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United States Senate

COMMITTEE ON
HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS

WASHINGTON, DC 20510-6250

October 25, 2023

DAVID M. WEINBERG, STAFF DIRECTOR
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The Honorable Xavier Becerra
Secretary
Department of Health and Human Services

The Honorable Robert Califf
Commissioner
Food and Drug Administration

Dr. Mandy Cohen
Director
Centers for Disease Control and Prevention

Dr. Lawrence Tabak
Acting Director
National Institutes of Health

Dear Secretary Becerra, Commissioner Califf, Director Cohen, and Acting Director Tabak:

Throughout the pandemic, when the American public's need for honest and complete information was never greater, the lack of transparency exhibited by federal health agencies has been appalling. Apparently, the entrenched bureaucrats and political appointees that run the Department of Health and Human Services (HHS), Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), and National Institutes of Health (NIH) have forgotten that they serve, and should be fully accountable to, the American people. As the top U.S. health officials, and for some of you, medical doctors who have sworn to uphold the Hippocratic Oath, you and your colleagues also bear the absolute responsibility of providing patients and the American public the benefit of informed consent.

By providing far less than a full response to my previous oversight letters and by not being fully transparent, it appears that public health agencies have not even come close to ensuring that doctors can provide informed consent on a new gene therapy masquerading as a "vaccine" that was rushed to market without adequate safety or efficacy testing. As new and alarming information continues to come to light, federal health agencies continue to stonewall and gaslight Congress and the public.

For example, on October 15, 2023, nearly three years after the COVID-19 "vaccines" became publicly available, FDA released a preprint of a study it funded acknowledging—albeit much too late—multiple adverse health outcomes, including seizures, associated with the COVID-19 "vaccines" among "vaccinated" children.¹ The results of this FDA-funded study

¹ Mao Hu et al., Safety of Monovalent BNT162b2 (Pfizer-BioNTech), mRNA-1273 (Moderna), and NVX-CoV2373 (Novavax) COVID-19 Vaccines in US Children Aged 6 months to 17 years, Oct. 15, 2023, MedRxiv, <https://www.medrxiv.org/content/10.1101/2023.10.13.23296903v1.full.pdf>. The study states, "The US Food and

reaffirm previous concerns about the safety of the COVID-19 “vaccines”—particularly for children—and underscore the need for federal health agencies to be transparent with the American people and responsive to Congress.

The study titled, “Safety of Monovalent BNT162b2 (Pfizer-BioNTech), mRNA-1273 (Moderna), and NVX-CoV2373 (Novavax) COVID-19 Vaccines in US Children Aged 6 months to 17 years,” reviewed health insurance databases with records for over 4.1 million “vaccinated” children to detect increases in certain adverse events following COVID-19 vaccination.² The study found statistically significant signals for myocarditis or pericarditis following the Pfizer COVID-19 “vaccine” in children aged 12-17 years old. The study also concluded:

“In the primary analysis, **seizures/convulsions met the statistical threshold for a signal in children aged 2-4 years following [Pfizer] vaccination in all three databases, and in children aged 2-5 years following [Moderna] vaccination** in two of the three databases. Dose-specific signals for signals for seizures/convulsions were detected in two of the three databases following dose 1 and dose 2 [Pfizer] vaccinations in ages 2-4 years and following dose 2 [Moderna] vaccination in ages 2-5 years.”³

Although the authors of this study wrote that the “new seizures/convulsions signal should be interpreted cautiously given study limitations,” this finding raises new questions regarding the risk-benefit calculation and whether federal health agencies should continue to approve these “vaccines” for children.⁴

On September 12, 2023, nearly one month before the FDA-funded study was published, the CDC announced its recommendation that “everyone 6 months and older get an updated COVID-19 vaccine to protect against the potentially serious outcomes of COVID-19 illness this fall and winter.”⁵ At the time of this announcement, the extent to which CDC had knowledge of the FDA-funded study and of the potential risk of seizures/convulsions following “vaccination” among children aged 2-5 years old remains unclear.

You and your colleagues have a duty to provide the American people with complete and transparent data regarding the safety and effectiveness of the COVID-19 “vaccines.” It is completely unacceptable that public health agencies have ignored requests for detailed information about “vaccine” lots that are associated with higher rates of adverse events and have failed to provide CDC’s and FDA’s complete data analyses (Proportional Reporting Ratio tables and empirical Bayesian data mining – if they exist) on “vaccine” adverse events.⁶ The fact that

Drug Administration provided funding for this study and contributed as follows: led the design of the study, interpretation of the results, writing of the manuscript, decision to submit, and made contributions to the coordination of data collection and analysis of the data.” *Id.* at 15.

² *Id.* at 2-3.

³ *Id.* at 10-11 (emphasis added).

⁴ *Id.* at 2.

⁵ Press release, CDC Recommends Updated COVID-19 Vaccine for Fall/Winter Virus Season, Centers for Disease Control and Prevention, Sept. 12, 2023, <https://www.cdc.gov/media/releases/2023/p0912-COVID-19-Vaccine.html>.

⁶ Letter from Sen. Ron Johnson, to Janet Woodcock, Acting Commissioner, Food and Drug Admin., and Rochelle Walensky, Dir., Centers for Disease Control and Prevention, Dec. 29, 2021,

the vast majority of my questions and information requests remain unanswered or outstanding only heightens my level of suspicion.

According to the Vaccine Adverse Event Reporting System (VAERS), as of October 18, 2023, there have been 1,596,983 adverse events and 36,324 deaths associated with the COVID-19 “vaccines” with 8,895 deaths (24 percent) occurring on day 0, 1, and 2 following “vaccination.”⁷ Individuals who willingly or reluctantly received the COVID-19 “vaccines” deserve to know the full truth about the adverse health outcomes they or their loved ones may face following “vaccination.”

However, your agencies continue to obstruct my efforts to provide the public with the truth about the COVID-19 “vaccines.” To help illustrate your agencies’ lack of transparency, I have listed below over a dozen letters I have sent over the last two years on COVID-19 “vaccines” that your agencies have failed to adequately address:

- **July 13, 2021** – Requesting information on “vaccine” safety monitoring.⁸
- **July 30, 2021** – Requesting data CDC used to create a slide deck on COVID-19 “vaccine” effectiveness.⁹
- **August 22, 2021** – Regarding the Vaccines and Related Biological Products Advisory Committee meeting.¹⁰

<https://www.ronjohnson.senate.gov/services/files/F564153D-89FD-40C9-A1B1-8663C22D2F0A>; Letter from Sen. Ron Johnson, to Robert Califf, Commissioner, Food and Drug Admin., Sept. 5, 2023, <https://www.ronjohnson.senate.gov/services/files/0E2CC41F-6202-4124-A7F6-8491E864FB23>.

⁷ See VAERS database query: United States Department of Health and Human Services (DHHS), Public Health Service (PHS), Centers for Disease Control (CDC) / Food and Drug Administration (FDA), Vaccine Adverse Event Reporting System (VAERS) 1990 - 9/29/2023, CDC WONDER On-line Database. Accessed at <http://wonder.cdc.gov/vaers.html> on October 24, 2023 1:59:23 PM. Query criteria –Vaccine Products: COVID-19 Vaccine (COVID19); COVID-19-2 (COVID-192). Group By: Month Received. State/Territory: All locations. Event Category: All Events. Show Totals: True. Show Zero Values: False; VAERS database query: United States Department of Health and Human Services (DHHS), Public Health Service (PHS), Centers for Disease Control (CDC) / Food and Drug Administration (FDA), Vaccine Adverse Event Reporting System (VAERS) 1990 - 9/29/2023, CDC WONDER On-line Database. Accessed at <http://wonder.cdc.gov/vaers.html> on October 24, 2023 1:59:23 PM. Query criteria – Vaccine Products: COVID-19 Vaccine (COVID19); COVID-19-2 (COVID-192). Group By: Month Received. State/Territory: All locations. Event Category: Death. Show Totals: True. Show Zero Values: False.

⁸ Letter from Sen. Ron Johnson, to Francis Collins, Dir., National Institutes of Health, Rochelle Walensky, Dir., Centers for Disease Control and Prevention, and Janet Woodcock, Acting Commissioner, Food and Drug Admin., July 13, 2021, <https://www.ronjohnson.senate.gov/services/files/17788FED-A947-4143-8C1B-95C59E60EE87>.

⁹ Letter from Sen. Ron Johnson, to Rochelle Walensky, Dir., Centers for Disease Control and Prevention, July 30, 2021, <https://www.ronjohnson.senate.gov/services/files/FB7EA061-5BD3-486E-B505-AC464A1127E7>.

¹⁰ Letter from Sen. Ron Johnson, to Francis Collins, Dir., National Institutes of Health, and Rochelle Walensky, Dir., Centers for Disease Control and Prevention, and Janet Woodcock, Acting Commissioner, Food and Drug Admin., Aug. 22, 2021, <https://www.ronjohnson.senate.gov/services/files/10CC4263-0337-453F-B9E5-1E5BA0DFD10>.

- **December 29, 2021** – Requesting information about COVID-19 “vaccine” lots that are associated with higher rates of adverse events.¹¹
- **March 1, 2022** – Reiterating previous unanswered questions to CDC regarding natural immunity and vaccine safety.¹²
- **March 23, 2022** – Requesting information about awareness of reports on COVID-19 “vaccine” adverse events.¹³
- **June 23, 2022** – Requesting CDC’s complete data analyses of COVID-19 “vaccine” safety surveillance data including Proportional Reporting Ratio tables.¹⁴
- **July 25, 2022** – Reiterating requests for CDC’s complete data analyses of COVID-19 “vaccine” safety surveillance data.¹⁵
- **September 12, 2022** – Requesting additional information about CDC’s surveillance of COVID-19 “vaccine” adverse events following CDC’s lack of transparency.¹⁶
- **January 10, 2023** – Reiterating previous requests for all of CDC’s surveillance data on COVID-19 “vaccine” adverse events following months of CDC’s obstruction.¹⁷
- **April 20, 2023** – Requesting records regarding the Countermeasure Injury Compensation Program (CICP) relating to COVID-19 “vaccine” injuries.¹⁸
- **August 28, 2023** – Requesting records regarding CDC’s apparent campaign to suppress social media posts about VAERS.¹⁹

¹¹ Letter from Sen. Ron Johnson, to Janet Woodcock, Acting Commissioner, Food and Drug Admin., and Rochelle Walensky, Dir., Centers for Disease Control and Prevention, Dec. 29, 2021, <https://www.ronjohnson.senate.gov/services/files/F564153D-89FD-40C9-A1B1-8663C22D2F0A>.

¹² Letter from Sen. Ron Johnson, to Rochelle Walensky, Dir., Centers for Disease Control and Prevention, Mar. 1, 2022, <https://www.ronjohnson.senate.gov/services/files/018E3CF9-DCE9-4F0D-836B-DC4DD9866FF2>.

¹³ Letter from Sen. Ron Johnson, to Xavier Becerra, Secretary, Department of Health and Human Services, Robert Califf, Commissioner, Food and Drug Admin., Anthony Fauci, Dir., National Institute of Allergy and Infectious Diseases, and Rochelle Walensky, Dir., Centers for Disease Control and Prevention, Mar. 23, 2022, <https://www.ronjohnson.senate.gov/services/files/08942E5E-4220-48A9-B989-9D5947C10BB4>.

¹⁴ Letter from Sen. Ron Johnson, to Rochelle Walensky, Dir., Centers for Disease Control and Prevention, June 23, 2022, <https://www.ronjohnson.senate.gov/services/files/9914278B-A73B-4434-8349-91091138E18B>.

¹⁵ Letter from Sen. Ron Johnson, to Rochelle Walensky, Dir., Centers for Disease Control and Prevention, July 25, 2022, <https://www.ronjohnson.senate.gov/services/files/D48FBED6-BDF3-4FB7-8B24-D52A2EDCE39E>.

¹⁶ Letter from Sen. Ron Johnson, to Rochelle Walensky, Dir., Centers for Disease Control and Prevention, Sept. 12, 2022, <https://www.ronjohnson.senate.gov/services/files/0CBE044E-4F2C-47F2-8272-4DB4F14D3359>.

¹⁷ Letter from Sen. Ron Johnson, to Rochelle Walensky, Dir., Centers for Disease Control and Prevention, Jan. 10, 2023, <https://www.ronjohnson.senate.gov/services/files/AB68101B-CDA4-49F1-8174-4274DDEB0120>.

¹⁸ Letter from Sen. Ron Johnson, to Xavier Becerra, Secretary, Department of Health and Human Services, and Carole Johnson, Administrator, Health Resources and Services Admin., Apr. 20, 2023, <https://www.ronjohnson.senate.gov/services/files/A80C5322-F694-4803-BC15-BE3B0D4708D1>.

¹⁹ Letter from Sen. Ron Johnson, to Mandy Cohen, Dir., Centers for Disease Control and Prevention, Aug. 28, 2023, <https://www.ronjohnson.senate.gov/services/files/A3D036E9-5930-49FF-84CF-D93D9FE8C7D6>.

- **September 5, 2023** – Reiterating requests for records regarding CICP.²⁰
- **September 5, 2023** – Requesting FDA’s complete data analyses of COVID-19 “vaccine” safety surveillance data including empirical Bayesian data mining.²¹

In addition to the oversight letters on the “vaccines,” below is a sample of other requests I have made regarding the COVID-19 pandemic, early treatment, and the virus’ origins that remain outstanding:

- **December 10, 2020** – Requesting NIH records on reviews of early treatments for COVID-19.²²
- **January 22, 2021** – Reiterating requests to NIH for information on early treatments for COVID-19.²³
- **March 1, 2021** – Requesting additional information from NIH on early treatment.²⁴
- **May 19, 2021** – Requesting records relating to teachers’ unions and CDC guidance.²⁵
- **June 11, 2021** – Requesting records regarding COVID-19 origins and the government’s response to the pandemic.²⁶
- **August 19, 2021** – Requesting information about U.S. health agencies’ awareness of safety concerns at the Wuhan Institute of Virology.²⁷

²⁰ Letter from Sen. Ron Johnson, to Xavier Becerra, Secretary, Department of Health and Human Services, Sept. 5, 2023, <https://www.ronjohnson.senate.gov/services/files/241E701E-A91E-4B82-B4A8-FF233A3C5C98>.

²¹ Letter from Sen. Ron Johnson, to Robert Califf, Commissioner, Food and Drug Admin, Sept. 5, 2023, <https://www.ronjohnson.senate.gov/services/files/0E2CC41F-6202-4124-A7F6-8491E864FB23>.

²² Letter from Sen. Ron Johnson, and Sen. Rand Paul, to Francis Collins, Dir., U.S. National Institutes of Health, Dec. 10, 2020, https://www.hsgac.senate.gov/wp-content/uploads/imo/media/doc/40-317_Comm.%20Homeland%20Security%20%20Gov.%20Affairs%2012-10-2020.pdf.

²³ Letter from Sen. Ron Johnson, to Francis Collins, Dir., U.S. National Institutes of Health, Jan. 22, 2021, <https://www.ronjohnson.senate.gov/services/files/FC8E1181-1B21-4CCA-8DA2-97B71C72ED9C>.

²⁴ Letter from Sen. Ron Johnson, to Francis Collins, Dir., U.S. National Institutes of Health, Mar. 1, 2021, <https://www.ronjohnson.senate.gov/services/files/001BBA41-33AB-4B7B-AB41-F9436AD9D168>.

²⁵ Letter from Sen. Ron Johnson, et al., to Xavier Becerra, Secretary, Department of Health and Human Services, May 19, 2021, <https://www.ronjohnson.senate.gov/services/files/69F90648-8F01-4445-81D3-CD4980A2C144>.

²⁶ Letter from Sen. Ron Johnson, et al., to Xavier Becerra, Secretary, Department of Health and Human Services, and Francis Collins, Dir., U.S. National Institutes of Health, June 11, 2021, <https://www.ronjohnson.senate.gov/services/files/53ED3ED4-1652-4F46-B89F-F0058382E9CA>.

²⁷ Letter from Sen. Ron Johnson, and Sen. Rand Paul, to Xavier Becerra, Secretary, Department of Health and Human Services, and Francis Collins, Dir., U.S. National Institutes of Health, Aug. 19, 2021, <https://www.ronjohnson.senate.gov/services/files/A60D3BD2-9083-4C61-91DA-72D2AEC39155>.

- **March 1, 2022** – Requesting records referring to CDC’s use of a potentially flawed study to support school mask guidance.²⁸
- **May 5, 2022** – Requesting records regarding CDC’s apparent use of location data during the pandemic.²⁹
- **March 31, 2023** – Reiterating requests for HHS records regarding the origins of COVID-19.³⁰
- **April 25, 2023** – Requesting unredacted Freedom of Information Act documents that appear to show communications about ivermectin as a potential treatment for COVID-19.³¹
- **September 21, 2023** – Reiterating requests for records regarding U.S. health agencies’ awareness of safety concerns at the Wuhan Institute of Virology.³²

This correspondence marks the 60th public letter I have sent to government agencies concerning various aspects of the COVID-19 pandemic. It is well past time for U.S public health agencies to be transparent. In addition to immediately providing full and complete responses to my previous letters, I respectfully request that you provide the following information by no later than November 8, 2023:

1. When was FDA and CDC first made aware of the findings of the FDA-funded study eventually published as a preprint on October 15, 2023? Provide the names and titles of the individuals who were initially made aware of the study’s findings.
2. Do FDA and CDC agree that parents should have complete awareness of all potential adverse health outcomes associated with the COVID-19 “vaccines” before deciding whether to get their child “vaccinated?”
 - a. If so, why have FDA and CDC failed to provide all the safety surveillance data mining analyses that I have requested since June 2022?
3. Given the findings of the October 15, 2023 FDA-funded study that revealed specific adverse health outcomes for children following COVID-19 “vaccination,” does CDC

²⁸ Letter from Sen. Ron Johnson, to Rochelle Walensky, Dir., Centers for Disease Control and Prevention, Mar. 1, 2022, <https://www.ronjohnson.senate.gov/services/files/6AF724B7-EBE0-4D2A-8E90-2D526F8DDB1E>.

²⁹ Letter from Sen. Ron Johnson, to Rochelle Walensky, Dir., Centers for Disease Control and Prevention, May 5, 2022, <https://www.ronjohnson.senate.gov/services/files/80B0C205-E4B0-4D71-B28D-5114893E0C3F>.

³⁰ Letter from Sen. Ron Johnson, et al., to Xavier Becerra, Secretary, Department of Health and Human Services, Mar. 31, 2023, <https://www.ronjohnson.senate.gov/services/files/6059A1B8-00BB-49C6-92F5-3288F3CF4739>.

³¹ Letter from Sen. Ron Johnson, to Xavier Becerra, Secretary, Department of Health and Human Services, Apr. 25, 2023, <https://www.ronjohnson.senate.gov/services/files/C0A2BC83-BC08-4659-B4D4-B0703418A9AD>.

³² Letter from Sen. Ron Johnson, to Xavier Becerra, Secretary, Department of Health and Human Services, and Lawrence Tabak, Acting Dir., National Institutes of Health, Sept. 21, 2023, <https://www.ronjohnson.senate.gov/services/files/D61A4108-714C-41C0-99D1-79FE59B67626>.

stand by its September 12, 2023 recommendation that “everyone 6 months and older get an updated COVID-19 vaccine”?³³

- a. If so, what analyses, if any, has CDC performed to ensure children (aged 17 or younger) are less likely to get a severe reaction to the COVID-19 “vaccine” compared to COVID-19? Please provide those analyses.
4. Provide all FDA and CDC records³⁴ referring or relating to the October 15, 2023 FDA-funded study titled, “Safety of Monovalent BNT162b2 (Pfizer-BioNTech), mRNA-1273 (Moderna), and NVX-CoV2373 (Novavax) COVID-19 Vaccines in US Children Aged 6 months to 17 years.”
5. Regarding the “new signal detected for seizures/convulsions among younger children,” the October 15, 2023 FDA-funded study called for “further investigat[ion] in a robust epidemiological study with better confounding adjustment.”³⁵
 - a. Is FDA pursuing a further study? If so, when was this decided?
 - b. Describe any other steps FDA or CDC has taken or will take following the results of the October 15, 2023 study.
6. According to Pfizer’s July 2021 response to FDA’s Center for Biologics Evaluation and Research (CBER) relating to concerns about myocarditis and pericarditis, Pfizer told CBER they “planned post-authorization safety studies.”³⁶ Has Pfizer provided CBER the following post-authorization studies: C4591009, C4591011, and C4591012? If so, please provide all records connected to those studies.

Thank you for your attention to this important matter.

Sincerely,



Ron Johnson
Ranking Member
Permanent Subcommittee on Investigations

³³ Press release, CDC Recommends Updated COVID-19 Vaccine for Fall/Winter Virus Season, Centers for Disease Control and Prevention, Sept. 12, 2023, <https://www.cdc.gov/media/releases/2023/p0912-COVID-19-Vaccine.html>.

³⁴ “Records” include any written, recorded, or graphic material of any kind, including letters, memoranda, reports, notes, electronic data (e-mails, email attachments, and any other electronically-created or stored information), calendar entries, inter-office communications, meeting minutes, phone/voice mail or recordings/records of verbal communications, and drafts (whether or not they resulted in final documents).

³⁵ Mao Hu et al., Safety of Monovalent BNT162b2 (Pfizer-BioNTech), mRNA-1273 (Moderna), and NVX-CoV2373 (Novavax) COVID-19 Vaccines in US Children Aged 6 months to 17 years, Oct. 15, 2023, MedRxiv, <https://www.medrxiv.org/content/10.1101/2023.10.13.23296903v1> at 4.

³⁶ Response to 30 June 2021 Information Request Regarding Updating Informed Consent Documents and Investigator’s Brochure with Information Related to Myocarditis and Pericarditis, Pfizer, Jul. 2021 at 10 [on file with Subcomm.].

October 25, 2023

Page 8

cc: The Honorable Richard Blumenthal
Chairman
Permanent Subcommittee on Investigations

The Honorable Christi Grimm
Inspector General
Department of Health and Human Services