the drug concerned, are invited to comment on the signal text. Signals are thereafter communicated to National Pharmacovigilance Centres, before being published in this Newsletter. Signal texts from UMC might be edited to some extent by WHO and may differ from the original version. More information regarding the ICSRs, their limitations and proper use, is provided in the UMC caveat document available at the end of Signal (page 41). For information on the UMC Measures of Disproportionate reporting please refer to WHO Pharmaceuticals Newsletter Issue No. 1, 2012.

UMC, a WHO Collaborating Centre, is an independent foundation and a centre for international service and scientific research within the field of pharmacovigilance. For more information, on the UMC Measures of Disproportionate Reporting etc., visit www.who-umc.org. To leave a comment regarding the signals in this Newsletter, please contact: the Uppsala Monitoring Centre, Box 1051, SE-751 40 Uppsala, Sweden. E-mail: signals@who-umc.org.

Covid-19 vaccines and hearing loss and tinnitus

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Summary

A recent signal detection activity at the Uppsala Monitoring Centre (UMC) identified hearing loss (including sudden cases) and tinnitus following COVID-19 vaccination as a preliminary signal to be further assessed. Up to 22 February 2021[i], there were 164 unique individual case safety reports (ICSRs) which reported 'hearing losses' (MedDRA High Level Term, HLT), and 367 ICSRs which reported 'tinnitus' (Preferred Term, PT) with 'COVID-19 vaccine' in the WHO global database of ICSRs, VigiBase. The cases were from 10 countries, most had no co-morbidities. Time-to-onset varied between 0 and 19 days with a median of 1 day. Based on well-documented cases, alternative causes were not identified for most of the patients, although some may have had contributing morbidities (e.g., allergies, high blood pressure, prior hearing loss, auto-immune related disorders). The most common co-reported symptoms were tinnitus, followed by headache, dizziness and nausea, and many patients experienced quick recovery, while some needed steroid treatment. A plausible mechanism of action involving the vestibulocochlear nerve has been suggested. Awareness of this possible link may help healthcare professionals and those vaccinated to monitor symptoms and seek care, as appropriate. As there is still only limited data in the literature providng evidence for this link, further monitoring is required.

Introduction

The emergence of the novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and the World Health Organization's declaration of the associated coronavirus disease 2019 (COVID-19) as a global pandemic, have led to a worldwide prioritization of research and development of protective vaccines. To date, several potential vaccines are under development and a few have received market authorization or emergency use authorization, including ChAdOx1-S - (AZD1222) (Covishield) developed by AstraZeneca/University of Oxford, mRNA-1273 developed by Moderna and the National Institute of Allergy and Infectious Diseases, and BNT162 developed by BioNTech, Pfizer and Fosun Pharma. At the time of this report, the current vaccines used have different

[i] Renewed search was conducted on 18 November 2021 (see Adendum on 24 November 2021)

mechanisms to provide protection against COVID-19.[1–3]

Hearing loss generally refers to the partially or completely diminished ability to hear in one or both ears. Hearing loss includes deafness, i.e. the inability to comprehend aural/verbal language, as well as sensorineural hearing loss which is defined by a hearing acuity below 30 dB and generally involves damage to the inner ear, cochlear nerve or vestibulocochlear nerve, or brain.[4,5] Sensorineural hearing loss can occur suddenly within three days or less, and it may be associated with tinnitus and vertigo.[4] Tinnitus can also occur as an isolated symptom and is defined as perception of an auditory sensation despite the absence of a auditory trigger.[6] Incidence of sensorineural hearing loss in the US is estimated at 27 per 100,000 persons per annum, with the incidence increasing with age.[7]

Depending on the aetiology, the age of onset for hearing loss can vary.[8] Hearing loss can be congenital, e.g. Alport-syndrome, or acquired through infections and inflammations due to viruses, as well as systemic disorders, such as hypertension.[9–12] Specific medications, e.g., aminoglycoside antibiotics, are known to be ototoxic and can cause direct damage to the vestibulocochlear apparatus. [13]

Reports in VigiBase

In a signal detection activity on 22 February 2021 screening for COVID-19 vaccines in the WHO global database of ICSRs, VigiBase, disproportional reporting was detected for 'COVID-19 vaccine' associated with MedDRA Preferred Terms (PTs) 'Sudden hearing loss' (24 observed and 8 expected; lower limit of the 95% credibility interval (IC_{025}=0.9) and 'Tinnitus' (367 observed and 259 expected; IC_{025}=0.4). In addition to the PT 'Sudden hearing loss' the search was extended to the High Level Term (HLT) 'Hearing losses' which included an additional 148 relevant cases, among which the PT 'Deafness unilateral' (31 observed and 15 expected; IC_{025}=0.4), and PT 'Deafness neurosensory' (19 observed and 9 expected; IC_{025}=0.4) also showed disproportional reporting. Other PTs within the HLT Hearing losses considered, but not disproportionate, were: Hypoacusis, Deafness, Deafness transitory and Neurosensory hypoacusis.

Hearing loss

Among the 172 ICSRs reporting hearing loss, 8 were duplicate cases, resulting in a total of 164 unique ICSRs. Of these 164 ICSRs, 104 (63%) were for females and 59 (36%) for males, in one case sex was not provided. The age in the reported cases ranged from 19 to 93 years with a median of 49. Reports were received from 10 countries including the USA (66), UK (36), and Italy (15). More than a third of the ICSRs (62, 38%) were from healthcare professionals; 'reporter category unknown' was stated in 66 reports (40%), and 'consumer/non health professionals' in 37 (23%). Some consumer reports were from physicians or other healthcare professionals who had been vaccinated. The most reported COVID-19 vaccines in these cases were Pfizer/BioNTech (142 cases), followed by Moderna (15 cases) and AstraZeneca (7 cases).

While most of the cases were recorded as non-serious (93 cases, 57%), 71 cases (43%) were recorded as serious. Seriousness criteria were most often 'Other medically important condition' (37 case reports), and 'Disabling/incapacitating' (29), followed by 'Caused/prolonged hospitalization' (5), and 'Life threatening' (2).

Of the 164 ICSRs the most commonly co-reported PTs were tinnitus (56), headache (26), dizziness (19), nausea (19), fatigue (14), hypoaesthesia (12), pyrexia (12), acoustic stimulation tests abnormal (11), vertigo (11), and ear discomfort (11).

Only a few reports included information on concomitant treatments and the most commonly reported was the influenza vaccine (four reports), which had been given at least 30 days prior to the COVID-19 vaccine, according to the narratives. Other medications mentioned included omeprazole, acetylsalicylic acid, propranolol, estradiol, calcium carbonate, dexamethasone, paracetamol, rivaroxaban, iron, and folic acid. All appeared in less than four reports and were only reported as concomitant. In some reporting interfaces there are limited options for reporters to note concomitant medication, so this may be underreported.

Time-to-onset (TTO) varied between the same day, i.e., several minutes, to 19 days, with a median of one day. Of the 164 ICSRs, 95 provided narratives for in-depth analysis. Table 1 presents the characteristics of the reports for sudden hearing loss (23), and Table 2 the selected reports of hearing loss

(HLT) with informative narratives (25) in association with a COVID-19 vaccine.

Based on Tables 1 and 2, the TTO is similar for all 164 reports. In 31 cases of the 48 reports displayed in Table 1 and 2, there were no apparent risk factors . In seven cases the reports specified hearing loss related to the second dose, and of these, two reported onset of hearing loss within half an hour to several hours, three within one to two days, and another two six or seven days after the second dose of COVID-19 vaccine. In three cases the reports described hearing loss as occurring with the first COVID-19 vaccine dose and re-occurring and worsening after administration of the second dose. One case of tinnitus following the first dose decreased over a couple of days but hearing loss recurred after the second dose, and the patient was started on steroid treatment; no risk factors were recorded. Another case described bilateral tinnitus more than a week after the first dose and worsening 1.5 weeks after the second dose. Receipt of unspecified medications were recorded, and the patient consulted an ear, nose and throat (ENT) physician. Another described hearing loss occurring which decreased within two days after the first dose, but re-occurring with the second dose, which required steroid treatment.

In 29 cases, patients contacted a physician or ENT specialist within a few days after receiving the vaccination due to hearing loss. Some of the reports were provided by consumers who were themselves physicians or other healthcare professionals. Seven patients confirmed an abnormal audiogram conducted by their physician, and 20 were treated with systemic steroids.

In the narratives of these cases where information on medical history and potential risk factors was present, the following are of note: prior history of hearing loss (n=6), hypothyroidism (n=3) and previous autoimmune thyroiditis (n=1), high blood pressure and cardio-vascular diseases (n=4), allergies, including nut allergy (n=2), and one case each of diabetes mellitus, antiphospholipid syndrome, prior COVID-19, hearing loss related to another viral infection, and unspecified auto-immune reaction or disease.

Of the 164 cases of hearing loss, four also described the feeling of numbness of the face on the affected side. In two narratives, the patients had consulted an ENT physician and received a potential diagnosis of labyrinthitis and vestibular neuritis. In five cases with information on the recovery of hearing following steroid treatment, two reported recovery after three days of steroids and another experienced hearing loss subsiding spontaneously after the first COVID-19 vaccine dose but requiring steroid treatment after the second COVID-19 vaccine dose, with partial recovery (report was received 18 days post-vaccination). A fourth case described mild improvements with steroid treatment (report received five days post-vaccination) and another had mild improvements five days after steroid treatment (report received 17 days post-vaccination).

Of the 164 cases, at the time of the report 51 (31%) were recovering or recovered from their symptoms and 50 (30%) had not recovered. In the remaining 63 (38%) cases no outcome information was recorded.

Tinnitus

There were 367 ICSRs reporting tinnitus with COVID-19 vaccines, of which 56 were also grouped into hearing losses (HLT). Of these 367, 268 (73%) were in females and 92 in males (25%), sex was missing in 7. Their ages ranged from 19 to 91 years with a median of 48. They came from 27 countries with the UK (115), the US (113), and Italy (42) having the most reports. More than a third of the ICSRs (160, 44%) were from healthcare professionals. Reporter category was unknown in 113 reports (31%) and consumer/non healthcare professionals in 97 (26%). The vaccines received were Pfizer/BioNTech (293, 80%), Moderna (39, 11%) AstraZeneca (31, 8.4%), and Sinovac (1, 0.3%). The TTO ranged from several minutes to 30 days after vaccination, with a median one of 1 day. Of the 367 reports, 90 were recorded as not recovered (25%), 164 as recovered (45%) and 112 were unknown (31%).

Most cases were recorded as non-serious (270, 74%), but 97 cases (26%) were recorded as serious. Seriousness criteria included 'other medically important condition' (59, 16%), 'disabling/incapacitating' (33, 9.0%), 'caused/prolonged hospitalization' (8, 2.2%) and 'life threatening' (2, 0.5%). The most co-reported PTs with tinnitus were headache (131, 36%), dizziness (65, 18%), fatigue (65, 18%), nausea (65, 18%), pyrexia (60, 16%), myalgia (54, 15%), chills (47, 13%), arthralgia (37, 10%), asthenia (33, 9.0%) and pain in extremity (30, 8.2%). Eight case narratives reported progression

from tinnitus to hearing loss, i.e., inability to hear in the affected ear.

Labelling and literature

The product labelling for COVID-19 vaccines does not refer to hearing loss. [1–3] However, for both mRNA vaccines, acute peripheral facial paralysis is listed as a rare adverse reaction. Apart from headaches, no other form of nerve or cranial nerve involvement is listed under adverse reactions.

No additional information exists in the scientific literature of an association between COVID-19 vaccines and hearing loss.

Discussion and conclusion

This analysis of reports in VigiBase includes 164 unique cases of hearing loss with COVID-19 vaccines.

The TTO ranged from 0 to 19 days. However, 97 (59%) cases indicated a TTO ranging from 0 to 1 day. The narratives contain information about relatively quick reactions, occurring from minutes to several hours after the injections, often described with tinnitus-like or muffled-hearing sensations, and in some instance headaches, vertigo, and nausea. Some patients described the muffled-hearing or tinnitus progressing into partial or complete hearing loss. Some well documented cases recorded an audiogram confirming the sudden hearing loss diagnosis, and in many cases, the need for treatment with high dose steroids.

Half of the cases noted that the patient was recovering or had recovered from their hearing loss, while no (or limited) additional information on follow-up was recorded for the other cases. The evidence for long-term hearing loss is therefore incomplete.

The analysis also shows that ICSRs with hearing loss came from ten countries and that most cases were young healthy adults with no comorbidities. The median age was 47 years, which appears young and reflects several countries' prioritization of healthcare worker vaccination. Some cases describe patients with a medical history of prior hearing loss, high blood pressure, environmental or seasonal allergies, as well as thyroid dysfunction. In seven cases the reaction of hearing loss was reported with the second dose of the COVID-19 vaccine, and in two cases a positive re-challenge was described.

In addition, several patients reported other co-occurring reactions such as headaches, nausea, and dizziness. The additional description of dizziness and nausea may suggest the involvement not only of the cochlear nerve, but also the vestibular nerve. Furthermore, among the ICSRs reporting hearing loss, two also reported facial paralysis, and four narratives a feeling of numbness in the face, both of which would point to the potential involvement of other cranial nerves apart from the vestibulocochlear, i.e., the facial nerve and trigeminal nerve. The product information for the COVID-19 vaccines does include the rare occurrence of acute facial nerve paralysis. No other reactions specific to other cranial nerves, including hearing loss, are listed. In a study on motor palsies of cranial nerves after vaccination the need for further studies was recommended.[14] The TTO for cranial nerve palsies was reported to be a median of 9-10 days, and with patients of all age groups.

To date, no studies assessing novel COVID-19 vaccines and hearing loss or cranial nerve involvement have been reported. The literature provides anecdotal references to an association between other vaccines and hearing loss.[15–18] In addition, there has been some publications about the potential role of vaccines in adverse reactions involving other cranial nerves.[14,19] However, a case-centred analysis of sudden-onset sensorineural hearing loss after immunization did not report any significant association for 28 different vaccines.[20] The study used a large medical records database and analyzed the first episodes of sensorineural hearing loss in patients who had been vaccinated in the preceding nine months between 2007 and 2013. The study identified 1,929 cases of sensorineural hearing loss within nine months of receiving a vaccine, and 57 that occurred within a week.[14] In addition, in 2020 the Brighton Collaboration published a case definition of sensorineural hearing loss to aid investigation of adverse events following immunization.[12]

A potential mechanism for COVID-19 vaccine-associated hearing loss could be an autoimmune process involving molecular mimicry related to the vaccine's antigen, or bystander activation of autoreactive T-cells that may involve the vestibulocochlear nerve (vestibular nerve is involved in balance and equilibrium functions, and cochlear nerve in hearing function).[21–24] Involvement of this nerve can contribute to symptoms related to labyrinthitis, which involves both vestibular and cochlear branches of the nerve or

vestibular neuritis, which involves vertigo, dizziness and nausea.[25] Two cases in the VigiBase analysis mentioned the potential diagnosis of labyrinthitis and vestibular neuritis made by ENT specialists. Furthermore, analysis of VigiBase in patients vaccinated with COVID-19 vaccine showed a disproportionality for vestibular neuronitis (13 observed and 2 expected) and labyrinthitis (19 observed and 6 expected). Studies on vaccinations and neurological disorders, including cranial nerve involvement reported the potential time windows for symptom onset as being several hours to several weeks depending on the neurological disorder.[14,20,21,26] Currently, clinical evidence and studies on potential mechanisms and the relation between vaccines and neurological disorders, cranial nerve palsies and hearing loss, remain limited.

Under-reporting is a well-known limitation of spontaneous adverse drug reaction reporting. However, there is high interest in COVID-19 and COVID-19 vaccines, which may contribute to increased reporting and therefore, potentially an overestimation of the risk. Additionally, the observed versus expected numbers and IC_{025} values need to be interpreted with caution, since reporting by healthcare providers and the sites is a requirement under the terms of the Emergency Use Authorizations for COVID-19 vaccines in some places (e.g., the USA where most of the cases were reported). For approved medicinal products this is not the case. Therefore, when an expected number is estimated using other medicinal products prior to the pandemic and then compared with the observed cases for COVID-19 vaccines, the result may overestimate the risk. It may be useful to approach the individual countries for more in-depth information and could be considered in future signal investigations.

In summary, cases of (sudden) hearing loss following COVID-19 vaccination have been reported to VigiBase from ten countries. Most of the patients were females (62%) and the age range was 19 to 93 years with a median of 49. However, it should be noted that 75% of the COVID-19 virus vaccine adverse reactions included in VigiBase concern female vaccinees, and the median age is just over 40 years. Most of the cases were young healthy adults with no comorbidities. A close temporal relationship has been observed, and based on well-documented cases, most of the patients did not have alternative causes identified, although some patients may have had contributing morbidities (e.g., high blood pressure, allergies, prior hearing loss, auto-immune related disorders). The most common co-reported symptoms were tinnitus, followed by headache, dizziness and nausea, and many patients experienced a quick recovery, although some patients needed steroid treatment. A plausible mechanism of action has been suggested and awareness of this possible link may help healthcare professions and those vaccinated to monitor symptoms and seek care as appropriate. As the literature and ICSR data are still limited for this link, further monitoring is required.

Addendum on 24 November 2021

Tinnitus is only listed as an adverse reaction for the Janssen COVID-19 vaccine.

An updated search of VigiBase has been performed for the PTs included in this signal assessment (Table-A) and for the terms with a positive (>0) IC_{025} values for each COVID-19 vaccine (Table-B).

In brief, the terms selected for hearing disorders included sudden hearing loss, tinnitus, deafness unilateral, neurosensory hypoacusis, deafness, deafness transitory, and hypoacusis. On 18 November 2021 there were 37 529 deduplicated cases, for which at least one of these terms was reported, from 86 countries: 21 countries reported more than 100 cases; another 22 countries reported 10-99 cases; 15 countries reported 5-9 cases and 28 countries reported 1-4 cases.

It seems that hearing disorders have been reported for most of the COVID-19 vaccines, but with different IC_{025} values. More in-depth assessment of narratives has not been performed for the recently reported cases.. The limitations and precautions for the data and its interpretation mentioned above need to be taken into consideration.

Table-A. The observed and expected numbers of selected hearing disorders with positive (>0) IC_{025} values in VigiLyze on 22 February 2021 and in a repeated search on 18 November 2021.

	Search on 22 February 2021			**Search on 18 November 2021**		
	Observed	Expected	IC_{025}	**Observed**	**Expected**	**IC_{025}**
Sudden hearing loss	24	8	0.9	**1290**	**284**	**2.1**
Tinnitus'	367	259	0.4	**31 644**	**8549**	**1.9**
Deafness unilateral	31	15	0.4	**1676**	**495**	**1.7**
Neurosensory hypoacusis			ND*	**55**	**20**	**1.1**
Deafness			ND*	**3167**	**2378**	**0.4**
Deafness transitory			ND*	**97**	**70**	**0.2**
Hypoacusis			ND*	**3278**	**3608**	**ND***

*Not disproportionate

Table-B. The observed and expected numbers of selected hearing disorders with positive (>0) IC_{025} values for each COVID-19 vaccine in VigiLyze on 18 November 2021.

	Observed	**Expected**	**IC_{025}**
Sudden hearing loss	**1290**	**284**	**2.1**
Tozinameran	**837**	**135**	**2.5**
Elasomeran	**218**	**53**	**1.8**
COVID-19 vaccine NRVV Ad (ChAdOx1 nCoV-19)	**199**	**74**	**1.2**
COVID-19 vaccine NRVV Ad26 (JNJ 78436735)	**28**	**12**	**0.6**
Tinnitus	**31 644**	**8549**	**1.9**
COVID-19 vaccine inact (Vero) HB02	**1507**	**142**	**3.3**
COVID-19 vaccine NRVV Ad26 (JNJ 78436735)	**1692**	**363**	**2.1**
Tozinameran	**15276**	**4049**	**1.9**
Elasomeran	**5946**	**1583**	**1.9**
COVID-19 vaccine NRVV Ad (ChAdOx1 nCoV-19)	**7131**	**2215**	**1.7**
Deafness unilateral	**1676**	**495**	**1.7**
Elasomeran	**458**	**92**	**2.2**
Tozinameran	**999**	**234**	**2.0**
COVID-19 vaccine NRVV Ad26 (JNJ 78436735)	**63**	**21**	**1.2**
Neurosensory hypoacusis	**55**	**20**	**1.1**
Tozinameran	**45**	**9**	**1.8**
Deafness	**3167**	**2378**	**0.4**
Tozinameran	**1854**	**1126**	**0.7**
COVID-19 vaccine NRVV Ad26 (JNJ 78436735)	**153**	**101**	**0.4**
Elasomeran	**571**	**440**	**0.3**
Deafness transitory	**97**	**70**	**0.2**
Tozinameran	**57**	**33**	**0.4**
Hypoacusis	**3278**	**3608**	**ND***
Tozinameran	**1965**	**1709**	**0.1**
COVID-19 vaccine NRVV Ad26 (JNJ 78436735)	**186**	**153**	**0.1**

*Not disproportionate

References

1. EMA Committee for Medicinal Products for Human Use (CHMP). Summary of product characteristics for COVID-19 vaccine Moderna [website]. 2021 [cited 2021 Feb 7]. Available from: https://www.ema.europa.eu/en/documents/product-information/covid-19-vaccine-moderna-epar-product-information_en.pdf

2. EMA Committee for Medicinal Products for Human Use (CHMP). Summary of product characteristics for Comirnaty. [website]. 2021 [cited 2021 Feb 7]. Available from: https://www.ema.europa.eu/en/documents/product-information/comirnaty-epar-product-information_en.pdf.

3. EMA Committee for Medicinal Products for Human Use (CHMP). Summary of product characteristics for COVID-19 vaccine AstraZeneca. [website]. 2021 [cited 2021 Feb 7]. Available from: https://www.ema.europa.eu/en/documents/product-information/covid-19-vaccine-astrazeneca-product-information-approved-chmp-29-january-2021-pending-endorsement_en.pdf

4. Schreiber BE, Agrup C, Haskard DO, Luxon LM. Sudden sensorineural hearing loss. Lancet. 2010 Apr 3;375(9721):1203–11.

5. Roeser RJ, Valente M, Hosford-Dunn H, editors. Audiology. Diagnosis. 2nd ed. New York: Thieme; 2007. 602 p.

6. Nondahl DM, Cruickshanks KJ, Huang G-H, Klein BEK, Klein R, Nieto FJ, et al. Tinnitus and its risk factors in the Beaver Dam offspring study. Int J Audiol. 2011 May;50(5):313–20.

7. Alexander TH, Harris JP. Incidence of sudden sensorineural hearing loss. Otol Neurotol. 2013 Dec;34(9):1586–9.

8. Shi X. Physiopathology of the cochlear microcirculation. Hear Res. 2011 Dec;282(1–2):10–24.

9. Ibekwe TS, Okokhere PO, Asogun D, Blackie FF, Nwegbu MM, Wahab KW, et al. Early-onset sensorineural hearing loss in Lassa fever. Eur Arch Otorhino-Laryngol . 2011;268(2):197–201.

10. van Beeck Calkoen EA, Engel MSD, van de Kamp JM, Yntema HG, Goverts ST, Mulder MF, et al. The etiological evaluation of sensorineural hearing loss in children. Eur J Pediatr. 2019 Aug;178(8):1195–205.

11. Korver AMH, Smith RJH, Van Camp G, Schleiss MR, Bitner-Glindzicz MAK, Lustig LR, et al. Congenital hearing loss. Nat Rev Dis Primer. 201712;3:16094.

12. Carol Liu Y-C, Ibekwe T, Kelso JM, Klein NP, Shehu N, Steuerwald W, et al. Sensorineural hearing loss (SNHL) as an adverse event following immunization (AEFI): Case definition & guidelines for data collection, analysis, and presentation of immunization safety data. Vaccine. 2020;38(30):4717–31.

13. Guthrie OW. Aminoglycoside induced ototoxicity. Toxicology. 2008;249(2–3):91–6.

14. Woo EJ, Winiecki SK, Ou AC. Motor palsies of cranial nerves (excluding VII) after vaccination. Hum Vaccin Immunother. 2014;10(2):301–5.

15. Kolarov C, Löbermann M, Fritzsche C, Hemmer C, Mlynski R, Reisinger EC. Bilateral deafness two days following influenza vaccination: a case report. Hum Vaccin Immunother. 2019;15(1):107–8.

16. Huang H-H, Huang C-C, Hsueh P-Y, Lee T-J. Bilateral sudden deafness following H1N1 vaccination. Otolaryngol Head Neck Surg. 2010;143(6):849–50.

17. De Marco F, De Cesare DP, Di Folco F, Massoni F, Tomei G, Di Luca NM, et al. Post vaccinal temporary sensorineural hearing loss. Int J Environ Res Public Health. 2018;15(8):1780.

18. Okhovat S, Fox R, Magill J, Narula A. Sudden onset unilateral sensorineural hearing loss after rabies vaccination. BMJ Case Rep. 2015 bcr2015211977

19. Mutsch M, Zhou W, Rhodes P, Bopp M, Chen RT, Linder T, et al. Use of the inactivated intranasal influenza vaccine and the risk of Bell's palsy in Switzerland. N Engl J Med. 2004;350(9):896–903.

20. Baxter R, Lewis N, Bohrer P, Harrington T, Aukes L, Klein NP. Sudden-onset sensorineural hearing loss after immunization: a case-centered analysis. Otolaryngol Head Neck Surg. 2016;155(1):81–6.

21. Principi N, Esposito S. Do vaccines have a role as a cause of autoimmune neurological syndromes? Front Public Health. 2020;8:361.

22. Ozonoff A, Nanishi E, Levy O. Bell's palsy and SARS-CoV-2 vaccines. Lancet Infect Dis. 2021;21(4):450-2

23. Liang Y, Meng F-Y, Pan H-F, Ye D-Q. A literature review on the patients with autoimmune diseases following vaccination against infections. Hum Vaccin Immunother. 2015;11(9):2274–80.

24. Institute of Medicine 2012. Adverse effects of vaccines: evidence and causality. Washington, DC: The National Academies Press. https://doi.org/10.17226/13164.

25. Baloh RW. Clinical practice. Vestibular neuritis. N Engl J Med. 2003;348(11):1027–32.

26. Paul R, Stassen LFA. Transient facial nerve paralysis (Bell's palsy) following administration of hepatitis B recombinant vaccine: a case report. Br Dent J. 2014;216(2):69–71.

Table 1. Individual characteristics of reports in VigiBase of sudden hearing loss in association with COVID-19 vaccines (n=23).

Case	Age / sex	Type of vaccine	Dose number	Relevant reactions (MedDRA preferred terms)	Time to onset	Outcome	Type of reporter	Additional information
1.	46/M	Pfizer/BioNTech	-	Tinnitus Sudden hearing loss	7 days	Not recovered	Physician	-
2.	52/F	Pfizer/BioNTech	-	Headache Myalgia Tinnitus Chest pain Sudden hearing loss	0 days	Recovered	Physician	-
3.	-/F	Moderna	-	Deafness neurosensory Deafness unilateral Sudden hearing loss	3 days	-	-	Lost hearing in left ear three days after the vaccination, diagnosed by an ENT with "sudden sensory nerve severe hearing loss".
4.	61/F	Pfizer/BioNTech	-	Acoustic stimulation tests abnormal Deafness Sudden hearing loss	1 day	-	-	Sudden total hearing loss, left ear; numbness in face and outer ear.
5.	54/M	Pfizer/BioNTech	-	Tinnitus Sudden hearing loss	1 day	Not recovered	Pharmacist	One day after the vaccine tinnitus in ear, 14 days later still constant tinnitus in ear, sudden hearing loss left diagnosed by a physician.
6.	70/M	Pfizer/BioNTech		Deafness unilateral Nausea Sudden hearing loss Tinnitus Vertigo Vision blurred	18 hours	-	Consumer	woke up with vertigo and imbalance, clogged left ear and tinnitus, started hyperventilating, went to the hospital with CT and MRI not showing any abnormalities, later referred to ENT, who started high dose steroids after audiogram showed abnormal findings, no improvements five days after treatment initiation.
7.	77/F	Pfizer/BioNTech	-	Acoustic stimulation tests abnormal Deafness unilateral Injection site pain Sudden hearing loss Tinnitus	1 day	-	Consumer	No medical history, arm tender after injection, one day later tinnitus right ear, two days after the vaccine consultation with an ENT for earwax removal, few minutes later reoccurrence of tinnitus and humming, three days after the vaccination complete hearing loss right ear and started on prednisolone 40 mg from ENT, four days after the treatment initiation still no improvement.
8.	61/F	Pfizer/BioNTech	-	Injection site inflammation Injection site pain Sudden hearing loss	1 day	Recovered	Consumer	Movicolon, pantoprazole
9.	46/M	Pfizer/BioNTech	-	Sudden hearing loss	5 days	Not recovered	Consumer	-
10.	52/F	Pfizer/BioNTech	-	Sudden hearing loss	6 days	Recovering	Consumer	-

				Hyperacusis				
11.	57/M	Pfizer/BioNTech	-	Sudden hearing loss	Same day	Not recovered	Physician	Previously known with acoustic neuroma right, cyberknife treated 2019, Last MRI November 2020 without new abnormalities.
12.	25/M	Pfizer/BioNTech	-	Sudden hearing loss	30 min	Not recovered	Physician	30 min post-vaccination sudden hearing loss, recovered three days after high dose steroid treatment.
13.	52/M	Pfizer/BioNTech	-	Sudden hearing loss	5 days	Not recovered	Consumer	-
14.	68/F	Moderna	-	Acoustic stimulation tests Deafness neurosensory Hypoacusis Sudden hearing loss Tinnitus	Same day	-	-	Sudden sensorineural hearing loss in left ear, day later sudden pop in left ear, two days after the vaccine could barely hear, hearing test proved SSHL and patient was started on steroid treatment plus local steroid treatment in ear, doctors feel it is a side effect due to compromised immune system, patient had a similar reaction 15 years ago from a virus.
15.	19/M	Moderna	-	Deafness Deafness unilateral Hypoacusis Sudden hearing loss Tinnitus	3 days	-	-	Three days after vaccination tinnitus and muffled hearing that went away and next day complete hearing loss left ear, still has tinnitus and muffled hearing at time of report.
16.	70/M	Pfizer/BioNTech	-	Sudden hearing loss Rash	Same day	-	Consumer	Rash over face and even over the ears, uses rivaroxaban.
17.	89/M	AstraZeneca	-	Sudden hearing loss	Same day	Not recovered	Physician	Not tested positive for COVID-19.
18.	39/F	Pfizer/BioNTech	-	Sudden hearing loss	2 days	Recovered	Consumer	-
19.	52/F	Pfizer/BioNTech	-	Sudden hearing loss	1 day	Not recovered	Consumer	Sudden hearing loss, one day after vaccination.
20.	37/F	Moderna	-	Acoustic stimulation tests abnormal Deafness unilateral Sudden hearing loss Tinnitus	10 days	-	-	Sudden hearing loss right, accompanied by tinnitus.
21.	31/M	Pfizer/BioNTech	-	Dizziness Sudden hearing loss Hypoaesthesia	12 days	Recovering	Consumer	13 days after vaccination developed sudden hearing loss and dizziness and hypoesthesia, lasting four days.
22.	-/M	Pfizer/BioNTech	-	Sudden hearing loss	6 days	-	Consumer	Six days after vaccine started on high dose prednisone for one week, high dose 250 mg for three days then daily reduction by 50 mg.
23.	40/F	Pfizer/BioNTech	-	Sudden hearing loss	1 day	Not recovered	Physician	Reporter is patient and healthcare professional, second dose with febrile reaction, and systemically ill, 20 hours later woke up due to tinnitus left ear, got prednisone from ENT after confirmed sensorineural hearing loss left, ENT believes inflammatory response to vaccination is possible, concomitant medications include estrogel, propranolol, utrogestran.

Table 2. Individual characteristics of selected reports in VigiBase of hearing loss (HLT) in association with COVID-19 vaccines (n=25).

Case	Age / sex	Type of vaccine	Dose number	Relevant reactions (MedDRA preferred terms)	Time to onset	Outcome	Type of reporter	Additional information
1.	68/F	Pfizer/BioNTech	-	Balance disorder Deafness unilateral Hypoaesthesia	8 hours	Recovering	Consumer	Past medical history with COVID in November and high blood pressure, 8 hours after injection feeling of ear "closing up", few days later hearing loss in right ear same side as the injected arm, had problems with hearing and equilibrium, contacted physician and was started on prednisone with partial improvement five days later.
2.	71/M	Moderna	-	Deafness unilateral Hypoacusis	3 days	-	-	Immediate loss of hearing right ear which recovered after six hours, next day partial loss of hearing left ear which did not return to normal.
3.	63/M	Pfizer/BioNTech	-	Deafness unilateral Malaise	2 days	-	Consumer	Patient received the first dose and experienced hearing loss left ear, had only 60% of hearing, unspecified treatment was initiated, and hearing returned to 90%, physician informed that hearing loss could be due to stress or a virus but was not sure if it was due to the vaccine.
4.	40/M	Moderna	2	Audiogram Deafness neurosensory Hypoacusis Tinnitus	1 day	-	-	Acute left sensorineural hearing loss with tinnitus, significant hearing impairment noted on audiometric evaluation, symptoms began a day after receiving the second dose of the vaccine.
5.	69/M	Pfizer/BioNTech	-	Deafness Deafness neurosensory Ear discomfort Hyperacusis Tinnitus	4 days	Recovered	-	Four days after the vaccine sudden onset of bilateral fullness in ears, tinnitus, hearing loss, hyperacusis without vertigo. Weber's test did not lateralize. Rinne's test showed air conduction greater than bone conduction consistent with neurosensory loss, initiated treatment with dexamethasone 8 mg a day for three days and symptoms resolved.
6.	40/F	Pfizer/BioNTech	-	Audiogram Hypoacusis	11 days	-	-	Approximately 11 days after receiving the first dose woke up with decreased hearing, went to audiologist and otolaryngologist, both concerned symptoms are related to having antibodies for COVID-19 or having had the vaccine.
7.	37/F	Pfizer/BioNTech	-	Acoustic stimulation tests abnormal Deafness neurosensory	7 days	-	-	Sudden onset right sensorineural hearing loss.
8.	28/F	Pfizer/BioNTech	-	Nervous system disorder Deafness unilateral Vertigo Endolymphatic hydrops Nausea	2 days	Recovering	-	One day post-vaccination sudden vertigo and nausea. Two days post vaccination sudden hearing loss right ear and feeling of fullness, no pain, hearing loss confirmed with audiogram and started on steroids for several days, differential diagnosis is endolymphatic hydrops.
9.	63/M	Pfizer/BioNTech	-	Deafness neurosensory Thyroid function test normal	2 days	Recovered	-	Left sudden sensorineural hearing loss and ear numbness 48 hours after injection, five days after vaccination started on prednisolone and trans-tympanic dexamethasone shots due to hearing loss, partial recovery after 3 weeks.

10.	32/M	Pfizer/BioNTech	2	Hypoacusis SARS-CoV-2 test negative Tinnitus VIIIth nerve injury	-	-	-	Took unspecified medications and stopped several of them prior to second vaccination, no prior medical history, worked as registered nurse, first vaccination dose in mid-December and second dose in January, bilateral tinnitus end of December and beginning of January, tinnitus got worse after the second dose, consultation with ENT who assumed it was the nerve, but could not explain bilateral hearing problem, COVID-19 test was negative.
11.	39/F	Pfizer/BioNTech	-	Acoustic stimulation tests abnormal Audiogram abnormal Deafness unilateral Fear Hypoacusis SARS-CoV-2 test negative	19 days	-	-	19 days after the first dose hearing loss and muffled sounds left, anaemia in past medical history and no medications, no prior hearing problems, contacted ENT who diagnosed 20% decreased hearing in affected ear and was started on steroid treatment without recovery at time of report, took COVID-19 test which was negative.
12.	89/F	Pfizer/BioNTech	-	Dizziness Deafness	4 days	Not recovered	Physician	Acute sudden hearing loss left with dizziness, audiology confirmed acute sudden hearing loss left with normal ear canals, started on prednisone treatment with improvements in dizziness symptoms, day later fall accident with worsening dizziness, ENT suspected viral labyrinthitis, likely to be viral infection but occurred four days after vaccination, did not test positive for COVID-19, CT head was nil, concomitant medications: influenza virus vaccine, furosemide, latanoprost, omeprazole, simvastatin, THEICAL-D3.
13.	34/F	Pfizer/BioNTech	2	Audiogram Deafness Hypoacusis	Few hours	-	-, -	Few hours after vaccination tinnitus right ear, recovered after a couple of days, after 2nd dose muffled hearing and did not subside and severe right sided low frequency hearing loss was noted, patient was started on high dose steroids with partial recovery.
14.	52/F	Pfizer/BioNTech	-	Acoustic stimulation tests Deafness Headache Injection site pain Tinnitus	1 day	-	-	Arm pain two days on injection site, day after injection right ear felt uncomfortable, felt like hearing loss and constant buzzing and fullness feeling, consulted ENT who started patient on prednisone, no information on recovery.
15.	79/M	Pfizer/BioNTech	-	Deafness neurosensory Deafness unilateral Fatigue Headache Myalgia Tinnitus	9 days	-	-	After nine days awoke with deafness and was started on high dose steroids 60 mg prednisone, ENT consulted severe neurosensory hearing loss right ear.
16.	34/F	Pfizer/BioNTech	2	Acoustic stimulation tests abnormal Audiogram abnormal Deafness unilateral	1 day	-	-	Fullness right ear, felt like fluid in ear, hearing loss right ear, soreness left arm, hearing loss two days after vaccination and subsided, then received second dose followed by myalgia, chills back pain, and constant ringing right ear, hearing loss had worsened, prescribed

				Myalgia Tinnitus				prednisone and local injections dexamethasone by ENT due to abnormal audiogram right ear, only 52% acuity, tested negative for COVID-19.
17.	25/F	Moderna	-	Deafness neurosensory	9 days	-	-	Sudden hearing loss right ear, currently treated with steroids, audiology and ENT assessment performed.
18.	57/F	Pfizer/BioNTech	2	Audiogram abnormal Auditory disorder Balance disorder Deafness Deafness bilateral Fatigue Myalgia Pyrexia Tinnitus Vertigo	1 day	-	Physician	Physician self-reports, after second dose of the vaccine severe myalgias, high fever and fatigue, two days after vaccine got vertigo, did not hear well in left ear, had hearing aid which was functioning, three days after vaccine severe vertigo and hearing loss, Epley's manoeuvre with no effect, could not work and was admitted to emergency department, audiogram showed profound hearing loss both ears, got prednisone, MRI negative, mild improvement after steroids.
19.	37/F	Pfizer/BioNTech	-	Deafness neurosensory Headache	1 day	-	-	Headache 24-48 hours after vaccine, 1 week after vaccine complete sensorineural hearing loss left ear, penicillin allergy, no other medications, started on prednisone via medical doctor, not recovered so far.
20.	36/F	Pfizer/BioNTech	-	Deafness	4 hours	Not recovered	-	Four hours after vaccination acute hearing loss, went to ENT and was started on high dose prednisolone 250 mg for three days.
21.	58/M	Pfizer/BioNTech	-	Audiogram abnormal Hypoacusis Inner ear disorder Tinnitus	1 day	-	-	One day later woke up with ringing both ears, called pcp, consulted ENT diagnosed abnormality left inner ear, started on prednisolone high dose, two weeks in the tinnitus got worse.
22.	58/F	Pfizer/BioNTech	-	Deafness unilateral Hypoaesthesia	Same day	-	-	Lost hearing right ear and right-side face was numb hours after vaccination.
23.	69/M	Pfizer/BioNTech	-	Acoustic neuritis Deafness neurosensory Dizziness Hyperacusis Tinnitus	5 days	-	-	Sudden onset acoustic neuritis without labyrinthitis, hyperacusis, loss of hearing and tinnitus, atrial fibrillation in history. No medications. Nerve related hearing loss recovered.
24.	42/F	Pfizer/BioNTech	-	Deafness unilateral	6 days	-	-	Left sided hearing loss, physician was the patient, Antiphospholipid syndrome in history.
25.	45/M	Pfizer/BioNTech	-	Acoustic stimulation tests abnormal Deafness neurosensory Tinnitus	1 day	-	-	Right ear tinnitus and sensorineural hearing loss, left arm injection, diabetes type 2, latex allergy and asthma, woke up with tinnitus, MD did test and found right sided hearing loss, prescribed prednisone for 10 days 60 mg, not recovered, concomitant medications, metformin and glipizide.

Methotrexate and muscle spasm

Rosa María Papale, Argentina and Mónica Tarapués, Ecuador

Summary

Methotrexate is a structural analogue of folic acid. As a folic acid antagonist, it blocks the synthesis of purines by inhibiting numerous regulatory enzymes. It produces an intense anti-inflammatory action and inhibits cell division. A screening of VigiBase, the WHO global database of individual case safety reports (ICSRs), identified the association of the MedDRA Preferred Term (PT) 'muscle spasm' with methotrexate. A qualitative analysis of 47 cases was undertaken with a completeness score of over 0.70. The similarity of characteristics with respect to time to onset, the biological plausibility, the improvement after drug withdrawal, all provide evidence of this association. The muscle spasms could be associated with methotrexate, especially in patients on long-term low doses. Prescribers and patients need to be aware that muscle spasms could be present with the use of methotrexate. This adverse reaction could impair the patients' quality of life, especially long-term users with chronic diseases.

Introduction

Methotrexate was granted US FDA approval in December 1953. Since then, it has been used via oral, intramuscular, intravenous, subcutaneous, intrapleural, and intrathecal routes of administration. Methotrexate acts by inhibiting enzymes responsible for nucleotide synthesis. It is used for the treatment of several neoplasmic conditions, such as acute leukaemia, lymphomas, osteosarcoma, breast cancer, and in autoimmune diseases, such as rheumatoid arthritis and psoriasis. In addition, it is used to treat gestational choriocarcinoma, chorioadenoma, hydatiform mole, and advanced mycosis fungoides.[1,2]

Muscle spasm covers several overlapping concepts of true spasm and cramps. Spasms are involuntary muscle contractions. When these are prolonged and painful, they are often referred to as cramps. Muscle cramps are sustained, painful contractions of muscle which occur in individuals with or without medical conditions. Muscle cramps are common in the general population and can be disabling. This description distinguishes muscle cramps from other painful muscle disorders that either do not include shortening of the muscle, e.g., myositis and myalgia, or that include involuntary shortening of muscle but do not cause pain, e.g., myotonia and tetany.[3] Myalgia and arthralgia are listed in the Summary of Product Characteristics (SPC) of methotrexate as rare adverse drug reactions (ADRs).[4,5] Other drugs such as diuretics may cause muscle spasm through dehydration or an electrolyte imbalance, especially hypokalaemia, hypocalcaemia, or hypomagnesemia. Muscle spasm can accompany myopathy, which has been associated with numerous drug classes, including antimalarials and statins. Other medications can cause muscle spasms, including beta-agonists, acetylcholinesterase inhibitors (often used for the treatment of myasthenia gravis), cimetidine, steroids, morphine, penicillamine, cardiotropic medications, antiretrovirals, and psychotropic medications.[6,7]

Reports in VigiBase

As of May 2020, there were 397 reports for the MedDRA Preferred Term 'muscle spasms' associated with methotrexate. Due to the large number of cases, a completeness score over 0.7 was set for this analysis so as to identify the causality patterns that strengthen the signal. In the present case series, 47 cases were evaluated.

The reports came from 18 countries, most of them in Europe but also from the Americas, Africa, and Asia. There were 30 females and 17 males. The age was recorded for 45 patients, ranged from 13 to 87 years (median 57); 31 were adults. Thirty-six cases (76%) were reported by health professionals (20 by physicians and 16 by pharmacists). Sixteen cases were considered serious, mainly under the criterion of other medically important condition (10 cases). The last report was received in March 2020. Thirty-three of the cases had a narrative; their characteristics are summarized in Table 1.

The most frequent therapeutic indication was rheumatoid arthritis (17 cases), followed by psoriasis or psoriatic arthritis.[8] There were also cases with neoplastic indications (6) and with polymyositis, meningitis, and Crohn's Disease (one of each). In 13 reports the therapeutic indications were not given. Methotrexate was administered orally in 26 (55%) patients, parenterally in 8 patients (6 intravenous and 2 intrathecal), and subcutaneously in four patients. The time to onset was highly variable in the whole group, ranging from one day to six years. However, 26 patients received a weekly dose: 17 orally, 4 subcutaneously, and 5 were unknown. In this subgroup of 26 patients, the time to onset, reported for 14, ranged from 1 day to 18 months, with a median of 29 days. A daily dose was reported for five patients who developed muscle spasms on the day of administration.

Methotrexate was the only suspected drug in 28 patients, and in 18 others, it was the only drug reported. Adalimumab was reported as a co-suspected drug in five patients, but methotrexate

was the last medication taken for two patients, and the other three patients were on chronic methotrexate treatment when adalimumab was administered. Etanercept was a co-suspected drug in two patients. Dates were available for only one patient who was a chronic user of methotrexate and etanercept was recently administered. Proton pump inhibitors (PPIs), were reported in five patients as co-suspected (lansoprazole (1), pantoprazole (2), and esomeprazole (2)). In additions PPIs were reported as concomitant medication, in eight patients but only four had dates that suggest that the PPI administration came before the ADR and was concurrent with the use of methotrexate. Esomeprazole was used after the occurrence of the ADR in one patient. Non-steroidal anti-inflammatory drugs (NSAIDs) were concomitant drugs for three patients (diclofenac (2), naproxen (1)) . Three cases reported concomitant statins, (atorvastatin and simvastatin).

Another ADR, decreased levels of calcium and magnesium was reported for one patient. Diarrhoea or vomiting were reported at the same time as muscle spasms in seven patients. The LLT term used for 31 patients was muscle cramps, and for some patients the location of the cramps was reported as a limb, legs, hand, or foot. The reported LLT was muscle spasms for 16 patients some of which were described as a cervical or back muscle spasm. The intensity of this ADR for a 63 year-old male patient, reported by a pharmacist, was described as *"very intense, disabling and painful on the arms or the legs, with frequency variable, 1 to 3 times a day".* . Methotrexate and pantoprazole were reported as suspected drugs. This patient also had concomitant diltiazem, digoxin, and paracetamol. Methotrexate was first used subcutaneously for rheumatoid arthritis. After about six months, the patient presented with muscle cramps, and five months later methotrexate was changed to an oral route. The patient was reported as not recovered.

Another 65 year-old patient, reported by a pharmacist, had muscle cramps that occurred at night following the administration of methotrexate (15 mg a week) for rheumatoid arthritis, with a latency of 14 days after increasing the dose. The dose was subsequently reduced to 7.5 mg a week and the patient felt better with fewer complaints. Only methotrexate was reported as suspected. The concomitant medications were carbasalate, diclofenac, misoprostol, amlodipine, isosorbide dinitrate, folic acid, metoprolol, alendronic acid, and simvastatin. The patient had never had a muscle disorder in association with simvastatin. The national centre mentioned that the official product information of methotrexate only describes myalgia.

Positive dechallenge was reported for 21 patients. Methotrexate was stopped in 18 patients, of whom 16 were reported as recovered, 1 was recovering, and 1 was recovered with sequelae. In the remaining three patients the dose was reduced, and the reported outcome was recovered. Individual causality assessment was undertaken for 16 patients, (10 using the Naranjo algorithm and 6 using the UMC/WHO global introspection method). The reported result was 'possible', for 15 patients and not assessable by the UMC/WHO method for the remaining patient.

Rechallenge was undertaken in 8 of the 47patients, and in three there was a positive rechallenge; however, there were no narratives for these patients. The outcome was reported as unknown for the other rechallenged patients, although they reported some interesting details. For example, a 57 year-old man, whose physician described muscle cramps and increased blood creatine phosphokinase with the use of methotrexate and lansoprazole. In the narrative, the physician wrote: *"This patient is being followed for non-erosive rheumatoid arthritis. Treatment with methotrexate 10 mg/week was introduced in February. The patient reports from the start of his treatment disabling muscle cramps preventing any sporting activity. He has also been treated with lansoprazole since February. This patient was also on hydrochlorothiazide- irbesartan, stopped in November of the same year, but without improvement in muscle symptoms".* It is worth noting that the rechallenge had an unknown outcome. However, with the dates given in the original report, it is possible to deduce that the rechallenge was without the lansoprazole, because at the beginning in February the patient was exposed to both drugs, but for the rechallenge, only methotrexate was reintroduced.

A 33 year-old woman, reported by a physician, with pain, muscle spasm, and tetany was rechallenge. The suspected drugs were methotrexate and adalimumab (both subcutaneous, weekly) and opipramol (daily, oral). The medical history included former smoker, adiposity, allergic bronchial asthma, depression, onychomycosis, bilateral gonalgia, and psoriatic arthritis. The starting date for methotrexate was January and for adalimumab, March of the same year. The muscle cramps began on 30 April and the tetany on 4 May. Complete tetany of the right leg, which was not resolved by administration of tetrazepam was reported for this patient. The patient was reported as rechallenged with an unknown outcome.

Literature and labelling

The main risks with the use of methotrexate are related to haematological toxicity, and reduced immunity in the presence of infections. However, neither the SPC in the US nor in Europe describe muscle spasm or cramps as ADRs. Myalgia,

arthralgia, osteonecrosis, and osteoporosis are listed as musculoskeletal ADRs.

There are several special warnings and precautions for use of methotrexate regarding potential interactions with other drugs. There is a warning for the concomitant use with NSAIDs, because it has been found to decrease the tubular secretion of methotrexate and possibly to increase its toxicity. Likewise, there is a precaution in the concomitant use of omeprazole and pantoprazole because of their potential impact on methotrexate elimination .[5] However, there are no warnings regarding concomitant use of statins or adalimumab, or other drugs that can cause musculoskeletal disorders.

There are no case reports about muscle cramps in the literature, although there are two case reports about musculoskeletal ADRs. One describes two cases of acute diffuse muscular pain following initiation of weekly low dose oral methotrexate in rheumatoid arthritis (women 70 and 49 years old).[8] The other report concerns a 59-year-old man with a folliculotropic cutaneous T-cell lymphoma taking low dose pulse methotrexate (15 mg intramuscularly, once a week), at the same time as being treated with pantoprazole (20 mg/day, orally). After the first injection of methotrexate the patient presented with generalized myalgia and bone pain. The symptoms recurred over the following four methotrexate cycles. Pantoprazole was replaced by ranitidine and the muscle symptoms disappeared. The report mentioned a positive rechallenge, during which a laboratory test showed an elevation in the serum concentration of the 7-hydroxymethotrexate, which the authors interpreted as an interaction in renal elimination, rather than a metabolic interaction.[9]

Discussion

Muscle spasms or cramps may sometimes overlap with myalgia, and myalgia has already been identified as an ADR. Nevertheless, this analysis presents a group of patients who suffered from spasm or cramp, with most cases reported by physicians. For that reason, it is plausible to think the muscle spasm or cramp is a worrisome clinical event that may prevent some patients from performing daily activities.

Methotrexate inhibits aminoimidazole caboxamide ribonucleotide transformylase (AICART). This inhibition leads to the accumulation of AICART ribonucleotide, which inhibits adenosine deaminase, leading to an accumulation of adenosine triphosphate and adenosine in the extracellular space, stimulating adenosine receptors. This action is well-known as the basis for its anti-inflammatory properties, however, this also acts on the skeletal muscle by the adenosine monophosphate-activated protein kinase (AMPK). Hence, the potential action of the methotrexate on the skeletal muscle is a concern. Recent research suggests that methotrexate could reduce the threshold for AMPK activation by AICART. AMPK has recently emerged as a novel target for the treatment of pain, with the exciting potential for disease modification. AMPK activators inhibit signalling pathways that are known to promote changes in the function and phenotype of peripheral nociceptive neurons and promote chronic pain.[2,10–12]

The literature suggests that muscle spasms could be associated with peripheric neuropathy and hypothyroidism, which were not identified in this case series due to the intrinsic limitations of spontaneous reporting. Other causes could be electrolyte imbalances, and calcium and magnesium imbalances were reported for one patient. It is well known that hypokalaemia can be associated with muscle cramps or other muscle disorders, however, hypokalaemia was not reported for any of the patients.

The concomitant drugs found in the case reports raise concerns about an incomplete profile of methotrexate interactions. Some drugs, such as adalimumab, or statins, could be strongly associated with the muscle ADRs, however, it is not possible to rule out the suspected role of methotrexate as its administration fits the same timeframe. Also, results with animal models and some pharmacokinetics studies suggest that other drugs such as NSAIDs and PPIs can decrease renal elimination and tubular secretion. Some studies that have analysed this interaction with low and high doses of methotrexate concluded that the elevation in methotrexate concentration as a consequence of the interaction has a low clinical impact, however, it is important to carefully assess the risk-benefit balance before deciding to prescribe it, and to follow-up the patients, especially those who are long-term users of methotrexate.[5,13,14]

Conclusion

Muscle spasms or muscle cramps are not currently mentioned in the SPC for methotrexate, and this ADR could have an impact on the quality of life of patients undergoing treatment with methotrexate. Patients, as well as physicians, should be aware of these ADRs to avoid a reaction that could affect the quality of life of patients. For this reason, it is reasonable to consider an in-depth clinical analysis when the patient mentions these complaints, especially patients on low doses.

Table 1. Summary characteristics of 47 cases in VigiBase of muscle cramps in association with methotrexate with a completeness score over 0.70.

Characteristic	47 cases with completeness score over 0.70
Age (mean / range)	53 years / 13-87
Patient sex distribution	30 females / 17 males, ratio 2:1
Top ten countries	Netherlands (15), France (6), Canada (5), Australia (2), Republic of Korea (2), Sweden (2), Croatia (2) Germany (2), Italy (2), Costa Rica (1)
Reporters	Physician (26), Pharmacist (10), Consumer (7), Other Healthcare Professional (4)
Single suspected drug	28 reports (59%)
Single reported drug	18 reports
Time-to-onset	1 day to 6 years
The action taken with the drug /outcome	25 cases with drug withdrawn / 16 recovered, 1 recovered with sequelae, 1 recovering, and 1 outcome unknown. 4 cases with dose reduced / 3 recovered and 1 not recovered. 12 cases with the drug not changed / 3 recovered, 1 recovered with sequelae, 7 not recovered and 1 outcome unknown. 6 drug action unknown / 3 recovered and 3 outcomes unknown

References

1. Cipriani P, Ruscitti P, Carubbi F, Liakouli V, Giacomelli R. Methotrexate in rheumatoid arthritis: optimizing therapy among different formulations. Current and emerging paradigms. Clin Ther. 2014;36(3):427–35.

2. Inoue K, Yuasa H. Molecular basis for pharmacokinetics and pharmacodynamics of methotrexate in rheumatoid arthritis therapy. Drug Metab Pharmacokinet. 2014;29(1):12–9.

3. Jansen PHP, Gabreëls FJM, van Engelen BGM. Diagnosis and differential diagnosis of muscle cramps: A clinical approach. J Clin Neuromuscul Dis. 2002;4(2):89–94.

4. Methotrexate 2.5 mg Tablets - Summary of Product Characteristics (SmPC). In: Electronic Medicines Compendium (emc) [website]. 2020 (https://www.medicines.org.uk/emc/product/511/smpc, accessed 30 November 2021).

5. DailyMed - METHOTREXATE- methotrexate sodium tablet [website]. In: US National Library of Medicine, Dailymed2021 (https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=8f1260de-b60c-4f0e-8af6-0e957b0a281b, accessed 30 November 2021).

6. Stamford B. Muscle cramps. Phys Sportsmed. 1993;21(7):115–6.

7. Miller TM, Layzer RB. Muscle cramps. Muscle Nerve. 2005:;32:431–42.

8. Eames P, Jones AC. Acute diffuse muscular pain following initiation of methotrexate therapy. Ann Rheum Dis. 1994;53(7): 478–9.

9. Tröger U, Stötzel B, Martens-Lobenhoffer J, Gollnick H, Meyer FP. Drug points: severe myalgia from an interaction between treatments with pantoprazole and methotrexate. BMJ. 2002;324(7352):1497.

10. Dolinar K, Jan V, Pavlin M, Chibalin AV, Pirkmajer S. Nucleosides block AICAR-stimulated activation of AMPK in skeletal muscle and cancer cells. Am J Physiol Cell Physiol. 2018;315(6):C803–17.

11. Asiedu MN, Dussor G, Price TJ. Targeting AMPK for the alleviation of pathological pain. 2016;107:257–85.

12. Pirkmajer S, Kulkarni SS, Tom RZ, Ross FA, Hawley SA, Hardie DG, et al. Methotrexate promotes glucose uptake and lipid oxidation in skeletal muscle via AMPK activation. Diabetes. 2015;64(2):360–9.

13. Reeves DJ, Moore ES, Bascom D, Rensing B. Retrospective evaluation of methotrexate elimination when co-administered with proton pump inhibitors. Br J Clin Pharmacol. 2014;78(3):565–71.

14. Hall JJ, Bolina M, Chatterley T, Jamali F. Interaction between low-dose methotrexate and nonsteroidal anti-inflammatory drugs, penicillins, and proton pump inhibitors: a narrative review of the literature. Ann Pharmacother. 2017;51(2):163–78.

Tocilizumab and gastric perforation

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Summary

Tocilizumab (TCZ), a humanized monoclonal antibody acting as an interleukin6 (IL-6) receptor antagonist, belongs to an important group of biological agents that has revolutionized the anti-inflammatory therapy of rheumatoid arthritis (RA). However, drugs that block IL-6 are reported to be associated with increased risk of gastrointestinal (GI) perforation, mainly intestinal. Gastric perforation associated with TCZ was identified as a potential signal in a screening of VigiBase, the WHO global database of individual case safety reports. As of March 2020, there were 20 unique patients (compared with 3 expected), from 9 countries, reporting gastric perforation with TCZ as a suspected medicine, in VigiBase. These cases occurred with a time to onset ranging from 0.5 to 36 months (median 5 months); 17/20 (85%) were considered as serious, 1 with a fatal outcome. The indication (known in 18 patients) for TCZ treatment was RA in 16 and temporalis arthritis, or giant cell arthritis (GCA), in two patients. The outcome was unknown for 7 patients, 11 patients recovered or were recovering, including four where a surgical procedure was reported, and two did not recover, including the fatal case. Known risk factors for gastric perforation existed in 10 patients, including co-mobilities or a history of GI disorders, smoking; and concomitant treatment with methotrexate (MTX), rituximab, steroids, NSAIDs, or a combination of these. There seemed to be more patients with a high body weight than with a low body weight, when information was available. Considering the seriousness of this reaction, it would be prudent to recommend close monitoring of patients when treated with TCZ, in particular those with risk factors for GI perforation as well as those with a high body weight, as its dose is determined by the patient's total body weight.

Introduction

Tocilizumab (TCZ) is a humanized monoclonal antibody that acts as an interleukin6 (IL-6) receptor antagonist. Thus, it is an immunosuppressive and interleukin repressive medicine, indicated for adult treatment of severe active and progressive rheumatoid arthritis (RA), especially in combination with methotrexate (MTX),[1] and giant cell arteritis (GCA).[2, 3] TCZ is often given to patients responding inadequately or being intolerant to previous therapy with disease-modifying anti-rheumatic drugs or tumour necrosis factor (TNF) antagonists.[4] Further, it can be given as monotherapy in case of intolerance to, or inappropriate continued treatment with glucocorticoids or MTX. TCZ reduces progression rate of joint damage and improves physical function when given in combination with MTX. It is also indicated for treatment of juvenile idiopathic polyarthritis in patients from two years of age who have not responded to previous MTX treatment. More recently, TCZ has been discussed and tested as an alternative treatment for COVID-19 patients with a risk of cytokine storms, since it has been suggested that IL-6 is one of the most important cytokines in the storms.[5]

Gastrointestinal (GI) perforation is a hole in the wall of GI tract which could include the oesophagus, stomach, small intestine and large intestine. Underlying causes of GI perforation may be gastric ulcers, duodenal ulcers, appendicitis, GI cancer, diverticulitis, inflammatory bowel disease, and use of medicines such as NSAIDs. Surgical intervention is usually required for haemostasis, and closure of perforation and conservative treatment is indicated only in selected patients who are clinically stable.[6]

Gastrointestinal perforation is mentioned in both the EMA and FDA labelling. However, the labelling is focused on **intestinal** perforation, and as a complication of diverticulitis. This was why **gastric** perforation was identified as a potential signal in a screening of VigiBase.

The objective of this study was to analyze the pattern and clinical features of gastric perforation associated with TCZ in the VigiBase cases, and to assess the causality alongside literature findings.

Reports in VigiBase

A clinical review of reports with gastric perforation (PT) associated with TCZ retrieved from VigiBase up to March 2020 was performed.

VigiBase contained 20 unique patients reporting gastric or stomach perforation with TCZ as a suspected or interacting medicine, compared with 3 expected. Table 1 shows the patients' demographics and their characteristics. The reports came from nine countries (Japan (5), USA (5), Colombia (3), Austria (2), and 1 each from UK, Ireland, Greece, Portugal and Hungary). The indications of TCZ, available for 18 patients, were RA (n=16) and GCA (n=2). There were 13 females, 6 males and one gender information missing, which reflects the population treated under the indications. Their ages ranged from 37 to 83 years (median: 61 years). When reporter category information was available, most reports came from physicians (n=16). Of the 20 cases, 17 (85%) were serious, including 4 life-threatening and one with a fatal outcome. In 11

cases (55%) there were narratives, although some of these were considered not informative.

In addition to gastric perforation, seven patients had co-reported reactions such as acute coronary syndrome, pulmonary embolism, cerebrovascular accident, neutropenia, transaminases increased, respiratory or urinary tract infections, while some patients had multiple co-reported reactions. TCZ was the only suspected drug in 15 patients (75%),. In the remaining five cases the co-reported suspected drugs included MTX, prednisolone, hormones (unspecified) and celecoxib, and two of these patients, on NSAIDs or steroid, no gastroprotection (such as antacids) was mentioned. Where information was provided, 12 patients were taking concomitant medications.

TCZ dosing information was available for eight patients: the mean dose, corresponding to four-weekly intervals, was 7.9 (SD 1.1; median 8.0) mg/kg, ranging from 6.0 to 10.0 mg/kg, based on the highest dose if different doses had been given. When information was available (n=9), the mean body weight was 80 kg (SD 24; median 89), ranging from 49 to 114 kg (49, 52, 53, 75, 88, 90, 98, 100 and 114 kg, respectively).

The time to onset (TTO) was reported for 13 patients, and ranged from 0.5 to 36 months (mean: 10; SD: 11; median: 5). The reaction led to withdrawal of TCZ in seven patients, when information was available. The outcome was reported as recovery for 11 patients, no recovery for 1, fatal for 1, and unknown for 7. Positive dechallenge was reported for four patients and rechallenge for one patient , who had no gastric symptoms reported two weeks after the restart of TCZ, at the time of reporting. Surgery was specifically mentioned in the management of the reaction for four patients.

Where information on the medical history and concomitant medications was available, known risk factors for gastric perforation were reported for 10 patients, including GI disorders, smoking; concomitant treatment with MTX, rituximab, steroids, NSAIDs, or a combination of these.

Table 1. Patients' demographics and characteristics of gastric perforations associated with tocilizumab in VigiBase.

Case	Age/sex /body weight	Indication / Dose (mg /4 w)	Other suspected (S) or concomitant drugs	Time to onset (months)	Outcome Recovery: Yes/No/ unknown	Co-reported adverse events	Relevant medical history and concomitant medicines
1	-/-/-	Unknown / -	-	Unknown	Unknown	-	-
2	55/F/ 88 kg	RA / -	Calcium carbonate, levothyroxine, losartan, omeprazole, vitamin D nos	Unknown	Unknown	Acute coronary syndrome, UGI haemorrhage	PPI; BW 88 kg
3	53/F/-	RA / 560	-	5	Yes (sequelae)	-	-
4	70/F/-	RA / 400	-	3	Yes (sequelae)	-	-
5	50/F/-	RA / 504	-	36	Yes	-	-
6	37/F/ 98 kg	RA / 780	Etoricoxib leflunomide hydroxychloroquine tramadol	2	Yes, after surgery	-	NSAID, diverticulitis, BW 98 kg
7	-/F/-	RA / -	-	Unknown	Unknown	-	-
8	67/-/-	RA / -	Rituximab (S), beclometasone, budesonide, fluticasone, folic acid, formoterol, furosemide, gabapentin, ipratropium, metformin, MTX, montelukast, pantoprazole, prednisone, ranitidine, salbutamol, salmeterol, simvastatin, sitagliptin, warfarin	Unknown	Unknown	Oesophagitis, pulmonary embolism, tongue ulceration	Steroid high dose, MTX, PPI, rituximab, higher than max dose
9	65/F/-	RA / 400		13	Yes	-	-

10	49/F/ 52 kg	RA / -	DMARDs, NSAIDs	17	Unknown	GI haemorrhage, neutropenia	NSAID
11	55/M/ 90 kg	RA / 680/35-40	Folic acid (S), hydroxy-chloroquine (S), MTX. Corticosteroids, PPI	27	Yes, after surgery	Transaminases increased, URTI	Smoking, MTX, steroids; PPI; high dose; BW 90 kg
12	58/M/ 49 kg	RA / 400	MTX (S), Prednisol (S), alfacalcidol allpurinol, aspartate calcium, diclofenac, dimeticone, etizolam, iron, lansoprazol, mizoribine, risedronic acid, tacrolimus, zopiclone	3	Yes	-	MTX, steroids, max dose
13	46/M/ 100 kg	RA / 800	Diclofenac, leflunomide omeprazole, prednisolone	3	Yes, after surgery	Abscess, (probably tamponated)	NSAID, steroids, PPI, BW 100 kg
14	-/F/-	Unknown / -	-	Unknown	Unknown		-
15	73/M/ 75 kg	RA / 600	Meloxicam, MTX, PPI.	11	Yes, after surgery	-	NSAID, PPI, MTX. ***No*** *history of GI disorders (ulcers, diverticulosis etc).*
16	62/F/ 113 kg	RA / -	Folic acid, metoprolol, oxybutynin, pravastatin, rivaroxaban, omeprazole	Unknown	Unknown	UTI, influenza	(Rivaroxaban), PPI, BW 113.5 kg. Mg/kg unknown.
17	79/M/-	GCATemp .art/-	-	Unknown	No	-	-
18	83/M/-	RA/162/1o r2v =	Hormones (S), iguratimod, Sulfasalazine	8	Yes	-	-
19	76/F/-	Temp.art / 162/1v (=648?) s.c./i.m.	Prednisone	3	Death	Cerebrovascular accident	Steroids; fatal
20	50/F/ 53 kg	RA /162/2v (= 324 mg?)	Celecoxib (S), prednisolone (S), folic acid, MTX, paracetamol, tramadol	0.5	Yes	-	NSAID, steroids, MTX

BW: Body weight; DMARDs: Disease-modifying antirheumatic drugs; F:Female; GCA: Giant cell arteritis; GI: Gastrointestinal; M: Male; MTX: Methotrexate; NSAIDs: Nonsteroidal anti-inflammatory drugs; PPI: Proton pump inhibitor; RA: Rheumatoid arthritis; TCZ: Tocilizumab; URTI: Upper respiratory tract infection;

Literature and labelling

Tocilizumab (RoActemra) EU summary of product characteristics (SPC)[4]

Posology and method of administration

Treatment should be initiated by healthcare professionals experienced in the diagnosis and treatment of RA, systemic juvenile idiopathic arthritis (sJIA), juvenile idiopathic polyarthritis (pJIA) or cytokine release syndrome (CRS). TCZ should be administered as an intravenous infusion over one hour.

For RA patients, the recommended posology is 8 mg/kg body weight, given once every four weeks.

For individuals whose body weight is more than 100 kg, doses exceeding 800 mg per infusion are not recommended. Dose adjustments are needed if laboratory abnormalities (liver enzyme abnormalities, low absolute neutrophil count, and low platelet count) are found. No dose adjustment is required in elderly patients >65 years of age, or in patients with mild renal impairment.

Special warnings and precautions for use

Complications of diverticulitis: perforations as complications of diverticulitis have been reported uncommonly with TCZ in RA patients. TCZ should be used with caution in patients with a previous history of intestinal ulceration or diverticulitis. Patients presenting with symptoms potentially indicative of complicated diverticulitis, such as abdominal pain, haemorrhage or unexplained change in bowel habits with fever should be evaluated promptly for early identification of diverticulitis, which can be associated with gastrointestinal perforation.

Adverse drug reactions relevant to the signal are presented in Table 2**.**

Table 2. Adverse drug reactions (relevant to the signal, selected by the authors).

MedDRA System Organ Class	Frequency categories with preferred terms
Infections and infestations	**Uncommon:** diverticulitis
Gastrointestinal disorders	**Common:** abdominal pain, mouth ulceration, gastritis **Uncommon:** stomatitis, gastric ulcer

Gastrointestinal perforation: during the 6-month controlled clinical trials, the overall rate of gastrointestinal perforation was 0.26 events per 100 patient years with TCZ therapy. The overall rate of gastrointestinal perforation was 0.28 events per 100 patient years in the long-term exposure population. Reports of gastrointestinal perforation in patients taking TCZ were primarily reported as complications of diverticulitis including generalized purulent peritonitis, lower gastrointestinal perforation, fistulae and abscess.

Discussion

TCZ, a monoclonal antibody targeting the IL-6 receptor, has been reported to increase the risk of GI perforation.[7] The risk for lower GI perforation associated with TCZ was estimated to be more than twice that for anti-tumour necrosis factor agents.[8] In a registry of lower intestinal perforation (LIP), the crude incidence rate of LIP was found to be significantly higher in patients taking TCZ (2.7/1000 person-years), compared with all other treatments (0.2−0.6/1000 person-years).[9] In the literature, more data are available for the risk of for lower GI tract perforation. More recently, based on updated data it was reported that, although data are limited, drugs that block IL-6 are associated with a greater increased risk of GI perforation, than other RA therapies.[7] In our current study, 20 patients with gastric perforation in VigiBase were reviewed with a focus on the clinical features. TTO ranged from 0.5 to 36 months (mean 10; median 5). About 2/3 of the patients were females, reflecting the treatment indication of RA where a female to male prevalence ratio of 2-3:1 has been reported.[10]

When TCZ (RoActemra) was approved in the EU (2009), the Member States were required to implement an educational pack to inform physicians and patients about the risks of serious infections and complications of diverticulitis.[11] In the summary of the Risk Management Plan (RMP) it was stated that the rate of serious infections appeared to increase with body weight.[12] The dose of TCZ is dependant on body weight: 8 mg/kg body weight, given once every four weeks. For individuals whose body weight is more than 100 kg, doses exceeding 800 mg per infusion are not recommended.[13]

In the current study, the mean body weight was about 80 kg. However, no patient weighed 80 kg. Only one patient weighed 75 kg, which was close to the mean body weight, while five patients were heavier (88.2, 90, 98, 100 and 113.5 kg) and three were lighter (49, 52.2 and 53 kg). It would seem that heavier patients are over-represented in this study. It has been reported that chronic dosing using total body weight can lead to drug toxicity in obese adults.[14] Although the body composition (lean versus adipose weight) and the body mass index were not reported, it seems prudent to recommend close monitoring of patients, in particular, those with a high body weight when the drug is dosed according to total body weight.

The findings in the present case series are in line with the literature reporting the commonly used concomitant medicines in RA, e.g. MTX, NSAIDs, and corticosteroids, all known to present risks for GI disorders, in particular gastric perforation.[7] As shown in Table 1, in five patients MTX was used, in five cases NSAIDs, and in six cases steroids, including one with higher dose of steroids. In addition, one patient concomitantly used rivaroxaban which is known to increase the risk of GI bleeding. Therefore, these drugs may also have contributed to the adverse events. In addition, six patients had also concomitantly used PPI, although it is unknown if it was used to prevent or treat GI problems.

Diverticulosis, was specifically mentioned for only two patients, one where it was reported present, and another where it was absent. Diverticular inflammation was reported for 0.8% of patients, who underwent colonoscopy but who lacked symptoms or clinical evidence of diverticulitis.[15] Up to 40% of the Western population may have diverticulosis.[16] It is unclear if patients with known severe diverticulosis should be excluded from TCZ treatment, or if they should have a colonoscopy before starting TCZ to assess whether they have diverticulosis. [17] It has also been suggested that IL-6 blockers should be avoided in patients with a history of diverticulitis, as they are known to increase the risk of subsequent intestinal perforation.[7] The impact of diverticulitis on gastric perforation is unclear.

One patient was a smoker, which could induce pathogenic and carcinogenic processes in the GI

tract.[18] This is because active compounds in cigarette smoke can damage GI tract structure through cellular apoptosis induction, and hamper the mucosal cell renewal. Cigarette smoke also interferes with the protective mechanisms of the GI tract through modulating the mucosal immune system, and reducing the mucosa blood flow. In addition, it inhibits the synthesis and release of EGF and polyamines, which reduces mucus secretion, which may compromise the integrity of the mucosal defence.

Eleven patients, when information was provided, had at least one factor that may have contributed to the occurrence of gastric damage, such as concomitant drugs (e.g., MTX, NSAIDs, steroids, rivaroxaban), or conditions (e.g., smoking, high body weight and associated high dose of TCZ). Eight of these patients had more than one of the factors, suggesting compounded risk for the reaction to occur.

Only four reports specifically mentioned surgery for the ADR. The current treatment of perforated peptic ulcer is surgical repair, although conservative treatment can be adopted in selected patients.[6] It is unclear in our case series whether the perforations without surgery mentioned in the reports were 'microperforation' (see definition of GI perforation[7]) for which surgery is not indicated, or if surgery was performed but not noted in the reports.

Conclusion

Gastrointestinal perforation is an important identified risk of TCZ treatment which may be life-threatening. However, the current labelling is focused on intestinal perforation, and as a complication of diverticulitis. In VigiBase, cases of gastric perforation have been reported, particularly in patients with high body weight and taking concomitant medications known to cause gastric perforation. Healthcare professionals should be aware of this potential risk and closely monitor patients, in particular those with risk factors for GI perforation, as well as those with high body weight, during treatment with TCZ, which is dosed according to total body weight.

We acknowledge with thanks the pharmacovigilance centres that provided additional case information upon request.

References

1. Dhillon, S. Intravenous tocilizumab: a review of its use in adults with rheumatoid arthritis. BioDrugs. 2014;28:75–106.

2. Toussirot É, Martin A, Soubrier M, Redeker S, Régent A. Rapid and sustained response to tocilizumab in patients with polymyalgia rheumatica resistant or intolerant to glucocorticoids: a multicenter open-label study. J Rheumatol. 2016;43(1):249-51.

3. Stone JH, Tuckwell K, Dimonaco S, Klearman M, Aringer M, Blockmans D, et al. Trial of Tocilizumab in Giant-Cell Arteritis. N Eng JMed. 2017;377(4)317-28.

4. Summary of Product Characteristics for Tocilizumab. In: Electronic Medicines Compendium [website]. (https://www.medicines.org.uk/emc/product/6673/smpc, accessed 5 April 2019

5. Luo P, Liu Y, Qiu L, Liu X, Liu D, Li J. Tocilizumab treatment in COVID-19: A single center experience. J Med Virol. 2020;1–5.

6. Hanumanthappa MB, Gopinathan S, Guruprasad Rai D, Dsouza N. A non-operative treatment of perforated peptic ulcer: a prospective study with 50 sases. JClinDiagn Res. 2012;6(4):696-9.

7. Jagpal A, Curtis J. Gastrointestinal perforations with biologics in patients with rheumatoid arthritis: implications for clinicians. Drug Saf. 2018;41(6):545–53

8. Xie F, Yun H, Bernatsky S, Curtis JR. Risk of gastrointestinal perforation among rheumatoid arthritis patients receiving tofacitinib, tocilizumab, or other biologic treatments. Arthritis Rheumatol., 2016;68(11);2612–7.

9. Strangfeld A, Richer A, Siegmund B, Herzer P, Rockwitz K, Demary W, et al. Risk for lower intestinal perforations in patients with rheumatoid arthritis treated with tocilizumab in comparison to treatment with other biologic or conventional synthetic DMARDs. Ann Rheum Dis. 2017;76(3):504-10.

10. Tedeschi SK, Bermas B, Costenbader KH. Sexual disparities in the incidence and course of SLE and RA. Clin Immunol. 2013;149(2):211-8.

11. European Medicines Agency. 2011. Conditions or restrictions with regard to the safe and effective use of medicinal product to be implemented by the member states – Annex IV. Available from: https://www.ema.europa.eu/en/documents/con

ditions-member-states/roactemra-epar-conditions-imposed-member-states-safe-effective-use-annex-iv_en.pdf, accessed 1 December 2021

12. European Medicines Agency. 2020. Summary of risk management plan for RoActemra (tocilizumab). (https://www.ema.europa.eu/en/documents/rmp-summary/roactemra-epar-risk-management-plan-summary_en.pdf, accessed 1 December 2021).

13. European Medicines Agency. 2021. EPAR, (EMA/686079/2018, EMEA/H/C/000955; https://www.ema.europa.eu/en/medicines/human/EPAR/roactemra, accessed 1 December 2021).

14. Barras M, Legg A. Drug dosing in obese adults. Aust Prescr. 2017;40(5):189–93.

15. Ghorai S, Ulbright TM, Rex DK. Endoscopic findings of diverticular inflammation in colonoscopy patients without clinical acute diverticulitis: prevalence and endoscopic spectrum. Am J Gastroenterol. 2003;98(4):802-6.

16. Storz C, Rothenbacher T, Rospleszcz S, Linseisen J, Messmann H, DeCecco CN, et al. Characteristics and associated risk factors of diverticular disease assessed by magnetic resonance imaging in subjects from a Western general population. Eur Radiol. 2019;29(3):1094–103

17. Giang J, Settergren N, Lute M, Fernandez, H. Tocilizumab associated hemorrhagic shock from gastrointestinal bleeding: Abstract 2606. Am J Gastroenterol. 2016;111(suppl):S1311-3

18. Li LF, Chan RLY, Lu L, Shen J, Zhang L, Wu WKK, et al. Cigarette smoking and gastrointestinal diseases: the causal relationship and underlying molecular mechanisms (review) Int J Mol Med. 2014;34(2):372-80.

CAVEAT DOCUMENT

Statement of reservations, limitations and conditions relating to data released from VigiBase, the WHO global database of individual case safety reports (ICSRs).

Understanding and accepting the content of this document are formal conditions for the use of VigiBase data.

Uppsala Monitoring Centre (UMC) in its role as the World Health Organization (WHO) Collaborating Centre for International Drug Monitoring receives reports of suspected adverse reactions to medicinal products from National Centres in countries participating in the WHO Programme for International Drug Monitoring. The information is stored in VigiBase, the WHO global database of individual case safety reports (ICSRs). It is important to understand the limitations and qualifications that apply to this information and its use.

Tentative and variable nature of the data

Uncertainty: The reports submitted to UMC generally describe no more than suspicions which have arisen from observation of an unexpected or unwanted event. In most instances it cannot be proven that a specific medicinal product is the cause of an event, rather than, for example, underlying illness or other concomitant medication.

Variability of source: Reports submitted to national centres come from both regulated and voluntary sources. Practice varies: some national centres accept reports only from medical practitioners; others from a broader range of reporters, including patients, some include reports from pharmaceutical companies.

Contingent influences: The volume of reports for a particular medicinal product may be influenced by the extent of use of the product, publicity, the nature of the adverse effects and other factors.

No prevalence data: No information is provided on the number of patients exposed to the product, and only a small part of the reactions occurring are reported.

Time to VigiBase: Some national centres make an assessment of the likelihood that a medicinal product caused the suspected reaction, while others do not. Time from receipt of an ICSR by a national centre until submission to UMC varies from country to country. Information obtained from UMC may therefore differ from that obtained directly from national centres.

For these reasons, interpretations of adverse effect data, and particularly those based on comparisons between medicinal products, may be misleading. The data comes from a variety of sources and the likelihood of a causal relationship varies across reports. Any use of VigiBase data must take these significant variables into account.

Prohibited use of VigiBase Data includes, but is not limited to:

- patient identification or patient targeting
- identification, profiling or targeting of general practitioners or practice

Any publication, in whole or in part, of information obtained from VigiBase must include a statement:

(i) recording 'VigiBase, the WHO global database of individual case safety reports (ICSRs)' as the source of the information

(ii) explaining that the information comes from a variety of sources, and the probability that the suspected adverse effect is drug-related is not the same in all cases

(iii) affirming that the information does not represent the opinion of the UMC or the World Health Organization.

Omission of this statement may exclude the responsible person or organization from receiving further information from VigiBase.
UMC may, in its sole discretion, provide further instructions to the user, responsible person and/or organization in addition to those specified in this statement and the user, responsible person and/or organization undertakes to comply with all such instructions.

Uppsala Monitoring Centre (UMC)
Box 1051, SE-751 40 Uppsala, Sweden
Tel: +46-18-65 60 60, E-mail: info@who-umc.org
www.who-umc.org

Advisory Committee on Safety of Medicinal Products (ACSoMP)
Eighteenth meeting

World Health Organization, Geneva (virtual Meeting)

26-27th October 2021

The WHO Advisory Committee on Safety of Medicinal Products (ACSoMP) was established in 2003, to provide advice to WHO, including its Collaborating Centre for International Drug Monitoring (the UMC), and through it, to the Member States, on safety issues relating to medicinal products. Topics discussed in the 18th meeting of ACSoMP consisted of updates on previously discussed safety issues such as the safety of sodium valproate in pregnancy, and request for advice on new topics such as integrating pharmacovigilance into the global leprosy programme. A full list of topics discussed is below:

1. Update on therapeutic investigational drugs for treatment of COVID-19 and latest vaccine safety issues.
2. Update on results of studies investigating neural tube defects and the use of dolutegravir.
3. Update on the use of sodium valproate during pregnancy.
4. Monitoring the safety of drugs used in leprosy.
5. Safety signal of hallucinations with the use of delamanid in children for tuberculosis.
6. Ocular adverse events with the use of miltefosine for visceral leishmaniasis and post-kala-azar dermal leishmaniasis.
7. Update on the safety of fexinidazole used for African trypanosomiasis in the Democratic Republic of Congo.

An overview of recommendations from the meeting will be published in a following issue of the Pharmaceuticals Newsletter.

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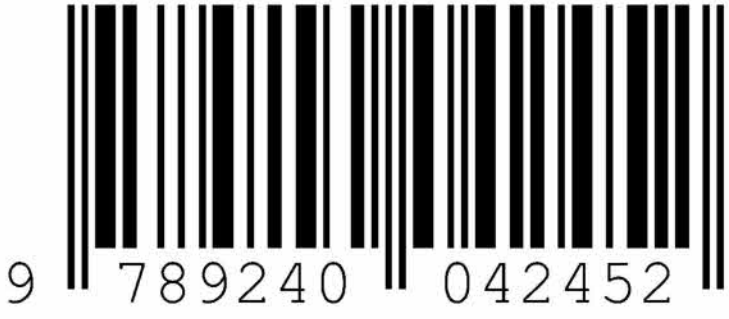

From: Kirkland, William (CDC/OCOO/OCIO/CEO) (CTR)
Sent: Fri, 9 Dec 2022 18:32:19 +0000
To: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP); Savel, Tom (CDC/OCOO/OCIO/CEO); David, Sanjith (CDC/OCOO/OCIO/DSO) (CTR)
Cc: Mccullum, Isaac (CDC/DDID/NCEZID/DHQP); Shay, David (CDC/DDID/NCEZID/DHQP); Myers, Tanya R. (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Subject: Re: Initial Scrubbing Ready For Review

A quick update, we have made all of the adjustments based on your feedback from last Friday, including:

(b)(5)

Following that, I ingested the full dataset and have started scrubbing it. The plan now is to let it run over the weekend and see how far we get on Monday.

Would you like us to continue the full dataset scrubbing process, or would your team like to review another iteration of the sample dataset? Let me know, happy to make whatever changes you need.

Eddie Kirkland
Principal Data Scientist
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From: Kirkland, William (CDC/OCOO/OCIO/CEO) (CTR) <qjg0@cdc.gov>
Date: Monday, December 5, 2022 at 4:13 PM
To: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>, Savel, Tom (CDC/OCOO/OCIO/CEO) <azn6@cdc.gov>, David, Sanjith (CDC/OCOO/OCIO/DSO) (CTR) <xjy5@cdc.gov>
Cc: Mccullum, Isaac (CDC/DDID/NCEZID/DHQP) <HHE0@cdc.gov>, Shay, David (CDC/DDID/NCEZID/DHQP) <dks4@cdc.gov>, Myers, Tanya R. (CDC/DDID/NCEZID/DHQP) <vje9@cdc.gov>, Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Subject: Re: Initial Scrubbing Ready For Review

Thank you Paige,

(b)(5)

Once the algorithm is working correctly, I'll dig into scrubbing the entire dataset based on the file you sent.

Unfortunately, I am not able to scrub non-English responses, so I will leave those records as-is.

I will follow up with more information as soon as I have it!

Eddie Kirkland
Principal Data Scientist
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From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>
Date: Friday, December 2, 2022 at 5:17 PM
To: Kirkland, William (CDC/OCOO/OCIO/CEO) (CTR) <qjg0@cdc.gov>, Savel, Tom (CDC/OCOO/OCIO/CEO) <azn6@cdc.gov>, David, Sanjith (CDC/OCOO/OCIO/DSO) (CTR) <xjy5@cdc.gov>
Cc: Mccullum, Isaac (CDC/DDID/NCEZID/DHQP) <HHE0@cdc.gov>, Shay, David (CDC/DDID/NCEZID/DHQP) <dks4@cdc.gov>, Myers, Tanya R. (CDC/DDID/NCEZID/DHQP) <vje9@cdc.gov>, Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Subject: RE: Initial Scrubbing Ready For Review

Hello All,
Sorry for the delay. We have reviewed your latest scrubbing file (**full_sample_scrubbed_alg4).**
I have provided some of the key issues/concerns/requests below. Let me know your thoughts on them.
I also wanted to let you know that we have uploaded the full data (up to 07.31.2022) for you to scrub as well. (b)(6)
Data is divided into two files: English and Non-English. Within the two files, each of the rows will indicate the language the participant chose to take the survey in.
Can you remind us of whether you are able to scrub the non-English responses?
Please let me know if you would like to meet and discuss any of the key findings and next steps.

Issues/Concerns/Request:

(b)(5) e

Paige Marquez
Statistician |Immunization Safety Office
CDC | Division of Healthcare Quality Promotion
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From: Kirkland, William (CDC/OCOO/OCIO/CEO) (CTR) <qjg0@cdc.gov>
Sent: Friday, October 21, 2022 2:02 PM
To: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>; Savel, Tom (CDC/OCOO/OCIO/CEO) <azn6@cdc.gov>; David, Sanjith (CDC/OCOO/OCIO/DSO) (CTR) <xjy5@cdc.gov>
Cc: Mccullum, Isaac (CDC/DDID/NCEZID/DHQP) <HHE0@cdc.gov>; Shay, David (CDC/DDID/NCEZID/DHQP) <dks4@cdc.gov>; Myers, Tanya R. (CDC/DDID/NCEZID/DHQP) <vje9@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Subject: Re: Initial Scrubbing Ready For Review

Hello VSAF team!

A quick follow-up from my last email: I've refined the scrubbing algorithm a little bit to improve speed, and we've seen an 80% efficiency improvement. This will be hugely helpful when we go to scrub the full dataset.

If you have already started your review of the 500k records we sent earlier this week (…alg3.csv), please continue working with that file and let us know your thoughts.

If you have not started, please disregard the alg3.csv file and use this instead (b)(6) (b)(6) The process is currently running to finish scrubbing all 500k records, so it will likely finish later this afternoon/evening.

Thank you, and please let me know if you have any questions.

Eddie Kirkland
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From: Kirkland, William (CDC/OCOO/OCIO/CEO) (CTR) <qjg0@cdc.gov>
Date: Friday, October 14, 2022 at 3:34 PM
To: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>, Savel, Tom (CDC/OCOO/OCIO/CEO) <azn6@cdc.gov>, David, Sanjith (CDC/OCOO/OCIO/DSO) (CTR) <xjy5@cdc.gov>
Cc: Mccullum, Isaac (CDC/DDID/NCEZID/DHQP) <HHE0@cdc.gov>, Shay, David (CDC/DDID/NCEZID/DHQP) <dks4@cdc.gov>, Myers, Tanya R. (CDC/DDID/NCEZID/DHQP) <vje9@cdc.gov>, Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Subject: Re: Initial Scrubbing Ready For Review

Thank you for the clarification, and I'm sorry I couldn't be on the call earlier today.

Unfortunately I (b)(5) (b)(5) to address your needs and will let you know how it goes!

Eddie Kirkland
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From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>
Date: Friday, October 14, 2022 at 3:07 PM
To: Kirkland, William (CDC/OCOO/OCIO/CEO) (CTR) <qjg0@cdc.gov>, Savel, Tom (CDC/OCOO/OCIO/CEO) <azn6@cdc.gov>, David, Sanjith (CDC/OCOO/OCIO/DSO) (CTR) <xjy5@cdc.gov>
Cc: Mccullum, Isaac (CDC/DDID/NCEZID/DHQP) <HHE0@cdc.gov>, Shay, David (CDC/DDID/NCEZID/DHQP) <dks4@cdc.gov>, Myers, Tanya R. (CDC/DDID/NCEZID/DHQP) <vje9@cdc.gov>, Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Subject: RE: Initial Scrubbing Ready For Review

On our call this morning, we talked about splitting up the final dataset into two files: English and non-English.
I hope to get some time next week to get a count of text cells that are non-English.
With that said, do you have scrubbers that you could apply to non-english entries (i.e. Spanish)?
If not, we may have to blank them out.
In the recent returned sample, I did notice they were not blanked out.

From: Kirkland, William (CDC/OCOO/OCIO/CEO) (CTR) <qjg0@cdc.gov>
Sent: Friday, October 14, 2022 2:44 PM
To: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>; Savel, Tom (CDC/OCOO/OCIO/CEO) <azn6@cdc.gov>; David, Sanjith (CDC/OCOO/OCIO/DSO) (CTR) <xjy5@cdc.gov>
Cc: Mccullum, Isaac (CDC/DDID/NCEZID/DHQP) <HHE0@cdc.gov>; Shay, David (CDC/DDID/NCEZID/DHQP) <dks4@cdc.gov>; Myers, Tanya R. (CDC/DDID/NCEZID/DHQP) <vje9@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Subject: Re: Initial Scrubbing Ready For Review

Thank you, Paige,

This all looks good. I will review the spreadsheet and do some investigating. We will keep you posted with our status early next week.

One quick question – (b)(5)

(b)(5)

Thank you,

Eddie Kirkland
Principal Data Scientist
ICF International
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From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>
Date: Friday, October 14, 2022 at 2:01 PM
To: Kirkland, William (CDC/OCOO/OCIO/CEO) (CTR) <qjg0@cdc.gov>, Savel, Tom (CDC/OCOO/OCIO/CEO) <azn6@cdc.gov>, David, Sanjith (CDC/OCOO/OCIO/DSO) (CTR) <xjy5@cdc.gov>
Cc: Mccullum, Isaac (CDC/DDID/NCEZID/DHQP) <HHE0@cdc.gov>, Shay, David (CDC/DDID/NCEZID/DHQP) <dks4@cdc.gov>, Myers, Tanya R. (CDC/DDID/NCEZID/DHQP) <vje9@cdc.gov>, Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Subject: RE: Initial Scrubbing Ready For Review

Hey team,
First of all thanks for your work on this project. We wanted to provide some feedback to the latest batch of redactions. I have saved a file called "full_sample_scrubbed_alg2_reviewed.xls" located here: (b)(6) that has various examples highlighted in different colors where we noted results of concern. Below I have provided some of the issues we noticed when reviewing your sample file.

We noticed the following:

(b)(5)

From: Kirkland, William (CDC/OCOO/OCIO/CEO) (CTR) <qjg0@cdc.gov>
Sent: Thursday, October 6, 2022 10:35 AM

To: Shay, David (CDC/DDID/NCEZID/DHQP) <dks4@cdc.gov>; Myers, Tanya R. (CDC/DDID/NCEZID/DHQP) <vje9@cdc.gov>; Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Cc: Savel, Tom (CDC/OCOO/OCIO/CEO) <azn6@cdc.gov>; David, Sanjith (CDC/OCOO/OCIO/DSO) (CTR) <xjy5@cdc.gov>; Mccullum, Isaac (CDC/DDID/NCEZID/DHQP) <HHE0@cdc.gov>
Subject: RE: Initial Scrubbing Ready For Review

Hello team,

Just finished a batch of redactions for your review: (b)(6)
(b)(6)

This is the full 500k records you supplied, with changes to the scrubbing algorithm:

(b)(5)

Please let me know if you have any trouble accessing the csv file or if you need any more info. Looking forward to your feedback and next steps!

Eddie Kirkland

From: Shay, David (CDC/DDID/NCEZID/DHQP) <dks4@cdc.gov>
Sent: Thursday, October 6, 2022 8:55 AM
To: Kirkland, William (CDC/OCOO/OCIO/CEO) (CTR) <qjg0@cdc.gov>; Myers, Tanya R. (CDC/DDID/NCEZID/DHQP) <vje9@cdc.gov>; Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Cc: Savel, Tom (CDC/OCOO/OCIO/CEO) <azn6@cdc.gov>; David, Sanjith (CDC/OCOO/OCIO/DSO) (CTR) <xjy5@cdc.gov>; Mccullum, Isaac (CDC/DDID/NCEZID/DHQP) <HHE0@cdc.gov>
Subject: RE: Initial Scrubbing Ready For Review

Hello –

An important point here is that (b)(5)
(b)(5)

Best, david

From: Kirkland, William (CDC/OCOO/OCIO/CEO) (CTR) <qjg0@cdc.gov>
Sent: Thursday, October 6, 2022 7:02 AM
To: Myers, Tanya R. (CDC/DDID/NCEZID/DHQP) <vje9@cdc.gov>; Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>; Shay, David (CDC/DDID/NCEZID/DHQP) <dks4@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Cc: Savel, Tom (CDC/OCOO/OCIO/CEO) <azn6@cdc.gov>; David, Sanjith (CDC/OCOO/OCIO/DSO) (CTR)

<xjy5@cdc.gov>; Mccullum, Isaac (CDC/DDID/NCEZID/DHQP) <HHE0@cdc.gov>
Subject: Re: Initial Scrubbing Ready For Review

Thank you for the feedback, that definitely makes sense (b)(5)

(b)(5)

I'll let you know as soon as it's done and available for analysis. Please let me know if you need any other adjustments!

Eddie Kirkland
Principal Data Scientist
ICF International
Emerging Technology & Design Acceleration Branch (ETDAB)
Office of the Chief Information Officer (OCIO)
Office of the Chief Operating Officer (OCOO)
Centers for Disease Control and Prevention (CDC)
qjg0@cdc.gov | (b)(6) cell

From: Myers, Tanya R. (CDC/DDID/NCEZID/DHQP) <vje9@cdc.gov>
Date: Wednesday, October 5, 2022 at 5:46 PM
To: Kirkland, William (CDC/OCOO/OCIO/CEO) (CTR) <qjg0@cdc.gov>, Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>, Shay, David (CDC/DDID/NCEZID/DHQP) <dks4@cdc.gov>, Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Cc: Savel, Tom (CDC/OCOO/OCIO/CEO) <azn6@cdc.gov>, David, Sanjith (CDC/OCOO/OCIO/DSO) (CTR) <xjy5@cdc.gov>, Mccullum, Isaac (CDC/DDID/NCEZID/DHQP) <HHE0@cdc.gov>
Subject: RE: Initial Scrubbing Ready For Review

+David Shay, acting lead for the DETECT team under which v-safe systems fall, and Tom Shimabukuro

Thanks for these explanations, Eddie.

(b)(5)

(b)(5) ? If it would be helpful ahead of the next iteration, we can also try to find a time to meet and discuss further.

Tanya

From: Kirkland, William (CDC/OCOO/OCIO/CEO) (CTR) <qjg0@cdc.gov>
Sent: Wednesday, October 5, 2022 2:14 PM
To: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>
Cc: Savel, Tom (CDC/OCOO/OCIO/CEO) <azn6@cdc.gov>; David, Sanjith (CDC/OCOO/OCIO/DSO) (CTR) <xjy5@cdc.gov>; Mccullum, Isaac (CDC/DDID/NCEZID/DHQP) <HHE0@cdc.gov>; Myers, Tanya R. (CDC/DDID/NCEZID/DHQP) <vje9@cdc.gov>
Subject: Re: Initial Scrubbing Ready For Review

Hi Paige,

Great questions. Here's my best attempt to answer them…

(b)(5)

I'll briefly describe the other scrubbers below, let me know if you have any other questions!!

(b)(5)

(b)(5)

Eddie Kirkland
Principal Data Scientist
ICF International
Emerging Technology & Design Acceleration Branch (ETDAB)
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From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>
Date: Wednesday, October 5, 2022 at 12:51 PM
To: Kirkland, William (CDC/OCOO/OCIO/CEO) (CTR) <qjg0@cdc.gov>
Cc: Savel, Tom (CDC/OCOO/OCIO/CEO) <azn6@cdc.gov>, David, Sanjith (CDC/OCOO/OCIO/DSO) (CTR) <xjy5@cdc.gov>, Mccullum, Isaac (CDC/DDID/NCEZID/DHQP) <HHE0@cdc.gov>, Myers, Tanya R. (CDC/DDID/NCEZID/DHQP) <vje9@cdc.gov>
Subject: RE: Initial Scrubbing Ready For Review

Hey Eddie,
In looking through your sample file, (b)(5)

(b)(5)

(b)(5)

Are you able to explain how each of the scrubbers work so we can understand your results better?

Thank you,
Paige

From: Myers, Tanya R. (CDC/DDID/NCEZID/DHQP) <vje9@cdc.gov>
Sent: Tuesday, October 4, 2022 7:37 AM
To: Kirkland, William (CDC/OCOO/OCIO/CEO) (CTR) <qjg0@cdc.gov>; Mccullum, Isaac (CDC/DDID/NCEZID/DHQP) <HHE0@cdc.gov>; Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>
Cc: Savel, Tom (CDC/OCOO/OCIO/CEO) <azn6@cdc.gov>; David, Sanjith (CDC/OCOO/OCIO/DSO) (CTR) <xjy5@cdc.gov>
Subject: RE: Initial Scrubbing Ready For Review

Good morning, William,

We had a critical deadline last week and are reviewing the below now. Let me loop in with the relevant folks here on schedules – will get back to you shortly.

Thanks,
Tanya

From: Kirkland, William (CDC/OCOO/OCIO/CEO) (CTR) <qjg0@cdc.gov>
Sent: Monday, October 3, 2022 1:59 PM
To: Myers, Tanya R. (CDC/DDID/NCEZID/DHQP) <vje9@cdc.gov>; Mccullum, Isaac (CDC/DDID/NCEZID/DHQP) <HHE0@cdc.gov>; Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>
Cc: Savel, Tom (CDC/OCOO/OCIO/CEO) <azn6@cdc.gov>; David, Sanjith (CDC/OCOO/OCIO/DSO) (CTR) <xjy5@cdc.gov>
Subject: Re: Initial Scrubbing Ready For Review

Hello Tanya and team,

Wanted to check and see if you've had a chance to review the initial sample? If so, we can set up a meeting to discuss adjustments and next steps.

Thank you for your patience while I was away last week!

Eddie Kirkland
Principal Data Scientist
ICF International
Emerging Technology & Design Acceleration Branch (ETDAB)
Office of the Chief Information Officer (OCIO)
Office of the Chief Operating Officer (OCOO)

Centers for Disease Control and Prevention (CDC)
qjg0@cdc.gov | (b)(6) cell

From: Myers, Tanya R. (CDC/DDID/NCEZID/DHQP) <vje9@cdc.gov>
Date: Saturday, September 24, 2022 at 9:43 AM
To: Kirkland, William (CDC/OCOO/OCIO/CEO) (CTR) <qjg0@cdc.gov>, Mccullum, Isaac (CDC/DDID/NCEZID/DHQP) <HHE0@cdc.gov>, Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>
Cc: Savel, Tom (CDC/OCOO/OCIO/CEO) <azn6@cdc.gov>, David, Sanjith (CDC/OCOO/OCIO/DSO) (CTR) <xjy5@cdc.gov>
Subject: RE: Initial Scrubbing Ready For Review

Eddie, thanks for your work on this. We'll look forward to talking more on your return.

Tanya

From: Kirkland, William (CDC/OCOO/OCIO/CEO) (CTR) <qjg0@cdc.gov>
Sent: Friday, September 23, 2022 11:30 AM
To: Mccullum, Isaac (CDC/DDID/NCEZID/DHQP) <HHE0@cdc.gov>; Myers, Tanya R. (CDC/DDID/NCEZID/DHQP) <vje9@cdc.gov>; Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>
Cc: Savel, Tom (CDC/OCOO/OCIO/CEO) <azn6@cdc.gov>; David, Sanjith (CDC/OCOO/OCIO/DSO) (CTR) <xjy5@cdc.gov>
Subject: Initial Scrubbing Ready For Review

Hello Tanya & Team,

I've finished an initial scrubbing for your review. The finished file is located here: (b)(6)

(b)(6)

Some things to note:

(b)(5)

(b)(5)

What we need from you:

(b)(5)

I am (b)(6) so it should give your team time to do a thorough review of the initial dataset and make recommendations. If you have any questions in the meantime, or if you're ready to set up a follow-up meeting for early the first week of October, please reach out to Tom/Sanjith (cc'ed above) while I am away.

Looking forward to next steps when (b)(6)

Eddie Kirkland
Principal Data Scientist
ICF International
Emerging Technology & Design Acceleration Branch (ETDAB)
Office of the Chief Information Officer (OCIO)
Office of the Chief Operating Officer (OCOO)
Centers for Disease Control and Prevention (CDC)
qjg0@cdc.gov (b)(6) cell

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Sent: Fri, 23 Sep 2022 15:19:00 +0000
To: Sharan, Martha (CDC/DDID/NCEZID/DHQP)
Subject: RE: MEDIA INQUIRY - National Geographic interview request - AEs from COVID vaccines
Attachments: Nat Geo.docx

Hi Martha – See attached. Thanks.
Tom

From: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Sent: Thursday, September 22, 2022 9:21 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Subject: MEDIA INQUIRY - National Geographic interview request - AEs from COVID vaccines

Hi Tom:
National Geographic reporter, Tara Haelle, has some follow-up questions after receiving our statement on tinnitus.
Please review. She mentioned a phone interview in her email, but I think she will be OK with written responses. If we can't provide more than what was provided in the statement I will let her know.
Thanks,
Martha

Martha Sharan
Public Affairs
CDC/Division of Healthcare Quality Promotion
Off.: 404-639-2683
Cell: 404-998-1787

From: Tara Haelle <(b)(6)
Sent: Thursday, September 22, 2022 2:31 AM
To: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Subject: Re: FW: National Geographic interview request - AEs from COVID vaccines

Martha,
Thank you for this. Is that VSD analysis published somewhere? If so, could you share the citation with me? Meanwhile, I've adjusted some of the questions below, including the order of them.

Thanks,
Tara

—A recent paper by Harpaz et al (doi: 10.1007/s40264-022-01186-z) suggests a strong association exists in VAERS reports for tinnitus and each of the three COVID-19 vaccines initially authorized by the FDA, but that the association is masked because of the high number of overall reports. Is this something that the CDC safety researchers have considered and/or that they are looking into?

—One of the challenges of considering tinnitus as a presumptive AE is that it is so common as a background condition in the general population. Does a condition's prevalence in the general population affect how CDC safety researchers consider potential associations from AEs reported in VAERS? Would shortening the time after vaccination that they looked for an association be likely to change any likelihood of finding an association?

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—Is there any possibility that the CDC will initiate another study study in the future, using VSD again or another data set, to investigate tinnitus as a potential AE correlated with any of the COVID-19 vaccines? Or is the matter considered settled? Why or why not?

—It seems statistically possible that a condition that has a naturally high prevalence in the general population (as tinnitus does) but is very rare as a vaccine adverse event could easily be missed as a true signal by traditional VSD analysis methods. How, if at all, have CDC safety researchers accounted for this possibility. (I'd wager that tinnitus is likely the most common condition that's ever been considered as a serious AE, which would make it fairly unique among presumptive AEs.)

Tara Haelle • @tarahaelle
Pronouns: She/Her • (b)(6) CST (no PR calls please)
tarahaelle.net
Journalist, author, public speaker & AHCJ Medical Studies Core Topic Leader
Books: Vaccination Investigation, The Informed Parent, various children's titles

On Wed, Sep 21, 2022 at 2:52 PM Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov> wrote:
Hi Tara:
CDC now has a statement that I am including below – not sure if this will have an impact on your list of questions. Let me know if you need to adjust any of them:

> CDC is aware of reports to the Vaccine Adverse Event Reporting System (VAERS) of tinnitus occurring in temporal association with COVID-19 vaccination (i.e., following vaccination). Tinnitus is a common condition and heterogenous in clinical presentation and course. There are

some established risk factors, such as exposure to loud noise; however, in many cases, no discernable cause for tinnitus is identified.

Hundreds of millions of people have received COVID-19 vaccinations under the most intensive monitoring in U.S. history. Because so many people have been vaccinated and because tinnitus is so common in the population, temporally-associated cases are expected, with some expected to occur shortly after vaccination. To further evaluate concerns about reports of tinnitus following COVID-19 vaccination, CDC conducted an analysis in the Vaccine Safety Datalink (VSD). Unlike VAERS, which relies primarily on voluntary reports from healthcare providers, patients, and others, the VSD uses data from electronic health records. Consequently, the VSD data are less likely to be affected by the reporting biases and other biases that impact spontaneous reporting patterns to VAERS and data quality. The VSD looked for clustering of tinnitus diagnoses in COVID-19 vaccinated patients during a post-vaccination observation period out to 70 days after vaccination. In the VSD's patient population of approximately 12 million people with 6.6 million COVID-19 vaccine doses administered, to date no clustering of tinnitus diagnoses has been observed post-vaccination.

Currently, the information from vaccine safety monitoring systems does not suggest a link between COVID-19 vaccination and tinnitus. CDC will continue to monitor the safety of COVID-19 vaccines and continue to evaluate the outcome of tinnitus as additional data are collected.

Thanks,
Martha

Martha Sharan
Public Affairs
CDC/Division of Healthcare Quality Promotion
Off.: 404-639-2683
Cell: 404-998-1787

From: Tara Haelle (b)(6)
Sent: Wednesday, September 21, 2022 3:27 PM
To: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Subject: Re: FW: National Geographic interview request - AEs from COVID vaccines

Hi Martha,
It took me a while to pull these questions together because most of my questions will depend on the answers he gives to the first questions. In other words, I'm almost certainly going to have follow-up questions in response to these because of the nature of the questions. I've tried to include that in these questions, but I wanted to give you a heads up about likely having follow-up questions. If it's at all possible to set up a phone or Zoom interview, that would be far preferable given the challenging nature of discussing adverse effects and vaccines and nuance required in those discussions.

Please let me know when Dr. Shimabukuro will be able to respond to these. If it's possible by the end of this week, that would be particularly helpful.

Thank you,

Tara Haelle

—Has the CDC investigated the potential association between tinnitus and COVID-19 vaccines? If so, can you tell me what the CDC vaccine safety researchers have done and found? Or, if not, can explain the reasoning behind that decision?

—One of the challenges of considering tinnitus as a presumptive AE is that it is so common as a background condition in the general population. Does a condition's prevalence in the general population affect how CDC safety researchers consider potential associations from AEs reported in VAERS?

—Does the CDC have plans to initiate a case control or other epidemiological study, using VSD or another data set, to investigate tinnitus as a potential AE correlated with any of the COVID-19 vaccines? Why or why not?

—A recent paper by Harpaz et al (doi: 10.1007/s40264-022-01186-z) suggests a strong association exists in VAERS reports for tinnitus and each of the three COVID-19 vaccines initially authorized by the FDA, but that the association is masked because of the high number of overall reports. Is this something that the CDC safety researchers have considered and/or that they are looking into?

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Journalist, author, public speaker & AHCJ Medical Studies Core Topic Leader
Books: Vaccination Investigation, The Informed Parent, various children's titles

On Thu, Sep 1, 2022 at 7:24 AM Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov> wrote:
Hi Tara:
Your request was forwarded to me. I work closely with Dr. Shimabukuro on media inquiries.
Would it be possible for you to send us a list of questions that you would like him to address. It would be easier for him to respond in writing.

Thanks,
Martha

Martha Sharan
Public Affairs
CDC/Division of Healthcare Quality Promotion
Off.: 404-639-2683
Cell: 404-998-1787

From: Tara Haelle (b)(6)
Sent: Wednesday, August 31, 2022 6:32 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Subject: National Geographic interview request - AEs from COVID vaccines

Hello Dr. Shimabukuro,
I'm not sure if you remember me, but I believe we met while I was on a CDC fellowship for AHCJ a number of years ago. I've been writing about vaccines for more than a decade, and I'm now writing an article for National Geographic about whether there is adequate evidence to determine whether tinnitus could be a potential adverse event linked to any of the COVID-19 vaccines.

I spoke with Patsy Stinchfield, and she mentioned you would be a good source on this since I have questions about the CDC's process in going through VAERS reports and determining what to further investigate using VSD or other epi studies.

Would you have time for an interview this week or next to discuss this topic for my article?

Thank you,
Tara Haelle

P.S. I realize discussing vaccine AEs with a reporter can be a precarious decision, so please feel free to contact others who might vouch for my credibility and reliance on the evidence, such as Dan Salmon, Paul Offit, Patsy Stinchfield, Walter Orenstein, Bruce Gellin, or Saad Omer, all of whom are familiar with me and my work.

– –

These are incredibly tough, strange times. Feeling awful and frustrated you can't "snap out of it?" Read this. If you're thinking of hurting yourself, please call the Suicide Hotline at 1-800-273-8255 or text 741741. You matter.

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(b)(5)

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(b)(5)

(b)(5)

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(b)(5)

From: Sharan, Martha (CDC/DDID/NCEZID/DHQP)
Sent: Thu, 22 Sep 2022 16:36:07 +0000
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Subject: RE: MEDIA INQUIRY - National Geographic interview request - AEs from COVID vaccines

Completely understand. I will let the reporter know that we will provide what we can next week.

Martha Sharan
Public Affairs
CDC/Division of Healthcare Quality Promotion
Off.: 404-639-2683
Cell: 404-998-1787

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Sent: Thursday, September 22, 2022 9:57 AM
To: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Subject: RE: MEDIA INQUIRY - National Geographic interview request - AEs from COVID vaccines

Hi Martha,

I can attempt to provide answers to at least some of these follow-up questions, but probably not until we deal with the issue at hand (which we have all been preparing for this week). Thanks.

Tom

From: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Sent: Thursday, September 22, 2022 9:21 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Subject: MEDIA INQUIRY - National Geographic interview request - AEs from COVID vaccines

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Public Affairs
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Off.: 404-639-2683
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From: Tara Haelle (b)(6)
Sent: Wednesday, August 31, 2022 6:32 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Subject: National Geographic interview request - AEs from COVID vaccines

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P.S. I realize discussing vaccine AEs with a reporter can be a precarious decision, so please feel free to contact others who might vouch for my credibility and reliance on the evidence, such as Dan Salmon, Paul Offit, Patsy Stinchfield, Walter Orenstein, Bruce Gellin, or Saad Omer, all of whom are familiar with me and my work.

– –

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Journalist, author, public speaker & AHCJ Medical Studies Core Topic Leader
Books: Vaccination Investigation, The Informed Parent, various children's titles

From: Yih, Katherine
Sent: Thu, 29 Sep 2022 14:12:54 +0000
To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP); Yih, Katherine; Jazwa, Amelia (CDC/DDID/NCEZID/DHQP); Duffy, Jonathan M. (CDC/DDID/NCEZID/DHQP); McNeil, Michael (CDC/DDID/NCEZID/DHQP); Schembri, Christopher P. (CDC/DDID/NCEZID/DHQP); Maro, Judy; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); rrosofsky@healthinfosys.net; LeBlanc, Jessica
Subject: RE: memo about hearing issues (based on TreeScan data)

I should add that I think a good next step (b)(5) is

(b)(5)

Katherine

From: Yih, Katherine
Sent: Thursday, September 29, 2022 10:09 AM
To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>; Yih, Katherine <Katherine_Yih@harvardpilgrim.org>; Jazwa, Amelia (CDC/DDID/NCEZID/DHQP) <wev7@cdc.gov>; Duffy, Jonathan M. (CDC/DDID/NCEZID/DHQP) <lzd5@cdc.gov>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <mmm2@cdc.gov>; Schembri, Christopher P. (CDC/DDID/NCEZID/DHQP) <gmi8@cdc.gov>; Maro, Judy <Judy.Maro@point32health.org>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; rrosofsky@healthinfosys.net; LeBlanc, Jessica <Jessica.Leblanc@point32health.org>
Subject: RE: memo about hearing issues (based on TreeScan data)

Dear all,

Some new information: 96% of tinnitus captured in any setting is in the ambulatory care setting, which does not include ED. Judy did temporal scans for tinnitus (H93.1*) in any setting for each of the three vaccines using the 140 days of follow-up. As we usually do, she set the parameters to look for clusters anywhere between 2 days and half the follow-up period (=70 days) in length. Interestingly, there were statistically significant temporal clusters, but quite long ones, for the mRNA vaccines. For Pfizer, the strongest one (with largest test statistic) was on Days 33-84 (52 days long), RR=1.14, p=0.001. For Moderna, the strongest one was on Days 41-105 (65 days long), RR=1.08, p=0.01. There were no statistically significant clusters (or any close to stat. signif.) for Janssen.

Both strongest clusters for the mRNA vaccines start around 12-13 days after when Dose 2 would likely have been received. The relative risks are quite low and certainly it's hard to see anything on visual inspection of the graphs, especially for Moderna, so this seems to be a subtle effect if it is truly a VAE (unless of course you're one of the unlucky ones who got tinnitus).

See "Graphs of temporal clusters" tab of the attached for the summarized information and to see the cluster periods superimposed on the graphs I sent earlier.

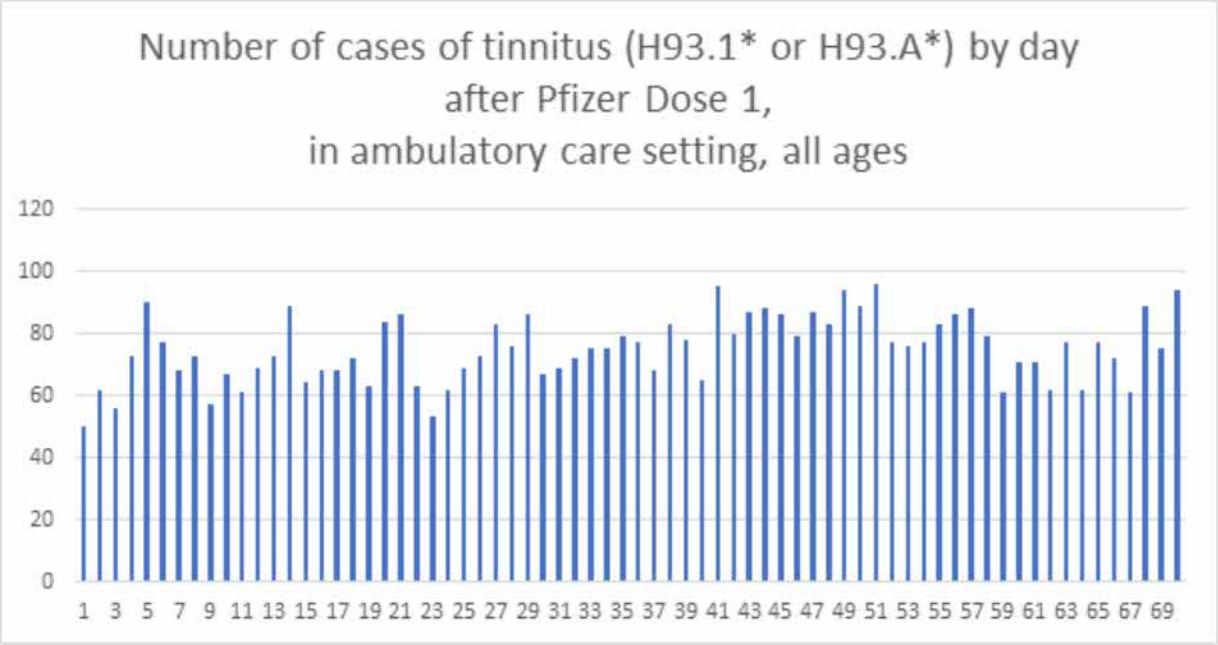
We can go over this and all the other pieces of information we've gathered on tinnitus on our October 7 call.

Katherine

From: Yih, Katherine
Sent: Friday, September 23, 2022 2:00 PM
To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>; Yih, Katherine <Katherine_Yih@harvardpilgrim.org>; Jazwa, Amelia (CDC/DDID/NCEZID/DHQP) <wev7@cdc.gov>; Duffy, Jonathan M. (CDC/DDID/NCEZID/DHQP) <lzd5@cdc.gov>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <mmm2@cdc.gov>; Schembri, Christopher P. (CDC/DDID/NCEZID/DHQP) <gmi8@cdc.gov>; Maro, Judy <Judy.Maro@point32health.org>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; rrosofsky@healthinfosys.net; LeBlanc, Jessica <Jessica.Leblanc@point32health.org>
Subject: RE: memo about hearing issues (based on TreeScan data)

Eric and all,

1. Regarding the AV-and-ED-only analysis Tom is interested in, we don't currently have that, but we do have AV-only data. The hearing-related outcomes do seem to be predominantly in the AV setting. Here's a graph of tinnitus I made several months ago from Pfizer AV-only data:



Note to self: This graph is here:

(b)(6)

2. Regarding the number of cases over the course of 140 days, Judy told me that the program actually did require 140 days of post-vaccination enrollment (so one can use temporal scan statistics without bias from incomplete follow-up). Judy created the attached graphs of tinnitus by day after Dose 1 up to Day 140, all ages combined, all settings (Sheet 2). There doesn't seem to be much drop-off after the original follow-up periods of 70 and 56 days. Also, the most

frequent other codes recorded within +/-5 days of a tinnitus code are listed to the right of each graph—no serious co-morbidities. Note to self: This file is here:

(b)(6)

From these, no association is jumping out at me for tinnitus. But we'll organize what we've got, and we can discuss more on Oct. 7.

Katherine

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>
Sent: Friday, September 23, 2022 12:19 PM
To: Yih, Katherine <Katherine_Yih@harvardpilgrim.org>; Jazwa, Amelia (CDC/DDID/NCEZID/DHQP) <wev7@cdc.gov>; Duffy, Jonathan M. (CDC/DDID/NCEZID/DHQP) <lzd5@cdc.gov>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <mmm2@cdc.gov>; Schembri, Christopher P. (CDC/DDID/NCEZID/DHQP) <gmi8@cdc.gov>; Maro, Judy <Judy.Maro@point32health.org>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; rrosofsky@healthinfosys.net; LeBlanc, Jessica <Jessica.Leblanc@point32health.org>
Subject: RE: memo about hearing issues (based on TreeScan data)

Sorry – let me caveat that last email – But still utilizing minimal resources…

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP)
Sent: Friday, September 23, 2022 12:19 PM
To: Yih, Katherine <Katherine_Yih@harvardpilgrim.org>; Jazwa, Amelia (CDC/DDID/NCEZID/DHQP) <wev7@cdc.gov>; Duffy, Jonathan M. (CDC/DDID/NCEZID/DHQP) <lzd5@cdc.gov>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <mmm2@cdc.gov>; Schembri, Christopher P. (CDC/DDID/NCEZID/DHQP) <gmi8@cdc.gov>; Maro, Judy <Judy.Maro@point32health.org>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; rrosofsky@healthinfosys.net; LeBlanc, Jessica <Jessica.Leblanc@point32health.org>
Subject: RE: memo about hearing issues (based on TreeScan data)

I think that is what we should discuss, (b)(6)

(b)(6)

(b)(6)

Eric

From: Yih, Katherine <Katherine_Yih@harvardpilgrim.org>
Sent: Friday, September 23, 2022 11:57 AM
To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>; Yih, Katherine

<Katherine_Yih@harvardpilgrim.org>; Jazwa, Amelia (CDC/DDID/NCEZID/DHQP) <wev7@cdc.gov>; Duffy, Jonathan M. (CDC/DDID/NCEZID/DHQP) <lzd5@cdc.gov>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <mmm2@cdc.gov>; Schembri, Christopher P. (CDC/DDID/NCEZID/DHQP) <gmi8@cdc.gov>; Maro, Judy <Judy.Maro@point32health.org>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; rrosofsky@healthinfosys.net; LeBlanc, Jessica <Jessica.Leblanc@point32health.org>
Subject: RE: memo about hearing issues (based on TreeScan data)

(b)(5)

(b)(5) (Judy, please correct me if I'm wrong.)

(b)(5)

Katherine

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>
Sent: Friday, September 23, 2022 11:47 AM
To: Yih, Katherine <Katherine_Yih@harvardpilgrim.org>; Jazwa, Amelia (CDC/DDID/NCEZID/DHQP) <wev7@cdc.gov>; Duffy, Jonathan M. (CDC/DDID/NCEZID/DHQP) <lzd5@cdc.gov>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <mmm2@cdc.gov>; Schembri, Christopher P. (CDC/DDID/NCEZID/DHQP) <gmi8@cdc.gov>; Maro, Judy <Judy.Maro@point32health.org>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; rrosofsky@healthinfosys.net; LeBlanc, Jessica <Jessica.Leblanc@point32health.org>
Subject: RE: memo about hearing issues (based on TreeScan data)

How far out did you happen to collect? And correct me if I'm wrong, (b)(5)

(b)(5)

(b)(5)

From: Yih, Katherine <Katherine_Yih@harvardpilgrim.org>
Sent: Friday, September 23, 2022 11:26 AM
To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>; Yih, Katherine <katherine_yih@harvardpilgrim.org>; Jazwa, Amelia (CDC/DDID/NCEZID/DHQP) <wev7@cdc.gov>; Duffy, Jonathan M. (CDC/DDID/NCEZID/DHQP) <lzd5@cdc.gov>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <mmm2@cdc.gov>; Schembri, Christopher P. (CDC/DDID/NCEZID/DHQP)

<gmi8@cdc.gov>; Maro, Judy <Judy.Maro@point32health.org>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; rrosofsky@healthinfosys.net; LeBlanc, Jessica <Jessica.Leblanc@point32health.org>
Subject: RE: memo about hearing issues (based on TreeScan data)

OK, we'll get all our tinnitus information organized in time for the Oct. 7 call. We collected tinnitus using longer follow-up periods in our last data extraction (after producing the memo), so we'll include that.

Sure, come on up for a site visit plus a Red Sox (or Celtics?) game!

Katherine

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>
Sent: Friday, September 23, 2022 9:58 AM
To: Yih, Katherine <katherine_yih@harvardpilgrim.org>; Jazwa, Amelia (CDC/DDID/NCEZID/DHQP) <wev7@cdc.gov>; Duffy, Jonathan M. (CDC/DDID/NCEZID/DHQP) <lzd5@cdc.gov>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <mmm2@cdc.gov>; Schembri, Christopher P. (CDC/DDID/NCEZID/DHQP) <gmi8@cdc.gov>; Maro, Judy <Judy.Maro@point32health.org>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; rrosofsky@healthinfosys.net; LeBlanc, Jessica <Jessica.Leblanc@point32health.org>
Subject: RE: memo about hearing issues (based on TreeScan data)

Lets revisit the tinnitus memo on our next call…. Tom's been receiving "question" from reporters, and maybe a short/brief letter from VSD can offer some scientific insight. Obviously with some limitations etc. – we can discuss in greater detail.

(b)(5)

(b)(5)

(b)(5)

Oh and congrats on becoming an infrastructure site!! It's good to have yall back! *I think we are ready for a site visit to Boston, especially when the Sox are playing…….*

Eric

From: Yih, Katherine <katherine_yih@harvardpilgrim.org>
Sent: Friday, May 6, 2022 3:06 PM

To: Jazwa, Amelia (CDC/DDID/NCEZID/DHQP) <wev7@cdc.gov>; Duffy, Jonathan M. (CDC/DDID/NCEZID/DHQP) <lzd5@cdc.gov>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <mmm2@cdc.gov>; Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>; Schembri, Christopher P. (CDC/DDID/NCEZID/DHQP) <gmi8@cdc.gov>; Maro, Judy <Judy.Maro@point32health.org>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; rrosofsky@healthinfosys.net; LeBlanc, Jessica <Jessica.Leblanc@point32health.org>
Subject: RE: memo about hearing issues (based on TreeScan data)

Sorry, please use this one (with "a" at end of filename) instead.
Katherine

From: Yih, Katherine
Sent: Friday, May 6, 2022 2:59 PM
To: Jazwa, Amelia (CDC/DDID/NCEZID/DHQP) <wev7@cdc.gov>; Duffy, Jonathan M. (CDC/DDID/NCEZID/DHQP) <lzd5@cdc.gov>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <mmm2@cdc.gov>; Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>; Schembri, Christopher P. (CDC/DDID/NCEZID/DHQP) <gmi8@cdc.gov>; Maro, Judy <Judy.Maro@point32health.org>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; rrosofsky@healthinfosys.net; LeBlanc, Jessica <Jessica.Leblanc@point32health.org>
Subject: RE: memo about hearing issues (based on TreeScan data)

Dear all,

Regarding the memo on hearing outcomes, I revised the table along the lines suggested in today's meeting and made a few edits to the text. The new version is attached with today's date in the filename.

Looking forward to more discussion,
Katherine

From: Yih, Katherine
Sent: Thursday, May 5, 2022 1:24 PM
To: Jazwa, Amelia (CDC/DDID/NCEZID/DHQP) <wev7@cdc.gov>; Duffy, Jonathan M. (CDC/DDID/NCEZID/DHQP) <lzd5@cdc.gov>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <mmm2@cdc.gov>; Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>; Schembri, Christopher P. (CDC/DDID/NCEZID/DHQP) <gmi8@cdc.gov>; Maro, Judy <Judy.Maro@point32health.org>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; rrosofsky@healthinfosys.net; LeBlanc, Jessica <Jessica.Leblanc@point32health.org>
Subject: memo about hearing issues (based on TreeScan data)

Hi all,

In case you haven't noticed the documents attached to the calendar invite for tomorrow, I'm sending the memo Judy and I wrote on hearing issues after COVID-19 vaccination, based on our TreeScan data. It's on the agenda to discuss tomorrow.

'Til then,

Katherine

SMR3.HarvardPilgrim.org made the following annotations

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copying or disclosing it.

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP)
Sent: Fri, 23 Sep 2022 13:57:35 +0000
To: Yih, Katherine; Jazwa, Amelia (CDC/DDID/NCEZID/DHQP); Duffy, Jonathan M. (CDC/DDID/NCEZID/DHQP); McNeil, Michael (CDC/DDID/NCEZID/DHQP); Schembri, Christopher P. (CDC/DDID/NCEZID/DHQP); Maro, Judy; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); rrosofsky@healthinfosys.net; LeBlanc, Jessica
Subject: RE: memo about hearing issues (based on TreeScan data)
Attachments: memo on hearing outcomes 2022-05-06a.docx

Lets revisit the tinnitus memo on our next call…. Tom's been receiving "question" from reporters, and maybe a short/brief letter from VSD can offer some scientific insight. Obviously with some limitations etc. – we can discuss in greater detail, (b)(5)

(b)(5)

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Sent: Friday, May 6, 2022 3:06 PM
To: Jazwa, Amelia (CDC/DDID/NCEZID/DHQP) <wev7@cdc.gov>; Duffy, Jonathan M. (CDC/DDID/NCEZID/DHQP) <lzd5@cdc.gov>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <mmm2@cdc.gov>; Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>; Schembri, Christopher P. (CDC/DDID/NCEZID/DHQP) <gmi8@cdc.gov>; Maro, Judy <Judy.Maro@point32health.org>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; rrosofsky@healthinfosys.net; LeBlanc, Jessica <Jessica.Leblanc@point32health.org>
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Sent: Friday, May 6, 2022 2:59 PM
To: Jazwa, Amelia (CDC/DDID/NCEZID/DHQP) <wev7@cdc.gov>; Duffy, Jonathan M. (CDC/DDID/NCEZID/DHQP) <lzd5@cdc.gov>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <mmm2@cdc.gov>; Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>; Schembri, Christopher P. (CDC/DDID/NCEZID/DHQP) <gmi8@cdc.gov>; Maro, Judy <Judy.Maro@point32health.org>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>;

rrosofsky@healthinfosys.net; LeBlanc, Jessica <Jessica.Leblanc@point32health.org>
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Katherine

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To: Jazwa, Amelia (CDC/DDID/NCEZID/DHQP) <wev7@cdc.gov>; Duffy, Jonathan M. (CDC/DDID/NCEZID/DHQP) <lzd5@cdc.gov>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <mmm2@cdc.gov>; Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>; Schembri, Christopher P. (CDC/DDID/NCEZID/DHQP) <gmi8@cdc.gov>; Maro, Judy <Judy.Maro@point32health.org>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; rrosofsky@healthinfosys.net; LeBlanc, Jessica <Jessica.Leblanc@point32health.org>
Subject: memo about hearing issues (based on TreeScan data)

Hi all,

In case you haven't noticed the documents attached to the calendar invite for tomorrow, I'm sending the memo Judy and I wrote on hearing issues after COVID-19 vaccination, based on our TreeScan data. It's on the agenda to discuss tomorrow.

'Til then,
Katherine

From: Sharan, Martha (CDC/DDID/NCEZID/DHQP)
Sent: Wed, 31 Aug 2022 12:22:56 +0000
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Subject: RE: National Geographic interview request - AEs from COVID vaccines

Sounds good! Talk to you later.

Martha Sharan
Public Affairs
CDC/Division of Healthcare Quality Promotion
Off.: 404-639-2683
Cell: 404-998-1787

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Sent: Wednesday, August 31, 2022 8:09 AM
To: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Subject: FW: National Geographic interview request - AEs from COVID vaccines

I'm (b)(6). I'll call you about this when I get back. My understanding is that this activity has been initiated b/c there are patient interest groups out there pushing for studies, so it's a bit tricky.

From: Tara Haelle <(b)(6)
Sent: Wednesday, August 31, 2022 6:32 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Subject: National Geographic interview request - AEs from COVID vaccines

Hello Dr. Shimabukuro,
I'm not sure if you remember me, but I believe we met while I was on a CDC fellowship for AHCJ a number of years ago. I've been writing about vaccines for more than a decade, and I'm now writing an article for National Geographic about whether there is adequate evidence to determine whether tinnitus could be a potential adverse event linked to any of the COVID-19 vaccines.

I spoke with Patsy Stinchfield, and she mentioned you would be a good source on this since I have questions about the CDC's process in going through VAERS reports and determining what to further investigate using VSD or other epi studies.

Would you have time for an interview this week or next to discuss this topic for my article?

Thank you,
Tara Haelle

P.S. I realize discussing vaccine AEs with a reporter can be a precarious decision, so please feel free to contact others who might vouch for my credibility and reliance on the evidence, such as Dan Salmon, Paul Offit, Patsy Stinchfield, Walter Orenstein, Bruce Gellin, or Saad Omer, all of whom are familiar with me and my work.

These are incredibly tough, strange times. Feeling awful and frustrated you can't "snap out of it?" Read this. If you're thinking of hurting yourself, please call the Suicide Hotline at 1-800-273-8255 or text 741741. You matter.

Tara Haelle • @tarahaelle
Pronouns: She/Her • 817.458.8133 CST (no PR calls please)
tarahaelle.net
Journalist, author, public speaker & AHCJ Medical Studies Core Topic Leader
Books: Vaccination Investigation, The Informed Parent, various children's titles

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP)
Sent: Wed, 21 Dec 2022 16:54:45 +0000
To: Yih, Katherine; Jazwa, Amelia (CDC/DDID/NCEZID/DHQP); Duffy, Jonathan M. (CDC/DDID/NCEZID/DHQP); McNeil, Michael (CDC/DDID/NCEZID/DHQP); Schembri, Christopher P. (CDC/DDID/NCEZID/DHQP); Maro, Judy; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); rrosofsky@healthinfosys.net; LeBlanc, Jessica
Subject: RE: outline of tinnitus exploration

Yea, I'd agree with this approach and Jonathan can weight in when (b)(6) Trying to

(b)(5)

We participated on a call with INSIS Network (https://insisvaccine.org/) on Monday and they had an expert present on tinnitus and sudden hearing loss.
Here were my 3 questions I asked that didn't get answered, but hopefully we can reach out to the expert from the VaST group after the new year to get his opinion.
For Tinnitus:

- Biologic risk window
- Automated case definition and onset of tinnitus or sudden/sensorial hearing loss and the timing for first medical appointment.
- Confounding of disease and vaccination. (asymptomatic disease?) – both experts have discussed association with disease. (one would expect if association with disease, any time XXX days after vaccination once a person as protection against disease, we would see a protective effect –
- (not asked) – should you look at both tinnitus and sudden/sensorial hearing loss?

I think most literature besides the Isreal study do not suggest an association with Sudden Hearing loss as even stated by the expert on the INSIS call from Stanford (https://med.stanford.edu/profiles/konstantina-stankovic)
But here are 3 articles on Sudden hearing loss, one is from a 3rd party and VAERS. The most recent one is from finland, which did not find an association and resharing isreal study.

Isreal - https://jamanetwork.com/journals/jamaotolaryngology/fullarticle/2789497?guestAccessKey=0590592c-736d-4007-9e64-2d34aca81f78&utm_source=silverchair&utm_campaign=altmetric&utm_content=2022_year-end&cmp=1&utm_medium=email
VAERS non CDC led - https://jamanetwork.com/journals/jamaotolaryngology/fullarticle/2789496?guestAccessKey=a21db9a7-c224-43e5-9067-88641b64118a&utm_source=silverchair&utm_campaign=altmetric&utm_content=2022_year-end&cmp=1&utm_medium=email
Finland - https://jamanetwork.com/journals/jamaotolaryngology/fullarticle/2799360

From: Yih, Katherine <Katherine_Yih@harvardpilgrim.org>
Sent: Monday, December 19, 2022 9:57 AM
To: Jazwa, Amelia (CDC/DDID/NCEZID/DHQP) <wev7@cdc.gov>; Duffy, Jonathan M. (CDC/DDID/NCEZID/DHQP) <lzd5@cdc.gov>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <mmm2@cdc.gov>; Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>; Schembri, Christopher P. (CDC/DDID/NCEZID/DHQP) <gmi8@cdc.gov>; Maro, Judy <Judy.Maro@point32health.org>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; rrosofsky@healthinfosys.net; LeBlanc, Jessica <Jessica.Leblanc@point32health.org>
Subject: outline of tinnitus exploration

Hi all,

At Jonathan's request, we developed an outline for a possible report on COVID vaccination and tinnitus, attached. (b)(5)

(b)(5)

I see that Jonathar (b)(6) , but we'd be interested in your comments at any point.

Thank you and best wishes,

Katherine

From: Yih, Katherine
Sent: Wed, 21 Dec 2022 19:20:46 +0000
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Weintraub, Eric (CDC/DDID/NCEZID/DHQP); Yih, Katherine; Jazwa, Amelia (CDC/DDID/NCEZID/DHQP); Duffy, Jonathan M. (CDC/DDID/NCEZID/DHQP); McNeil, Michael (CDC/DDID/NCEZID/DHQP); Schembri, Christopher P. (CDC/DDID/NCEZID/DHQP); Maro, Judy; rrosofsky@healthinfosys.net; LeBlanc, Jessica
Subject: RE: outline of tinnitus exploration

Hi Tom and Eric,

(b)(5)

Eric, thanks for the all the additional information about tinnitus and hearing loss.

Katherine

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Sent: Wednesday, December 21, 2022 1:08 PM
To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>; Yih, Katherine <Katherine_Yih@harvardpilgrim.org>; Jazwa, Amelia (CDC/DDID/NCEZID/DHQP) <wev7@cdc.gov>; Duffy, Jonathan M. (CDC/DDID/NCEZID/DHQP) <lzd5@cdc.gov>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <mmm2@cdc.gov>; Schembri, Christopher P. (CDC/DDID/NCEZID/DHQP) <gmi8@cdc.gov>; Maro, Judy <Judy.Maro@point32health.org>; rrosofsky@healthinfosys.net; LeBlanc, Jessica <Jessica.Leblanc@point32health.org>
Subject: RE: outline of tinnitus exploration

Agree with Eric. (b)(5)
(b)(5)
(b)(5) Anyway, I think the plan looks good. Thanks.

Tom

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>
Sent: Wednesday, December 21, 2022 11:55 AM
To: Yih, Katherine <Katherine_Yih@harvardpilgrim.org>; Jazwa, Amelia (CDC/DDID/NCEZID/DHQP) <wev7@cdc.gov>; Duffy, Jonathan M. (CDC/DDID/NCEZID/DHQP) <lzd5@cdc.gov>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <mmm2@cdc.gov>; Schembri, Christopher P. (CDC/DDID/NCEZID/DHQP) <gmi8@cdc.gov>; Maro, Judy <Judy.Maro@point32health.org>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; rrosofsky@healthinfosys.net; LeBlanc, Jessica <Jessica.Leblanc@point32health.org>
Subject: RE: outline of tinnitus exploration

Yea, I'd agree with this approach and Jonathan can weight in when (b)(6) (b)(5)

(b)(5)

We participated on a call with INSIS Network (https://insisvaccine.org/ [insisvaccine.org]) on Monday and they had an expert present on tinnitus and sudden hearing loss.
Here were my 3 questions I asked that didn't get answered, but hopefully we can reach out to the expert from the VaST group after the new year to get his opinion.
For Tinnitus:

- Biologic risk window
- Automated case definition and onset of tinnitus or sudden/sensorial hearing loss and the timing for first medical appointment.
- Confounding of disease and vaccination. (asymptomatic disease?) – both experts have discussed association with disease. (one would expect if association with disease, any time XXX days after vaccination once a person as protection against disease, we would see a protective effect –
- (not asked) – should you look at both tinnitus and sudden/sensorial hearing loss?

I think most literature besides the Isreal study do not suggest an association with Sudden Hearing loss as even stated by the expert on the INSIS call from Stanford (https://med.stanford.edu/profiles/konstantina-stankovic [med.stanford.edu])
But here are 3 articles on Sudden hearing loss, one is from a 3rd party and VAERS. The most recent one is from finland, which did not find an association and resharing isreal study.

Isreal -
https://jamanetwork.com/journals/jamaotolaryngology/fullarticle/2789497?guestAccessKey=0590592c-736d-4007-9e64-2d34aca81f78&utm_source=silverchair&utm_campaign=altmetric&utm_content=2022_year-end&cmp=1&utm_medium=email [jamanetwork.com]
VAERS non CDC led -
https://jamanetwork.com/journals/jamaotolaryngology/fullarticle/2789496?guestAccessKey=a21db9a7-c224-43e5-9067-

88641b64118a&utm_source=silverchair&utm_campaign=altmetric&utm_content=2022_year-end&cmp=1&utm_medium=email [jamanetwork.com]
Finland - https://jamanetwork.com/journals/jamaotolaryngology/fullarticle/2799360 [jamanetwork.com]

From: Yih, Katherine <Katherine_Yih@harvardpilgrim.org>
Sent: Monday, December 19, 2022 9:57 AM
To: Jazwa, Amelia (CDC/DDID/NCEZID/DHQP) <wev7@cdc.gov>; Duffy, Jonathan M. (CDC/DDID/NCEZID/DHQP) <lzd5@cdc.gov>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <mmm2@cdc.gov>; Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>; Schembri, Christopher P. (CDC/DDID/NCEZID/DHQP) <gmi8@cdc.gov>; Maro, Judy <Judy.Maro@point32health.org>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; rrosofsky@healthinfosys.net; LeBlanc, Jessica <Jessica.Leblanc@point32health.org>
Subject: outline of tinnitus exploration

Hi all,

At Jonathan's request, we developed an outline for a possible report on COVID vaccination and tinnitus, attached. (b)(5)

(b)(5)

I see that Jonathan is (b)(6), but we'd be interested in your comments at any point.

Thank you and best wishes,

Katherine

SMR3.HarvardPilgrim.org made the following annotations

Confidential, Proprietary, Exempt or Privileged: This email message with any attachments contains information intended for the exclusive use of the individual or entity to whom it is addressed and may contain information that is considered privileged, proprietary, confidential and/or exempt from disclosure under applicable law. If you are not the intended recipient, you are hereby notified that any review, disclosure, reproduction, distribution or other use of this communication is strictly prohibited. If you received this email in error, please notify the sender by reply or telephone and delete the message, including any attachments, without saving, copying or disclosing it.

Sent: Thu, 9 Feb 2023 20:59:17 +0000
To: Sharan, Martha (CDC/DDID/NCEZID/DHQP)
Subject: RE: PLEASE REVIEW CDC Response - Tinnitus Follow-up/AEs from COVID vaccines

I think we can say: (b)(5)

(b)(5)

Tom Shimabukuro, MD, MPH, MBA
Captain, U.S. Public Health Service
Director
Immunization Safety Office
Centers for Disease Control and Prevention (CDC)
1600 Clifton Road, MS H16-3, Atlanta, GA 30329

Phone: 404-498-0679, Fax: 404-498-0666
Email: TShimabukuro@cdc.gov

From: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Sent: Thursday, February 9, 2023 3:33 PM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Subject: PLEASE REVIEW CDC Response - Tinnitus Follow-up/AEs from COVID vaccines

Hi Tom: I have a reporter who continues to follow-up on tinnitus.

On 11/10/22 I sent her this email:

> At this time, vaccine safety monitoring efforts in CDC have identified no evidence of a causal association between COVID-19 vaccination and tinnitus or other hearing loss.
> The VSD analysis is in progress but the Immunization Safety Office can't discuss preliminary findings.
> No target date for completion has been given.
> Thanks,
> Martha

On 1/8/23 I updated her with the Dorney et al study and let her know that CDC doesn't have enough evidence to justify an epidemiologic study on tinnitus in VSD.

Current inquiry:

> It sounds like that analysis was stopped at some point between November, when we last corresponded about it, and now. Can you tell me when it was decided that the CDC doesn't have enough evidence to justify the VSD analysis and what happened to the one that was started in the fall? If you can give me a call at 817-675-2568, I would greatly appreciate it.
>
> Thank you,
> Tara Haelle

(b)(5)

Thanks,
Martha

Martha Sharan
Public Affairs
CDC/Division of Healthcare Quality Promotion
Off.: 404-639-2683
Cell: 404-998-1787

From: Sharan, Martha (CDC/DDID/NCEZID/DHQP)
Sent: Thu, 9 Feb 2023 21:15:59 +0000
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Subject: RE: PLEASE REVIEW CDC Response - Tinnitus Follow-up/AEs from COVID vaccines

Thank you…. I'll leave it at that!

Martha Sharan
Public Affairs
CDC/Division of Healthcare Quality Promotion
Off.: 404-639-2683
Cell: 404-998-1787

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Sent: Thursday, February 9, 2023 4:06 PM
To: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Subject: RE: PLEASE REVIEW CDC Response - Tinnitus Follow-up/AEs from COVID vaccines

I think we can say: (b)(5)

(b)(5)

From: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Sent: Thursday, February 9, 2023 3:33 PM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Subject: PLEASE REVIEW CDC Response - Tinnitus Follow-up/AEs from COVID vaccines

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Thank you,
Tara Haelle

(b)(5)

Thanks,
Martha

Martha Sharan
Public Affairs
CDC/Division of Healthcare Quality Promotion
Off.: 404-639-2683
Cell: 404-998-1787

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Sent: Thu, 9 Feb 2023 18:18:15 +0000
To: Ian Dorney
Subject: RE: Tinnitus - Extra Data

Dear Ian,

Thanks. If you and your co-investigators think this is a sound analysis, (b)(5)

(b)(5)

Regards,

Tom

From: Ian Dorney <ixd84@case.edu>
Sent: Thursday, February 9, 2023 12:34 PM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Subject: Tinnitus - Extra Data

Dr. Shimabukuro,

Here are the results of the additional protocols with an extended timeframe after vaccination - I performed a 6-week and 3-month post-vaccination window in two separate searches. The risk for newly diagnosed tinnitus remained higher after the flu shot than after the mRNA COVID-19 shot in the 6-week period, and leveled out to even risk in the 3-month period. These results are consistent with what was reported in my manuscript and are about what I was expecting - (b)(5)

(b)(5)

Let me know what you think of this and what else I can do to help.

Thanks,
Ian

--

Ian Dorney
CWRU School of Medicine | Class of 2024

From: Sharan, Martha (CDC/DDID/NCEZID/DHQP)
Sent: Mon, 3 Oct 2022 16:34:10 +0000
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Subject: Re: TWO MEDIA INQUIRIES - CDC Response - National Geographic interview request - AEs from COVID vaccines

5pm interview with BIO is good to go for today. Will send invite shortly.

Get Outlook for iOS
From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Sent: Monday, October 3, 2022 8:38:03 AM
To: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Subject: RE: TWO MEDIA INQUIRIES - CDC Response - National Geographic interview request - AEs from COVID vaccines

Hi Martha,

I'm spending much of today tying up loose ends and mopping up in preparation for starting this new assignment tomorrow. I could talk to the Bio reported at 5pm today. Re: this Nat Geo story, I have no idea what my schedule is going to be like with (b)(6) (b)(5)

(b)(5)

Tom

From: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Sent: Monday, October 3, 2022 8:26 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Subject: TWO MEDIA INQUIRIES - CDC Response - National Geographic interview request - AEs from COVID vaccines

Hi Tom:
I have two requests… this is the first one with the reporter from National Geographic. She sent follow-up questions (see below) but would prefer a short phone interview. I have indicated that we don't have much more to offer on tinnitus and that as a general rule, we don't comment on studies/findings that did not involve CDC experts or were conducted outside of the agency.

The second, is the interview with BIO about the aluminum paper. I finally received a response from the organization's reporter, Clary Estres. She has time today after 3:00 p.m. ET, all day tomorrow and Wednesday before 5:00 p.m.

I know you'll be moving into your role (b)(6), so do you want me to schedule these for today or push them to times later in the week.

Let me know,
Martha

From: Tara Haell[redacted] (b)(6)
Sent: Friday, September 30, 2022 6:22 AM
To: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Subject: Re: CDC Response - National Geographic interview request - AEs from COVID vaccines

Martha,
Thank you very much for sending these along. In reading the responses, I notice that several of the responses explain things I'm already aware of, such as the difference between incidence and prevalence; the difference between VAERS and VSD; and the substantial limitations of a passive monitoring system like VAERS. (I've reported on vaccine safety for over a decade, so I'm very familiar with all these issues and the CDC's mechanisms.)

I'm not sure if my questions weren't worded well or there was a misunderstanding otherwise, but I have follow-up questions to try to get better clarification on what I was asking. Would it be possible to set up a brief phone call with Dr. Shimabukuro to discuss this issue? It doesn't seem as though email questions are adequate for the level of specificity and nuance I'm seeking for this story. I'm a little different than most reporters in writing about vaccine adverse events because I've reported on them for so long, and I'm very familiar with all the tropes and misconceptions promoted by those who are anti-vaccine or who otherwise are unfamiliar with the specifics of CDC vaccine safety surveillance and research.

Thank you,
Tara Haelle

Tara Haelle • @tarahaelle
Pronouns: She/Her • 817.458.8133 CST (no PR calls please)
tarahaelle.net
Journalist, author, public speaker & AHCJ Medical Studies Core Topic Leader
Books: Vaccination Investigation, The Informed Parent, various children's titles

On Thu, Sep 29, 2022 at 7:07 AM Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov> wrote:
Hi Tara:
Yes, I have responses from Dr. Shimabukuro, Director, CDC's Immunization Safety Office. I will pass along your additional questions.

Please see below:

A recent paper by Harpaz et al (doi: 10.1007/s40264-022-01186-z) suggests a strong association exists in VAERS reports for tinnitus and each of the three COVID-19 vaccines initially authorized by the FDA, but that the association is masked because of the high number of overall reports. Is this something that the CDC safety researchers have considered and/or that they are looking into?

CDC did not participate in this analysis and recommends that you contact the authors if you have questions about their analysis.

One of the challenges of considering tinnitus as a presumptive AE is that it is so common as a background condition in the general population. Does a condition's prevalence in the general population affect how CDC safety researchers consider potential associations from AEs reported in VAERS? Would shortening the time after vaccination that they looked for an association be likely to change any likelihood of finding an association?

Per CDC (Principles of Epidemiology | Lesson 3 - Section 2 (cdc.gov)), "Prevalence refers to proportion of persons who have a condition at or during a particular time period, whereas incidence refers to the proportion or rate of persons who develop a condition during a particular time period. So prevalence and incidence are similar, but prevalence includes new and pre-existing cases whereas incidence includes new cases only." For vaccine safety monitoring, we are most concerned with incident cases, or new cases occurring following vaccination. Expected incidence (background incidence) is taken into consideration when conducting vaccine safety evaluations.

A vaccine adverse event is an adverse health event or other outcome or event (e.g., a medical error) occurring in temporal association with a vaccination. CDC monitors all VAERS data and can take into consideration incident versus prevalent conditions when information is available in the report, as well as biologically plausible risk intervals for symptom onset of the adverse event following vaccination. VAERS is a spontaneous reporting (passive surveillance) system that accepts all reports regardless of the plausibility of the vaccine causing the event or the clinical seriousness of the event. VAERS is a signal detection (hypothesis generating) system and is not designed to determine causality.

Many of the individuals I have spoken to have said that they either did not file a VAERS report because they were told it was pointless, or they asked their doctor to file one and the doctor refused or referred them to a different doctor to report it (who then refused or referred them back to the original doctor). I heard this frequently enough to wonder whether tinnitus was underreported in VAERS. How likely might it be that tinnitus is similarly underreported in the healthcare systems involved in VSD? Is there a way to take this into account in analyses of a potential association?

The Vaccine Safety Datalink (VSD) is an electronic health record (EHR)-based system that collects data (in the EHR) on patients with health insurance when they receive healthcare. This is one of the main differences between passive surveillance in VAERS and active surveillance in VSD; VAERS depends upon people filing reports, while in VSD, a diagnosis of tinnitus would be recorded in the EHR during a patient visit as part of standard healthcare practice.VSD data are not impacted by the types of reporting biases inherent to VAERS.

Is there any possibility that the CDC will initiate another study in the future, using VSD again or another data set, to investigate tinnitus as a potential AE correlated with any of the COVID-19 vaccines? Or is the matter considered settled? Why or why not?

CDC will continue to monitor COVID-19 vaccine safety in VAERS, VSD, and other systems. If we observe data that indicates a potential safety problem we will further investigate. Additional assessments of safety signals may include epidemiologic studies if appropriate.

It seems statistically possible that a condition that has a naturally high prevalence in the general population (as tinnitus does) but is very rare as a vaccine adverse event could easily be missed as a true signal by traditional VSD analysis methods. How, if at all, have CDC safety researchers accounted for this possibility. (I'd wager that tinnitus is likely the most common condition that's ever been considered as a serious AE, which would make it fairly unique among presumptive AEs.)

Please refer to our original response and the above response to your question on common conditions. Other relatively common conditions have been evaluated in vaccine safety research, such as febrile seizure and shoulder injury. While tinnitus prevalence in the general population is relatively high, the incidence of new onset tinnitus is a different concept.

VSD uses TreeScan data mining methods, which can detect pattens of clustering of diagnoses in a post-vaccination observation period, even if few diagnoses are made (because the diagnosis is rare). To date, VSD TreeScan data mining has not observed clustering of tinnitus in a post-vaccination observation period.

Thanks,
Martha

From: Tara Haelle (b)(6)
Sent: Thursday, September 29, 2022 5:31 AM
To: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Subject: Re: FW: National Geographic interview request - AEs from COVID vaccines

Hi Martha,
I wanted to check in on the status of the questions I sent, and I had some additional questions that arose in the process of my reporting on this story. Those additional questions are below. I certainly realize this will extend the time Dr. Shimabukuro needs to respond to my questions.

6) The WHO identified tinnitus as having a signal with the adenovirus vector vaccines (see attached), and the European Medicines Agency listed tinnitus as a possible side effect from the adenovirus vector vaccine, but the CDC has not. Can you comment on why the CDC has not followed the WHO's and EMA's lead on this and why an association would be seen with adenovirus vector vaccines?

7) When the CDC did their investigation into any associations between tinnitus and vaccination, did that analysis only look at a binary association (tinnitus did/did not occur within 90 days after vaccination), or did the analysis look at temporal patterns within that 90-day period (ie, whether there was a clustering of tinnitus reports within a shorter time period post-vaccination vs tinnitus reporting that was consistently spread out across the 90 days)?

8A) Tinnitus in the general population nearly always follows the same pattern as gradual hearing loss, with an estimated 90% of people who have tinnitus also having hearing loss. When

the CDC did their analysis of tinnitus and COVID-19 vaccines, did that analysis also look at whether the people who reported tinnitus also had concurrent hearing loss?
8B) In the WHO report, only 15% of those who reported tinnitus also had hearing loss, suggesting that their tinnitus was distinct from the "usual" tinnitus that develops in the general population. Another unpublished analysis of data looking at tinnitus and COVID-19 vaccines similarly found that a very low percentage of people who experienced tinnitus after the vaccination also had hearing loss. Can you comment on whether this information might strengthen the potential possibility of an association between tinnitus and COVID-19 vaccines?

Thank you,
Tara

Tara Haelle • @tarahaelle
Pronouns: She/Her • 817.458.8133 CST (no PR calls please)
tarahaelle.net
Journalist, author, public speaker & AHCJ Medical Studies Core Topic Leader
Books: Vaccination Investigation, The Informed Parent, various children's titles

On Thu, Sep 22, 2022 at 2:13 PM Tara Haelle (b)(6) wrote:
Thank you.

These are incredibly tough, strange times. Feeling awful and frustrated you can't "snap out of it?" Read this. If you're thinking of hurting yourself, please call the Suicide Hotline at 1-800-273-8255 or text 741741. You matter.

Tara Haelle • @tarahaelle
Pronouns: She/Her • 817.458.8133 CST (no PR calls please)
tarahaelle.net
Journalist, author, public speaker & AHCJ Medical Studies Core Topic Leader
Books: Vaccination Investigation, The Informed Parent, various children's titles

On Thu, Sep 22, 2022 at 11:56 AM Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov> wrote:
Hi Tara:

Dr. Shimabukuro will look at these, but he will not have time to get back to you until next week.
Thanks for your patience,
Martha

Martha Sharan
Public Affairs
CDC/Division of Healthcare Quality Promotion
Off.: 404-639-2683
Cell: 404-998-1787

From: Tara Haelle (b)(6)
Sent: Thursday, September 22, 2022 2:31 AM
To: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Subject: Re: FW: National Geographic interview request - AEs from COVID vaccines

Martha,
Thank you for this. Is that VSD analysis published somewhere? If so, could you share the citation with me? Meanwhile, I've adjusted some of the questions below, including the order of them.

Thanks,
Tara

—A recent paper by Harpaz et al (doi: 10.1007/s40264-022-01186-z) suggests a strong association exists in VAERS reports for tinnitus and each of the three COVID-19 vaccines initially authorized by the FDA, but that the association is masked because of the high number of overall reports. Is this something that the CDC safety researchers have considered and/or that they are looking into?

—One of the challenges of considering tinnitus as a presumptive AE is that it is so common as a background condition in the general population. Does a condition's prevalence in the general population affect how CDC safety researchers consider potential associations from AEs reported in VAERS? Would shortening the time after vaccination that they looked for an association be likely to change any likelihood of finding an association?

—Many of the individuals I have spoken to have said that they either did not file a VAERS report because they were told it was pointless, or they asked their doctor to file one and the doctor refused or referred them to a different doctor to report it (who then refused or referred them back to the original doctor). I heard this frequently enough to wonder whether tinnitus was underreported in VAERS. How likely might it be that tinnitus is similarly underreported in the healthcare systems involved in VSD? Is there a way to take this into account in analyses of a potential association?

—Is there any possibility that the CDC will initiate another study study in the future, using VSD again or another data set, to investigate tinnitus as a potential AE correlated with any of the COVID-19 vaccines? Or is the matter considered settled? Why or why not?

—It seems statistically possible that a condition that has a naturally high prevalence in the general population (as tinnitus does) but is very rare as a vaccine adverse event could easily be missed as a true signal by traditional VSD analysis methods. How, if at all, have CDC safety researchers accounted for this possibility. (I'd wager that tinnitus is likely the most common condition that's ever been considered as a serious AE, which would make it fairly unique among presumptive AEs.)

– –

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Books: Vaccination Investigation, The Informed Parent, various children's titles

On Wed, Sep 21, 2022 at 2:52 PM Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov> wrote:
Hi Tara:
CDC now has a statement that I am including below – not sure if this will have an impact on your list of questions. Let me know if you need to adjust any of them:

> CDC is aware of reports to the Vaccine Adverse Event Reporting System (VAERS) of tinnitus occurring in temporal association with COVID-19 vaccination (i.e., following vaccination). Tinnitus is a common condition and heterogenous in clinical presentation and course. There are some established risk factors, such as exposure to loud noise; however, in many cases, no discernable cause for tinnitus is identified.
>
> Hundreds of millions of people have received COVID-19 vaccinations under the most intensive monitoring in U.S. history. Because so many people have been vaccinated and because tinnitus is so common in the population, temporally-associated cases are expected, with some expected to occur shortly after vaccination. To further evaluate concerns about reports of tinnitus following COVID-19 vaccination, CDC conducted an analysis in the Vaccine Safety Datalink (VSD). Unlike VAERS, which relies primarily on voluntary reports from healthcare providers, patients, and others, the VSD uses data from electronic health records. Consequently, the VSD data are less likely to be affected by the reporting biases and other biases that impact spontaneous reporting patterns to VAERS and data quality. The VSD looked for clustering of tinnitus diagnoses in COVID-19 vaccinated patients during a post-vaccination observation period out to 70 days after vaccination. In the VSD's patient population of approximately 12 million people with 6.6 million COVID-19 vaccine doses administered, to date no clustering of tinnitus diagnoses has been observed post-vaccination.

Currently, the information from vaccine safety monitoring systems does not suggest a link between COVID-19 vaccination and tinnitus. CDC will continue to monitor the safety of COVID-19 vaccines and continue to evaluate the outcome of tinnitus as additional data are collected.

Thanks,
Martha

Martha Sharan
Public Affairs
CDC/Division of Healthcare Quality Promotion
Off.: 404-639-2683
Cell: 404-998-1787

From: Tara Haelle (b)(6)
Sent: Wednesday, September 21, 2022 3:27 PM
To: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Subject: Re: FW: National Geographic interview request - AEs from COVID vaccines

Hi Martha,
It took me a while to pull these questions together because most of my questions will depend on the answers he gives to the first questions. In other words, I'm almost certainly going to have follow-up questions in response to these because of the nature of the questions. I've tried to include that in these questions, but I wanted to give you a heads up about likely having follow-up questions. If it's at all possible to set up a phone or Zoom interview, that would be far preferable given the challenging nature of discussing adverse effects and vaccines and nuance required in those discussions.

Please let me know when Dr. Shimabukuro will be able to respond to these. If it's possible by the end of this week, that would be particularly helpful.

Thank you,
Tara Haelle

—Has the CDC investigated the potential association between tinnitus and COVID-19 vaccines? If so, can you tell me what the CDC vaccine safety researchers have done and found? Or, if not, can explain the reasoning behind that decision?

—One of the challenges of considering tinnitus as a presumptive AE is that it is so common as a background condition in the general population. Does a condition's prevalence in the general population affect how CDC safety researchers consider potential associations from AEs reported in VAERS?

—Does the CDC have plans to initiate a case control or other epidemiological study, using VSD or another data set, to investigate tinnitus as a potential AE correlated with any of the COVID-19 vaccines? Why or why not?

—A recent paper by Harpaz et al (doi: 10.1007/s40264-022-01186-z) suggests a strong association exists in VAERS reports for tinnitus and each of the three COVID-19 vaccines initially authorized by the FDA, but that the association is masked because of the high number

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– –

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Tara Haelle • @tarahaelle
Pronouns: She/Her • 817.458.8133 CST (no PR calls please)
tarahaelle.net
Journalist, author, public speaker & AHCJ Medical Studies Core Topic Leader
Books: Vaccination Investigation, The Informed Parent, various children's titles

On Thu, Sep 1, 2022 at 7:24 AM Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov> wrote:
Hi Tara:
Your request was forwarded to me. I work closely with Dr. Shimabukuro on media inquiries.
Would it be possible for you to send us a list of questions that you would like him to address. It would be easier for him to respond in writing.

Thanks,
Martha

Martha Sharan
Public Affairs
CDC/Division of Healthcare Quality Promotion
Off.: 404-639-2683
Cell: 404-998-1787

From: Tara Haelle (b)(6)
Sent: Wednesday, August 31, 2022 6:32 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Subject: National Geographic interview request - AEs from COVID vaccines

Hello Dr. Shimabukuro,
I'm not sure if you remember me, but I believe we met while I was on a CDC fellowship for AHCJ a number of years ago. I've been writing about vaccines for more than a decade, and I'm now writing an article for National Geographic about whether there is adequate evidence to determine whether tinnitus could be a potential adverse event linked to any of the COVID-19 vaccines.

I spoke with Patsy Stinchfield, and she mentioned you would be a good source on this since I have questions about the CDC's process in going through VAERS reports and determining what to further investigate using VSD or other epi studies.

Would you have time for an interview this week or next to discuss this topic for my article?

Thank you,
Tara Haelle

P.S. I realize discussing vaccine AEs with a reporter can be a precarious decision, so please feel free to contact others who might vouch for my credibility and reliance on the evidence, such as Dan Salmon, Paul Offit, Patsy Stinchfield, Walter Orenstein, Bruce Gellin, or Saad Omer, all of whom are familiar with me and my work.

– –

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Books: Vaccination Investigation, The Informed Parent, various children's titles

From: Sharan, Martha (CDC/DDID/NCEZID/DHQP)
Sent: Mon, 3 Oct 2022 12:40:47 +0000
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Subject: RE: TWO MEDIA INQUIRIES - CDC Response - National Geographic interview request - AEs from COVID vaccines

Sounds good. I will try to schedule the interview with BIO for today and push the other one based on additional analyses that we are doing.
I'll update your calendar with an invite, once I confirm the time with BIO.
Thank you!

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Sent: Monday, October 3, 2022 8:38 AM
To: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Subject: RE: TWO MEDIA INQUIRIES - CDC Response - National Geographic interview request - AEs from COVID vaccines

Hi Martha,

I'm spending much of today tying up loose ends and mopping up in preparation for starting this new assignment tomorrow. I could talk to the Bio reported at 5pm today. Re: this Nat Geo story, I have no idea what my schedule is going to be like (b)(6) (b)(5)

(b)(5)

Tom

From: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Sent: Monday, October 3, 2022 8:26 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Subject: TWO MEDIA INQUIRIES - CDC Response - National Geographic interview request - AEs from COVID vaccines

Hi Tom:
I have two requests… this is the first one with the reporter from National Geographic. She sent follow-up questions (see below) but would prefer a short phone interview. I have indicated that we don't have much more to offer on tinnitus and that as a general rule, we don't comment on studies/findings that did not involve CDC experts or were conducted outside of the agency.

The second, is the interview with BIO about the aluminum paper. I finally received a response from the organization's reporter, Clary Estres. She has time today after 3:00 p.m. ET, all day tomorrow and Wednesday before 5:00 p.m.

I know you'll be moving into your role leading the VTF for monkeypox tomorrow, so do you want me to schedule these for today or push them to times later in the week.

Let me know,
Martha

From: Tara Haelle [(b)(6)]
Sent: Friday, September 30, 2022 6:22 AM
To: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Subject: Re: CDC Response - National Geographic interview request - AEs from COVID vaccines

Martha,
Thank you very much for sending these along. In reading the responses, I notice that several of the responses explain things I'm already aware of, such as the difference between incidence and prevalence; the difference between VAERS and VSD; and the substantial limitations of a passive monitoring system like VAERS. (I've reported on vaccine safety for over a decade, so I'm very familiar with all these issues and the CDC's mechanisms.)

I'm not sure if my questions weren't worded well or there was a misunderstanding otherwise, but I have follow-up questions to try to get better clarification on what I was asking. Would it be possible to set up a brief phone call with Dr. Shimabukuro to discuss this issue? It doesn't seem as though email questions are adequate for the level of specificity and nuance I'm seeking for this story. I'm a little different than most reporters in writing about vaccine adverse events because I've reported on them for so long, and I'm very familiar with all the tropes and misconceptions promoted by those who are anti-vaccine or who otherwise are unfamiliar with the specifics of CDC vaccine safety surveillance and research.

Thank you,
Tara Haelle

– –

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Books: Vaccination Investigation, The Informed Parent, various children's titles

On Thu, Sep 29, 2022 at 7:07 AM Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov> wrote:
Hi Tara:
Yes, I have responses from Dr. Shimabukuro, Director, CDC's Immunization Safety Office. I will pass along your additional questions.

Please see below:

A recent paper by Harpaz et al (doi: 10.1007/s40264-022-01186-z) suggests a strong association exists in VAERS reports for tinnitus and each of the three COVID-19 vaccines initially authorized by the FDA, but that the association is masked because of the high number of overall reports. Is this something that the CDC safety researchers have considered and/or that they are looking into?

CDC did not participate in this analysis and recommends that you contact the authors if you have questions about their analysis.

One of the challenges of considering tinnitus as a presumptive AE is that it is so common as a background condition in the general population. Does a condition's prevalence in the general population affect how CDC safety researchers consider potential associations from AEs reported in VAERS? Would shortening the time after vaccination that they looked for an association be likely to change any likelihood of finding an association?

Per CDC (Principles of Epidemiology | Lesson 3 - Section 2 (cdc.gov)), "Prevalence refers to proportion of persons who have a condition at or during a particular time period, whereas incidence refers to the proportion or rate of persons who develop a condition during a particular time period. So prevalence and incidence are similar, but prevalence includes new and pre-existing cases whereas incidence includes new cases only." For vaccine safety monitoring, we are most concerned with incident cases, or new cases occurring following vaccination. Expected incidence (background incidence) is taken into consideration when conducting vaccine safety evaluations.

A vaccine adverse event is an adverse health event or other outcome or event (e.g., a medical error) occurring in temporal association with a vaccination. CDC monitors all VAERS data and can take into consideration incident versus prevalent conditions when information is available in the report, as well as biologically plausible risk intervals for symptom onset of the adverse event following vaccination. VAERS is a spontaneous reporting (passive surveillance) system that accepts all reports regardless of the plausibility of the vaccine causing the event or the clinical seriousness of the event. VAERS is a signal detection (hypothesis generating) system and is not designed to determine causality.

Many of the individuals I have spoken to have said that they either did not file a VAERS report because they were told it was pointless, or they asked their doctor to file one and the doctor refused or referred them to a different doctor to report it (who then refused or referred them back to the original doctor). I heard this frequently enough to wonder whether tinnitus was underreported in VAERS. How likely might it be that tinnitus is similarly underreported in the healthcare systems involved in VSD? Is there a way to take this into account in analyses of a potential association?

The Vaccine Safety Datalink (VSD) is an electronic health record (EHR)-based system that collects data (in the EHR) on patients with health insurance when they receive healthcare. This is one of the main differences between passive surveillance in VAERS and active surveillance in VSD; VAERS depends upon people filing reports, while in VSD, a diagnosis of tinnitus would be recorded in the EHR during a patient visit as part of standard healthcare practice.VSD data are not impacted by the types of reporting biases inherent to VAERS.

Is there any possibility that the CDC will initiate another study in the future, using VSD again or another data set, to investigate tinnitus as a potential AE correlated with any of the COVID-19 vaccines? Or is the matter considered settled? Why or why not?

CDC will continue to monitor COVID-19 vaccine safety in VAERS, VSD, and other systems. If we observe data that indicates a potential safety problem we will further investigate. Additional assessments of safety signals may include epidemiologic studies if appropriate.

It seems statistically possible that a condition that has a naturally high prevalence in the general population (as tinnitus does) but is very rare as a vaccine adverse event could easily be missed as a true signal by traditional VSD analysis methods. How, if at all, have CDC safety researchers accounted for this possibility. (I'd wager that tinnitus is likely the most common condition that's ever been considered as a serious AE, which would make it fairly unique among presumptive AEs.)

Please refer to our original response and the above response to your question on common conditions. Other relatively common conditions have been evaluated in vaccine safety research, such as febrile seizure and shoulder injury. While tinnitus prevalence in the general population is relatively high, the incidence of new onset tinnitus is a different concept.

VSD uses TreeScan data mining methods, which can detect pattens of clustering of diagnoses in a post-vaccination observation period, even if few diagnoses are made (because the diagnosis is rare). To date, VSD TreeScan data mining has not observed clustering of tinnitus in a post-vaccination observation period.

Thanks,
Martha

From: Tara Haelle (b)(6)
Sent: Thursday, September 29, 2022 5:31 AM
To: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Subject: Re: FW: National Geographic interview request - AEs from COVID vaccines

Hi Martha,
I wanted to check in on the status of the questions I sent, and I had some additional questions that arose in the process of my reporting on this story. Those additional questions are below. I certainly realize this will extend the time Dr. Shimabukuro needs to respond to my questions.

6) The WHO identified tinnitus as having a signal with the adenovirus vector vaccines (see attached), and the European Medicines Agency listed tinnitus as a possible side effect from the adenovirus vector vaccine, but the CDC has not. Can you comment on why the CDC has not followed the WHO's and EMA's lead on this and why an association would be seen with adenovirus vector vaccines?

7) When the CDC did their investigation into any associations between tinnitus and vaccination, did that analysis only look at a binary association (tinnitus did/did not occur within 90 days after vaccination), or did the analysis look at temporal patterns within that 90-day period (ie,

whether there was a clustering of tinnitus reports within a shorter time period post-vaccination vs tinnitus reporting that was consistently spread out across the 90 days)?

8A) Tinnitus in the general population nearly always follows the same pattern as gradual hearing loss, with an estimated 90% of people who have tinnitus also having hearing loss. When the CDC did their analysis of tinnitus and COVID-19 vaccines, did that analysis also look at whether the people who reported tinnitus also had concurrent hearing loss?
8B) In the WHO report, only 15% of those who reported tinnitus also had hearing loss, suggesting that their tinnitus was distinct from the "usual" tinnitus that develops in the general population. Another unpublished analysis of data looking at tinnitus and COVID-19 vaccines similarly found that a very low percentage of people who experienced tinnitus after the vaccination also had hearing loss. Can you comment on whether this information might strengthen the potential possibility of an association between tinnitus and COVID-19 vaccines?

Thank you,
Tara

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On Thu, Sep 22, 2022 at 2:13 PM Tara Haelle (b)(6) > wrote:
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On Thu, Sep 22, 2022 at 11:56 AM Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov> wrote:
Hi Tara:

Dr. Shimabukuro will look at these, but he will not have time to get back to you until next week.
Thanks for your patience,
Martha

Martha Sharan
Public Affairs
CDC/Division of Healthcare Quality Promotion
Off.: 404-639-2683
Cell: 404-998-1787

From: Tara Haelle <(b)(6)
Sent: Thursday, September 22, 2022 2:31 AM
To: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Subject: Re: FW: National Geographic interview request - AEs from COVID vaccines

Martha,
Thank you for this. Is that VSD analysis published somewhere? If so, could you share the citation with me? Meanwhile, I've adjusted some of the questions below, including the order of them.

Thanks,
Tara

—A recent paper by Harpaz et al (doi: 10.1007/s40264-022-01186-z) suggests a strong association exists in VAERS reports for tinnitus and each of the three COVID-19 vaccines initially authorized by the FDA, but that the association is masked because of the high number of overall reports. Is this something that the CDC safety researchers have considered and/or that they are looking into?

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On Wed, Sep 21, 2022 at 2:52 PM Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov> wrote:
Hi Tara:
CDC now has a statement that I am including below – not sure if this will have an impact on your list of questions. Let me know if you need to adjust any of them:

> CDC is aware of reports to the Vaccine Adverse Event Reporting System (VAERS) of tinnitus occurring in temporal association with COVID-19 vaccination (i.e., following vaccination). Tinnitus is a common condition and heterogenous in clinical presentation and course. There are some established risk factors, such as exposure to loud noise; however, in many cases, no discernable cause for tinnitus is identified.
>
> Hundreds of millions of people have received COVID-19 vaccinations under the most intensive monitoring in U.S. history. Because so many people have been vaccinated and because tinnitus is so common in the population, temporally-associated cases are expected, with some expected to occur shortly after vaccination. To further evaluate concerns about reports of tinnitus following COVID-19 vaccination, CDC conducted an analysis in the Vaccine Safety Datalink (VSD). Unlike VAERS, which relies primarily on voluntary reports from healthcare providers, patients, and others, the VSD uses data from electronic health records. Consequently, the VSD data are

less likely to be affected by the reporting biases and other biases that impact spontaneous reporting patterns to VAERS and data quality. The VSD looked for clustering of tinnitus diagnoses in COVID-19 vaccinated patients during a post-vaccination observation period out to 70 days after vaccination. In the VSD's patient population of approximately 12 million people with 6.6 million COVID-19 vaccine doses administered, to date no clustering of tinnitus diagnoses has been observed post-vaccination.

Currently, the information from vaccine safety monitoring systems does not suggest a link between COVID-19 vaccination and tinnitus. CDC will continue to monitor the safety of COVID-19 vaccines and continue to evaluate the outcome of tinnitus as additional data are collected.

Thanks,
Martha

Martha Sharan
Public Affairs
CDC/Division of Healthcare Quality Promotion
Off.: 404-639-2683
Cell: 404-998-1787

From: Tara Haelle (b)(6)
Sent: Wednesday, September 21, 2022 3:27 PM
To: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Subject: Re: FW: National Geographic interview request - AEs from COVID vaccines

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Please let me know when Dr. Shimabukuro will be able to respond to these. If it's possible by the end of this week, that would be particularly helpful.

Thank you,
Tara Haelle

—Has the CDC investigated the potential association between tinnitus and COVID-19 vaccines? If so, can you tell me what the CDC vaccine safety researchers have done and found? Or, if not, can explain the reasoning behind that decision?

—One of the challenges of considering tinnitus as a presumptive AE is that it is so common as a background condition in the general population. Does a condition's prevalence in the general population affect how CDC safety researchers consider potential associations from AEs reported

in VAERS?

—Does the CDC have plans to initiate a case control or other epidemiological study, using VSD or another data set, to investigate tinnitus as a potential AE correlated with any of the COVID-19 vaccines? Why or why not?

—A recent paper by Harpaz et al (doi: 10.1007/s40264-022-01186-z) suggests a strong association exists in VAERS reports for tinnitus and each of the three COVID-19 vaccines initially authorized by the FDA, but that the association is masked because of the high number of overall reports. Is this something that the CDC safety researchers have considered and/or that they are looking into?

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Martha

Martha Sharan
Public Affairs
CDC/Division of Healthcare Quality Promotion
Off.: 404-639-2683
Cell: 404-998-1787

From: Tara Haelle (b)(6)
Sent: Wednesday, August 31, 2022 6:32 AM

To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Subject: National Geographic interview request - AEs from COVID vaccines

Hello Dr. Shimabukuro,
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I spoke with Patsy Stinchfield, and she mentioned you would be a good source on this since I have questions about the CDC's process in going through VAERS reports and determining what to further investigate using VSD or other epi studies.

Would you have time for an interview this week or next to discuss this topic for my article?

Thank you,
Tara Haelle

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From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 7 Feb 2023 21:13:42 +0000
To: Duffy, Jonathan M. (CDC/DDID/NCEZID/DHQP)
Subject: RE: VSD COVID-19 TreeScan - abstract for ICPE
Attachments: TreeScan abstract for ICPE 2023-02-07_clean_tts.docx

Try this one.

From: Duffy, Jonathan M. (CDC/DDID/NCEZID/DHQP) <lzd5@cdc.gov>
Sent: Tuesday, February 7, 2023 2:08 PM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Subject: RE: VSD COVID-19 TreeScan - abstract for ICPE

I don't see any comments/edits in the copy you sent.

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Sent: Tuesday, February 7, 2023 1:56 PM
To: Duffy, Jonathan M. (CDC/DDID/NCEZID/DHQP) <lzd5@cdc.gov>; Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>
Cc: McNeil, Michael (CDC/DDID/NCEZID/DHQP) <mmm2@cdc.gov>
Subject: FW: VSD COVID-19 TreeScan - abstract for ICPE

A comment from me for consideration.

From: Yih, Katherine <Katherine_Yih@harvardpilgrim.org>
Sent: Tuesday, February 7, 2023 1:28 PM
To: Duffy, Jonathan M. (CDC/DDID/NCEZID/DHQP) <lzd5@cdc.gov>; Maro, Judy <Judy.Maro@point32health.org>; Jazwa, Amelia (CDC/DDID/NCEZID/DHQP) <wev7@cdc.gov>; Schembri, Christopher P. (CDC/DDID/NCEZID/DHQP) <gmi8@cdc.gov>; Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <mmm2@cdc.gov>; Kenigsberg, Tat'Yana A. (CDC/DDID/NCEZID/DHQP) <ynf1@cdc.gov>; LeBlanc, Jessica <Jessica.Leblanc@point32health.org>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; rrosofsky@healthinfosys.net
Subject: VSD COVID-19 TreeScan - abstract for ICPE

Dear Jonathan and all,

Some updates:

Summary of analyses

We've done the TreeScan analyses (in inpatient and ED settings) for:

- Pfizer bivalent (979,189 doses), all age groups combined as well as stratified
- Moderna bivalent (352,509 doses), all age groups combined as well as stratified
- JYNNEOS (20,073 doses), all ages combined

(b)(5)

For JYNNEOS, there were no statistically significant clusters.

Abstract

We wrote the attached draft abstract on the bivalent COVID-19 vaccines for ICPE. Please note that it's at the character limit. I have not sent it to the proposed co-authors at the sites yet but plan to do so by tomorrow (Wed.) a.m., for their information. I would like to submit the final approved version to ICPE by Monday morning, February 13.

Upcoming

Please let us know whether we should create slides on TreeScan findings for any of these vaccines for ACIP or its working groups in the near future.

We are working on tinnitus analyses and graphs and expect to report to you on those by next week.

Looking forward to your comments,

Katherine

(b)(5)

From: Yih, Katherine
Sent: Tue, 7 Feb 2023 18:43:03 +0000
To: Duffy, Jonathan M. (CDC/DDID/NCEZID/DHQP); Maro, Judy; Jazwa, Amelia (CDC/DDID/NCEZID/DHQP); Schembri, Christopher P. (CDC/DDID/NCEZID/DHQP); Weintraub, Eric (CDC/DDID/NCEZID/DHQP); McNeil, Michael (CDC/DDID/NCEZID/DHQP); Kenigsberg, Tat'Yana A. (CDC/DDID/NCEZID/DHQP); LeBlanc, Jessica; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); rrosofsky@healthinfosys.net
Subject: RE: VSD COVID-19 TreeScan - abstract for ICPE; no groupings of stroke seen

(b)(5)

Katherine

From: Yih, Katherine
Sent: Tuesday, February 7, 2023 1:28 PM
To: Duffy, Jonathan M. (CDC/DDID/NCEZID/DHQP) <lzd5@cdc.gov>; Maro, Judy <Judy.Maro@point32health.org>; Jazwa, Amelia (CDC/DDID/NCEZID/DHQP) <wev7@cdc.gov>; Schembri, Christopher P. (CDC/DDID/NCEZID/DHQP) <gmi8@cdc.gov>; Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <mmm2@cdc.gov>; Kenigsberg, Tat'Yana A. (CDC/DDID/NCEZID/DHQP) <ynf1@cdc.gov>; LeBlanc, Jessica <Jessica.Leblanc@point32health.org>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; rrosofsky@healthinfosys.net
Subject: VSD COVID-19 TreeScan - abstract for ICPE

Dear Jonathan and all,

Some updates:

Summary of analyses

We've done the TreeScan analyses (in inpatient and ED settings) for:

- Pfizer bivalent (979,189 doses), all age groups combined as well as stratified
- Moderna bivalent (352,509 doses), all age groups combined as well as stratified
- JYNNEOS (20,073 doses), all ages combined

(b)(5)

For JYNNEOS, there were no statistically significant clusters.

Abstract

We wrote the attached draft abstract on the bivalent COVID-19 vaccines for ICPE. Please note that it's at the character limit. I have not sent it to the proposed co-authors at the sites yet but plan to do so by tomorrow (Wed.) a.m., for their information. I would like to submit the final approved version to ICPE by Monday morning, February 13.

Upcoming

Please let us know whether we should create slides on TreeScan findings for any of these vaccines for ACIP or its working groups in the near future.

We are working on tinnitus analyses and graphs and expect to report to you on those by next week.

Looking forward to your comments,

Katherine

Sent: Thu, 9 Feb 2023 13:45:11 +0000
To: Tara Haelle
Cc: Trivedi, Bijal P.
Subject: RE: **Quick question for clarification - Time-sensitive

Hi Tara:

Dr. Shimabukuro said: We simply don't have sufficient evidence from our surveillance to justify launching an epidemiologic study in VSD.

Recently published studies (in VSD) for example include:
Incidence of Myocarditis/Pericarditis Following mRNA COVID-19 Vaccination Among Children and Younger Adults in the United States | Annals of Internal Medicine (acpjournals.org).
A safety study evaluating non-COVID-19 mortality risk following COVID-19 vaccination - ScienceDirect

Vaccine safety publications can be found here:

Martha Sharan
Public Affairs
CDC/Division of Healthcare Quality Promotion
Off.: 404-639-2683
Cell: 404-998-1787

From: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Sent: Wednesday, February 8, 2023 8:21 PM
To: Tara Haelle <(b)(6)
Cc: Trivedi, Bijal P. <Bijal.P.Trivedi@natgeo.com>
Subject: Re: **Quick question for clarification - Time-sensitive

Hmmmm - I believe we were talking in general about selected adverse events which we track, like myocarditis or TTS which signaled and requires further analysis in VSD..

So I think we had jumped from tinnitus to serious adverse events tracked in VSD.

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From: Tara Haelle (b)(6)
Sent: Wednesday, February 8, 2023 7:36:20 PM
To: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Cc: Trivedi, Bijal P. <Bijal.P.Trivedi@natgeo.com>
Subject: **Quick question for clarification - Time-sensitive

Martha,
When we spoke on the phone, you mentioned that Dr. Shimabukuro had said there isn't sufficient evidence from CDC surveillance to justify launching a tinnitus epidemiological study in VSD right now. But you had also said there was an ongoing analysis in VSD that you didn't

have a target ending date for right now. Those statements seem contradictory. Did I misunderstand, or is there a difference between the two? Could you please clarify?

Thanks,
Tara

Tara Haelle • @tarahaelle • @tarahaelle@mastodon.social
Pronouns: She/Her • 817.458.8133 CST (no PR calls please)
tarahaelle.net
Journalist, author, public speaker & AHCJ Medical Studies Core Topic Leader
Books: Vaccination Investigation, The Informed Parent, various children's titles

From: Tara Haelle
Sent: Thu, 9 Feb 2023 11:55:14 -0600
To: Sharan, Martha (CDC/DDID/NCEZID/DHQP)
Cc: Trivedi, Bijal P.
Subject: Re: **Quick question for clarification - Time-sensitive

Thank you for the clarification!

Thanks,
Tara

— —

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Pronouns: She/Her • 817.458.8133 CST (no PR calls please)
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Journalist, author, public speaker & AHCJ Medical Studies Core Topic Leader
Books: Vaccination Investigation, The Informed Parent, various children's titles

On Thu, Feb 9, 2023 at 8:31 AM Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov> wrote:

Hi Tara:

Sorry for any confusion.

Regarding tinnitus - CDC does not have sufficient evidence from our surveillance to justify launching an epidemiologic study in VSD.

However, as I mentioned there are other studies/ongoing analysis being done in VSD on other topics – for example, below are two recently published studies (in VSD):

Incidence of Myocarditis/Pericarditis Following mRNA COVID-19 Vaccination Among Children and Younger Adults in the United States | Annals of Internal Medicine (acpjournals.org).

A safety study evaluating non-COVID-19 mortality risk following COVID-19 vaccination - ScienceDirect

Vaccine Safety Datalink Publications can be found here: Vaccine Safety Datalink Publications | VSD | Monitoring | Ensuring Safety | Vaccine Safety | CDC;

Vaccine Safety Publications | Research | Vaccine Safety | CDC

Thanks,

Martha

Martha Sharan

Public Affairs

CDC/Division of Healthcare Quality Promotion

Off.: 404-639-2683

Cell: 404-998-1787

From: Tara Haelle [(b)(6)]
Sent: Wednesday, February 8, 2023 8:59 PM
To: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Cc: Trivedi, Bijal P. <Bijal.P.Trivedi@natgeo.com>
Subject: Re: **Quick question for clarification - Time-sensitive

Ok, so right now, there *is* a VSD analysis going on, but there's no target date currently available, correct? (I'm still not clear on which of the things are correct.)

— —

Tara Haelle • @tarahaelle • @tarahaelle@mastodon.social

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Journalist, author, public speaker & AHCJ Medical Studies Core Topic Leader

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To: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>
Cc: Trivedi, Bijal P. <Bijal.P.Trivedi@natgeo.com>
Subject: **Quick question for clarification - Time-sensitive

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Thanks,

Tara

— —

Tara Haelle • @tarahaelle • @tarahaelle@mastodon.social

Pronouns: She/Her • 817.458.8133 CST (no PR calls please)

tarahaelle.net

Journalist, author, public speaker & AHCJ Medical Studies Core Topic Leader

Books: Vaccination Investigation, The Informed Parent, various children's titles

From: Ian Dorney
Sent: Thu, 9 Feb 2023 12:34:10 -0500
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Subject: Tinnitus - Extra Data
Attachments: CDC Queries 2_9_2023.pdf

Dr. Shimabukuro,

Here are the results of the additional protocols with an extended timeframe after vaccination - I

(b)(5)

Let me know what you think of this and what else I can do to help.

Thanks,
Ian

--

Ian Dorney
CWRU School of Medicine | Class of 2024

Additional Queries Using TriNetX Database

Ian Dorney
Case Western Reserve University School of Medicine

For: CDC Vaccine Safety Department

(b)(5)

Note: All searches were performed from 1 day - X weeks from vaccine to exclude patients presenting with complaint of tinnitus before any vaccination was administered. Searches were performed using the U.S. Collaborative Network of the TriNetX Analytics Platform on 2/9/2023. All patients with any history of diagnosed tinnitus before the index event (vaccination) were excluded from the analysis.

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(b)(5)