From:	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
То:	Pekoc, Ken (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
Subject:	FW: Media request from Glenn Beck
Date:	2021/11/09 12:55:43
Priority:	Normal
Туре:	Note

Another request, see below.

Matthew J. Memoli, M.D., M.S. Director, LID Clinical Studies Unit Laboratory of Infectious Diseases National Institute of Allergy and Infectious Diseases National Institutes of Health MSC 3203 33 North Dr Bethesda, MD 20892-3203

UNITED STATES

Email: (b)(6) Phone: (b)(6) Pager: (b)(6)

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From: Rikki Ratliff <rikki@glennbeck.com>

Date: Tuesday, November 9, 2021 at 12:53 PM To: "Memoli, Matthew (NIH/NIAID) [E]" (b)(6)

Cc: Sarah Kolk <skolk@glennbeck.com>

Subject: Media request from Glenn Beck

Hi Dr. Memoli,

I read the WSJ feature on you yesterday: https://www.wsj.com/articles/vaccine-mandate-debatemakes-it-to-top-federal-research-agency-11636286400?mod=e2tw. We think you are incredibly

brave and thank you for your work during the pandemic. Glenn would love to interview you on his national radio show tomorrow if you're up for it. We understand it may come at an internal cost for you and will not push, but you're a lone voice that could use some amplification.

We are live from 9am-12pm ET and can do this by telephone for as short or as long as you have.

We look forward to hearing from you,

Rikki Ratliff-Fellman

Executive Producer, Glenn Beck

Mercury Radio Arts

Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6)

Recipient:
Pekoc, Ken (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6)
(b)(6)

Sent Date:
Delivered Date:
2021/11/09 12:55:43

From:	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
To:	Meredith Wadman <mwadman@aaas.org></mwadman@aaas.org>
Subject:	Re: Zoom invitation from a Science reporter
Date:	2021/11/09 12:38:53
Priority:	Normal
Туре:	Note

Meredith,

I wanted to send you one more piece of information. We talked about how people who got vaccinated, although less likely to get COVID for a period of time, if they became infected they were not much less likely to die.

Please see the data from CDC here: https://covid.cdc.gov/covid-data-tracker/#rates-by-vaccine-status Now of course there are a myriad of problems with how these data are collected, and a ton of confounding issues that interfere with clear interpretation. I wish CDC would recognize that a bit more. Now look at some recent numbers.

The most recent data: September 4 shows:

	Case Rate	Death Rate	Ratio
Unvaxxed	665.74	9.14	0.014
Vaxxed	113.66	0.74	0.007

For August 14 it shows:

	Case Rate	Death Rate	Ratio
Unvaxxed	720.85	13.23	0.018
Vaxxed	116.2	1.2	0.010

Obviously this fluctuates depending on the week or month it is looked at, but it basically hovers with the ratio of death rate to cases rate in each group around 0.01. There is very little difference between these groups. Now I wish we had access to the full data rather than just these ratios. Obviously there are limitations.

The last time I saw full data on deaths vs cases was here: https://www.cdc.gov/mmwr/volumes/70/wr/mm7037e1.htm

In this document you will find this table:

	Cas		
Age group, yrs	Not fully vaccinated	Fully vaccinated	Not fully vaccina

	Cases		
Age group, yrs	Not fully vaccinated	Fully vaccinated	Not fully vaccina
Totals	569,142 (92)	46,312 (8)	34,972 (92)

These are actual cases from April to July 2021

You will notice the following

	Cases	Hospitalizations	Death	Percent hospitalized	Percent Death
Unvaxxed	569142	34972	6132	6.14%	1.08%
Vaxxed	46312	2976	616	6.43%	1.33%

P value for hospitalizatoin 0.02 P value for deaths <0.0001 Calculated using Chi Square

So in this particular dataset published by CDC the hospitalizations and deaths were statistically higher in the vaccinated group when you look specifically at the confirmed cases.

Without having done a large scale randomized study with a proper control group we are just interpreting epidemiologic data. As you can see there is more than 1 interpretation. The point is, we should be looking at all aspects of the data, not just looking at it in a way that confirms a decision or a bias one may have.

When I look at this, I don't see it and say the vacine doesn't work, but I do look at it and say "hey I have questions, and I think we should slow down and consider all possibilities before we coerce large numbers of people into taking a risk on a vaccine they may not need".

Thanks, Matt

__

Matthew J. Memoli, M.D., M.S. Director, LID Clinical Studies Unit Laboratory of Infectious Diseases National Institute of Allergy and Infectious Diseases National Institutes of Health MSC 3203 33 North Dr Bethesda, MD 20892-3203

UNITED STATES

Email:	(b)(6)	
Phone:	(b)(6)	
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From: Meredith Wadman < mwadman@aaas.org>

Date: Monday, November 8, 2021 at 7:40 PM

To: "Memoli, Matthew (NIH/NIAID) [E]" (b)(6)

Subject: RE: Zoom invitation from a Science reporter

Matt, Many thanks again for your time and insights. And thanks for the very helpful list of references. I will review it carefully and will be in touch.

Best wishes,

Meredith

From: Memoli, Matthew (NIH/NIAID) [E] (b)(6)

Sent: Monday, November 8, 2021 7:20 PM
To: Meredith Wadman < mwadman@aaas.org>
Subject: Re: Zoom invitation from a Science reporter

[EXTERNAL EMAIL]

Hello Meredith

Here are a few links and attachments for you to look at. This is by no means comprehensive.

- 1. Study showing vaccination level has no effect on infection rates: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8481107/
- 2. Breakthrough infections in those vaccinated first vs those infected and then vaccinated. This study should have had a previously infected and no vaccine arm, but doesn't so we don't know if the vaccine after infection really offered any benefit over previous infection alone

here. https://jamanetwork.com/journals/jama/fullarticle/2785918

3. • Other studies supporting natural immunity being important

https://www.medrxiv.org/content/10.1101/2021.08.24.21262415v1 https://www.cell.com/cell-reports-medicine/pdfExtended/S2666-3791(21)00203-2 https://www.nature.com/articles/s41586-021-03696-9

- 4. The attached study (transmissionfull.pdf) is a preprint regarding transmission. The devil is in the details. I highlighted a key line at the end of the abstract and you can look at the data to see the result. In 12 weeks after vaccination transmission levels were similar to unvaccinated individuals.
 - "Transmission reductions declined over time since second vaccination, for Delta reaching similar levels to unvaccinated individuals by 12 weeks for ChAdOx1 and attenuating substantially for BNT162b2. Protection from vaccination in contacts also declined in the months after second vaccination."
- 5. The attached breakthrough.pdf from the Lancet is a study of transmission. You will see that they state "fully vaccinated individuals with breakthrough infections have peak viral load similar to unvaccinated cases and can efficiently transmit infection in household settings, including to fully vaccinated contacts. "Now of course they also state that vaccination reduces risk of infection, but it does not reduce transmission. The fact that this is Delta doesn't matter since basically most COVID in the U.S. is Delta now.
- 6. I attached another paper regarding classical H1N1 protection in 2009 and a paper on original antigenic sin. Here is the original paper on it https://www.jstor.org/stable/985534 Here is another link regarding imprinting and paradoxical effect of influenza vaccination https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6864978/. These are complex questions and we must consider that what we do now could have unintended consequences. Why vaccinate those at low risk when the many unknows exist?

Matt

--

Matthew J. Memoli, M.D., M.S.
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From: Meredith Wadman < mwadman@aaas.org> Date: Monday, November 8, 2021 at 5:16 PM To: "Memoli, Matthew (NIH/NIAID) [E]" (b)(6) Subject: Zoom invitation from a Science reporter Meredith Wadman is inviting you to a scheduled Zoom meeting. Topic: Matthew Memoli of NIAID on bioethics vaccine mandate grand rounds Time: Nov 8, 2021 05:30 PM Eastern Time (US and Canada) Join Zoom Meeting (b)(6) Meeting ID:(b)(6) Passcode: (b)(6) From: Memoli, Matthew (NIH/NIAID) [E] (b)(6) Sent: Monday, November 8, 2021 5:08 PM To: Meredith Wadman < mwadman@aaas.org> Subject: Re: interview request from a Science reporter [EXTERNAL EMAIL] That's fine Get Outlook for iOS From: Meredith Wadman < mwadman@aaas.org> Sent: Monday, November 8, 2021 5:05:14 PM To: Memoli, Matthew (NIH/NIAID) [E] (b)(6) Subject: Re: interview request from a Science reporter Great talk to you then. May I send a Zoom invitation? Meredith Wadman Sent from my iPhone On Nov 8, 2021, at 4:51 PM, Memoli, Matthew (NIH/NIAID) [E] (b)(6) wrote:

IEVT	EDNIAL	
	ERNAL	. EMAIL]

I can do 5:30.(b)(6)

Get Outlook for iOS

From: Meredith Wadman < mwadman@aaas.org Sent: Monday, November 8, 2021 4:45:28 PM

To: Memoli, Matthew (NIH/NIAID) [E] (b)(6)

Subject: RE: interview request from a Science reporter

Hi Matt, I'm sorry I missed your note earlier.

Could we speak at 5:30, or in the morning?

Best wishes,

Meredith

From: Memoli, Matthew (NIH/NIAID) [E] (b)(6)

Sent: Monday, November 8, 2021 4:19 PM

To: Meredith Wadman < mwadman@aaas.org>

Subject: Re: interview request from a Science reporter

[EXTERNAL EMAIL]

I have been approved to speak to you about this. I have some time at 4:30pm if you like.

Matt

--

Matthew J. Memoli, M.D., M.S.
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From: Meredith Wadman < mwadman@aaas.org>

Date: Monday, November 8, 2021 at 2:43 PM

To: "Memoli, Matthew (NIH/NIAID) [E]" (b)(6)

Subject: interview request from a Science reporter

Dear Dr. Memoli,

I 'm a staff reporter with Science. I noted the Wall Street Journal article about the upcoming Grand Rounds on the ethics of vaccine mandates, and your role in the story.

Would you be available for a phone or Zoom interview today? I would like to ask you about the story behind the story --- how you came to be involved in the Grand Rounds – how the idea for it evolved, and your role in all of it.

Thanks for considering this request.

Best wishes,

Meredith

Meredith Wadman, BM BCh Senior Reporter Science magazine 1200 New York Avenue N.W., #1144 Washington, D.C. 20005

https://www.sciencemag.org/author/meredith-wadman

Cell, What's App and Signal: (b)(6)

Twitter: @meredithwadman

Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group

Sender: (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6)

(b)(6)

Recipient: Meredith Wadman <mwadman@aaas.org>

Sent Date: 2021/11/09 12:38:53

From:	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
To:	(b)(6)
Subject:	Re: Neurological Effects from Covid Vaccine
Date:	2021/11/09 08:20:20
Priority:	Normal
Туре:	Note

Hello (b)(6)

Thank you for your note. I will continue to do my best as a scientist and infectious disease physician.

--

Matthew J. Memoli, M.D., M.S.
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From: (b)(6)

Date: Tuesday, November 9, 2021 at 12:14 AM

To: "Memoli, Matthew (NIH/NIAID) [E]" (b)(6)

Subject: Neurological Effects from Covid Vaccine

Dear Dr. Memoli:

Thank you for your years of service in the medical field. As a senior member at the NIH, you are helping to shape our country's response to the covid pandemic. I just read an article regarding the request to hold an ethics panel regarding covid vaccine mandates. Thank you for initiating this conversation that is

desperately needed. As a person who has been seriously injured by the covid vaccine, I unfortunately know first hand that these vaccines are not "one size fits all" and they can have devastating long term effects. I believe that these vaccines have a place in helping to control the pandemic, but they need to be used strategically, not pushed upon the entirety of our country.

For almost 10 months, I have silently dealt with numerous symptoms which began 45 minutes after my first dose: numbness, weakness in my extremities, tremors, parathesias, electrical buzzing, extreme fatigue, heat/cold/activity intolerance, chest pain, heart rate and blood pressure fluctuations, brain fog, light headedness, and digestive issues.

As the mandates have been increasing and as the vaccines are now being recommended for young children, I am compelled to speak up and share my story so that others, especially innocent children, do not experience the same types of injuries that I have. I had absolutely no clue that these adverse reactions were even a possibility. How can a vaccine be mandated when informed consent regarding the possible side effects is not provided?

There are many 1000s of people (most likely more) who are experiencing long term neurological reactions from the covid vaccine. These reactions have been reported to VAERS, the NIH, the CDC, the FDA, and the drug companies with little acknowledgment. Because there is little acknowledgement, doctors don't know how to treat us and some won't even consider that this is happening.

Thank you again for starting the dialogue within the NIH regarding vaccine mandates. I am hopeful that this discussion will help open the door for those of us who have been injured and will help the government to acknowledge us and research us in order to discover the cause and possible treatments.

Where there is risk, there should be choice.

If you want to see more stories like mine, please visit the following website:

https://www.realnotrare.com/

With Much Gratitud	e,
	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
Recipient:	(b)(6)
Sent Date:	2021/11/09 08:20:21
Delivered Date:	2021/11/09 08:20:20

From:	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
То:	NIH SPAM Alerting /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
Subject:	FW: Secure Email: Vaccination Mandate Concerns for Federal Employees
Date:	2021/11/08 17:31:24
Priority:	Normal
Туре:	Note

--

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From: "Kesselman, Leo A." (b)(6)	
Reply-To: (b)(6)	
Date: Monday, November 8, 2021 at 5:20 PM	
To: "Memoli, Matthew (NIH/NIAID) [E]" (b)(6)	
Subject: Secure Employees	

New ZixCorp secure email message from FDIC Secure Email

Open Message

To view the secure message, click Open Message.

The secure message expires on Nov 08, 2022 @ 10:20 PM (GMT).

Do not reply to this notification message; this message was auto-generated by the sender's security Open Message.

If clicking Open Message does not work, copy and paste the link below into your Internet browser ad

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Sender: Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6)
<memolim@niaid.nih.gov>

NIH SPAM Alerting /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6)
(b)(6)

Sent Date: 2021/11/08 17:31:25

Delivered Date: 2021/11/08 17:31:24

From:	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)	
То:	Haskins, Melinda (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)	
CC:	NIAID DIR-OCGR /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6) Selgrade, Sara (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)	
Subject:	Re: Vaccine-Mandate Debate Makes It to Top Federal Research Agency - WSJ	
Date:	2021/11/08 15:36:34	
Priority:	Normal	
Туре:	Note	
Thanks, Matt Matthew J. Memoli, M.D., M.S. Director, LID Clinical Studies Unit Laboratory of Infectious Diseases National Institute of Allergy and Infectious Diseases National Institutes of Health MSC 3203 33 North Dr Bethesda, MD 20892-3203 UNITED STATES Email: (b)(6) Phone: (b)(6) Pager: (b)(6) Pager: (b)(6) Disclaimer: The information in this e-mail and any of its attachments is confidential and may contain sensitive information. It should not be used by anyone who is not the original intended recipient. If you have received this e-mail in error please inform the sender and delete it from your mailbox or any other storage devices. National Institute of Allergy and Infectious Diseases shall not		
accept liability for any statements made that are sender's own and not expressly made on behalf of NIAID. On 11/8/21, 3:34 PM, "Haskins, Melinda (NIH/NIAID) [E]" (b)(6) wrote:		
Hi, Matt.		
Thank you for your email.		
You may recall that the NIAID Leg Team has a standard way of addressing direct congressional contact to NIAID employees. In particular, I will forward the Senator Johnson staff request to Adrienne Hallett, who directs the NIH Office of Legislative Policy and Analysis. Adrienne will seek guidance from the Office of the HHS Assistant Secretary for Legislation (ASL) regarding next steps.		
Until we hear from HHS ASL, please continue to refrain from contacting Mr. $(b)(6)$ Should you receive any additional congressional inquiries, just let us know.		
Thanks, Melinda Chief, LACMB/OCGR/NIAID		
Original Message From: Memoli, Matthew (NIH/NIAID) [E] (b)(6)		

Sent: Monday, Novembe To: Haskins, Melinda (Ni Subject: FW: Vaccine-Ma	
Hello Melinda,	
I was instructed to forwaresponded.	ard this request to you. I received it today from people who work for Senator Johnson. I have not
Matt	
3203 UNITED STATES Email: (b)(6) Phone: (b)(6) Pager: (b)(6)	dies Unit
should not be used by any sender and delete it from y	one who is not the original intended recipient. If you have received this e-mail in error please inform the your mailbox or any other storage devices. National Institute of Allergy and Infectious Diseases shall not ements made that are sender's own and not expressly made on behalf of NIAID.
On 11/8/21, 12:17 PM,	(Ron Johnson)" (b)(6) wrote:
https://www.wsj.com/artic speak with you regarding	email finds you well. My colleagues and I work for Senator Johnson. We saw this WSJ article cles/vaccine-mandate-debate-makes-it-to-top-federal-research-agency-11636286400 and would love to vaccine mandates, natural immunity, etc. your availability. Thanks for your time and hope you have a good afternoon.
Thanks, (b)(6)	
Sender:	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
Recipient:	Haskins, Melinda (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=[b)(6) [b)(6) NIAID DIR-OCGR /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=[b)(6) [b)(6) Selgrade, Sara (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=[b)(6) [b)(6)

Sent Date: 2021/11/08 15:36:35 **Delivered Date:** 2021/11/08 15:36:34

Eromi	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group
From:	(FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
То:	Billet, Courtney (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
Subject:	Re: Vaccine-Mandate Debate Makes It to Top Federal Research Agency -WSJ
	2021/11/08 14:50:48
Priority:	
Туре:	Note
Thank you. Matt Get <u>Outlook for iO</u> From: Billet, Courtne	<u>S</u> y (NIH/NIAID) [E] (^{(b)(6)}
	mber 8, 2021 1:48:43 PM
To: Memoli, Matthew	v (NIH/NIAID) [E] (b)(6)
Subject: RE: Vaccine-	Mandate Debate Makes It to Top Federal Research Agency -WSJ
HI Matt - this should	go to Melinda Haskins.
Sent: Monday, Nover To: Billet, Courtney	e new (NIH/NIAID) [E] (b)(6) mber 8, 2021 1:16 PM (NIH/NIAID) [E] (b)(6) e-Mandate Debate Makes It to Top Federal Research Agency -WSJ
Hi Courtney,	
I am not supposed to this request on to was	ving request from a staffer for Senator Ron Johnson. I have not responded as I realize respond to Congress on my own I was not sure who the appropriate person to send s. Could you either forward it or let me know who I am supposed to send this to? I need the speaking with members of Congress.
Thanks, Matt	
	al Studies Unit

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On 11/8/21, 12:17 PM, (b)(6)	(D = 1.1 = =)!! (b)(6)
On 11/8/21, 12:1/ PM,	(Ron Johnson)" (b)(6)

Dr. Memoli, hope this email finds you well. My colleagues and I work for Senator Johnson. We saw this WSJ article https://www.wsj.com/articles/vaccine-mandate-debate-makes-it-to-top-federal-research-agency-11636286400 and would love to speak with you regarding vaccine mandates, natural immunity, etc.

Please let us know of your availability. Thanks for your time and hope you have a good afternoon.

Thanks,	
(b)(6)	

Sender:	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) [b)(6)
Recipient:	Billet, Courtney (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
Sent Date:	2021/11/08 14:50:48

From:	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
To:	(b)(6)
Subject:	Re: Thank You
Date:	2021/11/08 10:58:49
Priority:	Normal
Туре:	Note

Thank you (b)(6)

--

Matthew J. Memoli, M.D., M.S.
Director, LID Clinical Studies Unit
Laboratory of Infectious Diseases
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On 11/8/21, 10:53 AM, (b)(6) wrote:

Dear Dr. Memoli,

I appreciate and agree with your position on vaccination for at-risk populations. I appreciate your strength for refusing to be subject to a mandated vaccination program especially with your career and reputation at risk with this unprecedented push for such rapid deployment of what is a new vaccine. If nothing more, at least you are creating the opportunity for a discussion of the benefits of acquired immunity after infection, which does seem to be far longer lasting than waning vaccine immunity. I still see the Cleveland Clinic study as the most impressive as they were seeking to prove post exposure immunity was actually less robust.

My family was exposed this summer. All tested positive. The children had no symptoms whatsoever. The adults however were sick for a week but required no hospitalization or intervention and quarantined at home.

In any event, good luck and my family and I appreciate your efforts.

Sincerely,	
(b)(6)	

Sender:	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
Recipient:	(b)(6)
Sent Date:	2021/11/08 10:58:50
Delivered Date:	2021/11/08 10:58:49

From:	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
To:	(b)(6)
Subject:	Re: mandatory vaccine
Date:	2021/11/02 11:03:26
Priority:	Normal
Туре:	Note

Thanks (b)(6) The testing is a good argument for you. If weekly testing was already working, there is no reason you shouldn't be able to continue that as a reasonable accommodation. In fact weekly testing is likely more effective than vaccination in stopping spread as clearly vaccinated people still get infected and spread disease. The reliance on vaccine has actually led to increased nor decreased spread in most institutions as they are reducing precautions with vaccinated people.

Good luck, Matt

--

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From: (b)(6)

Date: Tuesday, November 2, 2021 at 10:57 AM

To: "Memoli, Matthew (NIH/NIAID) [E]" (b)(6)

Subject: RE: mandatory vaccine

Hi Matt,

Thanks again so much for your insight; this is definitely such a mess!

I plan on applying for an exemption when I'm allowed to do so come Monday 11/8. I'm just not exactly sure what all to write in my exemption letter. I'm trying to stay optimistic, but it's (b)(6) so...

Unvaccinated staff are already testing weekly, I'm not sure why we just can't continue to do so. If staff does not comply, I will likely be out of a job 12/6. Not sure where to go after that....

I'm happy to hear your wife was exempted! I hope you do as well! Please keep me posted? I'm sad the SERO and Rare Disease projects are coming to an end. I have really enjoyed working on these and have learned so much! I sincerely thank you for the opportunity.

I hope you are able to get the data that you need.

Best, (b)(6)

From: Memoli, Matthew (NIH/NIAID) [E] (b)(6)

Sent: Tuesday, November 2, 2021 10:32 AM

To: (b)(6)

Subject: Re: mandatory vaccine

(b)(6)

First I want to say I am vehemently against the vaccine mandates. I think they are unethical and I have requested a full ethics consult on this topic. There is going to be a Ethics Grand Rounds which I am participating in on Dec 1 here. Interestingly bioethics was never consulted prior to the vaccine mandates. I do believe that the majority of businesses will or have already mandated the vaccines due to the pressure from the Federal government. Since many of the rely on government contracts or funding, they acquiesced very quickly. There are some states that have or are working to not allow mandates, so in some states businesses may not be able to. There are also some businesses that are being forced to rescind their mandates due to workers striking and so forth (i.e. Southwest airlines). A number of court cases are ongoing and so I think this is going to take time but my hope is that sanity and reasonable thought will win out allowing people to make their own healthcare decisions. I am certainly doing everything in my power to influence that.

If I were you I would simply apply for an exemption, do whatever they ask in terms of that. Hopefully your institution will be reasonable and respect your decisions. My wife and I have both applied for exemptions. Her hospital exempted her and I am waiting to see what NIH does. Now we are also dealing with a mandate from the DC dept of health who have threatened to take away our medical licenses, but so far since we applied for an exemption they haven't bothered us. I think everyone is waiting to see how things shake out legally. So all we can do is stay calm and do our jobs to the best of our ability.

Good luck. Just know not everyone at NIAID supports this.

Matt

--

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From: (b)(6)

Date: Monday, November 1, 2021 at 5:21 PM

To: "Memoli, Matthew (NIH/NIAID) [E]" (b)(6)

Subject: mandatory vaccine

Hi Dr. Memoli,

I was just informed that (b)(6) is mandating the COVID vaccine across all students, faculty and staff. We apparently have the option of requesting an exemption from this vaccine requirement for medical reasons, or reasons based on sincerely held religious belief or because of a strong moral or ethical conviction.

I still am not on board with the vaccine due to many reasons that are not based on religious beliefs but I believe that politics have gotten way too involved.

Do you believe that most businesses, corporations, etc. are all going to mandate the vaccine? Is it inevitable?

Thank you in advance,

(b)(6)			

It does seem to be a bad allergy season this year. Many people have told me similar stories. It may simply be a random natural phenomena, or related to the Cicadas, or something else about nature we don't understand. I am certainly not an expert in that arena. Could it have something to do with COVID? I guess it is possible or possible it has something to do with limited exposure to things over the course of the year due to mask wearing and staying home. Hard to really say. There are always things we don't understand.

As for the vaccine, we really have limited information on what impact the vaccines will have long term on people's immune systems. So there is no way to know if in some people it could cause increased responses to other antigens, etc. My personal opinion, and of course not the official position of NIH or NIAID, is that given the limited data and the risk benefit profile of vaccine and COVID, if you are over 65-70 years old or you are younger but have a significant health condition that puts you at clear risk of death from COVID you should probably get vaccinated as the benefit seem to outweigh the risk for now. If you are reasonably healthy and under that age, then I do not believe the benefits outweigh the potential risks at this time. To me you are better off improving your nutrition, exercise and overall health. This will likely have a bigger and safer impact on you long term with this and future pandemics. This will in no way have negative consequences to the overall course of the pandemic. Pandemics are like hurricanes, they are forces of nature and do what they do, we can only board up our houses and hope that IF it hits us we will make it through. No vaccine has ever stopped a respiratory virus pandemic or ended one. They end on their own due to forces we don't completely understand, just like a hurricane. Ultimately I feel the vaccine should be an individual decision, I just wish people were given better information regarding the risk benefit so they could be better informed when making this decision.

Matt

__

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From: (b)(6)
Date: Thursday, May 27, 2021 at 3:50 PM
To: "Memoli, Matthew (NIH/NIAID) [E]" (b)(6)
Subject: RE: Summary from weekly call today 5/26/21 - Rare Disease Seroprevalence Study
Hi Dr. Memoli,
I work with Shannon at PITT for the SERO study.
Sorry we missed you in yesterday's meeting. I had a random quick question, unrelated to SERO.
Why do you think it is that everyone's allergies are SO bad this time around? Both my husband and have
experienced allergy symptoms in the past, but this year it is almost debilitating and no medicine seems
to help with the symptoms of congestion and post nasal drip. It's definitely kicking us in!
He has received the Moderna vaccine. I'm still very much on the fence about the whole thing. Because
at first he thought having the vaccine had a bearing on his immunity with allergies.
Anyhow, I found it interesting that I haven't gotten Covid but the pollen has surely gotten me lol
Have a great holiday weekend to you and yours
Best,
(b)(6)
From: Memoli, Matthew (NIH/NIAID) [E] (b)(6)
Sent: Thursday, May 27, 2021 8:48 AM
To: Valenti, Shannon Lynn (b)(6) Baus, Holly Ann (NIH/NIAID) [E]
(b)(6) Reis, Steven E (b)(6)
Cc: Avolio, Jennifer Rae (b)(6) Underwood, Katherine (b)(6) Shepherd, Erin
Renee (b)(6) Paige Ottmar (b)(6) Gomez, Philip F. (b)(6)
Subject: Re: Summary from weekly call today 5/26/21 - Rare Disease Seroprevalence Study
Thanks Shannon. Great work all. Sorry I couldn't make the call yesterday.
Matthew J. Memoli, M.D., M.S.

Director, LID Clinical Studies Unit Laboratory of Infectious Diseases National Institute of Allergy and Infectious Diseases National Institutes of Health MSC 3203 33 North Dr Bethesda, MD 20892-3203 UNITED STATES

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From: "Valenti, Shannon Lynn" (b)(6)

Date: Wednesday, May 26, 2021 at 6:29 PM

To: "Memoli, Matthew (NIH/NIAID) [E]" (b)(6)

"Reis, Steven" (b)(6)

"Cc: "Avolio, Jennifer Rae" (b)(6)

"Shepherd, Erin Renee" (b)(6)

Paige Ottmar (b)(6)

Subject: Summary from weekly call today 5/26/21 - Rare Disease Seroprevalence Study

Hi Dr. Memoli, Holly Ann, and Steve,

I'm including a summary from our call today.

Below are the most up-to-date numbers for the Rare Disease Seroprevalence Study as of 7 AM EST today:

NCATS Rare Disease:

- 889 participants contacted via email (1,248 emails sent)
- 300 participants consented (43 legal guardians consented)
- 269 participants withdrawn
- 282 verified kits shipped (182 received by NIH)

I did send a request today to Dr. Macaluso about what to do with certain categories within the dataset, like duplicate participants (which PPT ID do they prefer we use), duplicate child records that have two different legal guardians, and participants with years of birth listed as 2020 although they self-reported information. I also sent a reminder we will not contact anyone whose birth year is 2003 because if their

legal guardian signed them up for the survey, and they have turned 18, we do not have the permission to contact them as an adult.

We are working through calls as we can. The consent script has been updated in Salesforce and is being sent to participants we are contacting.

anks,	
annon	
	-
annon Valenti, Pitt CTSI Executive Director, Regulatory Science & Research Facilitation	
nail: (b)(6)	

Please remember to refer to CTSI in all publications that were helped by this grant with the following citation: "The project described was supported by the National Institutes of Health through Grant Number UL1 TR001857, KL2 TR001856, and/or TL1 TR001858."



PittCTSI_2color

Sender:	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
Recipient:	(b)(6)
Sent Date:	2021/11/02 11:03:27
Delivered Date:	2021/11/02 11:03:26

From:	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
To:	Strasburg, Jenny <jenny.strasburg@wsj.com></jenny.strasburg@wsj.com>
Subject:	FW: From the NIH Director: CORONAVIRUS UPDATE: Sammies, Vaccination Mandate, Updated Travel Guidance, Boosters, Vaccines for Children
Date:	2021/11/02 10:09:12
Priority:	Normal
Туре:	Note

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From: NIH Executive Secretariat (b)(6) **Date:** Friday, October 29, 2021 at 4:52 PM **To:** List NIH-ALL-STAFF (b)(6)

Subject: From the NIH Director: CORONAVIRUS UPDATE: Sammies, Vaccination Mandate,

Updated Travel Guidance, Boosters, Vaccines for Children

Dear NIH Family:

Last night I was honored to attend the Partnership for Public Service's <u>Samuel J. Heyman Service to</u> <u>America Medals</u> (also known as the Sammies) Gala at the Kennedy Center. Drs. Kizzmekia Corbett and Barney Graham, formerly with the Vaccine Research Center, were named the 2021 Federal Employee of

the Year for their groundbreaking research that led to the development of highly effective mRNA vaccines. Also honored were NHLBI Director Dr. Gary Gibbons and NIMHD Director Dr. Eliseo Pérez-Stable for developing and implementing federal programs to increase testing and participation in COVID-19 treatment and vaccine trials in underserved communities across the country. And last but not least, Dr. Brigitte Widemann from NCI was a Sammies finalist for her work developing a treatment for children with a genetic disorder that causes inoperable tumors called plexiform neurofibromas. It was a great night for NIH, and wonderful to see the hard work of federal employees recognized on a grand scale.

Federal COVID-19 Vaccination Mandate

I'm pleased to share that over 88% of NIH federal employees are fully vaccinated, and others have applied for a medical or religious exception to meet the <u>federal COVID-19 vaccination mandate</u>. Thank you to all who have reported your proof of vaccination or submitted your request for an exception via the <u>COVID-19 Vaccination Status Form</u>. For those who haven't responded, it is REALLY important to act soon (respond no later November 8), as failure to meet the November 22 deadline may lead to disciplinary action up to and including removal from federal service. As a reminder, the COVID-19 boosters are not included as part of the COVID-19 vaccination mandate and need not be reported. Trainees, volunteers, and tenants are encouraged to proceed now with reporting your vaccination status received in the community (we have your information if you were vaccinated at NIH) or request a medical or religious exception via the <u>COVID-19 Vaccination Status Form</u>.

NIH contractors should proceed with reporting your vaccination status or request a medical or religious exception with your employer. The deadline for contractors to meet the federal mandate is December 8, 2021, so don't wait. If you have questions, please contact your employer or contracting officer.

Updated Travel Guidance - Big News!

Effective today, fully vaccinated staff can submit requests for non-mission critical <u>travel</u> for approval. Please work with your Institute or Center Executive Officer for travel requests that meet the criteria.

Boosters

The NIH Office of Research Services, Division of Occupational Health and Safety, Occupational Medical Service <u>announced</u> that Pfizer and Moderna boosters will be offered to a limited portion of staff starting Monday, November 1. Staff are eligible if they received both doses of either Pfizer or Moderna COVID-19 vaccinations at NIH and are in vaccination phases 1A, 1B and Office of Research Facilities staff in 2B (this qualifies as working in a high-risk setting). Here is a reminder of the staff included in these phases:

- • 1A: Direct/indirect patient care
- 1B: Critical on-site personnel—COVID researchers and COVID animal care workers, security guards, police and fire, childcare providers
- • 2B: Essential ORF personnel for campus operations (Central Utility Plant)

Eligible staff should have received an email from "OMSCovidVaccineProgram" inviting them to make an appointment. Since we only have a limited number of doses, staff vaccinated at NIH may be able to receive a booster faster in the community. And if you received your vaccination in the community and fall under the CDC's <u>recommended</u> populations to receive a booster, you should be able to schedule an appointment in your community now. At this time, please do not submit documentation of boosters to the Occupational Medical Service.

Vaccination for Children

This week, the U.S. Food and Drug Administration's <u>Vaccines and Related Biological Products Advisory Committee (VRBPAC)</u> met and voted to recommend emergency use authorization (EUA) of Pfizer's COVID-19 vaccine for children ages 5 through 11. The data showed that at one third of the adult dose, the vaccine is safe and 90.7% effective in preventing infections. Just this afternoon, the FDA issued the EUA. Next week on Tuesday and Wednesday, the Centers for Disease Control and Prevention <u>Advisory Committee on Immunization Practices (ACIP)</u> will meet to discuss and vote on whether to recommend the vaccine for this age group. I know many of you are anxiously awaiting the CDC decision on approving the Pfizer vaccine for this group of children. While not quite in time for Halloween, it seems likely that this decision will be positive next week. In anticipation of that result, the White House has been working with Pfizer, pharmacies, and pediatric practices to be sure the distribution can happen quickly. Expanding vaccines to this age group will come as welcome news to many parents.

Keep up the good work and have a safe and happy Halloween.

Francis S. Collins, M.D., Ph.D. NIH Director



Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group

Sender: (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6)

Recipient: Strasburg, Jenny <jenny.strasburg@wsj.com>

Sent Date: 2021/11/02 10:09:12

	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
To:	Strasburg, Jenny <jenny.strasburg@wsj.com></jenny.strasburg@wsj.com>
Subject:	FW: COVID-19 Vaccine Booster Information for NIH Staff
Date:	2021/10/28 10:05:28
Priority:	Normal
Туре:	Note

Just an fyi

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 $On \ 10/27/21, 9:03 \ PM, "OMSCovidVaccineProgram" < OMSCovidVaccineProgram@mail.nih.gov> \ wrote: \\$

The NIH is pleased to announce that Pfizer (now known as Comirnaty) and Moderna COVID-19 boosters will be offered to a limited portion of the NIH staff starting on November 1. For now, we are only able to provide a booster from the same manufacturer as your primary vaccination series (e.g. Pfizer = Pfizer). While we are offering these limited opportunities for COVID-19 vaccinations and booster doses, we continue to recommend NIH staff utilize community opportunities to receive their booster if possible. To find a COVID-19 vaccine or booster, visit https://www.vaccines.gov, text your ZIP code to 438829, or call 1-800-232-0233.

Important: Based on the current Safer Federal Workforce mandate (https://www.saferfederalworkforce.gov/faq/vaccinations/), at this time boosters are voluntary and not required to meet the definition of "fully vaccinated" and need not be reported.

Staff are eligible to make appointments if they:

- * Received either Pfizer or Moderna doses at the NIH.
- * Are in vaccination phases 1A, 1B and Office of Research Facilities staff in 2B (this qualifies as working in a high-risk setting).

Maryland staff will receive email invitations from "OMS Covid Vaccine Program" (omscovidvaccineprogram@mail.nih.gov). For staff at Rocky Mountain Laboratories and Research Triangle Park, specifics will be provided on dates and times directly from the ICOs located there.

Staff will be invited to make an appointment in the order in which they received their second dose, once they are at 6 months past dose 2 and fit the criteria listed above. Additional dates may be scheduled, based on demand and dose availability.

If, after receiving the email invitation, you need assistance scheduling your appointment or don't have access to VPN, please call that COVID-19 Call Center at 301-480-8990. Supervisors, if you have staff that do not have VPN or computer access, please provide the necessary assistance to allow them to schedule an appointment. Appointments are available on a first come, first serve basis, and once your appointment has been scheduled, you will receive a confirmation email.

Please arrive promptly at your scheduled time and do not arrive more than 10 minutes early to minimize the number of people waiting in line. Allow 20-40 minutes for your appointment (check-in, vaccination, observation area 15-30 minutes). If you exhibit

any COVID-19 symptoms the day of your appointment, please do not come in, call the COVID-19 Call Center, and reschedule.

Wishing you continued safety and health.

Jessica McCormick-Ell, Ph.D., SM(NRCM), CBSP, RBP. Director, Division of Occupational Health and Safety. Office of Research Services. National Institutes of Health.

 $\label{lem:memoli} \begin{tabular}{ll} Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group \\ \begin{tabular}{ll} Sender: & (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) \\ \end{tabular}$

Recipient: Strasburg, Jenny <jenny.strasburg@wsj.com>

Sent Date: 2021/10/28 10:05:28

Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6)
<memolim@niaid.nih.gov>

To: Strasburg, Jenny <jenny.strasburg@wsj.com>

Subject: Re: Pfizer booster data

Date: 2021/10/22 09:16:38

Priority: Normal

Type: Note

All of the factors you mention are or course unknown variables in these studies. However this is over 18,000 people vs 5000. To argue that lockdowns and masking are the big difference is a weak argument when you look at places with nearly no lockdowns or significant masking like Sweden vs for example U.S. and U.K, there is very little difference in overall infection rates over the course of the pandemic. Sweden had 114,000 cases per million people, U.S. 136,000 per million, and the U.K. 126,000 per million. This makes sense given that 90% of exhaled air particles are likely too small to be captured by the masks being worn based on the evidence and that most people are infected in their homes from close contact. Of course we don't know what the behavior of the people in the studies where and how it could confound the data in either study, but that's the point. Is the point to have a vaccine that works when everyone is staying home or one that works when everyone is living life? The Delta argument is weak as well given we have been told the vaccine is protective against Delta (https://www.cidrap.umn.edu/news-perspective/2021/10/trials-covid-vaccines-90-effective-againstdelta-infection-death) yet there was a 2.2% infection risk in fully vaccinated people in this study (we don't know how much of it was Delta). Again do we want a vaccine that protects against COVID or just one variant? This is what I was expressing to Fauci in my email that was ignored. Doubling down with boosters of the same failed strategy makes no sense. These vaccines are woefully inadequate and in the long run may do more harm than good. Clearly a vaccine mandate with a vaccine that can't stop the spread of a disease will not stop the spread of a disease.

Matt

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From: "Strasburg, Jenny" < jenny.strasburg@wsj.com>

Date: Friday, October 22, 2021 at 4:56 AM

To: "Memoli, Matthew (NIH/NIAID) [E]" (b)(6)

Subject: Re: Pfizer booster data

Good morning - Thanks for this.

I know there's a lot we can't discern without more data -- as you highlight, and has been the case with so many vaccine-related press releases - but isn't a huge factor in the pre-Dec 2020 (pre-vaccine) infection rates the fact that lockdowns were rampant, people *were* actually masking and distancing, vulnerable folks were isolating, etc? Now we have full stadiums, nightclubs, trains, planes (I can attest to in both London and the U.S., and not just NYC). Wouldn't that significantly skew the absolute risk of infection figures you're using?

With so many people vaccinated and the proven transmissibility of Delta -- and the factors above -- how can you really make that comparison ("people were worse off 6 months after vaccination than they were before in 2020")?

Thanks.

Jenny Strasburg Reporter

The Wall Street Journal

(b)(6) (office) (mob)

Jenny.strasburg@wsj.com
@jennystrasburg

The News Building, 1 London Bridge Street London SE1 9GF

On Thu, Oct 21, 2021 at 11:14 PM Memoli, Matthew (NIH/NIAID) [E] (b)(6) wrote: Jenny,

Took another look at that press release today. I hate trying to evaluate data from a press release and I wish they would just release the raw data tables so we can do our own analysis, but this is how things

work. Interestingly the comparator group was fully vaccinated people so they are reporting relative efficacy of 95.6% vs their own vaccine. In addition they had 106 infections in the fully vaccinated but not boosted group which is 106 out of approximately 5000 people (likely less as some people I am sure dropped out) so 2.12% absolute risk of infection. The boosted group saw 5 infections out of approximately 5000 (again likely a smaller denominator, but they don't give us the official one) which is 0.1% absolute risk of infection. In the initial Pfizer efficacy trial published in NEJM (https://www.nejm.org/doi/full/10.1056/NEJMoa2034577?query=RP) out of 18,325 completely unvaccinated participants they saw 162 infections, which is 0.9% absolute risk of infection. So ultimately the data suggests that fully vaccinated people have a higher absolute risk of infection now than unvaccinated people did before December 2020, and that fully vaccinated and boosted people now have fairly similar absolute risk to completely unvaccinated people from before 2020 at the height of the pandemic. Of course this is only for the three months they followed participants and shows how poor the vaccine efficacy is after 3-6 months as people were worse off 6 months after vaccination than they were before in 2020. These data are not impressive and seem to demonstrate problems somewhere. I don't know if it is the population they are studying, how they are measuring things, but these data are anything but reassuring. I await the publication, but under normal circumstances these data would be highly scrutinized.

Matt

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National Institutes of Health
MSC 3203 33 North Dr
Bethesda, MD 20892-3203

UNITED STATES
Email: (b)(6)

Phone: (b)(6)

Pager: (b)(6)

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Sender:	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
Recipient:	Strasburg, Jenny <jenny.strasburg@wsj.com></jenny.strasburg@wsj.com>
Sent Date:	2021/10/22 09:16:39
Delivered Date:	2021/10/22 09:16:38

Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6)
<memolim@niaid.nih.gov>

To: Strasburg, Jenny < jenny.strasburg@wsj.com>

Subject: Fwd: Talking Points for Supervisors and Leadership--COVID-19 Vaccine Mandate

Date: 2021/10/19 15:38:01

Priority: Normal

Type: Note

Here is the email for supervisors.

Get Outlook for iOS

From: NIAID News and Information (NIH/NIAID) (b)(6)

Sent: Wednesday, October 6, 2021 2:16 PM

To: NIAID Training SUP

Subject: Talking Points for Supervisors and Leadership--COVID-19 Vaccine Mandate

NIAID Supervisors,

NIH has offered talking points for supervisors and leadership to use when speaking with their staff about the COVID-19 vaccine mandate. Please use these to guide conversations to ensure we are sending a consistent message to staff. This is also a good opportunity to communicate with staff the deadlines for compliance.

- Supervisors and leadership should encourage vaccination amongst their staff and ensure they
 have provided the supporting documentation to ORS if they have been vaccinated outside of
 NIH
- Supervisors may ask if an employee is vaccinated
- Supervisors and leadership should refer staff to previous all staff emails from Dr. Collins about vaccinations as well as the 9/29 email from "OMSCovidVaccineProgram" (below) for information about processes related to requirements/POCs
- Supervisors may not ask why an employee is not vaccinated; however, if an employee offers information that could lend itself to the accommodation process, supervisors should provide the employee with the resources outlined in the below 9/29 email
- Supervisors should not provide medical guidance or advice, but rather refer staff to their medical professional for questions
- Supervisors should remind staff of vaccine deadlines and that in order to be in compliance with the November 22 deadline, the final vaccine dose must be received by November 8
- Supervisors should refer staff to the COVID-19 <u>Safer Federal Workforce Task Force</u> for more information
 - The <u>Vaccinations FAQ</u> page lists updated information on deadlines, documentation, limited exceptions, enforcement, and more

If you have qu	uestions, (contact v	our NIAID	Employ	ree and	Labor I	Relations	point of	contact:
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•	• For OD and extramural divisions, Adrienne Saunders: (b)(6)
	(b)(6)
	• For intramural divisions, Christine Hathway: (b)(6)

Note: Do not reply to this email. Replies will be sent to an email box that is not monitored.

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-----Original Message-----

From: NIAID News and Information (NIH/NIAID) (b)(6)

Sent: Thursday, September 30, 2021 10:40 AM

To: NIAID Training SUP (b)(6)

Subject: Supervisory Guidance for COVID-19 Vaccine Requirements for NIH Staff
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NIAID Supervisors,

As mentioned in the NIH-wide email below, NIH employees are required to be fully vaccinated by November 22, and a process has been established for staff who were not vaccinated at NIH to submit their vaccination information.

It is critical that NIAID staff respond to this mandate in a timely manner, so please encourage your staff to submit their proof of vaccination to OMS before the deadline. Also, please do not review or handle requests for exemptions; instead, have staff submit any exemption requests to OMS using the process below.

If you have questions, contact NIAID Emergency Coordinator.

Thank you, Jill

Jill R. Harper, Ph.D.
Deputy Director for Science Management, and
Executive Officer
NIAID/NIH/DHHS
Bldg. 31, Room 7A24, MSC 2520
Bethesda, MD 20892-2520

```
-----Original Message-----
From: OMSCovidVaccineProgram (b)(6)
Sent: Wednesday, September 29, 2021 9:09 AM
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To:	(b)(6)

Subject: Update on COVID-19 Vaccine Requirements for NIH Staff

NIH is committed to keeping all staff apprised of the federal mandatory COVID-19 vaccination requirements as information comes available. All NIH staff, including employees, contractors, trainees, volunteers and tenants will be required to be fully vaccinated with a COVID-19 vaccine, unless approved for a medical or religious exemption by NIH.

A person is considered fully vaccinated 2 weeks after their final dose. Accepted vaccines are those approved or authorized for emergency use by the Food and Drug Administration (Pfizer, Janssen/Johnson & Johnson and Moderna), those approved by the World Health Organization (https://extranet.who.int/pqweb/vaccines/covid-19-vaccines), or a full vaccine series (not a placebo) in a clinical trial (e.g., Novavax). Proof of vaccination can be your CDC vaccination card, or documentation from the immunization system or your provider. If you lost your card, visit this CDC website for help in locating your vaccination documentation: https://www.cdc.gov/vaccines/programs/iis/contacts-locate-records.html.

Information about the requirements and important dates are provided below by staff type – NIH Federal Employees and Other NIH Staff.

NIH FEDERAL EMPLOYEES

NIH federal employees are required to be fully vaccinated with a COVID-19 vaccine by November 22, 2021, unless approved for a medical or religious exemption by NIH. This means federal employees must receive the last shot of the series no later than November 8, 2021, to meet the fully vaccinated requirement by November 22, 2021. This requirement applies to all NIH federal employees, including those working onsite at an NIH facility, maximum telework and remotely. New NIH federal employees who start their tour of duty after November 22, 2021, will need to be fully vaccinated prior to their start date unless approved for a medical or religious exemption by NIH.

Vaccinated at NIH

Federal employees (including Public Health Service Commissioned Corps Officers) who were fully vaccinated at NIH do not need to take any action at this time as NIH has a record of your vaccination. Federal employees who received a partial vaccination at NIH (one dose in a two-dose series) are not considered fully vaccinated. If you still need your second dose, you can schedule an appointment at NIH. If one of your two doses was received in the community, that dose must be reported to NIH. Please follow the instructions in the 'Vaccinated in the Community' section of this email.

Vaccinated in the Community

Federal employees (including Public Health Service Commissioned Corps Officers) who were fully vaccinated in the community (not at NIH) and previously submitted an online vaccination form will receive an email from "OMSCovidVaccineProgram" with a unique link (only to be used by the recipient of the email) to update your information and submit your proof of vaccination as part of the new requirements. If you do not receive an email by October 1, 2021, you may use the link to the Vaccination Status form to submit this information: https://ors.od.nih.gov/Pages/report-vaccination-received.aspx.

Federal employees (including Public Health Service Commissioned Corps Officers) who were fully vaccinated in the community and did not submit an online vaccination form will need to upload proof of vaccination and complete the Vaccination Status form: https://ors.od.nih.gov/Pages/report-vaccination-received.aspx.

Proof of vaccination must be submitted and received in the system no later than November 22, 2021.

Get Vaccinated

Federal employees (including Public Health Service Commissioned Corps Officers) who have not received a COVID-19 vaccine or received one dose of a two-dose series at NIH can still get vaccinated at NIH by appointment. You can schedule an appointment at NIH in three ways:

- 1) Register and schedule online (https://clinweb.cc.nih.gov/cct).
- 2) Call 301-480-8990 (press 4) to speak to an NIH Occupational Medical Service (OMS) staff member (Interpretive services are available).
- 3) Email OMSCOVIDVaccineProgram@mail.nih.gov.

You also can get vaccinated in your community by going to https://www.vaccines.gov or texting your zip code to 438829, which will return the three closest vaccination sites near you. If you are vaccinated in the community, you will need to report it to NIH (see 'Vaccinated in the Community' above).

Requesting a Medical or Religious Exemption

Federal employees (including Public Health Service Commissioned Corps Officers) may request a medical or religious exemption to this mandate in the Vaccination Status form (https://ors.od.nih.gov/Pages/report-vaccination-received.aspx); those requests will be rigorously reviewed. After a federal employee submits a request for exemption, they will be contacted once the details of the process are finalized. Federal employees denied a religious or medical exemption who refuse to be vaccinated or provide proof of vaccination by November 22, 2021, may face disciplinary action up to and including removal from federal service.

OTHER NIH STAFF

Based on implementation requirements, contractors and other NIH staff (trainees, volunteers and tenants) will be asked to provide vaccination information (including possible requests for medical or religious exemption) at a later date. Covered contract employees must be fully vaccinated no later than December 8, 2021. This means contractors must receive the last shot of the series no later than November 24, 2021, to meet the fully vaccinated requirement by December 8, 2021. Additional information regarding contracts will be forthcoming. Contractors who were vaccinated at the NIH may be asked by their employers to provide documentation to verify vaccination. Misplaced vaccination cards can be downloaded from the Clinical Center Follow My Health App. Contractors should contact their employers or Contracting Officer Representatives (COR) with questions.

Contractors, trainees, volunteers and tenants who have not been vaccinated are strongly encouraged to get vaccinated. Please follow the instructions in the 'Not Yet Vaccinated' section above.

ADDITIONAL RESOURCES

More information about federal vaccination requirements is available on the following sites:

- * NIH Vaccination Requirements: https://employees.nih.gov/pages/coronavirus/vaccination-requirements.aspx
- * Safer Federal Workforce Overview: https://www.saferfederalworkforce.gov/overview/
- * Safer COVID Federal Workforce FAQs: https://www.saferfederalworkforce.gov/faq/vaccinations/

Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6)
(b)(6)

Recipient:
Strasburg, Jenny <jenny.strasburg@wsj.com>

Sent Date: 2021/10/19 15:38:01

	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
To:	Strasburg, Jenny <jenny.strasburg@wsj.com></jenny.strasburg@wsj.com>
Subject:	FW: Acknowledgement - Exception Request
Date:	2021/10/18 14:44:05
Priority:	Normal
Туре:	Note

The latest (see below)

Matthew J. Memoli, M.D., M.S. Director, LID Clinical Studies Unit Laboratory of Infectious Diseases National Institute of Allergy and Infectious Diseases National Institutes of Health MSC 3203 33 North Dr Bethesda, MD 20892-3203

UNITED STATES

Email: (b)(6) Phone: (b)(6) Pager: (b)(6)

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From: "edi.ra" (b)(6)

Date: Monday, October 18, 2021 at 1:52 PM

To: "Memoli, Matthew (NIH/NIAID) [E]" (b)(6)

Subject: Acknowledgement - Exception Request

Good afternoon,

OMS has indicated that you have requested an exception to the COVID-19 vaccination mandate. You are, therefore, in the exception process. No action is needed from you at this time. While you are in the exception process, you will not be required to meet the November 22, 2021, vaccination deadline.

Title VII of the Civil Rights Act mandates that employers must make accommodations for an employee's disabilities and religious beliefs, as long as the accommodation does not impose an undue hardship on the employer. All religious and medical exception requests will be considered, analyzed, and determined on a case-by-case basis and in accordance with HHS, the EEOC and OMB guidelines. Processing guidelines are forthcoming from HHS; we respectfully request your patience and will notify you once we have received them.

Please be assured your <u>exception request</u> will be processed in a timely manner and consistent with the guidelines. At this time, we do not need you to submit any statements or supporting documentation. Once we receive the HHS processing guidelines, you will receive further information about applicable requirements.

For additional federal guidance, review the <u>Safer Federal Workforce Task Force Vaccination FAQs</u> and <u>What you should know about COVID19 and the ADA, Rehab Act and other EEO laws.</u> If you have any further questions please email us at (b)(6)

Thank you for your patience.

Access and Equity Branch (A&E)

Division of Guidance, Education, and Marketing (GEM) Office of Equity, Diversity, and Inclusion (EDI) National Institutes of Health (NIH) 2 Center Dr., 3d Floor Bethesda, Maryland 20892

Website: edi.nih.gov Twitter: @nih edi Instagram: @nih edi YouTube: EDI Standard

Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group

Sender: (FYDIBOHF23SPDLT)/cn=Recipients/cn=4d3af4d9f3e54fbc80ddd844c16691cc-memolim

(b)(6)

Recipient: Strasburg, Jenny <jenny.strasburg@wsj.com>

Sent Date: 2021/10/18 14:44:05

From:	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
То:	(b)(6)
Subject:	Re: Reasonable Accommodation Information
Date:	2021/10/18 11:18:00
Priority:	Normal
Туре:	Note

yes

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Matthew J. Memoli, M.D., M.S. Director, LID Clinical Studies Unit Laboratory of Infectious Diseases National Institute of Allergy and Infectious Diseases National Institutes of Health MSC 3203 33 North Dr Bethesda, MD 20892-3203

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From: (b)(6)

Date: Monday, October 18, 2021 at 11:17 AM

To: "Memoli, Matthew (NIH/NIAID) [E]" (b)(6)

Subject: Re: Reasonable Accommodation Information

I got more for ya

Can I call? I actually need some advice - Covid related

From: "Memoli, Matthew (NIH/NIAID) [E]" (b)(6) Date: Monday, October 18, 2021 at 11:15 AM	
To: (b)(6)	
Subject: Re: Reasonable Accommodation Information	
Well that is just silly now isn't it. A completely unnecessary mandate causing everyone grief. This authoritarian approach to medicine is unethical and unscientific.	
Matt	
Matthew J. Memoli, M.D., M.S.	
Director, LID Clinical Studies Unit	
Laboratory of Infectious Diseases	
National Institute of Allergy and Infectious Diseases National Institutes of Health	
MSC 3203 33 North Dr	
Bethesda, MD 20892-3203	
UNITED STATES	
Email: (b)(6)	
Phone: (b)(6) Pager: (b)(6)	
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on behalf of NIAID.	
From: (b)(6)	
Date: Monday, October 18, 2021 at 11:13 AM	
To: "Memoli, Matthew (NIH/NIAID) [E]" (b)(6)	
Subject: Re: Reasonable Accommodation Information	
Not a typo – (b)(6) got the same date	
x	
HR Pulse (b)(6)	10:22 AM (49 m

me

to (b)(6)

Hi (b)(6)

At this time, our current guidelines have approval up to October 25th. We wish we had more information that we could share with you. Currently, we are continuing to monitor recommendations from government and health officials as guidance is changing frequency. Please monitor the company wide communications as well as the COVID-19 FAQs on the company website.

We appreciate your patience.

Human	Resources	Team
(b)(6)		

From: "Memoli, Matthew (NIH/NIAID) [E]" (b)(6)
Date: Friday, October 15, 2021 at 12:18 PM
To: (b)(6)
Subject: Re: Reasonable Accommodation Information
That's strange. Maybe they mean 2022? Check with them\
Matt
Matthew J. Memoli, M.D., M.S.
Director, LID Clinical Studies Unit
Laboratory of Infectious Diseases
National Institute of Allergy and Infectious Diseases
National Institutes of Health

Bethesda, MD 20892-3203 UNITED STATES

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Email: (b)(6)

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From: (b)(6)

Date: Friday, October 15, 2021 at 12:08 PM

To: "Memoli, Matthew (NIH/NIAID) [E]" (b)(6)

Subject: FW: Reasonable Accommodation Information

2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	7	7	7	7)

- (/L)(/C)
From: (b)(6)
Date: Friday, October 15, 2021 at 12:06 PM
To: (b)(6)
Subject: Fwd: Reasonable Accommodation Information
Forwarded message
From: (b)(6)
Date: Fri, Oct 15, 2021 at 12:04 PM
Subject: Reasonable Accommodation Information
To: (b)(6)
10.
From: HR Pulse (b)(6)
Sent: Thursday, October 14, 2021 11:23 AM
Subject: Reasonable Accommodation Information
(b)(6)

Your request to be exempt from receiving the vaccine has been approved through October 25, 2021 as long as the customer you support approves remote/telework for your role and you satisfactorily perform the full responsibilities of your position. Should you be asked to report to a company office site or government facility, you must adhere and comply with all safety measures including mask wearing, social distancing and receipt of a negative Covid test result within 3 days of reporting to that location. You must also have your vaccination attestation with you at all times while at a government facility.

You will also be required to complete a new accommodation form prior to October 26, 2021 for consideration.

Respectfully,	
(b)(6)	HR Department
Sender:	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
Recipient:	(b)(6)
Sent Date:	2021/10/18 11:18:00

From:	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
То:	(b)(6)
Subject:	Re: Letter for(b)(6)
Date:	2021/10/15 08:52:47
Priority:	Normal
Туре:	Note

I edited the documents for you. I shortened the exemption letter a bit. All the congressional investigation stuff and case law makes it seem to much like someone else wrote it for you. Better to leave that out and focus on the religious aspect and make it seem more personal. That way they can't question your sincerity.

Matt

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Matthew J. Memoli, M.D., M.S.
Director, LID Clinical Studies Unit
Laboratory of Infectious Diseases
National Institute of Allergy and Infectious Diseases
National Institutes of Health
MSC 3203 33 North Dr
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Email: (D)(6)

Email:	(b)(6)	
Phone:	(b)(6)	
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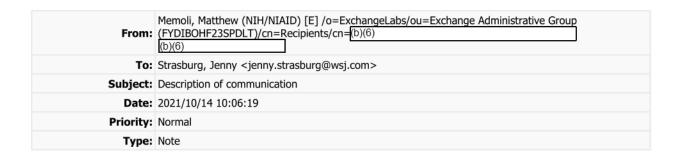
From: (b)(6)
Date: Friday, October 15, 2021 at 8:17 AM
To: "Memoli, Matthew (NIH/NIAID) [E]" (b)(6)
Subject: Letter for (b)(6)

Good morning Dr. Memoli,

Whenever you have time can you please review the 2 documents attached to this email please. I have copied/pasted the letter you have sent me and also I have added additional content (in blue) for your edits.

Thank you so much helping me to draft this letter and hopefully they will accept my request.

(b)(6)		
Sender:	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)	ıp
Recipient:	(b)(6)	
Sent Date:	2021/10/15 08:52:47	



Hi Jenny,

This is what I discussed in my communication

"Good morning,

I wanted to reach out to you regarding recent decisions and statements made in response to SARS-COV-2 virus pandemic by NIH, CDC, and the administration. I realize the enormous pressures that all of you have faced, and I would like to continue to be as helpful as possible in our efforts in dealing with this crisis. Therefore, I feel it is important that I attempt to briefly raise one of the major concerns that I have at this time.

I have been studying intra-host viral evolution of RNA respiratory viruses as a core part of my research since 2007, and from my experience and understanding of the current data and biology; the current strategies of mass and mandated vaccination is extraordinarily problematic, practically unrealistic, and possibly detrimental.

Variants of RNA respiratory viruses as you know are to be expected, but they only become dominant if the mutation gives the virus a fitness advantage. Early in pandemics the mutations that take hold are ones that adapt the virus to humans giving the virus a replicative advantage. As you are fully aware we saw this happen very rapidly during the first months of the pandemic. A year later in this late/post-pandemic period we now have variants taking hold that are not simple human adaptation but are a response to immunity. These variants do not emerge in the naïve or unvaccinated but emerge in response to people with waning immunity, those who have been previously infected or vaccinated. They can then infect the naïve and spread, but they emerged from those who were immune not

the unvaccinated naïve. This was also to be expected based on everything we know from RNA respiratory virus pandemics/epidemics of the past.

Vaccinating the naïve does nothing to stop the spread of these variants because you are always playing catch-up. In fact, it is possible that by vaccinating the naïve you are simply further selecting for these variants which will have an unknown effect on the trajectory of the viral evolution. Under no man-made selection pressures viral evolution will drive the virus to become more replicative and less dangerous to humans. This is simple selection and logic. The virus wants to replicate, and it can't replicate and spread if humans are dead or in an ICU. Therefore, as in all past pandemics the viruses slowly change, become human adapted to become more contagious, but less deadly. 1918 influenza is a perfect example of that as there was no man-made pressures at that time and the virus mutated, adapted to natural immunity through antigenic drift and circulated until 1957 with a far lower mortality rate than during the 1918 pandemic. Natural immunity driving viral evolution and the invention of good supportive care such as the invention of antibiotics improved the situation, not a vaccine.

In this case we are making certain mistakes that have been made with influenza vaccination for the last few decades. We have a single antigen vaccine strategy inducing limited immunity that is effective for a time in many, but then offers an opportunity for the virus to evolve to evade this immunity as it wanes. The only way this type of vaccine strategy might work to stop a pandemic is if you are able to vaccinate every person on earth at the exact same time (within days) with a nearly 100% effective vaccine in all people, something that is completely unrealistic. Otherwise, you have a situation where people have waning immunity at different times and the virus is able to evolve and evade immunity.

At best what we are doing with mandated mass vaccination does nothing and the variants emerge evading immunity anyway as they would have without the vaccine. At worst it drives evolution of the virus in a way that is different from nature and possibly detrimental, prolonging the pandemic or causing more morbidity and mortality than it should. There is evidence that yearly flu vaccination has done this during certain years, and further study is necessary. Either way coercing or forcing people to take a vaccine can have negative consequences from a biological, sociological, psychological, economical, and ethical standpoint and is not worth the cost even if the vaccine is 100% safe.

A more prudent approach that considers these issues would be to focus our efforts on those at high risk of severe disease and death, such as the elderly and obese, and do not push vaccination on the young and healthy any further. This uses the vaccine for maximum benefit to reduce morbidity and mortality while limiting the effect you are likely having on natural evolution of the virus and development of a more robust immunity in the population. You also do not lose political capital and trust of the public as has been happening with the current strategy. In the meantime, our focus should be on two things. The development of treatments for SARS-COV-2 and SIRS/sepsis as well as developing more broadly protective beta-coronavirus vaccines that use multiple antigen strategies inducing not only antibodies against a single antigen, but against multiple antigens as well as inducing mucosal, cellular, and other forms of immunity more like the response one has to a full infection. Vaccines such as this would likely be far more effective in these situations and need to be aggressively pursued. Jeff Taubenberger and I have been working on this and I know others are as well. In addition, I believe that the new mandates are a major mistake and should be rescinded immediately. This will not do any good and will cause biological and/or social harm to the medical community and our country as a whole.

I am happy to discuss this further or offer my thoughts and expertise at any time. Thank you for considering this and I hope you take it into account as you discuss the current response with the CDC and current administration."

__

Matthew J. Memoli, M.D., M.S.
Director, LID Clinical Studies Unit
Laboratory of Infectious Diseases
National Institute of Allergy and Infectious Diseases
National Institutes of Health
MSC 3203 33 North Dr
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Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group

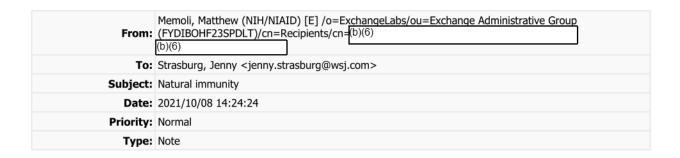
(FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6)

(b)(6)

Recipient: Strasburg, Jenny < jenny.strasburg@wsj.com>

Sent Date: 2021/10/14 10:06:17

Delivered Date: 2021/10/14 10:06:19



Jenny,

Please remember when you think or write about this topic that we are talking about vaccine induced immunity from the current vaccines, the two mRNA vaccines as well as JnJ and Astrazeneca. So we should always be clear that we are comparing immunity from those vaccines to natural infection. There are other vaccine strategies that could offer better immunity than natural immunity, but those are not currently available even though some could have been if pursued as vigorously as the current strategies. So everything below does not necessarily apply to all vaccines that could exist for COVID in the future.

Attached is the best clinical study that has been published at all on this topic. It is still a pre-print and there really is nothing else. CDC has some studies they claim show better immunity from vaccines, one that talks about how vaccines give higher levels of antibodies and another with some Kentucky Data showing people previously infected were 2X as likely to be reinfected than people who were previously infected and then vaccinated

https://www.cdc.gov/mmwr/volumes/70/wr/mm7032e1.htm?s cid=mm7032e1 w . However, there are significant problems with their studies: 1. High levels of antibodies against a single protein does not equal protection and it ignores the fact that although natural immunity may induce slightly lower levels of Spike RBD antibodies than vaccine it is inducing other types of Spike antibodies, nucleocapsid antibodies, T-cells with a whole host of T-cell antigens, all of which the vaccine can't do. Then there is the key issue of mucosal immunity and memory, again which the vaccine does not do 2. As for the Kentucky data they are ignoring the time issue. They are not comparing groups that are equivalent and sadly the CDC did not do this study properly showing some lack of understanding of respiratory viruses and immunity. You have to match the time from infection and the time from vaccination in the two groups to compare natural and vaccination immunity. You can't compare someone with natural immunity who was boosted with vaccine recently to someone naturally infected 6 months ago or more. Of course the vaccine boost protected them for some time, but if you look at them 6 months later it may be a different story and that slight benefit they showed would likely disappear based on all the data we have now showing how vaccine induced immunity from these vaccines fades. This is the problem with boosters with this type of vaccine. It is just a short term band-aid delaying the inevitable infections which you likely need to really have longer term immunity.

The most conservative view of this would be that there is no strong data to suggest either natural or vaccine immunity is better than the other, but there are some concepts in respiratory virus science that do suggest that natural immunity is likely better long term than these vaccines and there is no question in my mind that receiving a natural virus infection and having your immune system encounter the entirety of the virus at the site of infection is going to offer better long-term protection than just receiving a single antigen systemically. Many of these concepts and data I discussed in previous

emails. Original antigenic sin, having more antigens being presented, and mucosal immunity being more durable and protective. So if you haven't looked at all the papers I previously sent and those emails please do. Having said that we all need to realize and accept that respiratory virus infections do not offer long term sterilizing protection from infection and this is a significant problem we face. We all have numerous RSV, coronavirus, influenza and other respiratory virus infections in our lifetime. I even published a study showing I could infect people twice with the same influenza virus https://academic.oup.com/cid/article/70/5/748/5429562 within a year Ultimately this is a complicated topic with no simple answers and needs much more research to fully understand what protects people from COVID and if we can even achieve good protection. This takes time and significant effort. We have been trying to understand this with influenza for 100 years and we still have a vaccine that is only 10-60% effective depending on the year.

--

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(b)(6)

Strasburg, Jenny <jenny.strasburg@wsj.com>

Sent Date:

Delivered Date:

2021/10/08 14:24:24

From:	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
То:	(b)(6)
Subject:	Re: Accommodation form
Date:	2021/10/08 08:25:51
Priority:	Normal
Туре:	Note

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From: (b)(6)

Date: Friday, October 8, 2021 at 7:42 AM

To: "Memoli, Matthew (NIH/NIAID) [E]" (b)(6)

Subject: Accommodation form

From: (b)(6)

Sent: Thursday, October 7, 2021 1:20:07 PM

To:(b)(6)
Subject: A Company Message on Behalf of (b)(6)
This message is being sent on behalf of (b)(6)

Team,

As mentioned a few weeks ago, the President announced a <u>COVID-19 Action Plan</u> consisting of a six-pronged strategy to ensure the country uses every available tool to combat COVID-19, save lives, keep schools open, and protect the economy. Most recently, the Safer Federal Workforce Task Force published further details and guidance, "<u>COVID-19 Workplace Safety: Guidance for Federal Contractors and Subcontractors</u>," on September 24.

Based on the above guidance, as a Covered Contractor, we must comply with the following:

- All covered contractor employees are fully vaccinated for COVID-19 unless the employee is legally entitled to an accommodation. Covered contractor employees must be fully vaccinated no later than December 8, 2021.
- All individuals, including covered contractor employees and visitors, comply with published CDC guidance for masking and physical distancing at a covered contractor workplace.
- Designate a person or persons to coordinate implementation of and compliance with this Guidance and the workplace safety protocols detailed herein at covered contractor workplaces.

What does this mean for pemployees? All pemployees? All pemployees will need to be fully vaccinated by December 8, 2021, regardless of work location. All employees support an aspect of our federal contracts and, therefore, will be required to observe this guidance. Anyone that would like to request a medical or religious exemption will need to complete the ADA Accommodation Request Form located on the ADP website home screen for consideration.

Since individuals are considered fully vaccinated for COVID-19 two weeks after they have received the second dose in a two-dose series, or two weeks after they have received a single-dose vaccine, to meet the December 8 deadline, individuals will need to receive their vaccinations by the following dates:

- • Moderna First-dose deadline October 27; the second-dose deadline November 24.
- • Pfizer-BioNTech First-dose deadline November 3; the second-dose deadline by November 24.
- • J&J First (only) dose deadline November 24.

We are evaluating best practices for collecting individual vaccination information and will share more details in the coming weeks on how employees should submit their personal vaccination information to ensure compliance with the President's Executive Order.

We understand there may be questions or concerns, so we have added a new section of FAQs specific to this new guidance on our <u>COVID-19 FAQs</u> under "Vaccination Requirements." You can also visit the <u>CDC's COVID-19 guidance</u> regarding masking policies. For questions not answered in the FAQs, reach

out to your manager or the COVID-19 Response Tea	ım at (b)(6)
or (b)(6)	
Thank you for your understanding and coopera information on this topic as it becomes available.	ation. We will continue to share any additional
(b)(6)	

Sender:	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
Recipient:	(b)(6)
Sent Date:	2021/10/08 08:25:52
Delivered Date:	2021/10/08 08:25:51

From:	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
То:	Taylor, Holly (NIH/CC/BEP) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
CC:	Wendler, Dave (NIH/CC/BEP) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
Subject:	Re: Consult
Date:	2021/10/07 10:53:10
Priority:	Normal
Туре:	Note

Thanks

--

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From: "Taylor, Holly (NIH/CC/BEP) [E]" (b)(6)

Date: Thursday, October 7, 2021 at 10:52 AM

To: "Memoli, Matthew (NIH/NIAID) [E]" (b)(6)

Cc: "Wendler, Dave (NIH/CC/BEP) [E]" (b)(6)

Subject: RE: Consult

Hi Matt:

My assumption was this was exactly what you would share in your case presentation. The scientific evidence as you see it in reference to COVID vaccination.

I have cc'ed Dave Wendler who as you know has the lead on the session.

Holly

Holly Taylor, PhD, MPH
Department of Bioethics
Clinical Center
National Institutes of Health
(b)(6)

(b)(6)

From: Memoli, Matthew (NIH/NIAID) [E]

Sent: Thursday, October 7, 2021 10:45 AM **To:** Taylor, Holly (NIH/CC/BEP) [E] (b)(6)

Subject: Re: Consult

Hi Holly,

I am interested in this as I would like it to be evaluated, but not in general as a concept. I would like these specific vaccines being mandated for this specific disease to be evaluated taking into account the data we have that there is limited durability of protection of 3-6 months as demonstrated by a number of recent publications including in NEJM today

(https://www.nejm.org/doi/full/10.1056/NEJMoa2114583?query=TOC&ssotoken=U2FsdGVkX1%2BEvtf DXVN%2FiTQtQedBgy6DD5dphascXXRBD9RVD6%2BhqpupRQyk%2FbsXfixTfl0VTTfaThotzKDGVzNVi%2B uAE8TXWHyyeGDBD%2BkOcZqdMnM5lbPqsvnD1VJAlejAQobd4XdilthLfxZGHInJVpbz6Z19rEglp6%2Fg9p w8Wa3EnSsagESQKe7PYKIfltoWVnsxXnAX%2BY1Yy7UXbQ%3D%3D&cid=NEJM%20eToc,%20October%2 07,%202021%20DM356093 NEJM Non Subscriber&bid=643692261) and that people who receive the vaccine after 12 weeks are just as likely to spread the disease as those who are unvaccinated (https://www.medrxiv.org/content/10.1101/2021.09.28.21264260v1). There is also the safety issue with 2.13 out of every 100,000 people developing myocarditis, a single side effect nearly as common as death from COVID in younger age groups

(https://www.nejm.org/doi/full/10.1056/NEJMoa2110737?query=TOC&cid=NEJM%20eToc,%20October %207,%202021%20DM356093 NEJM Non Subscriber&bid=643692261)making a risk vs. benefit discussion important. There are also issues related to original antigenic sin and single antigen strategy not providing protection in future pandemics as people get older as I described in my email to Dr. Fauci. I believe all of these things need to be taken into account when considering if mandating these vaccines could be doing more harm than good.

So my question is, can and will an evaluation be done that will take into account the data we have and considering how these vaccines are being used, or will it simply be a discussion of if vaccine mandates are ethical? I am still interested in Bioethics thoughts on the second question, but am particularly interested in the bioethics of a mandate when the vaccine doesn't have the ability to stop spread of disease which is the purpose of the mandate.

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From: "Taylor, Holly (NIH/CC/BEP) [E]" (b)(6)

Date: Thursday, October 7, 2021 at 10:12 AM

To: "Memoli, Matthew (NIH/NIAID) [E]" (b)(6)

Subject: Consult

Matt:

I just want to check in with you as to whether you want to initiate a bioethics consult on the topic of vaccine mandates. Just let me know and I can forward to the faculty/fellow on call.

Holly

Holly Taylor, PhD, MPH
Department of Bioethics
Clinical Center
National Institutes of Health
(b)(6)
(b)(6)

Sender:	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
Recipient:	Taylor, Holly (NIH/CC/BEP) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=[b)(6) [b)(6)

Wendler, Dave (NIH/CC/BEP) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6)

Sent Date: 2021/10/07 10:53:11 **Delivered Date:** 2021/10/07 10:53:10

From:	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
To:	(b)(6)
Subject:	Re: Natural Immunity / Mandatory Vaccine
Date:	2021/10/06 15:38:14
Priority:	Normal
Туре:	Note

Hello^{(b)(6)}

Although I greatly appreciate your situation, in my current capacity as a researcher at NIH I am unable to provide you with testing and medical care as you desire. I will suggest that given the complications you had after suffering from COVID that you discuss with your physician that the immune response to the vaccine could trigger similar symptoms if they were immune mediated. Given that you now have robust natural immunity and the consequences of vaccination in this circumstance are unknown, it seems reasonable for your physician to write you a letter asking for a medical exemption from the vaccine mandate. I do not think you need a "battery of tests". I am sorry you are going through this. Please know that not all physicians and scientists agree on the mandates and that I for one believe that vaccination should be a personal choice based on your own informed decisions of risk and benefit.

--

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From: (b)(6)

Date: Wednesday, October 6, 2021 at 2:37 PM

To: "Memoli, Matthew (NIH/NIAID) [E]" (b)(6)	
Subject: Natural Immunity / Mandatory Vaccine	

Good day sir.

I am a healthy 55 year old black female who resides in the state of New Jersey.

I had COVID November 2020 and fully recovered.

I had a number of cardio related issues that miraculously disappeared, fraction was at 38%, pvc's were at 14k per hour. And other medical issues - benign adenoma of the liver that grew to the size of a large grape fruit, benign uterus fibroid.

I am being mandated to be vaccinated though my IgG and IgA have not dropped. I do understand there are other considerations such as the T-cells that I believe memorize antibodies.

I am looking for a doctor who would consider my individual state, conduct a a battery of tests to determine if I indeed can be excluded from taking the vaccination.

Please advise if you are able to provide that information.

I need to know asap.

Thank vou (b)(6) (b)(6) NJ	
For His Glory -(b)(6)	
Sender:	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
Recipient:	(b)(6)
Sent Date:	2021/10/06 15:38:15
Delivered Date:	2021/10/06 15:38:14

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From:	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
То:	Taylor, Holly (NIH/CC/BEP) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
Subject:	Re: Vacine mandates
Date:	2021/10/05 08:22:36
Priority:	Normal
Туре:	Note

Thank you Holly,

I am not the only one. I have had at least 4 other employees tell me similar stories. One was in the emergency room due to a panic attack.

Matt

--

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From: "Taylor, Holly (NIH/CC/BEP) [E]" (b)(6)

Date: Tuesday, October 5, 2021 at 7:41 AM

To: "Memoli, Matthew (NIH/NIAID) [E]" (b)(6)

Subject: RE: Vacine mandates

I am sorry this issue is causing you and your family so much distress.

Holly Taylor, PhD, MPH
Department of Bioethics
Clinical Center
National Institutes of Health
(b)(6)
(b)(6)

From: Memoli, Matthew (NIH/NIAID) [E] Sent: Monday, October 4, 2021 10:15 AM

To: Taylor, Holly (NIH/CC/BEP) [E] (b)(6)

Subject: Re: Vacine mandates

Thanks Holly,

So for our DC licenses and for her before exemption they offered medical and religious exemptions. The medical ones required a very specific diagnosis that is a clear contraindication of which there are very few. There should be more, but what is being accepted are very few. We applied for religious exemptions based on our beliefs which I could explain, but you may not need that verbosity now. Long and short of it is that I believe based on my faith that I must do what is moral, ethical, and right for myself and others. I believe strongly that the vaccine mandate is unethical and that the vaccines themselves in how they are being used may be doing more harm than good when it comes to dealing with the pandemic based on my own analysis of the data as a 17 year expert in respiratory virus infections. My wife has her own reasons.

Anyway it has been reported in the news that DC has rejected the first 20 religious exemptions they reviewed and I believe that Dr. Fauci on TV over the weekend was basically telling these groups and giving them an excuse not to accept religious exemptions. So we are expecting to be rejected. If rejected my wife will lose her job having a devastating effect on us and her patients. In the meantime the Federal Government have given me (and everyone else here) no clear information on how to apply for an exemption and when I ask questions I get the runaround and told they are waiting to figure this out. Needless to say we are not optimistic right now. Neither of us will get vaccinated. Speaking for myself I believe I have a God given right to autonomy in this circumstance and there I clearly no moral or ethical imperative to get this particular vaccine. As a physician and scientist I believe as I wrote in my email to Dr. Fauci that using these vaccines properly could be helpful, but what they are doing with them is incorrect and will lead to at best no benefit and at worst doing harm. I also find Dr. Fauci making personal statements about individual freedoms to be highly unethical as a leader of a major U.S. government organization that has taxpayers of all stripes paying his salary. He has been behaving exactly as I was taught not to behave as a physician in medical school, a judgmental, paternalistic, and aloof physician.

While all of this is going on Dr Collins and the HHS secretary send out insulting and hypocritical emails nearly daily on how they want to have a safe workplace, with equality, and diversity. Then today with "Taking care of your well-being". Well I am trying to do that, but apparently nobody in the hierarchy really cares about our well-being or diversity. They just want to force vaccination. I have multiple other employees who work with me or for me contacting me with similar concerns asking for advice. They are scared to speak up and quietly have supported my more vocal approach. This has created a very

unpleasant working environment and I have considered contacting the CIVIL office. I just assume they won't take me seriously.

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From: "Taylor, Holly (NIH/CC/BEP) [E]" (b)(6)

Date: Monday, October 4, 2021 at 9:57 AM

To: "Memoli, Matthew (NIH/NIAID) [E]" (b)(6)

Subject: RE: Vacine mandates

Matt:

I don't mind hearing from you. When we spoke about your wife's situation you had not yet heard whether there were medical exceptions to the vaccine mandate. I will assume by your email that no exceptions are allowed?

Holly

Holly Taylor, PhD, MPH **Department of Bioethics** Clinical Center National Institutes of Health

(b)(6)	
(b)(6)	

From: Memoli, Matthew (NIH/NIAID) [E]
Sent: Monday, October 4, 2021 9:21 AM
To: Taylor, Holly (NIH/CC/BEP) [E] (b)(6)

Subject: Vacine mandates

Holly,

As Dr. Fauci spent the weekend on TV stating that people should no longer have personal freedom to make medical decisions and that he knows more about their religion than they do (https://www.cnn.com/videos/politics/2021/10/03/sotu-dr-fauci-religion-vaccine-dana-bash.cnn) the attached study was released. As you can see in the line I highlighted in the results the vaccine effectiveness at preventing spread dropped off within 12 weeks from both Pfizer and the Astrazeneca vaccine. Again this demonstrates that the vaccine mandates intended to stop spread or "protect the vaccinated from the unvaccinated" as the President suggested does not do what they wish it did, showing there is no ethical justification for forced vaccination. All of the data show that within 3-6 months vaccinated people can spread the virus, get sick with the virus, become hospitalized with the virus, and die from the virus at the exact same rate as those who are unvaccinated. I am sorry Holly, but I don't understand how the NIAID director can just independently say these things without some sort of oversight. I don't understand how more people aren't up in arms about the ethics of all of this. I have had to get ethics reviews before I did simple things that affected 2 people. His statements, decisions, and advice affects millions. My wife is about to lose her medical license and job because of his statements. I have lost all faith in NIAID and NIH's ability to handle things properly. It is very disappointing. Again I am sorry you have been the target of my emails, but I am reaching out in hopes someone can either explain to me what is going on or do something that can make a difference.

Matt

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	Taylor, Holly (NIH/CC/BEP) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
Sent Date:	2021/10/05 08:22:36

From:	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
То:	Taylor, Holly (NIH/CC/BEP) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
Subject:	Sorry last time I annoy you today.
Date:	2021/10/04 17:37:56
Priority:	Normal
Туре:	Note

HI Holly,

If you look at the attached article in the Washington Post, please focus on the comments at the end (original here https://www.washingtonpost.com/dc-md-va/2021/10/02/dc-fire-religious-exemptions-covid-vaccine/). The rhetoric from NIH and CDC has led to what can only be described as hate and bigotry against the unvaccinated. I am devastated by what is happening. You could easily imagine in a different time these types of comments being made about a particular race or religious group. It is quite frightening that this is happening now. These are all human beings trying to make decisions for themselves in this world. And even if we all fall in line and comply, how long before we are required to get a booster and our kids vaccinated? Dr. Fauci has certainly put both of these on the table publicly including requiring boosters and vaccination of children. I fear it is too late for any rational discussion to be had.

Matt

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Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=[b)(6)

Recipient: Taylor, Holly (NIH/CC/BEP) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=[b)(6)

Sent Date: 2021/10/04 17:37:58

Delivered Date: 2021/10/04 17:37:56

From:	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
То:	(b)(6)
Subject:	Re: From the NIH Director: CORONAVIRUS UPDATE: Vaccination Mandate
Date:	2021/10/01 16:40:58
Priority:	Normal
Туре:	Note

Problem is they don't know how we apply for an exemption.

__

Matthew J. Memoli, M.D., M.S. Director, LID Clinical Studies Unit Laboratory of Infectious Diseases National Institute of Allergy and Infectious Diseases National Institutes of Health MSC 3203 33 North Dr Bethesda, MD 20892-3203

UNITED STATES

Email: (b)(6)

Phone: (b)(6)

Pager: (b)(6)

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From: (b)(6)

Date: Friday, October 1, 2021 at 2:58 PM

To: "Memoli, Matthew (NIH/NIAID) [E]" (b)(6)

Subject: FW: From the NIH Director: CORONAVIRUS UPDATE: Vaccination Mandate

This one looks like I (and other contractors) need to request that medical or religious exemption now...so that we can receive the exemption by Dec. 8th.

If I am reading that correctly

From: NIH Executive Secretariat (b)(6)

Date: Friday, October 1, 2021 at 2:43 PM **To:** List NIH-ALL-STAFF (b)(6)

Subject: From the NIH Director: CORONAVIRUS UPDATE: Vaccination Mandate

Dear NIH Family:

I want to focus this email on a topic that is on top of the minds of all our staff — the <u>federal COVID-19</u> <u>vaccination mandate</u>. On Wednesday, the NIH Office of Research Services (ORS) <u>issued an email</u> with more information about this new requirement. This information also can be found on the <u>Vaccination Requirements intranet page</u>. Below is a summary of updates for quick reference, but I encourage you to review the more detailed information.

Federal Employees:

- are covered by the <u>Executive Order</u>, which includes all NIH federal employees. That means employees are required to be fully vaccinated or have an NIH approved medical or religious exemption by November 22, 2021. To meet this deadline, you must receive your last vaccine dose no later than November 8.
- who were fully vaccinated at NIH do not need to take any action at this time, as NIH has a record of your vaccination.
- who were fully vaccinated in the community (not at NIH), can now report proof via the <u>Vaccination Status online form</u>. Thanks to the many of you who have already taken this action.
- who want to request a medical or religious exemption should use the <u>Vaccination Status online form</u> which allows users to check a box for either exemption. Such exemptions will require individual review. HHS is developing guidance on exemptions, and the NIH Equity, Diversity, and Inclusion Office will follow up with those requesting exemptions when that guidance is provided. In the meantime, here is information about <u>COVID-19</u> and <u>Workplace Accommodations</u>.
- who previously reported your vaccination in the community (not at NIH) should have received an email on September 29 from OMSCovidVaccineProgram that included a custom link (just for you) to update your vaccination information and upload documentation.

Contractors:

- who are covered by the <u>Executive Order</u> must be fully vaccinated or have received an NIH-approved medical or religious exemption by December 8, 2021, which means the last dose must be received no later than November 24, 2021.
- who were fully vaccinated at NIH do not need to take any action at this time, as NIH has a record of your vaccination.
- should not report vaccination received in the community to NIH at this time. Additional
 information about required contractor actions, including requests for exemptions, will be
 forthcoming.

<u>Trainees, Volunteers, and Tenants:</u>

• NIH is still determining how the federal vaccination mandate affects trainees, volunteers, and tenants. We will provide more information to these staff as soon as it comes available.

All NIH staff (federal employees, contractors, trainees, volunteers, and tenants) who are not yet vaccinated can <u>schedule a COVID-19 vaccine appointment at NIH</u>.

We will have further information soon about the possibility of booster shots for those who are eligible and were originally immunized more than six months ago with Pfizer. Stay tuned on that one.

As one little science tidbit, I am excited to see today's <u>Phase 3 trial report from Merck and Ridgeback Biotherapeutics that an oral antiviral agent called molnupiravir</u> reduced hospitalizations by 50% when given to high-risk outpatients with a recent diagnosis of COVID-19. (I'm happy to note that molnupiravir was originally developed by NIH-grantee Emory University.) The company plans to submit data soon to the U.S. Food and Drug Administration. If it is truly safe and effective and FDA grants emergency use authorization, it would be great to have an oral medication like this available. But let's be clear — the most important action we can all take right now is to prevent the disease in the first place, and that's what the vaccines do.

We will continue to keep you apprised as we receive additional information about the vaccination mandate. With heartfelt thanks for all you do,

Francis S. Collins, M.D., Ph.D. NIH Director



Sender:	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
Recipient:	(b)(6)
Sent Date:	2021/10/01 16:40:58

From:	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
То:	(b)(6)
Subject:	Re: Update on COVID-19 Vaccine Requirements for NIH Staff
Date:	2021/10/01 13:17:29
Priority:	Normal
Туре:	Note

Looks like you are fine. Plus your deadline isn't until Christmas!

Matt

--

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On 10/1/21, 12:41 PM, (b)(6) wrote:

This is the only email I can find (that I still have) but there is no place for contractors to request and exemption... I'm trying to get a hold of (b)(6) to see if she has anything, because I don't see anything in my (b)(6) emails that give me that option either

On 9/29/21, 9:22 AM, "OMSCovidVaccineProgram" <OMSCovidVaccineProgram@mail.nih.gov> wrote:

NIH is committed to keeping all staff apprised of the federal mandatory COVID-19 vaccination requirements as information comes available. All NIH staff, including employees, contractors, trainees, volunteers and tenants will be required to be fully vaccinated with a COVID-19 vaccine, unless approved for a medical or religious exemption by NIH.

A person is considered fully vaccinated 2 weeks after their final dose. Accepted vaccines are those approved or authorized for emergency use by the Food and Drug Administration (Pfizer, Janssen/Johnson & Johnson and Moderna), those approved by the World Health Organization (https://extranet.who.int/pqweb/vaccines/covid-19-vaccines), or a full vaccine series (not a placebo) in a clinical trial (e.g., Novavax). Proof of vaccination can be your CDC vaccination card, or documentation from the immunization system or your provider. If you lost your card, visit this CDC website for help in locating your vaccination documentation: https://www.cdc.gov/vaccines/programs/iis/contacts-locate-records.html.

Information about the requirements and important dates are provided below by staff type – NIH Federal Employees and Other NIH Staff.

NIH FEDERAL EMPLOYEES

NIH federal employees are required to be fully vaccinated with a COVID-19 vaccine by November 22, 2021, unless approved for a medical or religious exemption by NIH. This means federal employees must receive the last shot of the series no later than

November 8, 2021, to meet the fully vaccinated requirement by November 22, 2021. This requirement applies to all NIH federal employees, including those working onsite at an NIH facility, maximum telework and remotely. New NIH federal employees who start their tour of duty after November 22, 2021, will need to be fully vaccinated prior to their start date unless approved for a medical or religious exemption by NIH.

Vaccinated at NIH

Federal employees (including Public Health Service Commissioned Corps Officers) who were fully vaccinated at NIH do not need to take any action at this time as NIH has a record of your vaccination. Federal employees who received a partial vaccination at NIH (one dose in a two-dose series) are not considered fully vaccinated. If you still need your second dose, you can schedule an appointment at NIH. If one of your two doses was received in the community, that dose must be reported to NIH. Please follow the instructions in the 'Vaccinated in the Community' section of this email.

Vaccinated in the Community

Federal employees (including Public Health Service Commissioned Corps Officers) who were fully vaccinated in the community (not at NIH) and previously submitted an online vaccination form will receive an email from "OMSCovidVaccineProgram" with a unique link (only to be used by the recipient of the email) to update your information and submit your proof of vaccination as part of the new requirements. If you do not receive an email by October 1, 2021, you may use the link to the Vaccination Status form to submit this information: https://ors.od.nih.gov/Pages/report-vaccination-received.aspx.

Federal employees (including Public Health Service Commissioned Corps Officers) who were fully vaccinated in the community and did not submit an online vaccination form will need to upload proof of vaccination and complete the Vaccination Status form: https://ors.od.nih.gov/Pages/report-vaccination-received.aspx.

Proof of vaccination must be submitted and received in the system no later than November 22, 2021.

Get Vaccinated

Federal employees (including Public Health Service Commissioned Corps Officers) who have not received a COVID-19 vaccine or received one dose of a two-dose series at NIH can still get vaccinated at NIH by appointment. You can schedule an appointment at NIH in three ways:

- 1) Register and schedule online (https://clinweb.cc.nih.gov/cct).
- 2) Call 301-480-8990 (press 4) to speak to an NIH Occupational Medical Service (OMS) staff member (Interpretive services are available).
 - 3) Email OMSCOVIDVaccineProgram@mail.nih.gov.

You also can get vaccinated in your community by going to https://www.vaccines.gov or texting your zip code to 438829, which will return the three closest vaccination sites near you. If you are vaccinated in the community, you will need to report it to NIH (see 'Vaccinated in the Community' above).

Requesting a Medical or Religious Exemption

Federal employees (including Public Health Service Commissioned Corps Officers) may request a medical or religious exemption to this mandate in the Vaccination Status form (https://ors.od.nih.gov/Pages/report-vaccination-received.aspx); those requests will be rigorously reviewed. After a federal employee submits a request for exemption, they will be contacted once the details of the process are finalized. Federal employees denied a religious or medical exemption who refuse to be vaccinated or provide proof of vaccination by November 22, 2021, may face disciplinary action up to and including removal from federal service.

OTHER NIH STAFF

Based on implementation requirements, contractors and other NIH staff (trainees, volunteers and tenants) will be asked to provide vaccination information (including possible requests for medical or religious exemption) at a later date. Covered contract employees must be fully vaccinated no later than December 8, 2021. This means contractors must receive the last shot of the series no later than November 24, 2021, to meet the fully vaccinated requirement by December 8, 2021. Additional information regarding contracts will be forthcoming. Contractors who were vaccinated at the NIH may be asked by their employers to provide documentation to verify vaccination. Misplaced vaccination cards can be downloaded from the Clinical Center Follow My Health App. Contractors should contact their employers or Contracting Officer Representatives (COR) with questions.

Contractors, trainees, volunteers and tenants who have not been vaccinated are strongly encouraged to get vaccinated. Please follow the instructions in the 'Not Yet Vaccinated' section above.

ADDITIONAL RESOURCES

More information about federal vaccination requirements is available on the following sites:

- * NIH Vaccination Requirements: https://employees.nih.gov/pages/coronavirus/vaccination-requirements.aspx * Safer Federal Workforce Overview: https://www.saferfederalworkforce.gov/overview/ * Safer COVID Federal Workforce FAQs: https://www.saferfederalworkforce.gov/faq/vaccinations/

Sender:	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
Recipient:	(b)(6)
Sent Date:	2021/10/01 13:17:30
Delivered Date:	2021/10/01 13:17:29

From:	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
То:	OMSCovidVaccineProgram /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6c035d7cdc3b471aaba167c9214b2324-OMSCovidVac <omscovidvaccineprogram@mail.nih.gov></omscovidvaccineprogram@mail.nih.gov>
CC:	McGowan, Colleen (NIH/OD/ORS) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
Subject:	Re: Vaccine mandate and exceptions
Date:	2021/09/30 09:46:10
Priority:	Normal
Туре:	Note

Jessica,

Thank you for responding to my questions. I also appreciate you directly responding to me and explaining the situation. Obviously not your fault or decision, but I do think it would make quite a bit more sense to have a plan prior to announcing a controversial mandate such as this. Threatening people with disciplinary action including termination in order to coerce vaccination goes against everything I have ever learned about medical ethics and therefore it seems like a process to except people should be transparent, easily accessible, and clearly described. The way it is being handled now seems like an effort to downplay this option so as to coerce employees as much as possible to get the vaccine. Again thank you for addressing my concerns I will continue working within the system and do plan to file an exception as directed. I simply feel it is my responsibility as a physician scientist to raise what I consider to be important ethical and scientific issues as I have watched this unfold. As an expert in respiratory viruses, I have many concerns as it relates to the scientific justification of these mandates, the harm they could do, but more importantly I have significant problems with the ethics of them. I have been in contact with Dr. Fauci, the Bioethics department, and others in this regard. So please do not feel I have singled out you or OMS. I do hope however that everyone in any position of leadership reconsiders the appropriateness of these mandates and speaks to those above them about it as I am doing if they have any reservations.

Thank you, Matt

__

Matthew J. Memoli, M.D., M.S.
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Pager:	(b)(6)	

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From: OMSCovidVaccineProgram <OMSCovidVaccineProgram@mail.nih.gov>
Date: Wednesday, September 29, 2021 at 8:17 PM

To: "Memoli, Matthew (NIH/NIAID) [E]" (D)(6) OMSCovidVaccineProgram@cOMSCovidVaccineProgram@mail.nih.gov>
Cc: "McGowan, Colleen (NIH/OD/ORS) [E]" (D)(6)

Subject: RE: Vaccine mandate and exceptions

Matt,

I have received and passed along your detailed information to my leadership, OHR and EDI. HHS is developing department-wide Religious Accommodation policy and procedures, and the NIH is developing a process to review medical exemption requests. Your question will be forwarded to EDI for further review. If you are expecting to make a request for medical or religious exemption, please continue to complete the form and indicate that information there, as that way your possible request will be addressed promptly upon receipt of the policy and procedures. In the meantime, please visit the following U.S. Equal Employment Opportunity Commission's webpage to learn more about Workplace Religious Accommodation: https://www.eeoc.gov/laws/guidance/what-you-should-know-workplace-religious-accommodation.

This form was designed to collect the names of those wishing to request an exemption and then once the process was finalized, you would receive additional information. We are working very hard to ensure this is done consistently across the board, as it is sensitive and really important to do right.

This information is not being widely shared and if you are already vaccinated no details are shared, only that you are compliant with the requirements for vaccination. I hope this has helped to address your concerns. Please reach out directly if you have additional questions that I may be able to answer, or forward along to someone who can.

Sincerely, Jessica

If you are receiving this email outside of your typical working hours, I hope you feel no pressure to read or respond until your schedule and workload permit.

Director, Division of Occupational Health and Safety National Institutes of Health (b)(6)(office) (b)(6)Pronouns: she, her, hers Text Description automatically generated From: Memoli, Matthew (NIH/NIAID) [E] (b)(6) Sent: Wednesday, September 29, 2021 12:48 PM To: OMSCovidVaccineProgram < OMSCovidVaccineProgram@mail.nih.gov> Subject: Re: Vaccine mandate and exceptions Good afternoon, This is not satisfactory. I am being asked to provide private medical information on my vaccine status and then my own personal religious, moral, and ethical beliefs to my employer. I feel I have a legal right to know who I am going to be providing that information to, how it is going to be used, and what the process will be prior to submitting what many would consider sensitive information. I do not make a habit of discussing my personal religious beliefs at work or my medical history, and certainly not without knowing to whom I am providing it to. I think my questions are reasonable and deserve an answer. I would like to speak to someone as soon as possible to address my questions so that I can properly engage in the process I have been required to engage in and provide the appropriate information. Thank you, Matt Matthew J. Memoli, M.D., M.S. Director, LID Clinical Studies Unit Laboratory of Infectious Diseases National Institute of Allergy and Infectious Diseases National Institutes of Health MSC 3203 33 North Dr Bethesda, MD 20892-3203 **UNITED STATES** Email: (b)(6) Phone: (b)(6)

Pager: (b)(6)

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From: OMSCovidVaccineProgram < OMSCovidVaccineProgram@mail.nih.gov>

Date: Wednesday, September 29, 2021 at 11:54 AM

To: "Memoli, Matthew (NIH/NIAID) [E]" (b)(6)

Subject: RE: Vaccine mandate and exceptions

Hello Dr. Memoli,

Thank you for your questions. We can only offer the following information at this time:

Federal employees (including Public Health Service Commissioned Corps Officers) may request a medical or religious exemption to this mandate in the Vaccination Status form

(https://ors.od.nih.gov/Pages/report-vaccination-received.aspx); those requests will be rigorously reviewed. After a federal employee submits a request for exemption, they will be contacted once the details of the process are finalized. Federal employees denied a religious or medical exemption who refuse to be vaccinated or provide proof of vaccination by November 22, 2021, may face disciplinary action up to and including removal from federal service.

After submission of an exception request, you will be contacted by the party who will be reviewing the request. You can pose questions about the process at that time.

Kind regards,

The OMS COVID Vaccine Program

COVID-19 Vaccination Plan for NIH Staff

NIH Vaccine FAQs

From: Memoli, Matthew (NIH/NIAID) [E] (b)(6)

Sent: Wednesday, September 29, 2021 10:41 AM

To: OMSCovidVaccineProgram < OMSCovidVaccineProgram@mail.nih.gov >

Subject: Vaccine mandate and exceptions

Good morning,

After receiving the email today regarding the vaccine reporting and exception process I had a number of questions. I called the number provided in the email which was occupational health who then referred me to this email address. Here are my questions:

1. • The email stated that exception requests will be "rigorously reviewed". Who will perform this review? Could you please list those individuals positions and provide their credentials and

backgrounds? This should be transparent as they will be determining if a person's religious or personal beliefs are valid in regard to this issue? Without this type of transparency the process may seem very arbitrary and discriminatory.

- 2. If an exception is denied will there be an appeals process? If so how will that be done and has that process been determined?
- 3. If an exception is denied and the employee wishes not to be vaccinated it states that disciplinary action will be taken. Who will determine what that disciplinary action will be? How will it be determined? On what grounds will a Federal GS employee be able to be terminated without making reasonable accommodation?
- 4. Given Dr Collin's clear dedication of equality, diversion, inclusion, and providing a harassment free workplace as he described in his video that accompanies the antiharassment training we are all currently required to take, how does threatening people to get a vaccine or lose their job fit into that paradigm? Is that not harassment? Is it not creating a hostile workplace based on someone's scientific, religious, ethical, or moral beliefs?
- 5. To my knowledge (I asked them) NIH bioethics has not been consulted at all regarding the ethical nature of this mandate for SARS-COV2 vaccination. Given that this is the case does anyone within DOH, or NIH as a whole think maybe a serious discussion with bioethicists should take place before coercing employees to get a vaccine?

Thank you for considering my questions. I am seriously concerned about the direction we have gone in 2021 in regard to this violation of medical autonomy, return to paternalistic medicine of old, and coercion without any legitimate debate or discussion. These questions I believe need to be addressed immediately.

Thank	you,
Matt	

--

Matthew J. Memoli, M.D., M.S.
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National Institute of Allergy and Infectious Diseases
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	DSTATES	
Email:	(b)(6)	
Phone:	(b)(6)	
Pager:	(b)(6)	

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Recipient:	OMSCovidVaccineProgram /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6c035d7cdc3b471aaba167c9214b2324-OMSCovidVac <omscovidvaccineprogram@mail.nih.gov>; McGowan, Colleen (NIH/OD/ORS) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6)</omscovidvaccineprogram@mail.nih.gov>
Sent Date:	2021/09/30 09:46:10

	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
То:	Taubenberger, Jeffery (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
Subject:	FW: Vaccine mandate and exceptions
Date:	2021/09/29 16:07:59
Priority:	Normal
Туре:	Note

Look at this email exchange I had below today. This is a sad state of affairs. They are asking us to submit information and they don't even know the process by which it will be examined. They set a deadline but have no idea what they are doing. This is clearly unethical and creates a hostile work environment since they are making inappropriate threats to employees jobs.

Matt

--

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From: "Memoli, Matthew (NIH/NIAID) [E]" (b)(6)

Date: Wednesday, September 29, 2021 at 12:48 PM

To: OMSCovidVaccineProgram < OMSCovidVaccineProgram@mail.nih.gov>

Subject: Re: Vaccine mandate and exceptions

Good afternoon,

This is not satisfactory. I am being asked to provide private medical information on my vaccine status and then my own personal religious, moral, and ethical beliefs to my employer. I feel I have a legal right to know who I am going to be providing that information to, how it is going to be used, and what the process will be prior to submitting what many would consider sensitive information. I do not make a habit of discussing my personal religious beliefs at work or my medical history, and certainly not without knowing to whom I am providing it to. I think my questions are reasonable and deserve an answer. I would like to speak to someone as soon as possible to address my questions so that I can properly engage in the process I have been required to engage in and provide the appropriate information.

Thank you, Matt

--

Matthew J. Memoli, M.D., M.S.
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From: OMSCovidVaccineProgram < OMSCovidVaccineProgram@mail.nih.gov>

Date: Wednesday, September 29, 2021 at 11:54 AM

To: "Memoli, Matthew (NIH/NIAID) [E]" (b)(6)

Subject: RE: Vaccine mandate and exceptions

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After submission of an exception request, you will be contacted by the party who will be reviewing the request. You can pose questions about the process at that time.

Kind regards,

The OMS COVID Vaccine Program

COVID-19 Vaccination Plan for NIH Staff

NIH Vaccine FAQs

From: Memoli, Matthew (NIH/NIAID) [E] (b)(6)

Sent: Wednesday, September 29, 2021 10:41 AM

To: OMSCovidVaccineProgram < OMSCovidVaccineProgram@mail.nih.gov>

Subject: Vaccine mandate and exceptions

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- 1. The email stated that exception requests will be "rigorously reviewed". Who will perform this review? Could you please list those individuals positions and provide their credentials and backgrounds? This should be transparent as they will be determining if a person's religious or personal beliefs are valid in regard to this issue? Without this type of transparency the process may seem very arbitrary and discriminatory.
- 2. If an exception is denied will there be an appeals process? If so how will that be done and has that process been determined?
- 3. If an exception is denied and the employee wishes not to be vaccinated it states that disciplinary action will be taken. Who will determine what that disciplinary action will be? How will it be determined? On what grounds will a Federal GS employee be able to be terminated without making reasonable accommodation?
- 4. Given Dr Collin's clear dedication of equality, diversion, inclusion, and providing a harassment free workplace as he described in his video that accompanies the antiharassment training we are all currently required to take, how does threatening people to get a vaccine or lose their job fit into that paradigm? Is that not harassment? Is it not creating a hostile workplace based on someone's scientific, religious, ethical, or moral beliefs?
- 5. To my knowledge (I asked them) NIH bioethics has not been consulted at all regarding the ethical nature of this mandate for SARS-COV2 vaccination. Given that this is the case does anyone within DOH, or NIH as a whole think maybe a serious discussion with bioethicists should take place before coercing employees to get a vaccine?

Thank you for considering my questions. I am seriously concerned about the direction we have gone in 2021 in regard to this violation of medical autonomy, return to paternalistic medicine of old, and coercion without any legitimate debate or discussion. These questions I believe need to be addressed immediately.

Thank	you,
Matt	

--

Matthew J. Memoli, M.D., M.S. Director, LID Clinical Studies Unit Laboratory of Infectious Diseases National Institute of Allergy and Infectious Diseases National Institutes of Health MSC 3203 33 North Dr Bethesda, MD 20892-3203

UNITED STATES

Email:	(b)(6)	
Phone:	(b)(6)	
Pager:	(b)(6)	

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Sender:	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
Recipient:	Taubenberger, Jeffery (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
Sent Date:	2021/09/29 16:07:59

From:	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
To:	(b)(6)
Subject:	FW: Vaccine mandate and exceptions
Date:	2021/09/29 16:05:52
Priority:	Normal
Туре:	Note

Here is the email exchange I had today. To me this is sad that it has come to this. They don't even know how to answer my questions.

__

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From: "Memoli, Matthew (NIH/NIAID) [E]" (b)(6)

Date: Wednesday, September 29, 2021 at 12:48 PM

To: OMSCovidVaccineProgram < OMSCovidVaccineProgram@mail.nih.gov>

Subject: Re: Vaccine mandate and exceptions

Good afternoon,

This is not satisfactory. I am being asked to provide private medical information on my vaccine status and then my own personal religious, moral, and ethical beliefs to my employer. I feel I have a legal right to know who I am going to be providing that information to, how it is going to be used, and what the process will be prior to submitting what many would consider sensitive information. I do not make a

habit of discussing my personal religious beliefs at work or my medical history, and certainly not without knowing to whom I am providing it to. I think my questions are reasonable and deserve an answer. I would like to speak to someone as soon as possible to address my questions so that I can properly engage in the process I have been required to engage in and provide the appropriate information.

Thank you, Matt

--

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From: OMSCovidVaccineProgram < OMSCovidVaccineProgram@mail.nih.gov>

Date: Wednesday, September 29, 2021 at 11:54 AM

To: "Memoli, Matthew (NIH/NIAID) [E]" (b)(6)

Subject: RE: Vaccine mandate and exceptions

Hello Dr. Memoli,

Thank you for your questions. We can only offer the following information at this time:

Federal employees (including Public Health Service Commissioned Corps Officers) may request a medical or religious exemption to this mandate in the Vaccination Status form

(https://ors.od.nih.gov/Pages/report-vaccination-received.aspx); those requests will be rigorously reviewed. After a federal employee submits a request for exemption, they will be contacted once the details of the process are finalized. Federal employees denied a religious or medical exemption who refuse to be vaccinated or provide proof of vaccination by November 22, 2021, may face disciplinary action up to and including removal from federal service.

After submission of an exception request, you will be contacted by the party who will be reviewing the request. You can pose questions about the process at that time.

Kind regards,

The OMS COVID Vaccine Program

COVID-19 Vaccination Plan for NIH Staff

NIH Vaccine FAQs

From: Memoli, Matthew (NIH/NIAID) [E] (b)(6)

Sent: Wednesday, September 29, 2021 10:41 AM

To: OMSCovidVaccineProgram < OMSCovidVaccineProgram@mail.nih.gov>

Subject: Vaccine mandate and exceptions

Good morning,

After receiving the email today regarding the vaccine reporting and exception process I had a number of questions. I called the number provided in the email which was occupational health who then referred me to this email address. Here are my questions:

- 1. The email stated that exception requests will be "rigorously reviewed". Who will perform this review? Could you please list those individuals positions and provide their credentials and backgrounds? This should be transparent as they will be determining if a person's religious or personal beliefs are valid in regard to this issue? Without this type of transparency the process may seem very arbitrary and discriminatory.
- 2. If an exception is denied will there be an appeals process? If so how will that be done and has that process been determined?
- 3. If an exception is denied and the employee wishes not to be vaccinated it states that disciplinary action will be taken. Who will determine what that disciplinary action will be? How will it be determined? On what grounds will a Federal GS employee be able to be terminated without making reasonable accommodation?
- 4. Given Dr Collin's clear dedication of equality, diversion, inclusion, and providing a harassment free workplace as he described in his video that accompanies the antiharassment training we are all currently required to take, how does threatening people to get a vaccine or lose their job fit into that paradigm? Is that not harassment? Is it not creating a hostile workplace based on someone's scientific, religious, ethical, or moral beliefs?
- 5. To my knowledge (I asked them) NIH bioethics has not been consulted at all regarding the ethical nature of this mandate for SARS-COV2 vaccination. Given that this is the case does anyone within DOH, or NIH as a whole think maybe a serious discussion with bioethicists should take place before coercing employees to get a vaccine?

Thank you for considering my questions. I am seriously concerned about the direction we have gone in 2021 in regard to this violation of medical autonomy, return to paternalistic medicine of old, and coercion without any legitimate debate or discussion. These questions I believe need to be addressed immediately.

Thank you,

Matt

--

Matthew J. Memoli, M.D., M.S.
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Sender:	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
Recipient:	(b)(6)
Sent Date:	2021/09/29 16:05:53
Delivered Date:	2021/09/29 16:05:52

From:	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
То:	Taylor, Holly (NIH/CC/BEP) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
Subject:	FW: Vaccine mandate and exceptions
Date:	2021/09/29 10:49:46
Priority:	Normal
Туре:	Note

Hello Holly,

I just wanted to give you another update into some issues that I see with the current situation. Below is an email I sent to the COVID vaccine program group. I was instructed to ask my questions via this email when I called the phone number in the recent email we received. I am awaiting a response. This process to me seems to open a whole host of issues that I consider ethical in nature. I am very concerned that there has not been any legitimate discussion or debate regarding these issues. These are serious actions with serious consequences being taken/threatened. In my work we have had huge ethics debates about much smaller issues that have had a minimal effect on a tiny number of people, yet this huge issue that is affecting thousands is not being discussed or considered by those in charge.

Matt

--

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From: "Memoli, Matthew (NIH/NIAID) [E]" (b)(6)

Date: Wednesday, September 29, 2021 at 10:40 AM

To: OMSCovidVaccineProgram < OMSCovidVaccineProgram@mail.nih.gov>

Subject: Vaccine mandate and exceptions

Good morning,

After receiving the email today regarding the vaccine reporting and exception process I had a number of questions. I called the number provided in the email which was occupational health who then referred me to this email address. Here are my questions:

- 1. The email stated that exception requests will be "rigorously reviewed". Who will perform this review? Could you please list those individuals positions and provide their credentials and backgrounds? This should be transparent as they will be determining if a person's religious or personal beliefs are valid in regard to this issue? Without this type of transparency the process may seem very arbitrary and discriminatory.
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- 5. To my knowledge NIH bioethics has not been consulted at all regarding the ethical nature of this mandate for SARS-COV2 vaccination. Given that this is the case does anyone within DOH, or NIH as a whole think maybe a serious discussion with bioethicists should take place before coercing employees to get a vaccine?

Thank you for considering my questions. I am seriously concerned about the direction we have gone in 2021 in regard to this violation of medical autonomy, return to paternalistic medicine of old, and coercion without any legitimate debate or discussion. These questions I believe need to be addressed immediately.

Thank you, Matt

--

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Sender:	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
Recipient:	Taylor, Holly (NIH/CC/BEP) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
Sent Date:	2021/09/29 10:49:46

	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
To:	Strasburg, Jenny <jenny.strasburg@wsj.com></jenny.strasburg@wsj.com>
Subject:	FW: Update on COVID-19 Vaccine Requirements for NIH Staff
Date:	2021/09/29 10:00:05
Priority:	Normal
Туре:	Note

Latest email about the mandate. They say we can be removed from Federal service. I don't know how that is possible. I am not aware that a GS employee can be removed that easily. There are laws and regulations that protect us from this kind of thing. I also find it interesting that they mandate numerous trainings on diversity, inclusion, harassment, hostile work environments, but then they feel it is appropriate to threaten people who disagree with them about getting the vaccine. This is severely unethical.

Matt

--

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On 9/29/21, 9:22 AM, "OMSCovidVaccineProgram" (b)(6) wro
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NIH is committed to keeping all staff apprised of the federal mandatory COVID-19 vaccination requirements as information comes available. All NIH staff, including employees, contractors, trainees, volunteers and tenants will be required to be fully vaccinated with a COVID-19 vaccine, unless approved for a medical or religious exemption by NIH.

A person is considered fully vaccinated 2 weeks after their final dose. Accepted vaccines are those approved or authorized for emergency use by the Food and Drug Administration (Pfizer, Janssen/Johnson & Johnson and Moderna), those approved by the World Health Organization (https://extranet.who.int/pqweb/vaccines/covid-19-vaccines), or a full vaccine series (not a placebo) in a clinical trial (e.g., Novavax). Proof of vaccination can be your CDC vaccination card, or documentation from the immunization system or your provider. If you lost your card, visit this CDC website for help in locating your vaccination documentation: https://www.cdc.gov/vaccines/programs/iis/contacts-locate-records.html.

Information about the requirements and important dates are provided below by staff type – NIH Federal Employees and Other NIH Staff.

NIH FEDERAL EMPLOYEES

NIH federal employees are required to be fully vaccinated with a COVID-19 vaccine by November 22, 2021, unless approved for a medical or religious exemption by NIH. This means federal employees must receive the last shot of the series no later than November 8, 2021, to meet the fully vaccinated requirement by November 22, 2021. This requirement applies to all NIH federal employees, including those working onsite at an NIH facility, maximum telework and remotely. New NIH federal employees who start their tour of duty after November 22, 2021, will need to be fully vaccinated prior to their start date unless approved for a medical or religious exemption by NIH.

Vaccinated at NIH

Federal employees (including Public Health Service Commissioned Corps Officers) who were fully vaccinated at NIH do not need to take any action at this time as NIH has a record of your vaccination. Federal employees who received a partial vaccination at NIH (one dose in a two-dose series) are not considered fully vaccinated. If you still need your second dose, you can schedule an appointment at NIH. If one of your two doses was received in the community, that dose must be reported to NIH. Please follow the instructions in the 'Vaccinated in the Community' section of this email.

Vaccinated in the Community

Federal employees (including Public Health Service Commissioned Corps Officers) who were fully vaccinated in the community (not at NIH) and previously submitted an online vaccination form will receive an email from "OMSCovidVaccineProgram" with a unique link (only to be used by the recipient of the email) to update your information and submit your proof of vaccination as part of the new requirements. If you do not receive an email by October 1, 2021, you may use the link to the Vaccination Status form to submit this information: https://ors.od.nih.gov/Pages/report-vaccination-received.aspx.

Federal employees (including Public Health Service Commissioned Corps Officers) who were fully vaccinated in the community and did not submit an online vaccination form will need to upload proof of vaccination and complete the Vaccination Status form: https://ors.od.nih.gov/Pages/report-vaccination-received.aspx.

Proof of vaccination must be submitted and received in the system no later than November 22, 2021.

Get Vaccinated

Federal employees (including Public Health Service Commissioned Corps Officers) who have not received a COVID-19 vaccine or received one dose of a two-dose series at NIH can still get vaccinated at NIH by appointment. You can schedule an appointment at NIH in three ways:

- 1) Register and schedule online (https://clinweb.cc.nih.gov/cct).
- 2) Call 301-480-8990 (press 4) to speak to an NIH Occupational Medical Service (OMS) staff member (Interpretive services are available).
- 3) Email OMSCOVIDVaccineProgram@mail.nih.gov.

You also can get vaccinated in your community by going to https://www.vaccines.gov or texting your zip code to 438829, which will return the three closest vaccination sites near you. If you are vaccinated in the community, you will need to report it to NIH (see 'Vaccinated in the Community' above).

Requesting a Medical or Religious Exemption

Federal employees (including Public Health Service Commissioned Corps Officers) may request a medical or religious exemption to this mandate in the Vaccination Status form (https://ors.od.nih.gov/Pages/report-vaccination-received.aspx); those requests will be rigorously reviewed. After a federal employee submits a request for exemption, they will be contacted once the details of the process are finalized. Federal employees denied a religious or medical exemption who refuse to be vaccinated or provide proof of vaccination by November 22, 2021, may face disciplinary action up to and including removal from federal service.

OTHER NIH STAFF

Based on implementation requirements, contractors and other NIH staff (trainees, volunteers and tenants) will be asked to provide vaccination information (including possible requests for medical or religious exemption) at a later date. Covered contract employees must be fully vaccinated no later than December 8, 2021. This means contractors must receive the last shot of the series no later than November 24, 2021, to meet the fully vaccinated requirement by December 8, 2021. Additional information regarding contracts will be forthcoming. Contractors who were vaccinated at the NIH may be asked by their employers to provide documentation to verify vaccination. Misplaced vaccination cards can be downloaded from the Clinical Center Follow My Health App. Contractors should contact their employers or Contracting Officer Representatives (COR) with questions.

Contractors, trainees, volunteers and tenants who have not been vaccinated are strongly encouraged to get vaccinated. Please follow the instructions in the 'Not Yet Vaccinated' section above.

ADDITIONAL RESOURCES

More information about federal vaccination requirements is available on the following sites:

- * NIH Vaccination Requirements: https://employees.nih.gov/pages/coronavirus/vaccination-requirements.aspx
- * Safer Federal Workforce Overview: https://www.saferfederalworkforce.gov/overview/

* Safer COVID Federal Workforce FAQs: https://www.saferfederalworkforce.gov/faq/vaccinations/

Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6)
(b)(6)

Recipient: Strasburg, Jenny <jenny.strasburg@wsj.com>

Sent Date: 2021/09/29 10:00:05

	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
To:	Strasburg, Jenny <jenny.strasburg@wsj.com></jenny.strasburg@wsj.com>
Subject:	Letter
Date:	2021/09/28 10:04:23
Priority:	Normal
Туре:	Note

Hi Jenny,

Here is the letter as discussed. The part you will likely be most interested in is under #2. Of course I tried to keep it simple for them.

This was submitted here as per the requirement: https://doh.force.com/ver/s/vaccinereporting

The instructions there state: "For religious exemptions, individuals will need to upload a letter, stating that their vaccination against COVID-19 would violate a sincerely held religious belief and the vaccination would in fact violate a sincerely held religious belief of the person."

Matt

--

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Sender: Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6)

(b)(6)

Recipient: Strasburg, Jenny <jenny.strasburg@wsj.com>

Sent Date: 2021/09/28 10:04:23

From:	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
To:	Strasburg, Jenny <jenny.strasburg@wsj.com></jenny.strasburg@wsj.com>
Subject:	FW: Vaccination verification
Date:	2021/09/28 09:51:42
Priority:	Normal
Туре:	Note

Email #2 below

Matthew J. Memoli, M.D., M.S. Director, LID Clinical Studies Unit Laboratory of Infectious Diseases National Institute of Allergy and Infectious Diseases National Institutes of Health MSC 3203 33 North Dr Bethesda, MD 20892-3203

UNITED STATES

Email: (b)(6) Phone: (b)(6) Pager: (b)(6)

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From: "HHS News (HHS/ASPA)" (b)(6) Reply-To: "HHS News (HHS/ASPA)" (b)(6)

Date: Friday, September 24, 2021 at 4:42 PM

To: List HHS-NEWS-ALL (b)(6)

Subject: Vaccination verification

Dear HHS Family,

Earlier this month, President Biden issued two executive orders: The first requires federal employees to get fully vaccinated against COVID-19; and the second requires compliance with certain workplace safety guidance for federal contractors.

These policies will go into effect on November 22, 2021 for federal employees and starting on October 15, 2021 for federal contractors, and their purpose is simple: to protect the health and safety of the federal workforce and the health and safety of the members of the public with whom you may interact. That remains our top priority.

To comply with the President's directive, HHS will begin vaccination verification efforts as early as next week, and continue them on a rolling basis. Your Operating or Staff Division will share more detailed information about these plans, as they relate to you and your office.

As a reminder, "fully vaccinated" means you are:

- <u>Two weeks</u> out from your second dose of a two-dose vaccine series (Moderna, Pfizer-BioNTech); or
- • <u>Two weeks</u> out from a single-dose vaccine (Johnson & Johnson/Janssen).

Below is a list of dates to help you plan your schedule and meet the November 22, 2021 deadline. For a list of acceptable supporting documentation of vaccination, please see <u>my email from last week</u>, which may be found on our HHS "Your Workplace" Intranet page.**

- • October 11: First-dose deadline (Moderna COVID-19 vaccine).
- • October 18: First-dose deadline (Pfizer-BioNTech COVID-19 vaccine).
- November 8: Second-dose deadline (for Moderna and Pfizer-BioNTech).
- November 8: First (only)-dose deadline (for Johnson and Johnson [J&J]/Janssen COVID-19 vaccine).
- • November 22: Covered federal employees must be fully vaccinated.
- **By Start Date:** New employees need to be fully vaccinated by their start date or November 22, 2021 whichever is later.

We have received questions from many of you along the following lines: are there any legal exceptions for certain individuals, and what are the consequences of missing the November 22, 2021 deadline to get fully vaccinated without an exception? All federal employees must be fully vaccinated unless they receive a legal exception, i.e., a reasonable accommodation for a disability or sincerely held religious belief, practice, or observance. If a federal employee misses the deadline to become fully vaccinated or does not provide proof of vaccination without a legal exception, disciplinary action may result. Additional information on legally required exceptions will be provided as soon as possible.

Remember, COVID-19 vaccines are free and widely available; any federal employee can receive their vaccine during duty time, and is eligible for administrative leave to accompany family members for their vaccinations.

If you need a COVID-19 vaccine, please visit <u>Vaccines.gov</u> to find a COVID-19 vaccine location near you. If you lost your vaccination card, or never received one, please visit the Centers for Disease Control and Prevention (CDC) website for guidance.

Below are resources on best public health practices and additional information related to COVID-19 vaccinations, workplace safety, and return to workplace planning:

- Your COVID-19 Vaccination | CDC
- When You've Been Fully Vaccinated | CDC
- • Frequently Asked Questions (FAQs) | Safer Federal Workforce Task Force

We all have a critical role to play in meeting this deadline. By getting vaccinated, you are helping us fulfill our commitment to the health and safety of our workforce—and setting an example for the nation. You are also making sure we send a clear message to our federal partners and to other stakeholders: HHS continues to follow the science and remains committed to ending this pandemic.

Thank you for your patience and professionalism as we work through this process. You are stewards of our nation's health and well-being, and your efforts are saving and improving lives every single day.

Please stay safe and take care of one another. As Secretary Becerra and Deputy Secretary Palm remind me each day, we are a family, and we will get through this together.

Be Well and Stay Safe, Cheryl R. Campbell Assistant Secretary for Administration

**Hyperlinks with asterisks next to them can only be viewed if you're logged into VPN.

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Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn={b)(6) (b)(6)

Recipient: Strasburg, Jenny <jenny.strasburg@wsj.com>

Sent Date: 2021/09/28 09:51:42

From:	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
To:	Strasburg, Jenny <jenny.strasburg@wsj.com></jenny.strasburg@wsj.com>
Subject:	FW: COVID-19 vaccines
Date:	2021/09/28 09:51:27
Priority:	Normal
Туре:	Note

Email #1 below

--

Matthew J. Memoli, M.D., M.S.
Director, LID Clinical Studies Unit
Laboratory of Infectious Diseases
National Institute of Allergy and Infectious Diseases
National Institutes of Health
MSC 3203 33 North Dr
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From: "HHS News (HHS/ASPA)" (b)(6)

Reply-To: "HHS News (HHS/ASPA)" (b)(6)

Date: Friday, September 17, 2021 at 2:31 PM

To: List HHS-NEWS-ALL (b)(6)

Subject: COVID-19 vaccines

Dear HHS Team,

Last week, President Biden <u>signed</u> two executive orders requiring COVID-19 vaccination for federal employees and compliance with certain workplace safety guidance for contractors. The government-wide vaccination requirement will go into effect on November 22, 2021 – meaning that everyone should be fully vaccinated by this date, other than in limited circumstances where the law requires an

exception. We will share further information about the reasonable accommodation process for these limited circumstances in the coming weeks.

Here are deadlines -- by vaccine manufacturer -- to help you plan your schedule to meet the November 22, 2021 timeline:

- • October 11: First-dose deadline (Moderna COVID-19 vaccine).
- • October 18: First-dose deadline (Pfizer-BioNTech COVID-19 vaccine).
- November 8: Second-dose deadline (for Moderna and Pfizer-BioNTech).
- November 8: First (only)-dose deadline (Johnson and Johnson [J&J]/Janssen COVID-19 vaccine).
- November 22: Covered Federal employees must be fully vaccinated.
- **By Start Date:** New employees need to be fully vaccinated by their start date or November 22, 2021 whichever is later.

Fully vaccinated means you are <u>two weeks</u> after your second dose of a two-dose series or <u>two weeks</u> after a single-dose vaccine.

To help ensure we, as an agency, meet the November 22nd deadline specified by the President, we will soon launch an electronic form for our employees to confirm their COVID-19 vaccination status and upload supporting documentation. The electronic form will be kept in accordance with applicable privacy requirements and will require federal employees to attest to vaccination status by indicating one of the following: (1) fully vaccinated; (2) not fully vaccinated; or (3) not vaccinated. Contractor staff should contact their employer for guidance on whether they need to be fully vaccinated and any needed reporting requirements.

Federal employees will be required to provide supporting documents and additional information about their vaccination, including the below, by November 22, 2021:

- • Type of vaccination administered;
- Number of doses received;
- Date(s) of administration; and
- Name of health care professional(s) or clinic site(s) administering the vaccine(s).

Acceptable supporting documents include a copy of any of the following (digital copies are OK):

- Immunization record from a health care provider or pharmacy;
- COVID-19 Vaccination Record Card (Centers for Disease Control and Prevention [CDC] Form MLS-319813_r, published on September 3, 2020);
- · Medical records documenting the vaccination; or
- Immunization records from a public health or state immunization information system.

Please note that COVID-19 vaccines are free. If you need to obtain a COVID-19 vaccine, please visit <u>Vaccines.gov</u> to find a COVID-19 vaccine location near you. If you lost your vaccination card, or never received one, please visit the CDC website for <u>helpful guidance</u>.

Below are resources on best public health practices and additional information related to COVID-19 vaccinations from CDC:

Your COVID-19 Vaccination | CDC When You've Been Fully Vaccinated | CDC

I encourage you to visit <u>our HHS intranet site</u>, where we have a return-to-the-workplace web page to keep you informed. We continue to monitor the public health conditions, and continue to lead with safety and science in our workplace planning efforts, including the timeline to begin our phased return to the workplace. The Safer Federal Workforce Task Force also has <u>Frequently Asked Questions</u> (<u>FAQs</u>) on COVID-19 workplace safety and return to the workplace planning that you may find helpful. If you have any immediate questions, please direct them to your Operating Division or Staff Division point of contact, which you can find by visiting our Intranet page <u>here</u>.

As Secretary Becerra, Deputy Secretary Palm, and I mentioned during last month's department-wide town hall, the health and safety of our federal workforce is a top priority.

Be Well and Stay Safe!

Cheryl R. Campbell
Assistant Secretary for Administration

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Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group

Sender: (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6)

(b)(6)

Recipient: Strasburg, Jenny <jenny.strasburg@wsj.com>

Sent Date: 2021/09/28 09:51:26 **Delivered Date:** 2021/09/28 09:51:27

From:	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
	Pekoc, Ken (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
Subject:	Re: (follow up Qs, next week) FW: Wall Street Journal inquiry - manufacturing of coronavirus for research
Date:	2021/09/23 12:58:51
Priority:	Normal
Туре:	Note

HI Ken,

I did the interview cleared below today with Jenny Strasburg from the WSJ. I wanted to give you a heads up about it and ask a question. This reporter asked me about vaccine mandates and my thoughts on the current state of the vaccines, messaging, etc. I was honest and said a number of things related to how vaccines and data are presented to the public, deficiencies in how we make them, etc. These are not new issues for me and ones that I have discussed publicly even before COVID, but my scientific opinions do differ significantly from the mainstream narrative/opinions given by Dr. Fauci, Dr.Collins, CDC, and the administration. In addition I am very much against vaccine mandates. This is well known as I have personally emailed Drs. Fauci, Auchincloss, and Lane about this in the past and I asked the NIH Ethics Department to take it up as a topic which they are doing in December. So I was honest about this with the reporter, explained why I was against mandates, and that I had let others know this at NIH. She also knows I am unvaccinated and plan to apply for an exception. I am honest with reporters and therefore I wanted to let you know about this so that there were no surprises when she writes her story. In addition, the reporter has asked me if I was willing to provide the email I sent Dr. Fauci about this. I told her I had to check with you all first. She said this way she could avoid a FOIA request. So my question is should I share the email or not? I have no reservations about sharing, but wanted to follow appropriate procedure. I have attached the email in question to this email.

Thanks, Matt

--

Matthew J. Memoli, M.D., M.S.
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From: "Pekoc, Ken (NIH/NIAID) [E]" (b)(6)

Date: Monday, September 13, 2021 at 11:12 AM

To: "Memoli, Matthew (NIH/NIAID) [E]" (b)(6)

Subject: (follow up Qs, next week) FW: Wall Street Journal inquiry - manufacturing of

coronavirus for research

Are you available next week for a follow up discussion, per topics below? If so, she says she can email Qs in advance and you two can arrange a specific time to talk.

From: Strasburg, Jenny <jenny.strasburg@wsj.com>

Sent: Monday, September 13, 2021 8:25 AM

To: Pekoc, Ken (NIH/NIAID) [E] (b)(6)

Subject: Re: Wall Street Journal inquiry - manufacturing of coronavirus for research

Hi, Ken. I hope you're doing well.

I'm working on some reporting about natural immunity and vaccine mandates and related topics. I'm talking to some infectious-disease folks about this and am hoping to follow up with Dr. Memoli when I'm back (I'm visiting family in the Western U.S. this week - first time in a long time) so that would be early next week.

He and I broached this briefly in our challenge-trial discussion -- but those trials were the purpose of that conversation (thanks again - did I send you the links? They're below...they were very well-read and still are).

So I've wanted to follow up with him, please. I know he has discussed natural immunity quite frequently including in the context of the national serostudy and since. I'm just pinging you while I'm getting a little work done before everyone is awake here. Thanks so much.

Best Jenny

Main story:

https://www.wsj.com/articles/researchers-infect-volunteers-with-coronavirus-hoping-to-conquer-covid-19-11630747801

Common Cold Unit 'visual sidebar':

https://www.wsj.com/story/catching-cold-in-the-countryside-decadeslong-uk-studiesinspire-new-covid-19-trials-f1063c61

https://www.wsj.com/podcasts/the-journal/the-man-who-chose-to-get-covid/5bb6acde-4907-4d8f-9bad-9f1b3f6c39fe

4307-4001-3Dau-311D310C331E		
Jenny Strasburg Reporter		
The Wall Street Journal (b)(6) (office) (mob) Jenny.strasburg@wsj.com @jennystrasburg		
The News Building, 1 London Bridge Street London SE1 9GF		
On Thu, Aug 26, 2021 at 9:08 PM Pekoc, Ken (NIH/NIAID) [E] (b)(6) wrote: Here is who I've lined up am waiting now to see if he can talk now (or tomorrow?), and if he will be calling you or if he prefers that you reach out will apprise asap.		
Matthew J. Memoli, M.D., M.S. Director, LID Clinical Studies Unit Laboratory of Infectious Diseases National Institute of Allergy and Infectious Diseases		
From: Strasburg, Jenny < jenny.strasburg@wsj.com > Sent: Thursday, August 26, 2021 1:21 PM To: Pekoc, Ken (NIH/NIAID) [E] (b)(6) Subject: Re: Wall Street Journal inquiry - manufacturing of coronavirus for research		
Hi, Ken - that's great, and yes, definitely in the next hour or so. After about 10p UK time, I just need to know if I should stay up;) I'll keep my phone near me and if you're able to send anything - a name of who I'll be talking to, that would be helpful, please. Thank you so much.		
Jenny Strasburg Reporter		
The Wall Street Journal (b)(6) (office)		

The News Building, 1 London Bridge Street London SE1 9GF

Jenny.strasburg@wsj.com @jennystrasburg

(mob)

(b)(6)

On Thu, Aug 26, 2021 at 8:12 PM Pekoc, Ken (NIH/NIAID) [E] (b)(6) Sorry for the delay, had a staff meeting and needed to wrap up another project am working to line up someone for you knowledgeable on all fronts as far as I know, shouldn't be long are you available in the next hour or so? At this number, right?
From: Strasburg, Jenny < jenny.strasburg@wsj.com > Sent: Thursday, August 26, 2021 9:40 AM To: Pekoc, Ken (NIH/NIAID) [E] (b)(6) Subject: Re: Wall Street Journal inquiry - manufacturing of coronavirus for research
Ken, I just tried to reach you by phone. I don't have the best number for you so was transferred and left a message (but was cut off). Can you please call me? Thanks. (b)(6) Bet Jenny
Jenny Strasburg Reporter
The Wall Street Journal (b)(6) (office) (mob) Jenny.strasburg@wsj.com @jennystrasburg
The News Building, 1 London Bridge Street London SE1 9GF

On Thu, Aug 26, 2021 at 3:14 PM Strasburg, Jenny < jenny.strasburg@wsj.com > wrote:
Oh I see - I wasn't grasping the not-a-spokesperson vs. not-NIH. Thank you.
Do you have a moment by phone, please? BEI Resources and ATCC referred me back to NIAID.

I didn't grasp the relationship at first last night.

I am needing some context to what's happening in the UK.

It's clear from looking at BEI (as you said) that the U.S. is keeping/growing SARS-CoV-2 variants of concern.

It seems that the big difference between what I'm writing about happening in the UK and what's happening at BEI is that the U.K. is growing the Delta variant for human use (in the challenge studies).

But do we know (does the NIH/NIAID/BEI) know how widely the Delta and other variants are being propagated for research purposes -- and anywhere else besides the U.K. for human use in particular?

Is there someone at NIAID with whom I can have a brief discussion about this, please?

Thank you for being so helpful. I don't mean to make it harder as a result; I'm just sorting this out and want to be 100% accurate.

Best	
Jenn	y

Jenny Strasburg Reporter

The Wall Street Journal

(b)(6) (office) (mob) Jenny.strasburg@wsj.com @jennystrasburg

The News Building, 1 London Bridge Street London SE1 9GF

On Thu, Aug 26, 2021 at 2:49 PM Pekoc, Ken (NIH/NIAID) [E] (b)(6) wrote: Checking on the top part and will follow up asap.

On the bottom part; I work for NIAID, which is one of 27 branches of the NIH. (In one of you emails you referred to me working for NIH, so I was clarifying that I am part of NIAID, not part of NIH.)

Within my role at NIAID I am not a spokesperson, and all of our comms staff asks that information we provide not be attributed to us personally, but rather to NIAID generally.

Does that help?

From: Strasburg, Jenny <jenny.strasburg@wsj.com>

Sent: Thursday, August 26, 2021 5:27 AM

To: Pekoc, Ken (NIH/NIAID) [E] (b)(6)

Subject: Re: Wall Street Journal inquiry - manufacturing of coronavirus for research

Hi, Ken -- Apologies but I wanted to come back to you after looking closely at BEI and what is on its website, how it's funded, etc.

I see it's NIAID-funded, and NIAID has this Delta variant in stock for research purposes (information sheet attached).

The specimen was taken from an infected person in Memphis, Tenn., and grown for research purposes though NOT for use in humans.

So NIAID is funding the propagation of variants for research purposes, though not for use in humans, is that right? Thanks for clarifying.

Also just triple checking: I'm correct to say the NIH is NOT doing or planning to do human challenge studies, right?

also -

In one email you say you are not a spokesperson for NIAID, but in another email you say, "I am NIAID, not NIH."

But you suggest I attribute to NIAID?

Thank you. Best Jenny

Jenny Strasburg Reporter

The Wall Street Journal

(b)(6) (office) (mob) Jenny.strasburg@wsj.com @jennystrasburg

The News Building, 1 London Bridge Street London SE1 9GF

On Wed, Aug 25, 2021 at 7:16 PM Pekoc, Ken (NIH/NIAID) [E] (b)(6) wrote: Jenny ... we need to make sure we're understanding your question correctly; there is some confusion at my end in the context of human challenge trial studies.

Is this summary of our phone conversation accurate?

- Human challenge trials are taking place in the UK and it's no secret that virus variants are being developed as part of the testing.
- Reporter knows the US is not doing human challenge trials, but was told that the NIH is developing virus variants to have on hand if needed.
- Reporter wants to know if this is true, so she can say in the article that this is occurring elsewhere besides in the UK.

On background (and please note that I am not a spokesperson for NIAID)

- • NIAID (part of the NIH) is not currently making variant viruses to do human challenge studies.
- NIAID supported an initial manufacturing run for a human challenge stock based on the Washington-1 strain in the event that it was needed. However, NIAID is not supporting further development of this or any variant challenge stocks at this time.
- You would have to ask companies if they are making vaccines based on variants (e.g., Delta).
- • BEI Resources is growing and distributing variant isolates for use in lab testing.

From: Strasburg, Jenny < jenny.strasburg@wsj.com > Sent: Wednesday, August 25, 2021 11:04 AM To: Pekoc, Ken (NIH/NIAID) [E] (b)(6) Subject: Re: Wall Street Journal inquiry - manufacturing of coronavirus for research
Thanks very much, Ken.
Jenny Strasburg Reporter
The Wall Street Journal (b)(6) (office) (mob) Jenny.strasburg@wsj.com @jennystrasburg The News Building, 1 London Bridge Street London SE1 9GF
On Wed, Aug 25, 2021 at 6:02 PM Pekoc, Ken (NIH/NIAID) [E] (b)(6) wrote: Per our phone conversation, I'm checking into this for you.
Ken Pekoc NIAID Communications Office
From: Strasburg, Jenny < jenny.strasburg@wsj.com > Sent: Wednesday, August 25, 2021 12:53 PM To: NIAID NEWS (NIH/NIAID) (b)(6) Cc: Deatrick, Elizabeth (NIH/NIAID) [E] (b)(6) Subject: Wall Street Journal inquiry - manufacturing of coronavirus for research

I'm reporting on work being done to manufacture coronavirus variants - up to GMP / regulatory standards - for use in research.

I've been told by researchers that the NIH has been working on developing variants in the lab for research purposes.

I wondered whether I could find out, please:

Is the NIH undertaking this work described?

If so, does the NIH work include working to manufacture a laboratory specimen of the Delta strain?

Can you please let me know whether my questions are landing with the right person/people or direct me to them?

Γhanks very much.	
Best	
Jenny	
b)(6)	

Jenny Strasburg Reporter

The Wall Street Journal
(b)(6) (office) (mob)

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Sender:	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn= $(b)(6)$ (b)(6)
Recipient:	Pekoc, Ken (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
Sent Date:	2021/09/23 12:58:51
From:	Memoli, Matthew (NIH/NIAID) [E] /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=(b)(6) (b)(6)
To:	Fauci, Anthony (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) Auchincloss, Hugh (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) Lane, Cliff (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
Subject:	SARS-COV-2 response concern
Date:	2021/07/30 09:02:40
Туре:	Note

Good morning,

I wanted to reach out to you regarding recent decisions and statements made in response to SARS-COV-2 virus pandemic by NIH, CDC, and the administration. I realize the enormous pressures that all of you have faced, and I would like to continue to be as helpful as possible in our efforts in dealing with this crisis. Therefore, I feel it is important that I attempt to briefly raise one of the major concerns that I have at this time.

I have been studying intra-host viral evolution of RNA respiratory viruses as a core part of my research since 2007, and from my experience and understanding of the current data and biology; the current strategies of mass and mandated vaccination is extraordinarily problematic, practically unrealistic, and possibly detrimental.

Variants of RNA respiratory viruses as you know are to be expected, but they only become dominant if the mutation gives the virus a fitness advantage. Early in pandemics the mutations that take hold are ones that adapt the virus to humans giving the virus a replicative advantage. As you are fully aware we saw this happen very rapidly during the first months of the pandemic. A year later in this late/post-pandemic period we now have variants taking hold that are not simple human adaptation but are a response to immunity. These variants do not emerge in the naïve or unvaccinated but emerge in response to people with waning immunity, those who have been previously infected or vaccinated. They can then infect the naïve and spread, but they emerged from those who were immune not the unvaccinated naïve. This was also to be expected based on everything we know from RNA respiratory virus pandemics/epidemics of the past.

Vaccinating the naïve does nothing to stop the spread of these variants because you are always playing catch-up. In fact, it is possible that by vaccinating the naïve you are simply further selecting for these variants which will have an unknown effect on the trajectory of the viral evolution. Under no man-made selection pressures viral evolution will drive the virus to become more replicative and less dangerous to humans. This is simple selection and logic. The virus wants to replicate, and it can't replicate and spread if humans are dead or in an

ICU. Therefore, as in all past pandemics the viruses slowly change, become human adapted to become more contagious, but less deadly. 1918 influenza is a perfect example of that as there was no man-made pressures at that time and the virus mutated, adapted to natural immunity through antigenic drift and circulated until 1957 with a far lower mortality rate than during the 1918 pandemic. Natural immunity driving viral evolution and the invention of good supportive care such as the invention of antibiotics improved the situation, not a vaccine.

In this case we are making certain mistakes that have been made with influenza vaccination for the last few decades. We have a single antigen vaccine strategy inducing limited immunity that is effective for a time in many, but then offers an opportunity for the virus to evolve to evade this immunity as it wanes. The only way this type of vaccine strategy might work to stop a pandemic is if you are able to vaccinate every person on earth at the exact same time (within days) with a nearly 100% effective vaccine in all people, something that is completely unrealistic. Otherwise, you have a situation where people have waning immunity at different times and the virus is able to evolve and evade immunity.

At best what we are doing with mandated mass vaccination does nothing and the variants emerge evading immunity anyway as they would have without the vaccine. At worst it drives evolution of the virus in a way that is different from nature and possibly detrimental, prolonging the pandemic or causing more morbidity and mortality than it should. There is evidence that yearly flu vaccination has done this during certain years, and further study is necessary. Either way coercing or forcing people to take a vaccine can have negative consequences from a biological, sociological, psychological, economical, and ethical standpoint and is not worth the cost even if the vaccine is 100% safe.

A more prudent approach that considers these issues would be to focus our efforts on those at high risk of severe disease and death, such as the elderly and obese, and do not push vaccination on the young and healthy any further. This uses the vaccine for maximum benefit to reduce morbidity and mortality while limiting the effect you are likely having on natural evolution of the virus and development of a more robust immunity in the population. You also do not lose political capital and trust of the public as has been happening with the current strategy. In the meantime, our focus should be on two things. The development of treatments for SARS-COV-2 and SIRS/sepsis as well as developing more broadly

protective beta-coronavirus vaccines that use multiple antigen strategies inducing not only antibodies against a single antigen, but against multiple antigens as well as inducing mucosal, cellular, and other forms of immunity more like the response one has to a full infection. Vaccines such as this would likely be far more effective in these situations and need to be aggressively pursued. Jeff Taubenberger and I have been working on this and I know others are as well. In addition, I believe that the new mandates are a major mistake and should be rescinded immediately. This will not do any good and will cause biological and/or social harm to the medical community and our country as a whole.

I am happy to discuss this further or offer my thoughts and expertise at any time. Thank you for considering this and I hope you take it into account as you discuss the current response with the CDC and current administration.

Thank you, Matt

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Sent Date:	2021/07/30 09:02:40

From:	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
То:	Giurgea, Luca (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
Subject:	Re: Uh oh
Date:	2021/09/07 09:00:49
Priority:	Normal
Туре:	Note

Luca,

'The protection against severe disease is not maintained. You have to look at people who were vaccinated in the same time period. Including people vaccinated 1 month ago with people vaccinated 6 months ago and then comparing to people who are unvaccinated is not a valid way to look at it. Of course it looks like it works. What they don't tell you in that MSNBC article is when they say it is effective at reducing severity they include data going back to January. The way the data is being analyzed to say severe disease is reduced is not valid and cherry picked. Once the immunity wanes severe disease is just as prevalent as in unvaccinated. Real world data is showing this everywhere when you look at breakthrough cases vs unvaccinated using raw data. The only way to evaluate this right now without a real study designed to do it is to compare breakthrough cases to unvaccinated cases in the last 2-3 months. If you do that you see no difference. That Clark County data I sent you is raw unmanipulated data. It is the real world.

The vaccines are doing more harm than good. The only way out of this is strong natural immunity in as many people as possible. That means healthy people need to get infected with SARS-COV2, maybe more than once so we develop true immunity that pushes this to endemic levels. This absurd vaccine strategy will fail because it kicks the can down the road and prolongs things. There are significant numbers of adverse events occurring in people who have no risk of death or even significant illness from COVID. The vaccine should only be given to those at high risk to protect them as much as possible while the rest of us get COVID. Without a better vaccine that should be the strategy. In fact if it was from the beginning the world would be better off right now. We are ignoring history and ignoring reality with this arrogant notion that we can vaccinate it away.

There is no mandate for an influenza vaccine except for very specific people (i.e. healthcare workers) and we have decades of safety data. We never took away people's livelihoods over it or refused to let them go to a restaurant or concert, etc. It probably doesn't do much good either, but at least we know what it does and had data beyond 6 months before we mandated it for those specific individuals. I don't support that mandate either by the way and never have.

Matt

--

Matthew J. Memoli, M.D., M.S. Director, LID Clinical Studies Unit

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From: "Giurgea, Luca (NIH/NIAID) [E]" (b)(6)

Date: Friday, September 3, 2021 at 11:45 AM

To: "Memoli, Matthew (NIH/NIAID) [E]" (b)(6) Jeffery Taubenberger

(b)(6)

Subject: Re: Uh oh

Hey Matt,

Its very possible whole virus vaccine will do better in the long-term, even if it provides much less robust antibody titers initially. My guess is that the diversity of (more conserved, non-neutralizing) epitopes offered may provide a better safety net as Spike continues to mutate. But I think we have yet to see good data on this. So far, from what I have heard from the UK and Israel in the news (but not yet published) confirms stability of protection against severe disease (90%) as anti-S immunity wanes and protection against symptomatic disease drops (as low as 39%,

 $\frac{\text{https://www.cnbc.com/2021/07/23/delta-variant-pfizer-covid-vaccine-39 percent-effective-in-israel-prevents-severe-illness.html).}{}$

In terms of mandates it seems to me the argument for the first 2 doses is as strong as the mandate for yearly flu vaccines. What risks are you worried about?

With respect to boosters, we agree on that, and I think the FDA folks do too. That aspect of things has been a mess, from HCQ last year to booster doses this year.

I guess my logic has been that if protection against severe disease is maintained at 90% for a long period of time, then that would reduce the \sim 500,000 deaths over a one year period to 50,000, which would be right in the ballpark for season flu, which also makes sense to me. In that case, we can all go back to caring about COVID as much as we care about flu, haha...

Luca T. Giurgea, M.D. Clinical Fellow, LID Clinical Studies Unit Laboratory of Infectious Diseases NIAID, NIH MSC 3203 33 North Dr Bethesda, MD 20892-3203 United States

Email: (b)(6) Phone: (b)(6)

From: "Memoli, Matthew (NIH/NIAID) [E]" (b)(6)

Date: Friday, September 3, 2021 at 11:10 AM

To: "Giurgea, Luca (NIH/NIAID) [E]" (b)(6) "Taubenberger, Jeffery

(NIH/NIAID) [E]" (b)(6)

Subject: Re: Uh oh

Luca,

The Chile study supports my point. Whole virus vaccine is performing much better than single antigen strategy mRNA when it comes to preventing severe illness. The mRNA phase 2/3 trials were too short (they crossed everyone over) and don't tell us anything about the real world. The real world data from everywhere demonstrates that. Many of those breakthrough cases around the world are people who had good responses to vaccine, their immunity waned. The vaccine effectiveness drops after a number of months and will continue to do so to the point where people who were vaccinated will essentially have no immunity after a year. We need natural immunity or more robust vaccines. Forcing people unethically to get mRNA single antigen strategy vaccines is a huge mistake in many ways. Everyone is perpetuating utter nonsense when it comes to these mRNA vaccines. The risk for a large majority of the population is not worth the temporary benefit. This is why you have high level resignations from FDA. They know it just as we do. The push to force boosters and vaccines on children will be devastating to the entire public health infrastructure and we will not recover trust. It should be stopped. There will be a public ethics meeting on this on December 1st. I requested an ethics review of vaccine mandates. I wish it was sooner. I fear December will be too late.

Matthew J. Memoli, M.D., M.S. Director, LID Clinical Studies Unit Laboratory of Infectious Diseases National Institute of Allergy and Infectious Diseases National Institutes of Health MSC 3203 33 North Dr Bethesda, MD 20892-3203 **UNITED STATES**

Email: (b)(6)

Phone: (b)(6)

Pager:	(b)(6)				

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From: "Giurgea, Luca (NIH/NIAIE)) [E]" (b)(6)		
Date: Friday, September 3, 2021	at 10:46 AM		
To: "Memoli, Matthew (NIH/NIA	(ID) [E]" (b)(6)	Jeffery Tau	benberger
(b)(6)			
Subject: Re: Uh oh			

I think the data you showed is saying indirectly: if you are vaccinated and you still get sick (maybe because you didn't respond well to the vaccine), then you get just as sick as if you didn't get vaccinated (which seems plausible).

But the question here is, are the number of severe cases reduced by vaccination? I think the data is actually pretty good now to show this. First the randomized studies:

- In the moderna phase 3 trial. The placebo group had 30 severe cases while the vaccine group had 0. I calculated the p-value myself and it is <0.0001 (https://www.nejm.org/doi/full/10.1056/nejmoa2035389)
- In the Pfizer phase 3 trial. The placebo group had 9 severe cases, while the vaccine group had
 I calculated the p-value myself and it is 0.0114
 (https://www.nejm.org/doi/full/10.1056/nejmoa2034577)
- 3. In the Astrazeneca phase 3 trial. The placebo group had 10 hospitalizations, with 2 severe cases. There were 0 in the vaccine group.

 (https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)32661-1/fulltext)
- 4. In the Russian vaccine phase 3 trial. The placebo group had 20 cases of moderate-severe COVID, the vaccine group had 0. (https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00234-8/fulltext)

This other non-randomized study from Qatar looked at effectiveness against variants using the same test-negative case-control strategy we use to estimate flu vaccine effectiveness. It showed an overall effectiveness of the Pfizer vaccine at 89.5% against Alpha, 75% against Beta. Effectiveness against severe disease was 97.4% against both variants. (https://www.nejm.org/doi/full/10.1056/nejmc2104974)

Finally, just out yesterday, a prospective study of 10 million participants in Chile (not randomized though) who got inactivated SARS-COV-2. Vaccine efficacy was 65.9% against COVID-19, 87.5% against hospitalization, 89.2% against ICU and 86.3% for COVID-related death.

(https://www.nejm.org/doi/full/10.1056/NEJMoa2107715)

But it does not seem surprising to me that some degree of immunity would attenuate disease severity.

--

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Laboratory of Infectious Diseases
NIAID, NIH
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United States
Email: (b)(6)
Phone: (b)(6)

From: "Memoli, Matthew (NIH/NIAID) [E]" (b)(6)

Date: Friday, September 3, 2021 at 8:31 AM

To: "Giurgea, Luca (NIH/NIAID) [E]" (b)(6) "Taubenberger, Jeffery

(NIH/NIAID) [E]" (b)(6)

Subject: Re: Uh oh

Luca there is no evidence that vaccines prevent severe disease. People who get COVID when vaccinated or unvaccinated are hospitalized and die at the exact same rate everywhere in the world. Just look at Clark County Nevada.

Clark County Nevada Data: https://covid.southernnevadahealthdistrict.org/cases/breakthrough/

In all people:

303,487 COVID Cases Since the beginning of the pandemic 19,382 Hospitalizations 6% 5198 deaths. 1.7%

In Vaccinated:

7084 breakththrough cases since vaccines available 349 Hospitalizations 5% 104 Deaths 1.4%

So you can see the 5% hospitalization and 1.4% death is pretty darn similar to 6% hospitalization and 1.7% deaths that has happened in all comers since the beginning of the pandemic. The vaccine is not changing the rate of severe illness or death once you are clinically infected.

I can show you Data like this from Israel, Massachussetts, the UK, Japan, etc. There is data from Chile that the WHO has (Mike Levine told me about it two days ago) that shows that the Sinovac whole virus vaccine gives much better long term protection against severe disease than any of the vaccines we are using in the U.S.

We need to stop perpetuating this myth of these mRNA vaccines. Lies being told to get people vaccinated are unethical and wrong. These vaccines are perpetuating the pandemic. Young healthy people getting COVID and developing natural immunity is the only way out of this. These vaccines just delay infections, that's it. They do not protect you from severe disease or death. In 3-6 months vaccine effectiveness will be 0.

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From: "Giurgea, Luca (NIH/NIAII	D) [E]" (b)(6)	
Date: Thursday, September 2, 2	021 at 11:24 AM	
To: "Memoli, Matthew (NIH/NIA	AID) [E]" (b)(6)	Jeffery Taubenberger
(b)(6)		
Subject: Re: Uh oh		

I agree the booster dose thing is rather premature. It seems other people in the ID community agree too, from what I see on the IDSA news briefing. Well we knew immunity would wane, and we were worried mutations would arise and now they did. Not surprising that we see vaccine efficacy drop, though what we're seeing with delta is more an effect of host adaptation mutations rather than immune escape ones. Delta's host adaptation mutations allowed it to outcompete the strains with better immune escape mutations like Beta (in Africa) and Gamma (in North America). So far, I have not seen any data that the effectiveness in preventing severe disease (>90%) has waned yet. So I am not worried, even if it does wane in the future, it seems to be fairly slow. In that case, boosters (with wild-type Spike)

would only serve to bump effectiveness in preventing symptomatic COVID from 60% back to the original >90%, if we ignore any effects of antigenic drift.

It really depends on what the public health goal is and I think almost everyone agrees the pandemic cat is way out of the bag. In that case, we should just focus on preventing severe disease and limiting excess deaths from strain on healthcare systems. I think we have already achieved that here, at least with everyone that is willing to get it. From an ethical perspective, it seems the obvious answer would be to send the extra doses out to high risk individuals who have no access to vaccines.

__

Luca T. Giurgea, M.D. Clinical Fellow, LID Clinical Studies Unit Laboratory of Infectious Diseases NIAID, NIH MSC 3203 33 North Dr Bethesda, MD 20892-3203

United States
Email: (b)(6)

Phone: (b)(6)

From: "Memoli, Matthew (NIH/NIAID) [E]" (b)(6)	
Date: Thursday, September 2, 2021 at 10:37 AM	
To: "Taubenberger, Jeffery (NIH/NIAID) [E]" (b)(6)	"Giurgea, Luca
(NIH/NIAID) [E]" (b)(6)	
Subject: Uh oh	

https://www.nejm.org/doi/full/10.1056/NEJMc2112981

This is only going to get worse. Reality is slapping us in the face. The vaccine mandates are unethical and based on a false premise. We have made a lot of mistakes.

Matt

--

Matthew J. Memoli, M.D., M.S.
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Sender:	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
Recipient:	Giurgea, Luca (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
Sent Date:	2021/09/07 09:00:49

From:	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
То:	Taylor, Holly (NIH/CC/BEP) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
CC:	Wendler, Dave (NIH/CC/BEP) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
Subject:	Re: Mandates
Date:	2021/08/30 11:41:16
Priority:	Normal
Туре:	Note

Yes I would be happy to present.

Matt

--

Matthew J. Memoli, M.D., M.S. Director, LID Clinical Studies Unit Laboratory of Infectious Diseases National Institute of Allergy and Infectious Diseases National Institutes of Health MSC 3203 33 North Dr Bethesda, MD 20892-3203

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From: "Taylor, Holly (NIH/CC/BEP) [E]" (b)(6)

Date: Monday, August 30, 2021 at 11:35 AM

To: "Memoli, Matthew (NIH/NIAID) [E]" (b)(6)

Cc: "Wendler, Dave (NIH/CC/BEP) [E]" (b)(6)

Subject: RE: Mandates

Not a bother! This is an important issue.

Would you be willing to be a part of our Ethics Grand Rounds on the topic on December 1 from noon to 1:00? Your role would be to present for 10 minutes on background leading to question raised: Should COVID vaccination be mandated? We would then have an ethicist (usually from outside our Department but known to be an expert on the topic) to provide the analysis and then you would engage in a moderated discussion (moderator from our Department). I have cc'ed Dr. Dave Wendler who runs our Ethics Ground Rounds.

Thanks for considering.

Holly

(b)(6)

Holly Taylor, PhD, MPH
Department of Bioethics
Clinical Center
National Institutes of Health
(b)(6)

From: Memoli, Matthew (NIH/NIAID) [E]
Sent: Monday, August 30, 2021 9:55 AM

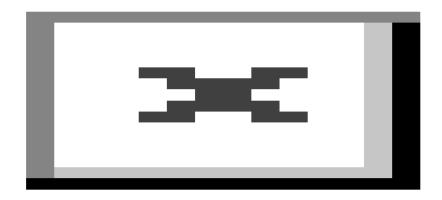
To: Taylor, Holly (NIH/CC/BEP) [E] (b)(6)

Subject: Mandates

Hi Holly,

I promise I will stop bothering you with this, but just to give you a little more information for what I am concerned about, please see the email I received below about the Fairfax County Schools. Now my children are too young for this, but there is a lot wrong with this email and the public health leaders are at fault. Mandating vaccines for high school kids to play sports is wrong given what we discussed about it being a false premise, but on top of it the FDA is currently looking into myocarditis as a major safety concern of the vaccines in this age group. An age group with nearly no chance of death from COVID. They have more chance to dying from influenza. I see no discussion of exemptions here either. Somebody needs to get out in front and talk about this if these kinds of things are going to be done ethically.

Matt



wAiM375S+UiggAAAABJRU5ErkJggg==

Dear FCPS Community,

Beginning November 8, FCPS will require proof of a COVID-19 vaccination for any student participating in Virginia High School League (VHSL) winter and spring sports for the remainder of the 2021-22 school year.

Proof of a COVID-19 vaccination will also be required for participation in any other activity that requires a physical. This includes dance team, and step team, as well as out-of-season practices and workouts.

Vaccinating our students is a critical step in mitigating the spread of COVID-19 and minimizing any disruption to learning. The majority of pauses to instruction for our high school students come as a result of exposure during athletic activities, which the Virginia Department of Education classifies as a high-risk activity. These pauses impact participation in activities and in-person learning while the Fairfax County Health Department (FCHD) investigates and determines close contacts and next steps.

FCPS will be working with the FCHD to ensure all students who wish to be vaccinated have access to the COVID-19 vaccine before the requirement kicks in on November 8. A total of 75.4% of all Fairfax County 16-18 year-olds are currently fully vaccinated, and 85.7% have had one dose. This timeline allows unvaccinated students ample time to fulfill the participation requirement before the winter sports season begins.

FCPS is committed to providing the safest learning environment possible for our students and is proud to lead the way by requiring COVID-19 vaccination for athletic participation. Our decision is supported by the American Academy of Pediatrics (AAP), the American Medical Society for Sports Medicine (AMSSM), and ten other sports and medicine organizations that urge members to incorporate COVID-19 vaccination into sports physicals for student-athletes.

While we know this is a difficult decision for some families, it is an essential step that we must take to limit the duration of a pause, getting students back to the classroom and their activities sooner, but still safely. We will share more information in the coming weeks on how to provide proof of vaccination and vaccination opportunities for students.

Thank you for continuing to support our students and staff and our ongoing commitment to safe, inperson learning.

Scott S. Brabrand Superintendent Fairfax County Public Schools

--

Matthew J. Memoli, M.D., M.S.
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Recipient:	Taylor, Holly (NIH/CC/BEP) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) [b)(6) Wendler, Dave (NIH/CC/BEP) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) [b)(6)
Sent Date:	2021/08/30 11:41:16

From:	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
To:	Wang Memoli, Jessica S (b)(6)
Subject:	Re: IMPORTANT! Message from (b)(6) President & CEO
Date:	2021/08/30 10:23:41
Priority:	Normal
Туре:	Note

It says: and we will offer medical and religious exemptions.

Matthew J. Memoli, M.D., M.S. Director, LID Clinical Studies Unit Laboratory of Infectious Diseases National Institute of Allergy and Infectious Diseases National Institutes of Health MSC 3203 33 North Dr Bethesda, MD 20892-3203

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Email: (b)(6) Phone: (b)(6) Pager: (b)(6)

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From: (b)(6)	
Date: Monday, August 30, 2021 at 10:21 AM	_
To: "Memoli, Matthew (NIH/NIAID) [E]" (b)(6)	
Subject: FW: IMPORTANT! Message from (b)(6)	President &CEO
Well, here's the email. No mention of exemptions	
(b)(6)	

From: OfficeofthePresidentandCl	EO ^{(b)(6)}		
Sent: Monday, August 30, 2021 9			
To: OfficeofthePresidentandCEO	(b)(6)		
Subject: IMPORTANT! Message fi	rom ^{(b)(6)}	President &CEO	
		_	
Dear Associates,			
,			

I write to you today to make you aware of an important safety commitment for our patients, one another and our communities. In June, we shared our intention to mandate COVID-19 vaccinations once the U.S. Food and Drug Administration (FDA) fully approved one or more of the COVID-19 vaccines. Last week, the FDA fully approved the Pfizer COVID-19 vaccine. Additionally, Maryland Governor Larry Hogan and District of Columbia Mayor Muriel Bowser issued mandates for vaccinations among healthcare workers. And, as you know all too well, the Delta variant continues to impact our patients, our work and our ways of life.

As a leading healthcare system, we must come together as One (b)(6) and do our part. Showcasing our highest commitment to protecting the safety of those we serve, (b)(6) is requiring all associates, physicians, residents/fellows, students, Board members, medical staff members and other non-employed credentialed professionals, contractors, volunteers, agency employees, and vendors to be fully vaccinated against COVID-19 by November 1, 2021, as a condition of employment in accordance with the **Mandatory COVID-19 Vaccination Policy.** Fully vaccinated is defined as receiving both doses of a two-dose COVID-19 vaccine (Pfizer or Moderna) or the single-dose COVID-19 vaccine (Johnson & Johnson), and we will offer medical and religious exemptions.

Like other healthcare organizations and federal and local institutions, we support the science and safety of COVID-19 vaccines. We are joined by the Maryland Hospital Association (MHA), District of Columbia Hospital Association (DCHA), and their member healthcare systems and hospitals in endorsing mandatory COVID-19 vaccinations for healthcare workers. Many have already implemented these requirements as part of local mandates, as have non-healthcare organizations and entities. The goal of protecting and caring for others through vaccination is a common and uniting commitment throughout our community, region and nation.

Associates, including employed physicians and residents/	fellows, who are not vaccinated will need to
schedule their COVID-19 vaccinations at (b)(6)	Vaccinations are provided free of
charge. For vaccine education and resources, visit (b)(6)	

For the more than 70% of our associates and 80% of our clinicians already vaccinated—thank you. Compliance with this requirement from the remainder of our organization will further protect our patients, those who care for them, and our communities. It will move us closer to realizing the normalcy we no longer take for granted. Our $One^{[b](6)}$ commitment requires our shared and united dedication to protect the safety of those we serve.

We chose health care to help people. The losses, stresses and impact of this pandemic are beyond anything we anticipated in our careers—or lifetimes—which is why I know you will join me in doing everything we can to help end it. Science and medicine, with reinforcement from trusted sources,

including the FDA and Centers for Disease Control and Prevention (CDC), indicate the best defense against COVID-19 is to be vaccinated.

Your efforts in responding to this pandemic continue to be extraordinary. I am honored and proud to serve alongside each of you. Thank you for joining me in fulfilling this critically important commitment.

b)(6)		
(b)(6)		

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	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
Recipient:	(b)(6)
Sent Date:	2021/08/30 10:23:41

From:	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
To:	(b)(6)
Subject:	Re: IMPORTANT! Message from (b)(6) President & CEO
Date:	2021/08/30 10:22:39
Priority:	Normal
Туре:	Note

Well you need to contact them about exemption. They have to offer it for it to be ethical.

__

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Email: (b)(6)

Phone: (b)(6)

Pager: (b)(6)

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From: (b)(6)		1	
	21 2+ 10,21 AM		
Date: Monday, August 30, 202			
To: "Memoli, Matthew (NIH/N			
Subject: FW: IMPORTANT! Me	essage from (D)(D)	President &CEO	
Well, here's the email. No menti	on of exemptions		
4.10	·		
(b)(6)			

From: OfficeofthePresidentandCEO (b)(6) Sent: Monday, August 30, 2021 9:00 AM To: OfficeofthePresidentandCEO (b)(6) Subject: IMPORTANT! Message from (b)(6) President &CEO
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As a leading healthcare system, we must come together as One (b)(6) and do our part. Showcasing our highest commitment to protecting the safety of those we serve, (b)(6) is requiring all associates, physicians, residents/fellows, students, Board members, medical staff members and other non-employed credentialed professionals, contractors, volunteers, agency employees, and vendors to be fully vaccinated against COVID-19 by November 1, 2021, as a condition of employment in accordance with the Mandatory COVID-19 Vaccination Policy . Fully vaccinated is defined as receiving both doses of a two-dose COVID-19 vaccine (Pfizer or Moderna) or the single-dose COVID-19 vaccine (Johnson & Johnson), and we will offer medical and religious exemptions.
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Associates, including employed physicians and residents/fellows, who are not vaccinated will need to schedule their COVID-19 vaccinations at $(b)(6)$ Vaccinations are provided free of charge. For vaccine education and resources, visit $(b)(6)$
For the more than 70% of our associates and 80% of our clinicians already vaccinated—thank you. Compliance with this requirement from the remainder of our organization will further protect our patients, those who care for them, and our communities. It will move us closer to realizing the normalcy

We chose health care to help people. The losses, stresses and impact of this pandemic are beyond anything we anticipated in our careers—or lifetimes—which is why I know you will join me in doing everything we can to help end it. Science and medicine, with reinforcement from trusted sources, including the FDA and Centers for Disease Control and Prevention (CDC), indicate the best defense against COVID-19 is to be vaccinated.

commitment requires our shared and united

we no longer take for granted. Our One (b)(6)

dedication to protect the safety of those we serve.

Your efforts in responding to this pandemic continue to be extraordinary. I am honored and proud to serve alongside each of you. Thank you for joining me in fulfilling this critically important commitment.

(b)(6)		
(b)(6)		

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Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6)

(b)(6)

Recipient: (b)(6)

Sent Date: 2021/08/30 10:22:39

From:	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
То:	Taylor, Holly (NIH/CC/BEP) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
Subject:	Re: Ethics report
Date:	2021/08/27 10:14:23
Priority:	Normal
Туре:	Note

Thank you Holly,

I would greatly welcome the opportunity to take part in any and all activities related to this. Please let me know.

Matt

--

Matthew J. Memoli, M.D., M.S.
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From: "Taylor, Holly (NIH/CC/BEP) [E]" (b)(6)

Date: Friday, August 27, 2021 at 10:12 AM

To: "Memoli, Matthew (NIH/NIAID) [E]" (b)(6)

Subject: RE: Ethics report

Thanks Matt. I appreciate your taking the time to add to the consult and provide all the information below. You will see in the attached I included some of your comment in the body of the consult and some as a footnote. I have discussed the consult with my Department Chief and we agree that the topic of Vaccine Mandates would be a good topic for our Bioethics Interest Group or our Ethics Grand Rounds (I added the latter to the recommendation). I am hoping you would be want to be involved in either? I will keep this your email in anticipation of moving forward with one or the other.

Holly Taylor, PhD, MPH
Department of Bioethics
Clinical Center
National Institutes of Health
(b)(6)
(b)(6)

From: Memoli, Matthew (NIH/NIAID) [E] Sent: Thursday, August 26, 2021 9:44 AM

To: Taylor, Holly (NIH/CC/BEP) [E] (b)(6)

Subject: Re: Ethics report

HI Holly,

First I want to thank you for taking my concerns seriously and trying to address them. I put a small comment in the document just adding one of the main issues that I have. I wanted to summarize this and some other thoughts I have here for you to make my positions clear and to document for any future discussions:

Although I agree that exceptions should exist with a mandate, and that those would address the autonomy issue if handled properly, I have greater concerns. My position is that the NIH and its leaders should be vocally against COVID-19 vaccine mandates as inappropriate at this time. This should be the case even if it goes against the politicians.

As I put in my comment, the number one issue and primary argument (this goes beyond autonomy) is that the vaccine mandates are based on a false premise that the vaccine stops the spread of COVID or reduces it significantly. This has turned out not to be the case. The CDC has specifically said it doesn't stop spread, and the data demonstrate that vaccinated people are getting and spreading COVID. It is even possible that some vaccinated people could more easily spread the virus as if they have reduced symptoms they are less likely to be identified and quarantined. Cases in vaccinated people are increasing weekly worldwide demonstrating that the virus is spreading despite vaccines due to some combination of waning immunity, vaccine failures, and viral evolution to evade the vaccine. I have personally been reviewing data from multiple countries and counties in the U.S. that demonstrate this. All of this was expected with an RNA respiratory virus like this. Any comparison to polio, typhoid, varicella, measles, smallpox, etc. make no sense as primarily respiratory mucosal RNA respiratory viruses with animal reservoirs like coronaviruses and influenza viruses behave in a completely different way. So even if we all agree that mandates are legal, ethical, and necessary under certain circumstances, they cannot be ethical when what they are designed to do clearly will not be achieved by the mandate.

A secondary concern of mine, but not a small one is the long term consequences of mass vaccination with this vaccine are not understood.:

- 1. There is evidence that mass vaccinations could drive evolution of the virus against nature which could have unintended consequences and produce variants that would not have arisen from natural immunity. We are just starting to learn this about influenza and we are making the same mistakes again without adequately exploring this issue.
- 2. There is the concerning issue of antibody dependent enhancement where vaccination could make illness worse for some in the future. There is conflicting evidence right now in the literature and this issue is very unclear with minimal data and studies. This is a complex issues that we still don't fully understand with other viruses and it clearly has not been adequately explored to the point where we should be comfortable taking the risk with healthy young people.
- 3. Vaccinating the young now could lead to less adequate immunity in the future when they are old setting up the population for a future coronavirus pandemic with a new virus. This may be avoided with more robust and broad natural immunity without vaccine in the young. Again this has not been discussed. The notion that just because people who are vaccinated have more anti-RBD antibodies means vaccine immunity is better is a false way of looking at things. Natural infection offers other types of antibodies, cellular, and mucosal immunity that the vaccine never can. So even if the vaccine induces more very specific immunity to the Spike RBD, it lacks in all the other areas that are likely very important for broad, long-term protection as we have seen with influenza.
- 4. Safety of these vaccines was only evaluated for 6-8months or so and then the control groups crossed over. We have no long term safety data and we already have more deaths and severe adverse events reported than with any large scale vaccine product ever according to the CDC's own VAERS data which generally underestimates vaccine related events. There seem to be a broad spectrum of adverse events and so it seems very difficult to pinpoint what is going on. This needs more careful analysis and clarification. With other mandated products we have more than 3 years (and generally far more) of safety data from large numbers of people prior to mandates. These are completely new technologies that had never been used in humans before, not a flu vaccine that was rapidly updated like in 2009.

I feel that these risks of doing harm outweigh the benefits for anyone under 70 who is relatively healthy where COVID survival is >99% if you even get infected in the first place. That number also does not take into account asymptomatic cases which my own study demonstrated was at least 5 for every 1 known case by July of 2020 (likely higher now), published in Science Translational Medicine https://www.scienceopen.com/document?vid=303e2100-7529-4319-924e-859e515f6b8d. This means case fatality rates for all ages is much lower than thought, and may be in line with bad flu years for most 0.01-0.1%CFR.

I have a whole host of other issues and data I could discuss, but I have bothered you enough with this. I have grave scientific concerns with what our public health leaders are saying publicly and feel these statements and the mandates they have led to have already and will do further harm to the future of biomedical science and public health. I hope further discussion can be had. I think it is extremely important.

Thank you again, Matt

__

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From: "Taylor, Holly (NIH/CC/BEP) [E]" (b)(6)

Date: Wednesday, August 25, 2021 at 3:49 PM

To: "Memoli, Matthew (NIH/NIAID) [E]" (b)(6)

Subject: RE: Ethics report

Of course. Here it is.

Holly Taylor, PhD, MPH

Department of Bioethics Clinical Center National Institutes of Health (b)(6) (b)(6)

Pager: (b)(6)

From: Memoli, Matthew (NIH/NIAID) [E]
Sent: Wednesday, August 25, 2021 3:42 PM

To: Taylor, Holly (NIH/CC/BEP) [E] (b)(6)

Subject: Ethics report

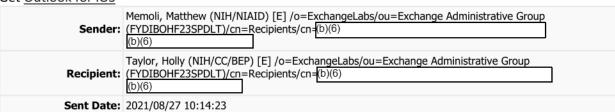
Hi Holly,

I thought I saw an e-mail from you with a report to look at but when I came back to my e-mail I can't find it anywhere. I am not sure what I did. Can you please resend the email?

Thanks,

Matt Memoli

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From:	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
To:	Morens, David (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) Giurgea, Luca (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) [b)(6) Kash, John (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) [b)(6) Taubenberger, Jeffery (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) [b)(6) Gygli, Sebastian (NIH/NIAID) [F] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) [b)(6) Park, Jaekeun (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) [b)(6) Qi, Li (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6)
Subject:	Re: Infection-enhancing anti-SARS-CoV-2 antibodies recognize both the original Wuhan/D614G strain and Delta variants. A potential risk for mass vaccination ? - Journal of Infection
Date:	2021/08/24 14:04:02
Priority:	Normal
Туре:	Note

I agree that mandates can be legal, useful, and necessary in very rare circumstances. However, in this case we clearly see that these vaccines have very limited ability to prevent spread of disease. The CDC has clearly stated this as fact. In addition it is likely natural immunity, especially in the young who have near zero risk of severe outcome will do more to reduce the effects of this pandemic than vaccination will. RNA respiratory viruses are different and when they have animal reservoirs it makes it even more difficult. Immunity will wane and you will just delay the inevitable surge that is going to happen. The pandemic must run its course.

Taking away medical licenses, jobs, access to services unless vaxxed will be remembered as an overreaction where rights were taken away inappropriately. These mandates should not be recommended or supported. They are clearly based on a false premise and are unethical because they will not do what they say it will.

Get Outlook for iOS From: Morens, David (NIH/NIAID) [E] (b)(6) Sent: Tuesday, August 24, 2021 1:26:31 PM To: Memoli, Matthew (NIH/NIAID) [E] (b)(6) Giurgea, Luca (NIH/NIAID) [E] (b)(6) Taubenberger, Jeffery (NIH/NIAID) [E] (b)(6) Gygli, Sebastian (NIH/NIAID) [F] (b)(6) Qi, Li (NIH/NIAID) [E] (b)(6) Qi, Li (NIH/NIAID)

Subject: RE: Infection-enhancing anti-SARS-CoV-2 antibodies recognize both the original Wuhan/D614G strain and Delta variants. A potential risk for mass vaccination? - Journal of Infection

Matt,

I don't have a horse in the race, but would observe that vaccine mandates have been broadly in place (e.g., for school exclusion policies for kids in public schools whose parents refuse measles, polio, etc. vaccines) since the 1960s, and the political and PH "classes" consider them important, also realizing the balance between insuring the public health (for all) and forcing some people to do things they don't want to do. I think the feeling in PH is that even though PH has absolute police power, it should be used only as a last resort, when the inevitable pushback seems worth it. This lesson was learned around 1905 with "Typhoid Mary" Mallon, who was thrown in jail for infecting people with typhoid as a cook.

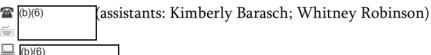
I am not a politician and am really not all that interested in these things. From my point of view, people like us should just make better vaccines so people like Tony wouldn't have to make imperfect policies.



David M. Morens, M.D.

CAPT, United States Public Health Service
Senior Advisor to the Director
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National Institute of Allergy and Infectious Diseases
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Building 31, Room 7A-03
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(b)(6) (assistants: Kimberly Barasch; Whitn



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they are working on it.

DMM Portrait B 12 29 15 P0923

From: Memoli, Matthew (NIH/NIAID) [E] (b)(6)
Sent: Tuesday, August 24, 2021 12:39 PM
To: Giurgea, Luca (NIH/NIAID) [E] (b)(6) Morens, David (NIH/NIAID) [E]
(b)(6) Kash, John (NIH/NIAID) [E] (b)(6) Taubenberger, Jeffery
(NIH/NIAID) [E] (b)(6) Gygli, Sebastian (NIH/NIAID) [F]
(b)(6) Park, Jaekeun (NIH/NIAID) [E] (b)(6) Qi, Li (NIH/NIAID)
[E] (b)(6)
Subject: Re: Infection-enhancing anti-SARS-CoV-2 antibodies recognize both the original Wuhan/D614G
strain and Delta variants. A potential risk for mass vaccination ? - Journal of Infection
My biggest problem is we are now forcing people to get these vaccines on a false premise. There are many people who don't want it who are having their livelihoods taken away if they don't because politicians advised by Fauci and his ilk say the vaccine gets rid of the problem. This is a false premise and the forced, mandated vaccines are unethical given the data. This should be stopped and NIH should not support these mandates.
Matt
Get <u>Outlook for iOS</u>
From: Giurgea, Luca (NIH/NIAID) [E] (b)(6)
Sent: Tuesday, August 24, 2021 12:10:39 PM
To: Morens, David (NIH/NIAID) [E] (b)(6) Kash, John (NIH/NIAID) [E]
(b)(6) Memoli, Matthew (NIH/NIAID) [E] (b)(6) Taubenberger,
Jeffery (NIH/NIAID) [E] (b)(6) Gygli, Sebastian (NIH/NIAID) [F]
(b)(6) Park, Jaekeun (NIH/NIAID) [E] (b)(6) Qi, Li (NIH/NIAID)
[E] (b)(6)
Subject: Re: Infection-enhancing anti-SARS-CoV-2 antibodies recognize both the original Wuhan/D614G
strain and Delta variants. A potential risk for mass vaccination ? - Journal of Infection

My preference would be for another prospective randomized trial to show the benefit of boosters. I am extremely curious how efficacy would look like then, especially compared to flu vaccines. This would be a much more comparable study since now the control group would not be immunologically naïve.

I was about to make some comment regarding updated mRNA vaccines as John, but I am glad to hear

Would we see it in the 10-60% range too? Or do mRNA have enough adjuvant effect to push beyond that?

In the paper, it's too bad they didn't challenge passively immunized mice with Delta 4+, I am still curious about the effects these disease enhancing NTD-targeting non-neutralizing antibodies would have in vivo.

--

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Clinical Fellow, LID Clinical Studies Unit
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From: "Morens, David (NI	H/NIAID) [E]" (b)(6)	
Date: Tuesday, August 24	, 2021 at 12:09 PM	
To: "Kash, John (NIH/NIAI	D) [E]" (b)(6)	"Memoli, Matthew (NIH/NIAID) [E]"
(b)(6)	"Taubenberger, Jef	fery (NIH/NIAID) [E]"
(b)(6)	"Giurgea, Luca	(NIH/NIAID) [E]" (b)(6)
"Gygli, Sebastian (NIH/NIA	AID) [F]" (b)(6)	"Park, Jaekeun (NIH/NIAID) [E]"
(b)(6)	"Qi, Li (NIH/NIAID) [E]]" (b)(6)

Subject: RE: Infection-enhancing anti-SARS-CoV-2 antibodies recognize both the original Wuhan/D614G strain and Delta variants. A potential risk for mass vaccination? - Journal of Infection

Yes, both are being updated, but they are still mRNA vaccines and are likely to induce protection that is transient. We'll see,



David M. Morens, M.D.

CAPT, United States Public Health Service Senior Advisor to the Director Office of the Director National Institute of Allergy and Infectious Diseases National Institutes of Health Building 31, Room 7A-03 31 Center Drive, MSC 2520 Bethesda, MD 20892-2520

	(b)(6)	(assistants: Kimberly Barasch; Whitney Robinso	n)
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From: Kash, John (NIH/NIAID) [E]	(b)(6)		
Sent: Tuesday, August 24, 2021	12:04 PM		
To: Memoli, Matthew (NIH/NIAII	D) [E] (b)(6)	Taubenberger, Jeffer	y (NIH/NIAID) [E]
(b)(6)	Giurgea, Luca (NIH/NIAID) [E] (b)(6	6)	Morens, David
(NIH/NIAID) [E] (b)(6)	Gygli, Sebastian (NIH/N	NIAID) [F] (b)(6)	
Park, Jaekeun (NIH/NIAID) [E] (b)	(6) Qi, Li (NIH	I/NIAID) [E] (b)(6)	
Subject: Re: Infection-enhancing	anti-SARS-CoV-2 antibodies recog	gnize both the origina	l Wuhan/D614G
strain and Delta variants. A poter	ntial risk for mass vaccination? - J	ournal of Infection	

Wasn't rapid ability to update one of the touted benefits of the mRNA vaccine platform? Does anyone know if Moderna or Pfizer vaccines are being developed using updated S antigens (e.g. delta)? Regardless, for vulnerable populations, a booster of the current vaccine may help to boost waning memory B and T cell populations for conserved epitopes, which presumably are why vaccinated people have much lower rates of severe disease. But I agree using the same vaccine over and over will be of greatly diminishing benefit.

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From: "Matthew J. Memo	(b)(6)		
Date: Tuesday, August 24	, 2021 at 11:49 AM		
To: Jeffrey Taubenberger	(b)(6)	☐ "Giurgea, Luca (NIH/NIAID) [E]"	
(b)(6)	"Morens, David (NIH/NIAID) [E]	" (b)(6) "Gygli,	
Sebastian (NIH/NIAID) [F]	" (b)(6) "F	Park, Jaekeun (NIH/NIAID) [E]"	
(b)(6)	"Kash, John (NIH/NIAID) [E]" (E	"Qi, Li	
(NIH/NIAID) [E]" (b)(6)			
Subject: Re: Infection-enhancing anti-SARS-CoV-2 antibodies recognize both the original Wuhan/D614G strain and Delta variants. A potential risk for mass vaccination ? - Journal of Infection			
https://www.biorxiv.org/co	ntent/10.1101/2021.08.22.45711	<u>4v1.full.pdf</u>	
solution. We are going to los	se all credibility left when everyor	of the same vaccine are not going to be a ne is forced to be vaccinated, then boosted, ne strategies fast and stop forcing these	

vaccines on people who don't need it and would be better served with natural immunity.

Matt

__

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From: Jeffery Taubenberger (0)(6) Date: Friday, August 20, 2021 at 6:38 PM To: "Giurgea, Luca (NIH/NIAID) [E]" (0)(6)		
To: "Giurgea, Luca (NIH/NIAID) [E]" David Morens (b)(6)	From: Jeffery Taubenberger (b)(6)	
David Morens Park, Jaekeun NIH/NIAID E] David Morens Gygli, Sebastian (NIH/NIAID) E] David Morens Gygli, Sebastian NIH/NIAID E] David Morens Davi	Date: Friday, August 20, 2021 at 6:38 PM	
(NIH/NIAID) [E]" [b)(6)	To: "Giurgea, Luca (NIH/NIAID) [E]" (b)(6) Jeffery Taubenberger	
"Park, Jaekeun (NIH/NIAID) [E]" [D)(6) Subject: Re: Infection-enhancing anti-SARS-CoV-2 antibodies recognize both the original Wuhan/D614G strain and Delta variants. A potential risk for mass vaccination? - Journal of Infection Thanks! Jeff From: "Giurgea, Luca (NIH/NIAID) [E]" [D)(6) Date: Friday, August 20, 2021 at 5:00:54 PM To: "Taubenberger, Jeffery (NIH/NIAID) [E]" [D)(6) "Memoli, Matthew (NIH/NIAID) [E]" [D)(6) "Park, Jaekeun (NIH/NIAID) [E]" [D)(6) "Qi, Li (NIH/NIAID) [E]" [D)(6) "Qi, Li (NIH/NIAID) [E]" [D)(6) Subject: Re: Infection-enhancing anti-SARS-CoV-2 antibodies recognize both the original Wuhan/D614G strain and Delta variants. A potential risk for mass vaccination? - Journal of Infection Recent paper in NEJM I thought was interesting and relevant. They took serum from 5 groups (listed below) and looked for RBD-binding capacity (they call it surrogate virus neutralization) of multiple diverse coronaviruses: SARS-COV-1 survivors SARS-COV-2 survivors Pfizer vaccinated patients SARS-COV-2 survivors who were also Pfizer vaccinated	(b)(6) David Morens (b)(6) "Memoli,	Matthew
Color Colo	(NIH/NIAID) [E]" (b)(6) "Gygli, Sebastian (NIH/NIAID) [F]"	
Subject: Re: Infection-enhancing anti-SARS-CoV-2 antibodies recognize both the original Wuhan/D614G strain and Delta variants. A potential risk for mass vaccination? - Journal of Infection Thanks! Jeff From: "Giurgea, Luca (NIH/NIAID) [E]" Di/G)	(b)(6) "Park, Jaekeun (NIH/NIAID) [E]" (b)(6)	John Kash
Wuhan/D614G strain and Delta variants. A potential risk for mass vaccination? - Journal of Infection Thanks! Jeff From: "Giurgea, Luca (NIH/NIAID) [E]" [b)(6) Date: Friday, August 20, 2021 at 5:00:54 PM To: "Taubenberger, Jeffery (NIH/NIAID) [E]" (b)(6) "Memoli, Matthew (NIH/NIAID) [E]" (b)(6) "Gygli, Sebastian (NIH/NIAID) [F]" (b)(6) "Qi, Li (NIH/NIAID) [E]" (b)(6) "Qi, Li (NIH/NIAID) [E]" (b)(6) Subject: Re: Infection-enhancing anti-SARS-CoV-2 antibodies recognize both the original Wuhan/D614G strain and Delta variants. A potential risk for mass vaccination? - Journal of Infection Recent paper in NEJM I thought was interesting and relevant. They took serum from 5 groups (listed below) and looked for RBD-binding capacity (they call it surrogate virus neutralization) of multiple diverse coronaviruses: SARS-COV-1 survivors SARS-COV-2 survivors Pfizer vaccinated patients SARS-COV-2 survivors who were also Pfizer vaccinated	(b)(6) "Qi, Li (NIH/NIAID) [E]" (b)(6)	
Infection Thanks! Jeff From: "Giurgea, Luca (NIH/NIAID) [E]" [b)(6) Date: Friday, August 20, 2021 at 5:00:54 PM To: "Taubenberger, Jeffery (NIH/NIAID) [E]" [b)(6) "Morens, David (NIH/NIAID) [E]" [b)(6) "Memoli, Matthew (NIH/NIAID) [E]" [b)(6) "Gygli, Sebastian (NIH/NIAID) [F]" [b)(6) "Qi, Li (NIH/NIAID) [E]" [b)(6) Subject: Re: Infection-enhancing anti-SARS-CoV-2 antibodies recognize both the original Wuhan/D614G strain and Delta variants. A potential risk for mass vaccination? - Journal of Infection Recent paper in NEJM I thought was interesting and relevant. They took serum from 5 groups (listed below) and looked for RBD-binding capacity (they call it surrogate virus neutralization) of multiple diverse coronaviruses: SARS-COV-1 survivors SARS-COV-2 survivors Pfizer vaccinated patients SARS-COV-2 survivors who were also Pfizer vaccinated	Subject: Re: Infection-enhancing anti-SARS-CoV-2 antibodies recognize both the original	inal
From: "Giurgea, Luca (NIH/NIAID) [E]" (b)(6) Date: Friday, August 20, 2021 at 5:00:54 PM To: "Taubenberger, Jeffery (NIH/NIAID) [E]" (b)(6)	Wuhan/D614G strain and Delta variants. A potential risk for mass vaccination? - Jour	rnal of
From: "Giurgea, Luca (NIH/NIAID) [E]" (b)(6) Date: Friday, August 20, 2021 at 5:00:54 PM To: "Taubenberger, Jeffery (NIH/NIAID) [E]" (b)(6)	Infection	
Date: Friday, August 20, 2021 at 5:00:54 PM To: "Taubenberger, Jeffery (NIH/NIAID) [E]" (b)(6)	Thanks! Jeff	
(b)(6) "Gygli, Sebastian (NIH/NIAID) [F]" (b)(6) "Park, Jaekeun (NIH/NIAID) [E]" (b)(6) "Kash, John (NIH/NIAID) [E]" (b)(6) "Qi, Li (NIH/NIAID) [E]" (b)(6) Subject: Re: Infection-enhancing anti-SARS-CoV-2 antibodies recognize both the original Wuhan/D614G strain and Delta variants. A potential risk for mass vaccination? - Journal of Infection Recent paper in NEJM I thought was interesting and relevant. They took serum from 5 groups (listed below) and looked for RBD-binding capacity (they call it surrogate virus neutralization) of multiple diverse coronaviruses: SARS-COV-1 survivors SARS-COV-2 survivors Pfizer vaccinated patients SARS-COV-2 survivors who were also Pfizer vaccinated	Date: Friday, August 20, 2021 at 5:00:54 PM To: "Taubenberger, Jeffery (NIH/NIAID) [E]" (b)(6) "Morens, David	I
Jaekeun (NIH/NIAID) [E]" (b)(6) "Kash, John (NIH/NIAID) [E]" (b)(6) Subject: Re: Infection-enhancing anti-SARS-CoV-2 antibodies recognize both the original Wuhan/D614G strain and Delta variants. A potential risk for mass vaccination? - Journal of Infection Recent paper in NEJM I thought was interesting and relevant. They took serum from 5 groups (listed below) and looked for RBD-binding capacity (they call it surrogate virus neutralization) of multiple diverse coronaviruses: SARS-COV-1 survivors SARS-COV-2 survivors Pfizer vaccinated patients SARS-COV-2 survivors who were also Pfizer vaccinated	, , , , , , , , , , , , , , , , , , , ,	lark
"Qi, Li (NIH/NIAID) [E]" (b)(6) Subject: Re: Infection-enhancing anti-SARS-CoV-2 antibodies recognize both the original Wuhan/D614G strain and Delta variants. A potential risk for mass vaccination? - Journal of Infection Recent paper in NEJM I thought was interesting and relevant. They took serum from 5 groups (listed below) and looked for RBD-binding capacity (they call it surrogate virus neutralization) of multiple diverse coronaviruses: SARS-COV-1 survivors SARS-COV-2 survivors Pfizer vaccinated patients SARS-COV-2 survivors who were also Pfizer vaccinated		ark,
Subject: Re: Infection-enhancing anti-SARS-CoV-2 antibodies recognize both the original Wuhan/D614G strain and Delta variants. A potential risk for mass vaccination ? - Journal of Infection Recent paper in NEJM I thought was interesting and relevant. They took serum from 5 groups (listed below) and looked for RBD-binding capacity (they call it surrogate virus neutralization) of multiple diverse coronaviruses: SARS-COV-1 survivors SARS-COV-2 survivors Pfizer vaccinated patients SARS-COV-2 survivors who were also Pfizer vaccinated	, , , , , , , , , , , , , , , , , , , ,	
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	below) and looked for RBD-binding capacity (they call it surrogate virus neutralization) of mudiverse coronaviruses: SARS-COV-1 survivors SARS-COV-2 survivors Pfizer vaccinated patients	,

The conclusions support the kind of vaccine strategies we are pursuing:

The SARS-COV-1 survivors had good response against SARS-COV-1 and a closely related bat species WIV1 but little against a distantly related bat coronavirus and SARS-COV-2

The SARS-COV-2 survivors had good response against alpha, beta, delta and some activity against some bat coronaviruses but little against SARS-COV-1 and WIV1

Pfizer vaccinated patients looked similar to SARS-COV-2 survivors, with maybe somewhat better response overall

SARS-COV-2 survivors who were also Pfizer vaccinated had a much broader response, with decent

activity even against SARS-COV-1 and WIV1 SARS-COV-1 survivors who were also Pfizer vaccinated had an amazing response against everything they tested They also did neutralizing titers and had similar(ish) results. Luca T. Giurgea, M.D. Clinical Fellow, LID Clinical Studies Unit **Laboratory of Infectious Diseases** NIAID, NIH MSC 3203 33 North Dr Bethesda, MD 20892-3203 **United States** Email: (b)(6) **Phone:** (b)(6) On 8/13/21, 1:10 PM, "Taubenberger, Jeffery (NIH/NIAID) [E]" (b)(6) wrote: Thanks David and Luca for the good discussion! On 8/13/21, 1:07 PM, "Giurgea, Luca (NIH/NIAID) [E]" (b)(6) wrote: Interesting! Thanks for sharing all that David. I will have to do some more reading on the atypical measles epidemic. In addition, I believe the RSV vaccine failures were also blamed on priming of a Th2 response, which was investigated a little bit during the pre-clinical/early clinical studies of the COVID vaccines, but I have not heard much about it since. Luca T. Giurgea, M.D.

Luca T. Giurgea, M.D.
Clinical Fellow, LID Clinical Studies Unit
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Bethesda, MD 20892-3203
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Email: (b)(6)
Phone: (b)(6)

On 8/13/21, 12:29 PM, "Morens, David (NIH/NIAID) [E]" (b)(6) wrote:

Luca, I am not sure anyone thinks that there is evidence that ADE is involved in COVID, but it keeps coming up, and FDA is likely to want to know before vaccines gets licensed (this was the case with the EUA vaccines, although the FDA looked at only cursory data foir ADE). Remember that ADE is a term for

in vitro phenomena, not a mechanism for disease pathogenesis, although there is evidence that ADE is ASSOCIATED, causally or not, with pathogenesis in dengue, as you say. In addition, some speculate, but I think the data are inconclusive, that ADE was involved in the epidemic of so-called "atypical measles" after vaccination with the original inactivated vaccine in the 1960s, with RSV enhanced disease after the 1960s LID vaccine, and with a variety of veterinary diseases such as FIPV. Also, we know that ADE occurs with influenza, associated with antibodies to both the H and the N, per work of Webster et al decades ago. Nancy Sullivan here in the VRC has done nice work with HIV ADE, identifying 5 separate ADE mechanisms for lentiviruses. Anyway, since few are doing this sort of work anymore, it's an easy-to-fill niche of unknown importance. I might also add that there are other explanations for enhanced dissease associated with ADE that are NOT causal, and these could be explored as well. No one has ever done that, ever.... Just sayin'!

d

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Original Me	essage			
From: Giurgea,	Luca (NIH/NIAID) [E] (b)(6)		
Sent: Friday, Au	ugust 13, 2021 12:14 PM		<u> </u>	
To: Morens, Da	avid (NIH/NIAID) [E] (b)(6)		Taubenberger, Jeffer	y (NIH/NIAID)
[E] (b)(6)	Memoli,	Matthew (NIH/NIA	(b)(6)	Gygli,
Sebastian (NIH/NIAID) [F] (b)(6)	Park, Jaek	eun (NIH/NIAID) [E]	
(b)(6)	Kash, John (NIH/NI)	AID) [E] (b)(6)	Qi, Li (NIH/N	IAID) [E]
(b)(6)				

Subject: Re: Infection-enhancing anti-SARS-CoV-2 antibodies recognize both the original Wuhan/D614G strain and Delta variants. A potential risk for mass vaccination? - Journal of Infection

I am curious what everyone else thinks but I am still rather skeptical of the ADE thing in COVID. It makes sense to me for Dengue, where infection of immune cells is part of the pathophysiology of disease, and naughty antibodies can facilitate entry into those cells. With covid, I can see antigenic sin being an issue down the road, but I suspect many non-neutralizing antibodies can still be helpful in protection through other mechanisms. The early clinical data is showing decreased vaccine efficacy against delta (from mutation? From waning immunity?) but still pretty good efficacy against severe disease (https://www.medrxiv.org/content/10.1101/2021.08.06.21261707v2) which I think makes sense. We saw similar trends with the other variants (https://www.nejm.org/doi/full/10.1056/NEJMc2104974).

-

Luca T. Giurgea, M.D.

Clinical Fellow, LID Clinical Studies Unit Laboratory of Infectious Diseases NIAID, NIH MSC 3203 33 North Dr Bethesda, MD 20892-3203 United States

Email: (b)(6)
Phone: (b)(6)

On 8/13/21, 11:31 AM, "Morens, David (NIH/NIAID) [E]" (b)(6) wrote:

that's "logs" not "ogs" d

David M. Morens, M.D.
CAPT, United States Public Health Service
Senior Advisor to the Director
Office of the Director
National Institute of Allergy and Infectious Diseases
National Institutes of Health
Building 31, Room 7A-03
31 Center Drive, MSC 2520
Bethesda, MD 20892-2520
B (b)(6) (assistant: Whitney Robinson)
W (b)(6) (assistant: Whitney Robinson)

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	Original Message
	From: Morens, David (NIH/NIAID) [E]
	Sent: Friday, August 13, 2021 11:31 AM
	To: Taubenberger, Jeffery (NIH/NIAID) [E] (b)(6) Memoli, Matthew
	AID) [E] (b)(6) Gygli, Sebastian (NIH/NIAID) [F] (b)(6) Kash, John (NIH/NIAID) [E]
(b)(6)	keun (NIH/NIAID) [E] (b)(6) Kash, John (NIH/NIAID) [E] Qi, Li (NIH/NIAID) [E] (b)(6) Giurgea, Luca (NIH/NIAID) [E]
(b)(6)	
-	Subject: RE: Infection-enhancing anti-SARS-CoV-2 antibodies recognize both the original D614G strain and Delta variants. A potential risk for mass vaccination ? - Journal of Infection
serums,	It is basically tissue culture work with various antibody reagents, including MAbs and immune including those that Nt and those that bind but don't Nt. They need to be in high enough titer to table" over at least 3-4 ogs and preferrably more.
(d
National	David M. Morens, M.D. CAPT, United States Public Health Service Senior Advisor to the Director Office of the Director Institute of Allergy and Infectious Diseases National Institutes of Health Building 31, Room 7A-
03	31 Center Drive, MSC 2520
	Bethesda, MD 20892-2520
	B (b)(6) (assistant: Whitney Robinson) W (b)(6) 3 (b)(6)
may con dissemin documen recipient	Disclaimer: This message is intended for the exclusive use of the recipient(s) named above. It tain information that is PROTECTED, PRIVILEGED, and/or CONFIDENTIAL, and it should not be nated, distributed, or copied to persons not authorized to receive such information. All sensitive nts must be properly labeled before dissemination via email. If you are not the intended t, any dissemination, distribution, or copying is strictly prohibited. If you have received this nication in error, please erase all copies of the message and its attachments and notify us steely.
(b)(6)	Original Message From: Taubenberger, Jeffery (NIH/NIAID) [E] (b)(6) Sent: Friday, August 13, 2021 11:28 AM To: Morens, David (NIH/NIAID) [E] (b)(6) Memoli, Matthew (NIH/NIAID) [E] Gygli, Sebastian (NIH/NIAID) [F] (b)(6) Park, Jaekeun AID) [E] (b)(6) Kash, John (NIH/NIAID) [E] (b)(6) Qi, Li
(IVIE) IVIE	Trasii, Joilii (NIT/MAID) [E] (PA)

(NIH/NIAID) [E] (b)(6) Giurgea, Luca (NIH/NIAID) [E] (b)(6) Subject: Re: Infection-enhancing anti-SARS-CoV-2 antibodies recognize both the original Wuhan/D614G strain and Delta variants. A potential risk for mass vaccination? - Journal of Infection
Yes, I'm sure we could.
On 8/13/21, 11:27 AM, "Morens, David (NIH/NIAID) [E]" (b)(6)
TY can't we get a student or someone to set up an ADE ability for flu, coronas, etc?
David M. Morens, M.D. CAPT, United States Public Health Service Senior Advisor to the Director Office of the Director National Institute of Allergy and Infectious Diseases National Institutes of Health Building 31, Room 7A-03 31 Center Drive, MSC 2520 Bethesda, MD 20892-2520 Bethesda, MD 20892-2520 B
Original Message From: Taubenberger, Jeffery (NIH/NIAID) [F] (b)(6)

Li (NIH/NIAID) [E] (b)(6) Giurgea, Luca (NIH/NIAID) [E] (b)(6)

Subject: FW: Infection-enhancing anti-SARS-CoV-2 antibodies recognize both the original Wuhan/D614G strain and Delta variants. A potential risk for mass vaccination? - Journal of Infection

Gygli, Sebastian (NIH/NIAID) [F] (b)(6)

Kash, John (NIH/NIAID) [E] (b)(6)

Memoli, Matthew (NIH/NIAID)

Park,

Qi,

FYI. I just came across this and read abstract. Haven't read paper yet.

Sent: Friday, August 13, 2021 11:24 AM To: Morens, David (NIH/NIAID) [E] (b)(6)

[E] (b)(6)

Jaekeun (NIH/NIAID) [E] (b)(6)

On 8/13/21, 11:22 AM, "Jeffery Taubenberger"	(b)(6)	wrote:
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https://www.journalofinfection.com/article/S0163-4453(21)00392-3/fulltext

	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
Recipient:	Morens, David (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) [b)(6) Giurgea, Luca (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) [b)(6) Kash, John (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) [b)(6) Taubenberger, Jeffery (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) [b)(6) Gygli, Sebastian (NIH/NIAID) [F] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) [b)(6) Park, Jaekeun (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) [b)(6) Qi, Li (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6)
	2021/08/24 14:04:01 2021/08/24 14:04:02
2 C FCI CU DUCCI	2021,00,2 . 2 . 10 . 102

From:	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
То:	Giurgea, Luca (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
Subject:	Re: New perspective piece on herd immunity
Date:	2021/05/24 11:26:30
Priority:	Normal
Туре:	Note

I finally looked at these protocols. Sorry. I have no experience with this paired protocol situation, so it seems weird to me not to just have it all in one, but I assume this was the advice you received? For the actual sample collection protocol do you want to solely rely on referral or do you want to try to get permission to approach investigators after someone has been diagnosed with a resp virus? In that case we will need to arrange a system with the lab where you can be alerted. For example, you could call them once a day or go down to micro to find out if there were any positives. Then you would identify patients of interest and contact the team. We would need permission from IRB for that though. Decide and then let's plan a scientific review for this. There may be an uptick in disease in the fall or Flu returns so would be good to have this ready. May be an interesting cold and flu season coming up.

Let's talk tomorrow morning, maybe around 10am.

Matt

--

Matthew J. Memoli, M.D., M.S.
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Pager:	(b)(6)	

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From: "Giurgea, Luca (NIH/NIAID) [E]" (b)(6) Date: Monday, May 24, 2021 at 9:25 AM To: "Memoli, Matthew (NIH/NIAID) [E]" (b)(6) Subject: Re: New perspective piece on herd immunity
Sounds good. When do you want to chat?
Luca T. Giurgea, M.D. Clinical Fellow, LID Clinical Studies Unit Laboratory of Infectious Diseases NIAID, NIH MSC 3203 33 North Dr Bethesda, MD 20892-3203 United States Email: (b)(6) Phone: (b)(6)
From: "Memoli, Matthew (NIH/NIAID) [E]" (b)(6) Date: Monday, May 24, 2021 at 8:59 AM To: "Giurgea, Luca (NIH/NIAID) [E]" (b)(6) Subject: Re: New perspective piece on herd immunity
Luca,
We should talk about this. I don't think this is a good idea. I don't want to discourage you for being aggressive, I like how hard you have been working on getting papers out, but I have many issues with this.
Matt
Matthew J. Memoli, M.D., M.S. Director, LID Clinical Studies Unit Laboratory of Infectious Diseases National Institute of Allergy and Infectious Diseases National Institutes of Health MSC 3203 33 North Dr Bethesda, MD 20892-3203 UNITED STATES Email: (b)(6) Phone: (b)(6) Pager: (b)(6)

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From: "Giurgea, Luca (NIH/NIAID) [E]" (b)(6)

Date: Friday, May 21, 2021 at 6:22 PM

To: "Memoli, Matthew (NIH/NIAID) [E]" (b)(6)

Subject: New perspective piece on herd immunity

Hey Matt,

I have been thinking about writing a piece on covid herd immunity, considering that everyone keeps talking about it and how we need to get to 70% vaccination, despite obvious caveats with respiratory viruses regarding mutation, imperfect immunity, and waning immunity. I held off for a bit since there have been pieces written in the past, raising these issues at least theoretically, as well as some recent ones in popular media. But the numbers continues to pop up, so I thought it would be worthwhile to write a well-referenced piece discussing the issue. Let me know what you think.

--

Phone: (b)(6)

Luca T. Giurgea, M.D.
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Email: (6)(6)

Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6)
(b)(6)

Giurgea, Luca (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6)
(b)(6)

Sent Date:

Delivered Date:

2021/05/24 11:26:30

From:	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
To:	Lynn Brainard (b)(6)
Subject:	Re: Urgent:) need availability to pre-record asap:) confirmed Keynote speaker: Coronavirus event (LabRoots) - April 14th
Date:	2021/04/07 10:16:58
Priority:	Normal
Туре:	Note

Here is my abstract:

Asymptomatic SARS-CoV-2 infection and delayed implementation of diagnostics have led to poorly defined viral prevalence rates. To address this, we analyzed seropositivity in US adults who have not previously been diagnosed with COVID-19. Individuals with characteristics that reflect the US population were selected by quota sampling from volunteers. Enrolled participants provided medical, geographic, demographic, socioeconomic information, and dried blood samples. The majority (88.7%) of samples were collected between May 10th and July 31st, 2020. The highest undiagnosed seropositivity was detected in Black/African American participants, younger, female, Hispanic, and Urban residents, and lower undiagnosed seropositivity in those with chronic diseases. These data indicate that there were 4.8 undiagnosed cases for every diagnosed case of COVID-19, and an estimated 16.8 million undiagnosed cases by mid-July 2020. Given the high point estimate of undiagnosed seropositivity in younger donors, lower point estimates in individuals with pre-existing conditions such as diabetes, and the vaccine rollout starting with older persons and those at risk, long-term study of naturally acquired immunity, vaccine acquired immunity, and vaccine boosted naturally acquired immunity will be necessary to fully understand the correlates of protection, durability of SARS-CoV-2 immunity, and the impact immunity will have long-term on the spread of SARS-CoV-2 and other future variants or novel coronaviruses. It is also clear from these data that novel coronaviruses can spread rapidly throughout human populations despite public health measures and we must therefore prepare for future novel coronaviruses and begin investigation into broadly protective countermeasures such as vaccines to mitigate this risk.

Learning Objectives:

1.Understand the spread of SARS-CoV-2 in the first 6 months of the pandemic, the limitations of testing, and how this impacts the overall epidemiologic data being used to direct public health measures

- 2.Understand what we can learn from these data and how we can alter our future pandemic responses to reduce the negative consequences of a pandemic
- 3.Understand the need for broadly protective vaccines/countermeasures, how we failed in the past, what research needs to be done, how novel vaccines they could be evaluated, and what real expectations are for them

Matt

__

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From: Lynn Brainard (b)(6)	
Date: Tuesday, April 6, 2021 at 9:19 PM	
To: "Memoli, Matthew (NIH/NIAID) [E]" (b)(6)	
Subject: RE: Urgent:) need availability to pre-record asap:) conf	firmed Keynote speaker:
Coronavirus event (LabRoots) - April 14th	

Also, Matt, we'll need your abstract (no more than 2,000 characters) at your earliest, and 2-3 learning objectives to add to the agenda.

From: Lynn Brainard
Sent: Tuesday, April 06, 2021 11:46 AM
To: Memoli, Matthew (NIH/NIAID) [E] (b)(6)
Subject: Urgent:) need availability to pre-record asan:) confirmed Keynote speaker: Coronavirus event

(LabRoots) - April 14th Importance: High
Hi Matt,
Hope all is well:)
Let me know your availability to pre-record your keynote presentation; the event is April 14th and we'll need to schedule this on a day on or before April 12th?
Please advise and we'll send the calendar invitation with details:)
Thanks!
Lynn
LYNN BRAINARD Senior PR &Content Manager, Virtual Events facebook twitter linkedin pinterest instagram youtube email (b)(6) phone + (b)(6) fax + 714.463.4673
Let's Talk Science. Let's Talk Medicine. View our 2021 Media Kit Check out our witty Science T-Shirt Store
From: Lynn Brainard Sent: Wednesday, February 24, 2021 11:40 AM To: Memoli, Matthew (NIH/NIAID) [E] (b)(6) Subject: RE: friendly reminder:) need talk title to add to agenda:) required info:) talk title:) confirmed Keynote speaker: Coronavirus event (LabRoots) - April 14th Importance: High
Fantastic! We'll be getting this detail up on the agenda accordingly:)
Thanks again, Matt!
From: Memoli, Matthew (NIH/NIAID) [E] (b)(6) Sent: Wednesday, February 24, 2021 11:10 AM

To: Lynn Brainard	(b)(6)

Subject: Re: friendly reminder:) need talk title to add to agenda:) required info:) talk title:) confirmed Keynote speaker: Coronavirus event (LabRoots) - April 14th

Hi Lynn,

Let's use this "What the NIH Serosurvey Tells Us So Far and Why We Should Try to Develop a Broadly Protective/Universal Beta-Coronavirus Vaccine".

Matt

__

Matthew J. Memoli, M.D., M.S.
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From: Lynn Brainard (b)(6)

Date: Wednesday, February 24, 2021 at 1:05 PM

To: "Memoli, Matthew (NIH/NIAID) [E]" (b)(6)

Subject: friendly reminder:) need talk title to add to agenda:) required info:) talk title:)

confirmed Keynote speaker: Coronavirus event (LabRoots) - April 14th

Hi Matt,

Sorry to send another follow up email, but I'm hoping to obtain your presentation talk title at your earliest convenience, so we can add you as a keynote speaker to the agenda and include the detail in the event promotions. We can use your bio/image we have on file, if okay by you, just need your presentation talk title.

Many thanks again, Matt!

Best,

Lynn

From: Lynn Brainard

Sent: Wednesday, February 17, 2021 11:47 AM

To: Memoli, Matthew (NIH/NIAID) [E] (b)(6)

Subject: RE: need talk title to add to agenda:) required info:) talk title:) confirmed Keynote speaker:

Coronavirus event (LabRoots) - April 14th

Importance: High

Fantastic! Wonderful to hear Matt:) We're delighted to have you present a keynote delivery presenting exactly what you outlined below.

Next step, we would simply need the following at your earliest to add you to the agenda and included in event promotions:

- -updated bio (we can use what we have on file?)
- -image (we can use what we have on file?)
- -credentials, how you would like your title listed by your name
- -presentation talk title
- -abstract (short summary of your talk, no more than 2,000 characters, can send a tad later, if you don't have it handy)
- -2-3 learning objectives for continuing education credits (can send a tad later, if you don't have it handy)
- (need to be measurable objectives of what an attendee will learn or understand once they have listened to your presentation) here's just an example below:
- 1. Define the effective combination therapy
- 2. Identify various challenges in designing the rational combination therapy
- 3. Explain current approaches to combination therapy in the clinic

Looking forward to receiving the talk title at your earliest:)

Best,

Lynn

From: Memoli, Matthew (NIH/NIAID) [E] (b)(6)

Sent: Thursday, February 04, 2021 5:22 AM

To: Lynn Brainard (b)(6)

Subject: Re: revisit, provide update? confirm interest Keynote speaker: Coronavirus event (LabRoots) - April 14th

HI Lynn,

Yes I am willing to do another presentation. I can discuss the final results of the 1st phase our serosurvey and work I am doing related to broadly protective/universal Coronavirus vaccines.

Matt

Matthew J. Memoli, M.D., M.S. Director, LID Clinical Studies Unit Laboratory of Infectious Diseases National Institute of Allergy and Infectious Diseases National Institutes of Health MSC 3203 33 North Dr Bethesda, MD 20892-3203

UNITED STATES

Email:	(b)(6)	
Phone:	(b)(6)	
Pager:	(b)(6)	

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From: Lynn Brainard (b)(6) Date: Wednesday, February 3, 2021 at 3:38 PM

To: "Memoli, Matthew (NIH/NIAID) [E]" (b)(6)

Subject: RE: revisit, provide update? confirm interest Keynote speaker: Coronavirus event

(LabRoots) - April 14th

Dear Dr. Memoli,

Hope this email finds you safe and well:)

I'm reaching out to you to gauge your interest in providing an update possibly for our upcoming Coronavirus Virtual Event, scheduled on April 14th, https://www.labroots.com/virtualevent/coronavirus and giving a pre-recorded keynote presentation on a topic of your choice sharing your work/expertise. Keep in mind you presented for the Dec 3rd event.

Of course, too don't hesitate to recommend any colleagues as well, I'd be happy to extend an invitation:)

Attached is the program agenda from prior events in the series (4/2, 6/17, 9/17, 12/3) with additional information including presentation talk titles from prior presenters. We've endured stellar keynote deliveries by yourself, Linfa Wang, Sumit Chanda, Ashish Jha, Ali Mokdad, Stephen Morse, Adolfo GarciaSastre, Monica Gandhi, Amesh Adalja, John Hopkins, naming just a few, and other amazing featured presenters and panelists.

Your talk can be pre-recorded via webcam on a date/time that works best for your schedule anytime on or before April 7th via our online studio link, and will then be broadcasted the day of the event. We'd be delighted to highlight you on the agenda!

General topics, (but not limited too):

- The Origins and Symptoms of the virus
- · Testing, Research, and Diagnostics
- Clinical Manifestations of COVID-19
- Prevention, Containment, and Transmission
- Vaccines (host immune response clinical outcomes with vaccines)

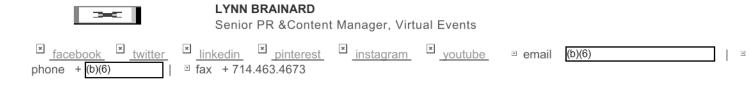
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We would be honored to have you present again for us! Please let me know if you are interested, and if so, what your proposed talk title will be. Next immediate step, would be to obtain your updated bio and image to add your detail to the event site and agenda to begin promotions.

Thanks as always for your time and consideration.

Lynn



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x

From: Lynn Brainard

Sent: Wednesday, December 02, 2020 9:31 AM

To: Memoli, Matthew (NIH/NIAID) [E] (b)(6)

Subject: RE: need abstract:) thoughts? Quote next week, press release/ confirmed Keynote speaker: Coronavirus event (LabRoots)

Hi Matt,

Wonderful, the abstract is great! Adding to the agenda:)

Many thanks again, we're looking forward to your presentation.

Best,

Lynn

From: Memoli, Matthew (NIH/NIAID) [E] (b)(6)

Sent: Wednesday, December 02, 2020 7:45 AM

To: Lynn Brainard (b)(6)

Subject: Re: need abstract:) thoughts? Quote next week, press release/confirmed Keynote speaker:

Coronavirus event (LabRoots)

Hi Lynn,

Here is an abstract:

The 2020 SARS-CoV-2 pandemic is now the 5th respiratory virus pandemic since 1918. No matter the time in history that these pandemics occur and no matter the severity we see public health efforts and scientists stymied in their efforts to truly change the course of these pandemics. The reasons for this are numerous as there are so many unanswered questions regarding respiratory virus infections that lead to many of the failed, confusing, and sometimes harmful actions taken by governments, health officials, and physicians/scientists. In order to address the current and future pandemics we must work hard to better understand the correlates of protection of respiratory viruses.

During the early stage of this pandemic we started a trial to look at the prevalence of SARS-CoV2 antibody in a nationwide sampling of individuals who were not diagnosed with COVID19. The goal of this study was to achieve a highly representative sample that could be used to estimate the true prevalence nationwide and in different groups based on multiple demographic and other factors. This study performed April to August, gave us the opportunity to take an early sample and then currently follow up at 6 and 12 months to assess change over time, longevity of response, and begin to probe questions regarding correlates of protection. This study sets the stage for much more work and raises questions that will need to be addressed in future studies.

With focused efforts and thoughtful science, we can achieve a much better understanding of respiratory viruses and the correlates of protection. This will require significant collaboration, communication, and of course funding. It is important that we try to get this right so that we are better prepared for the next pandemic and do not find ourselves still in the same situation we have been in during every pandemic since 1918.

--

Matthew J. Memoli, M.D., M.S. Director, LID Clinical Studies Unit

Laboratory of Infectious Diseases National Institute of Allergy and Infectious Diseases National Institutes of Health MSC 3203 33 North Dr Bethesda, MD 20892-3203

UNITED STATES

Email: (b)(6)

Phone: (b)(6)

Pager: (b)(6)

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From: Lynn Brainard (b)(6)

Date: Tuesday, December 1, 2020 at 2:32 PM

To: "Memoli, Matthew (NIH/NIAID) [E]" (b)(6)

Subject: RE: need abstract:) thoughts? Quote next week, press release/ confirmed Keynote

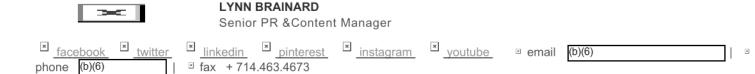
speaker: Coronavirus event (LabRoots)

Hi Matt,

Hope you had a nice holiday weekend:) Just a friendly reminder to send your short abstract so we can add to the agenda:)

Thanks again,

Lynn



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From: Lynn Brainard

Sent: Monday, November 23, 2020 12:12 PM

To: Memoli, Matthew (NIH/NIAID) [E] (b)(6)

Subject: need abstract:) thoughts? Quote next week, press release/ confirmed Keynote speaker:

Coronavirus event (LabRoots)

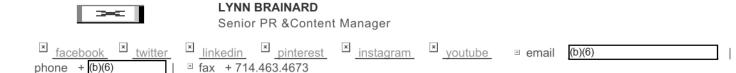
Hi Matt,

Happy Monday!

Just checking in on the timing of your short abstract (brief summary of your talk, no more than 2,000 characters) to be added to the agenda:)

Thank you,

Lynn



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x

From: Lynn Brainard

Sent: Friday, November 20, 2020 1:21 PM

To: Memoli, Matthew (NIH/NIAID) [E] (b)(6)

Subject: RE: thoughts? Quote next week, press release/confirmed Keynote speaker: Coronavirus event

(LabRoots)

Fantastic, this is perfect! Thank you Matt:) Very much appreciated!

Lynn

>=c	LYNN BRAINARD Senior PR &Content	t Manager			
phone + (b)(6) twitter	■ linkedin ■ pinterest □ fax + 714.463.4673	instagram instagram	youtube_	□ email	(b)(6)
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From: Memoli, Matthew (NIH/NIAID) [E] (b)(6)

Sent: Friday, November 20, 2020 5:34 AM

To: Lynn Brainard (b)(6)

Subject: Re: thoughts? Quote next week, press release/ confirmed Keynote speaker: Coronavirus event

(LabRoots)

HI Lynn,

x

"Respiratory viruses like COVID-19 and Influenza challenge scientists to explore the complexity of the immune response and correlates of protection. Broad investigation using translational studies in humans are imperative to our efforts to design efficacious, balanced countermeasures in an informed way that will lead to significant success in limiting the deleterious impact of these infections without destroying society or removing our humanity."

Matt

Matthew J. Memoli, M.D., M.S. Director, LID Clinical Studies Unit Laboratory of Infectious Diseases National Institute of Allergy and Infectious Diseases National Institutes of Health MSC 3203 33 North Dr Bethesda, MD 20892-3203

UNITED STATES

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From: Lynn Brainard (b)(6)

Date: Thursday, November 19, 2020 at 4:16 PM

To: "Memoli, Matthew (NIH/NIAID) [E]" (b)(6)

Subject: RE: thoughts? Quote next week, press release/ confirmed Keynote speaker:

Coronavirus event (LabRoots)

Hi Matt,

I know you're super busy, but also wanted to see by chance if you'd like to provide a quote (see below) as one of our keynote speakers for our event press release.

Thanks so much!

Lynn

From: Lynn Brainard

Sent: Sunday, November 15, 2020 11:37 AM

To: 'Memoli, Matthew (NIH/NIAID) [E]' (b)(6)

Subject: RE: thoughts? Quote next week, press release/ confirmed Keynote speaker: Coronavirus event

(LabRoots)

Hi Matt,

One more thing...I'd like to gauge your interest in possibly providing a quote for our event press release as our "keynote" speaker for this event of our Coronavirus Virtual Event Series, given your stellar expertise:) I've provided a few sample quotes below as information. If able, timing would be at the time you send the abstract over:)

Sample quotes:

"While we are living with and in a new pandemic, COVID-19, other infectious diseases have not ceased to exist causing widespread morbidity and mortality," said Peter Palese, Professor & Chair Dept. of Microbiology, Professor, Dept. of Medicine and Infectious Diseases, Ichan School of Medicine at

Mount Sinai. "It is important not to forget these "old" infectious diseases and even consider the possibility that the "old" and "new" pathogens together will be responsible for complex clinical outcomes and further put pressure on our health care system. LabRoots' platform will provide us with a comprehensive picture of what is going on in the field and how we can try to protect us from these disease-causing pathogens."

"COVID-19 is the most important pandemic in a century and while in the upcoming months, we will begin to see its more pernicious effects dissipate, we will continue to have to live with this virus for years to come. And it won't be the last pandemic we have to manage in this decade. Given that we are entering an age of pandemics, we should expect more disease outbreaks and pandemics like this. Since we can't predict, all we can do is prepare. And we must prepare to live in that new normal." Ashish K. Jha, Dean Brown University

"At the Center for Advanced Genome Engineering (CAGE), we create a broad range of genome edits both in terms of genomic loci and cell type," said Dr. Shondra Miller, Founding Director of the CAGE, St. Jude Children's Research Hospital. "At this conference, I will discuss how we use next generation sequencing to quickly and cost-effectively evaluate different genome editing strategies to efficiently create most types of custom edits, and I'm excited to share our pipeline and best practices via LabRoots' unique virtual platform."

"Since microfluidics has proven to be a valuable tool to operate at the "live" single cell level, it is ideal to both scale-up towards organ-level functions and scale-down towards genomics and proteomics expressions for a complete picture of the physiological health status," said **Dr. Abraham** "Abe" Lee, Professor, Department of Biomedical Engineering, University of California, Irvine. "The future of microfluidic precision medicine will enable patients to have access to their own health information in real-time and provide personalized options to help them live lives to their fullest. During the LabRoots conference you will learn about the advances in research labs that are rapidly moving into the clinic, and even the home-based medical solutions as the shelter-in-place orders are inevitably accelerating these developments."

Matt, I'm looking forward to hearing from you at your earliest. Feel free to draft a couple of sentences, I'll be happy to edit it if necessary. I'd be delighted to have you provide a quote for our event press release. Let me know your thoughts at your earliest convenience:)

Many than	ıKS,
-----------	------

Lynn



LYNN BRAINARD

Senior PR &Content Manager

https://public.labroots.com/signature/images/lr.logo.pn

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https://public.labroots.com/signature/images/lr.store.png

Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=[b)(6)

[b)(6)

Recipient: Lynn Brainard (b)(6)

Sent Date: 2021/04/07 10:16:59

Delivered Date: 2021/04/07 10:16:58

From:	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
To:	Lynn Brainard (b)(6)
Subject:	Re: Urgent:) need availability to pre-record asap:) confirmed Keynote speaker: Coronavirus event (LabRoots) - April 14th
Date:	2021/04/06 14:47:40
Priority:	Normal
Туре:	Note

Can we do April 12th at 1pm?

--

Matthew J. Memoli, M.D., M.S.
Director, LID Clinical Studies Unit
Laboratory of Infectious Diseases
National Institute of Allergy and Infectious Diseases
National Institutes of Health
MSC 3203 33 North Dr
Bethesda, MD 20892-3203
UNITED STATES

	DOTTILLO	
Email:	(b)(6)	
Phone:	(b)(6)	
Pager.	(b)(6)	

Hope all is well:)

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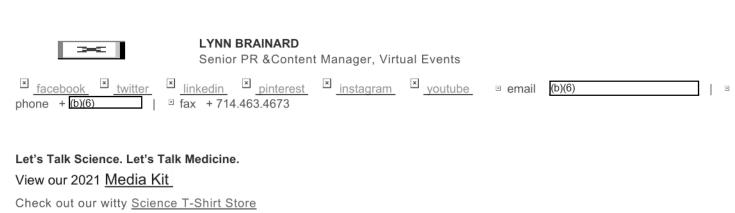
From: Lynn Brainard (b)(6)
·
Date: Tuesday, April 6, 2021 at 2:46 PM
To: "Memoli, Matthew (NIH/NIAID) [E]" (b)(6)
Subject: Urgent:) need availability to pre-record asap:) confirmed Keynote speaker: Coronavirus
event (LabRoots) - April 14th
Hi Matt,

Let me know your availability to pre-record your keynote presentation; the event is April 14th and we'll need to schedule this on a day on or before April 12th?

Please advise and we'll send the calendar invitation with details:)

Thanks!

Lynn



From: Lynn Brainard

Sent: Wednesday, February 24, 2021 11:40 AM

To: Memoli, Matthew (NIH/NIAID) [E] (b)(6)

Subject: RE: friendly reminder:) need talk title to add to agenda:) required info:) talk title:) confirmed

Keynote speaker: Coronavirus event (LabRoots) - April 14th

Importance: High

Fantastic! We'll be getting this detail up on the agenda accordingly:)

Thanks again, Matt!

From: Memoli, Matthew (NIH/NIAID) [E] (b)(6)

Sent: Wednesday, February 24, 2021 11:10 AM

To: Lynn Brainard (b)(6)

Subject: Re: friendly reminder:) need talk title to add to agenda:) required info:) talk title:) confirmed

Keynote speaker: Coronavirus event (LabRoots) - April 14th

Hi Lynn,

Let's use this "What the NIH Serosurvey Tells Us So Far and Why We Should Try to Develop a Broadly Protective/Universal Beta-Coronavirus Vaccine".

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Matthew J. Memoli, M.D., M.S. Director, LID Clinical Studies Unit Laboratory of Infectious Diseases National Institute of Allergy and Infectious Diseases National Institutes of Health MSC 3203 33 North Dr Bethesda, MD 20892-3203

UNITED STATES

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From: Lynn Brainard (b)(6)

Date: Wednesday, February 24, 2021 at 1:05 PM

To: "Memoli, Matthew (NIH/NIAID) [E]" (b)(6)

Subject: friendly reminder:) need talk title to add to agenda:) required info:) talk title:) confirmed Keynote speaker: Coronavirus event (LabRoots) - April 14th

Hi Matt,

Sorry to send another follow up email, but I'm hoping to obtain your presentation talk title at your earliest convenience, so we can add you as a keynote speaker to the agenda and include the detail in the event promotions. We can use your bio/image we have on file, if okay by you, just need your presentation talk title.

Many thanks again, Matt!

Best,

Lynn

From: Lynn Brainard

Sent: Wednesday, February 17, 2021 11:47 AM

To: Memoli, Matthew (NIH/NIAID) [E] (b)(6)

Subject: RE: need talk title to add to agenda:) required info:) talk title:) confirmed Keynote speaker:

Coronavirus event (LabRoots) - April 14th

Importance: High

Fantastic! Wonderful to hear Matt:) We're delighted to have you present a keynote delivery presenting exactly what you outlined below.

Next step, we would simply need the following at your earliest to add you to the agenda and included in event promotions:

- -updated bio (we can use what we have on file?)
- -image (we can use what we have on file?)
- -credentials, how you would like your title listed by your name
- -presentation talk title
- -abstract (short summary of your talk, no more than 2,000 characters, can send a tad later, if you don't have it handy)
- -2-3 learning objectives for continuing education credits (can send a tad later, if you don't have it handy)
- (need to be measurable objectives of what an attendee will learn or understand once they have listened to your presentation) here's just an example below:
- 1. Define the effective combination therapy
- 2. Identify various challenges in designing the rational combination therapy
- 3. Explain current approaches to combination therapy in the clinic

Looking forward to receiving the talk title at your earliest:)

Best,

Lynn

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Sent: Thursday, February 04, 2021 5:22 AM

To: Lynn Brainard (b)(6)

Subject: Re: revisit, provide update? confirm interest Keynote speaker: Coronavirus event (LabRoots) -

April 14th

HI Lynn,

Yes I am willing to do another presentation. I can discuss the final results of the 1st phase our serosurvey and work I am doing related to broadly protective/universal Coronavirus vaccines.

Matt

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Matthew J. Memoli, M.D., M.S. Director, LID Clinical Studies Unit

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(LabRoots) - April 14th

Dear Dr. Memoli,

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I'm reaching out to you to gauge your interest in providing an update possibly for our upcoming <u>Coronavirus Virtual Event, scheduled on April 14th, https://www.labroots.com/virtual-event/coronavirus</u> and giving a pre-recorded keynote presentation on a topic of your choice sharing your work/expertise. Keep in mind you presented for the Dec 3rd event.

Of course, too don't hesitate to recommend any colleagues as well, I'd be happy to extend an invitation:)

Attached is the program agenda from prior events in the series (4/2, 6/17, 9/17, 12/3) with additional information including presentation talk titles from prior presenters. We've endured stellar keynote deliveries by yourself, Linfa Wang, Sumit Chanda, Ashish Jha, Ali Mokdad, Stephen Morse, Adolfo Garcia-Sastre, Monica Gandhi, Amesh Adalja, John Hopkins, naming just a few, and other amazing featured presenters and panelists.

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Thanks as always for your time and consideration.

Lynn

3=0	Senior PR &Content	t Manager, Virtu	ıal Events		
	 ■ linkedin ■ pinterest ■ fax + 714.463.4673 	instagram instagram	× youtube	≖ email	(b)(6)

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Sent: Wednesday, December 02, 2020 9:31 AM

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Subject: RE: need abstract:) thoughts? Quote next week, press release/ confirmed Keynote speaker:

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Hi Matt,

Wonderful, the abstract is great! Adding to the agenda:)

Many thanks again, we're looking forward to your presentation.

Best,

Lynn

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Hi Lynn,

Here is an abstract:

The 2020 SARS-CoV-2 pandemic is now the 5th respiratory virus pandemic since 1918. No matter the time in history that these pandemics occur and no matter the severity we see public health efforts and scientists stymied in their efforts to truly change the course of these pandemics. The reasons for this are numerous as there are so many unanswered questions regarding respiratory virus infections that lead to many of the failed, confusing, and sometimes harmful actions taken by governments, health officials, and physicians/scientists. In order to address the current and future pandemics we must work hard to better understand the correlates of protection of respiratory viruses.

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With focused efforts and thoughtful science, we can achieve a much better understanding of respiratory viruses and the correlates of protection. This will require significant collaboration, communication, and of course funding. It is important that we try to get this right so that we are better prepared for the next pandemic and do not find ourselves still in the same situation we have been in during every pandemic since 1918.

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Matthew J. Memoli, M.D., M.S.
Director, LID Clinical Studies Unit
Laboratory of Infectious Diseases
National Institute of Allergy and Infectious Diseases
National Institutes of Health
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Date: Tuesday, December 1, 2020 at 2:32 PM

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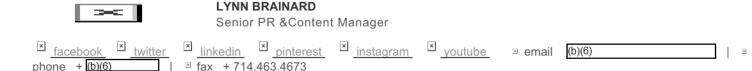
speaker: Coronavirus event (LabRoots)

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Thanks again,

Lynn



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Hi Matt,
Happy Monday!
Just checking in on the timing of your short abstract (brief summary of your talk, no more than 2,000 characters) to be added to the agenda:)
Thank you,
Lynn
LYNN BRAINARD Senior PR &Content Manager facebook twitter linkedin pinterest instagram youtube email (b)(6) fax + 714.463.4673 Let's Talk Science. Let's Talk Medicine. View our 2021 Media Kit Check out our witty Science T-Shirt Store
From: Lynn Brainard Sent: Friday, November 20, 2020 1:21 PM To: Memoli, Matthew (NIH/NIAID) [E] (b)(6) Subject: RE: thoughts? Quote next week, press release/ confirmed Keynote speaker: Coronavirus event (LabRoots) Fantastic, this is perfect! Thank you Matt:) Very much appreciated! Best, Lynn

LYNN BRAINARD Senior PR &Content Manager
★ facebook ★ twitter twitter ★ linkedin ★ pinterest ★ instagram ★ youtube □ email (b)(6) phone + (b)(6)
Let's Talk Science. Let's Talk Medicine. View our 2021 Media Kit Check out our witty Science T-Shirt Store
From: Memoli, Matthew (NIH/NIAID) [E] (b)(6) Sent: Friday, November 20, 2020 5:34 AM To: Lynn Brainard (b)(6) Subject: Re: thoughts? Quote next week, press release/ confirmed Keynote speaker: Coronavirus event (LabRoots)
HI Lynn,
"Respiratory viruses like COVID-19 and Influenza challenge scientists to explore the complexity of the immune response and correlates of protection. Broad investigation using translational studies in humans are imperative to our efforts to design efficacious, balanced countermeasures in an informed way that will lead to significant success in limiting the deleterious impact of these infections without destroying society or removing our humanity."
Matt
Matthew J. Memoli, M.D., M.S. Director, LID Clinical Studies Unit Laboratory of Infectious Diseases National Institute of Allergy and Infectious Diseases National Institutes of Health MSC 3203 33 North Dr Bethesda, MD 20892-3203 UNITED STATES Email: (D)(6)

Phone: (b)(6)
Pager: (b)(6)

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From: Lynn Brainard (b)(6)

Date: Thursday, November 19, 2020 at 4:16 PM

To: "Memoli, Matthew (NIH/NIAID) [E]" (b)(6)

Subject: RE: thoughts? Quote next week, press release/ confirmed Keynote speaker:

Coronavirus event (LabRoots)

Hi Matt,

I know you're super busy, but also wanted to see by chance if you'd like to provide a quote (see below) as one of our keynote speakers for our event press release.

Thanks so much!

Lynn

From: Lynn Brainard

Sent: Sunday, November 15, 2020 11:37 AM

To: 'Memoli, Matthew (NIH/NIAID) [E]' (b)(6)

Subject: RE: thoughts? Quote next week, press release/ confirmed Keynote speaker: Coronavirus event

(LabRoots)

Hi Matt,

One more thing...I'd like to gauge your interest in possibly providing a quote for our event press release as our "keynote" speaker for this event of our Coronavirus Virtual Event Series, given your stellar expertise:) I've provided a few sample quotes below as information. If able, timing would be at the time you send the abstract over:)

Sample quotes:

"While we are living with and in a new pandemic, COVID-19, other infectious diseases have not ceased to exist causing widespread morbidity and mortality," said Peter Palese, Professor & Chair Dept. of Microbiology, Professor, Dept. of Medicine and Infectious Diseases, Ichan School of Medicine at Mount Sinai. "It is important not to forget these "old" infectious diseases and even consider the possibility that the "old" and "new" pathogens together will be responsible for complex clinical outcomes and further put pressure on our health care system. LabRoots' platform will provide us with a comprehensive picture of what is going on in the field and how we can try to protect us from these disease-causing pathogens."

"COVID-19 is the most important pandemic in a century and while in the upcoming months, we will begin to see its more pernicious effects dissipate, we will continue to have to live with this virus for years to come. And it won't be the last pandemic we have to manage in this decade. Given that we are entering an age of pandemics, we should expect more disease outbreaks and pandemics like this. Since we can't predict, all we can do is prepare. And we must prepare to live in that new normal." Ashish K. Jha, Dean Brown University

"At the Center for Advanced Genome Engineering (CAGE), we create a broad range of genome edits both in terms of genomic loci and cell type," said Dr. Shondra Miller, Founding Director of the CAGE, St. Jude Children's Research Hospital. "At this conference, I will discuss how we use next generation sequencing to quickly and cost-effectively evaluate different genome editing strategies to efficiently create most types of custom edits, and I'm excited to share our pipeline and best practices via LabRoots' unique virtual platform."

"Since microfluidics has proven to be a valuable tool to operate at the "live" single cell level, it is ideal to both scale-up towards organ-level functions and scale-down towards genomics and proteomics expressions for a complete picture of the physiological health status," said **Dr. Abraham** "Abe" Lee, Professor, Department of Biomedical Engineering, University of California, Irvine. "The future of microfluidic precision medicine will enable patients to have access to their own health information in real-time and provide personalized options to help them live lives to their fullest. During the LabRoots conference you will learn about the advances in research labs that are rapidly moving into the clinic, and even the home-based medical solutions as the shelter-in-place orders are inevitably accelerating these developments."

Matt, I'm looking forward to hearing from you at your earliest. Feel free to draft a couple of sentences, I'll be happy to edit it if necessary. I'd be delighted to have you provide a quote for our event press release. Let me know your thoughts at your earliest convenience:)

Many thanks,

Lynn

⇒=c	LYNN BRAINARD		
https://public.labroots.com/signature/images/lr.logo.pn	Senior PR &Content Manage	er	
g			
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	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6)
Recipient:	Lynn Brainard (b)(6)
Sent Date:	2021/04/06 14:47:40

From:	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
To:	KAZI, Fatema (b)(6)
Subject:	Re: Presentation information required_WHO meeting on human challenge studies_23 Feb
Date:	2021/02/22 14:42:44
Priority:	Normal
Туре:	Note

HI Kazi,

I put together a few quick slides that I will use to lead my discussion. They are mostly so I can remember what I would like to say and to keep everyone from getting bored. I will share from my desktop as I may make small changes, but here it is as a backup in case something goes wrong.

Also as a piece of info I will log in at 7am EST, however I will have to drop my son at his preschool just before 8amEST. I will be settled by the time I am scheduled to speak at 8:30am EST. I just wanted to let you know between 7:45am and 8am I may be a bit in and out due to my morning childcare issues. I will try to limit how much I am missing.

Thanks, Matt

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From: "KAZI, Fatema" (b)(6)	
Date: Monday, February 22, 2021 at 3:19 AM	
To: "Memoli, Matthew (NIH/NIAID) [E]" (b)(6)	
Cc: "Levine, Myron" (b)(6) "RIVEROS BALTA, Ximena"	
(b)(6) "HENAO RESTREPO, Ana Maria" (b)(6)	
Subject: Presentation information required_WHO meeting on human challenge studies_23 Feb	
Dear Matt,	
We are pleased to know that you will be presenting on challenge studies and we look forward to you sharing your vast knowledge and experience in the meeting.	
In terms of the logistics, we will provide you with co-host access which will enable you to share your own slides. However, it would be great as a back up if you can provide us with a copy of your presentation as soon as feasible.	
Best wishes Fatima	
From: KAZI, Fatema Sent: Friday, February 19, 2021 9:18 PM To: Levine, Myron (b)(6) HENAO RESTREPO, Ana Maria (b)(6) Cc: Memoli, Matthew (NIH/NIAID) [E] (b)(6) Subject: RE: [EXT] Matt Memoli is wiling to present	
Dear Mike,	
Thank you for this. I will add Matt into the agenda.	
Dear Matt, Please find attached (in case you haven't seen this yet), the list of questions we have sent to the other speakers to provide their feedback on. You will be made a co-host so that you have the option to share your own slides, however it would be great if you can send us a copy of your presentation to have as a back-up. Thank you for presenting and we look forward to your participation.	
Kind regards Fatima	
From: Levine, Myron (b)(6) Sent: Friday, February 19, 2021 8:41 PM To: KAZI, Fatema (b)(6) RIVEROS BALTA, Ximena (b)(6) HENAO RESTREPO, Ana	

Maria (b)(6)	
Cc: Memoli, Matthew (NIH/NIAID)	[E] (b)(6)
Subject: [EXT] Matt Memoli is wilin	g to present

Dear all:

After our videoconference today, I contacted Matt Memoli at NIH. It was a very informative conversation and Matt agreed to give a short talk at the AG meeting.

With respect to the goal of next week's meeting of the WHO Advisory Group, Matt Memoli made the following points (among many others), some of which he may cover as part of a 10-minute talk.

- 1. There is a group at NIH that has a clinical protocol to perform challenge studies with SARs-CoV-2.
- 2. They have had a challenge inoculum of a D614G SARS-CoV-2 strain prepared, should the need for setting up challenge studies arise. It has taken 6 months to get the GMP challenge virus batch and the titer of virus is lower than they anticipated.
- 3. They did the above on a "just in case" possible need for studies. They remain in a "wait and see" mode.
- 4. The lack of a reliable "rescue treatment" influences their decision. It is always in the background.
- 5. It would take considerable time (multiple months) to get a GMP lot of a SARS-CoV-2 Variant of concern grown and ready for challenge studies.
- 6. The main role of challenge studies with any SARS-CoV-2 will be to address certain basic questions of human-virus interaction that cannot be unraveled in other ways and that would have relevance to advising on the development of improved <u>future</u> COVID-19 vaccines. Such future vaccines may be very different from current vaccines. He sees this as the main role of a COVID-19 challenge model.
- 7. He appreciates that such human challenge studies can be misconstrued by anti-vaccine activists and this could amplify vaccine hesitancy in segments of the general population.

Matt has vast experience and he made many other cogent points. I am copying Matt on this email, lest I have inadvertently mis-represented any comments from my notes of our conversation.

Obviously, Matt is free to present whatever he deems relevant to the purpose of the meeting. If he can squeeze in some of the above, that would help to keep WHO abreast of the landscape of groups with clinical protocols and GMP challenge lots, and their plans.

Warm regards,

Mike

Myron M. Levine, M.D., D.T.P.H.
Simon &Bessie Grollman Distinguished Professor
Associate Dean for Global Health, Vaccinology &Infectious Diseases
Founder &Former Director, Center for Vaccine Development (1974)
University of Maryland School of Medicine
685 W. Baltimore Street

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Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)

Recipient: KAZI, Fatema (b)(6)

Sent Date: 2021/02/22 14:42:50 **Delivered Date:** 2021/02/22 14:42:44

From:	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
To:	Raphael Viscidi (b)(6)
CC:	Brie Falkard (b)(6) Omar Vandal (b)(6)
Subject:	Re: Novel vaccine technology
Date:	2021/02/17 14:05:16
Priority:	Normal
Туре:	Note

Hi Raphael,

I was speaking with some of my contacts at the Gates Foundation. They have become interested in respiratory virus transmission blocking agents. I told them about your technology. I thought it would make sense for you to connect with them. I have CC'd Omar Vandal and Brie Falkard from the Gates Foundation so they can reach out to you.

Thanks, Matt

--

Matthew J. Memoli, M.D., M.S.
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From: Raphael Viscidi (b)(6)
Date: Monday, February 15, 2021 at 10:53 AM
To: "Memoli, Matthew (NIH/NIAID) [E]" (b)(6)

Subject: Re: Novel vaccine technology

Hi Matt,

Let me know when you have discussed my proposal with your colleague who runs the BSL3 facility. I would like to explore collaborations through a CRADA arrangement.

I am also very interested in reaching out to the Gates Foundation through your contact. Can we discuss how to do that most effectively? Would you contact them first? What is their position within the organization?

Your thoughts on how to present our proposal will also be appreciated. I think a reasonable use of the immunization strategy is to identify infected individuals through testing and then use contact tracing to identify and treat all exposed individuals. The strategy is designed to treat the infected individuals and be prophylactic for the exposed. Because the treatment would provide long term immunity, this approach would, as it were, snuff out a mini epidemic in the making, something that is not possible with current prophylactic vaccines in this setting since full protection would require weeks or months to achieve depending on dosage schedules, and unlike an anti-viral, the protection would be permanent. Just some thoughts for now.

Ray

From: Memoli, Matthew (NIH/NIAID) [E] (b)(6)

Sent: Thursday, February 11, 2021 9:28 AM
To: Raphael Viscidi (b)(6)
Subject: Re: Novel vaccine technology

External Email - Use Caution

Dr. Viscidi,

I would like to speak with you about this. Please call me at (b)(6)

Thank you, Matt

--

Matthew J. Memoli, M.D., M.S.
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From: Raphael Viscidi (b)(6)

Date: Wednesday, February 10, 2021 at 2:11 PM

To: (b)(6) "Memoli, Matthew

(NIH/NIAID) [E]" (b)(6) , Eric Topol

Subject: Novel vaccine technology

Dear Drs. Topol, Modjarrad, Memmoli and Hoft:

Each of your names was referenced in a New York Times article written by Carl Zimmer a few days ago. The article suggests that each of you has a strong professional desire to ensure the development of a single solution that can protect against Covid-19, its variants and the next pathogenic coronavirus to emerge.

I have invented technology that I have good reason to believe will do each of those things and clear an early infection with SARS-CoV-2 within about a day. This technology is described in a pending patent entitled "Cytolytic T Cell Immunotherapy for Highly Pathogenic Coronaviruses." Please allow me the opportunity to explain the reason for my email.

As a virologist at Johns Hopkins, I have focused much of my research on human papillomavirus and polyomaviruses. My interests also cover seroepidemiological studies of human coronaviruses, and development of a SARS-CoV-1 coronavirus subunit vaccine. About 10 years ago I began the research that culminated in a Patent being issued for "Polyionic Papilloma Virus-Like Particle (VLP) Vaccines."

In May 2020 I invented a way to use the VLPs to induce a T cell-mediated immune response to coronaviruses. The pending patent embodies that invention. Briefly, the self-adjuvanting VLP delivers strategically selected antigens that, through a reversible disulfide bond, are released within the endosome to induce a CD8+ T cell-mediated immune response through cross presentation. The construct is designed to include SARS-CoV-2-specific antigens to induce CD8+ T cells intended to provide long-term protection from future infection. In addition, immune escape concerns are reduced because these strategically selected antigens target multiple proteins of the virus.

But, as important, my VLP construct for pathogenic coronaviruses targets antigenic regions shared by endemic coronaviruses. Using this strategy to treat infection with SARS-CoV-2, the VLP construct targets antigenic regions shared by the endemic OC43 and HKU12 and SARS-CoV-2. This stimulates pre-existing OC43 and HKU1 tissue-resident CD8+ memory T cells that will attack cells infected with SARS-CoV-2. As described in the attached summary written for the pharmaceutical industry, a blitz of CD8+ tissue-resident memory T cells can clear infection in a day. This strategy can be an on-the-shelf product and ready immediately upon emergence of any new coronavirus that shares antigenic regions with one or more of the 4 endemic coronaviruses. The VLP is intended for intranasal delivery (directly to the site of endemic coronavirus tissue-resident memory T cells). By administering the VLPs through this route, the immune response is designed to be immediate.

Since October, I and my partner have worked diligently to expose my invention to the pharmaceutical industry and the Biden administration. The attached summary has, with other data, been provided to the FDA and NIH. Despite these efforts and the strong support for my strategy found in academic literature, it has been seemingly impossible to convince anyone to show an interest in my approach.

If you each are interested in a single technology that can clear early infection with SARS-CoV-2, prevent consequential future infection, and be available on the shelf to treat and provide long-term protection against new coronaviruses, then I would like to enlist your assistance. I understand you each have your own interests and pursuits; by no means is this an attempt to divert your attention. I also understand that you may be invested in the notion that antibodies are the best avenue to address the pandemic and future risk. And I understand that without data, what I have invented remains theoretical for the most part. But I appeal to you to review the attached with an open mind and apply scientific logic to appreciate the potential of my technology as one we owe society a duty to put to the test. At the very least, in case variants, disease enhancement and/or other concerns prevent a successful antibody solution, it would be more than just prudent that my technology be fully developed and available as a back-up.

Time is too short for our venture to be a start-up. We need to acquire a qualified pharmaceutical partner immediately. Without support from you and others like you, and without government encouragement we hope your support might garner, we fear we will be unable to convince a qualified company to do what is required to get my technology to clinical trials expeditiously. Like any such solution, studies and/or trials may prove it to be ineffective. But based on existing science, there is no reason to believe, without testing, it will not achieve its intended benefit. You may see reasons, on the face of it, for skepticism, but I am confident that a

dialogue with me will be able to address any such skepticism and convince you that we would be remiss not to exhaust my invention as a way to meet society's goals as outlined in Carl Zimmer's article. Thus, I welcome the opportunity to discuss my technology with any or all of you at your convenience. Thank you for your time and consideration.

Yours,

Raphael Viscidi

Professor of Pediatrics and Infectious Diseases Johns Hopkins University School of Medicine

As an aside to Dr. Modjarrad, I have known Nelson Michael for a long time, and I recently worked with Diane Bolton and Gordon Joyce on ideas for an HIV vaccine based on the VLP technology.

Sender:	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=[h)(6) [b)(6)
Recipient:	Raphael Viscidi (b)(6) Brie Falkard (b)(6) Omar Vandal (b)(6)
Sent Date:	2021/02/17 14:05:15
Delivered Date:	2021/02/17 14:05:16

From:	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4d3af4d9f3e54fbc80ddd844c16691cc-memolim (b)(6)
To:	Raphael Viscidi (b)(6)
Subject:	Re: Novel vaccine technology
Date:	2021/02/17 13:29:02
Priority:	Normal
Туре:	Note

I am talking with Gates today. I am going to give them your info and proposal document.

Matt

--

Matthew J. Memoli, M.D., M.S.
Director, LID Clinical Studies Unit
Laboratory of Infectious Diseases
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From: Raphael Viscidi (b)(6)

Date: Monday, February 15, 2021 at 10:53 AM

To: "Memoli, Matthew (NIH/NIAID) [E]" (b)(6)

Subject: Re: Novel vaccine technology

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Sent: Thursday, February 11, 2021 9:28 AM **To:** Raphael Viscidi (b)(6)

Subject: Re: Novel vaccine technology

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From: Raphael Viscidi (b)(6)	
Date: Wednesday, February 10, 2021 at 2:11 PM	
To: (b)(6)	"Memoli, Matthew
(NIH/NIAID) [E]" (b)(6)	Eric Topol
(b)(6)	
Subject: Novel vaccine technology	

Dear Drs. Topol, Modjarrad, Memmoli and Hoft:

Each of your names was referenced in a New York Times article written by Carl Zimmer a few days ago. The article suggests that each of you has a strong professional desire to ensure the development of a single solution that can protect against Covid-19, its variants and the next pathogenic coronavirus to emerge.

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Yours,

Raphael Viscidi

Professor of Pediatrics and Infectious Diseases Johns Hopkins University School of Medicine

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	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
Recipient:	Raphael Viscidi (b)(6)
Sent Date:	2021/02/17 13:29:00
Delivered Date:	2021/02/17 13:29:02

From:	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
To:	Hall, Matthew (NIH/NCATS) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6) (Chanock, Stephen (NIH/NCI) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
Subject:	Re: Aftervax proposal
Date:	2021/02/15 09:52:38
Priority:	Normal
Туре:	Note

Hi Matt and Stephen,

Thanks,

Attached is a draft protocol for the AFTERVAX study that I developed. This is currently a draft and being reviewed by my statisticians to finalize N numbers, analysis procedures, etc. Therefore the numbers may change a bit, but the overall concept and procedures are all there. Let me know if here are any questions. I appreciate your review and interest. I think this type of study is very important and sorely needed. The simple follow up of adverse events in the short term that the vax companies and CDC may be doing is not enough. We need more thorough exploration of a large nationwide sample of individuals and comparison to unvaccinated individuals. We likely need even more thorough studies than what I am proposing here, but we have to start somewhere and work with the resources available. There are so many long term unknowns about introducing this vaccine to large numbers of people and scientifically/ethically we need to be carefully studying what is happening. Happy to discuss further.

Matthew J. Memoli, M.D., M.S.
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On 2/13/21, 11:21 AM, "Hall, Matthew (NIH/NCATS) [E]" (b)(6) wrote

Matt; would you mind forwarding a copy (or summary) of your Aftervax study concept to Stephen Chanock (cc'd)? If there's a concept summary that would be adequate too.

Matt

Sent from my iPad

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Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group

Sender: (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6)

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Recipient: Hall, Matthew (NIH/NCATS) [E] /o=ExchangeLabs/ou=Exchange Administrative Group
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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6) Chanock, Stephen (NIH/NCI) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)]
Sent Date:	2021/02/15 09:52:38	

From:	Memoli, Matthew (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
То:	Taubenberger, Jeffery (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=(b)(6) (b)(6)
Subject:	FW: Novel vaccine technology
Date:	2021/02/11 10:57:32
Priority:	Normal
Туре:	Note

Call me if you can. I spoke to this guy and wanted to talk to you about it.

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From: Raphael Viscidi (b)(6)	
Date: Wednesday, February 10, 2021 at 2:11 PM	
To: (b)(6)] "Memoli, Matthew
(NIH/NIAID) [E]" (b)(6)	Eric Topol
(b)(6)	

Subject: Novel vaccine technology

Dear Drs. Topol, Modjarrad, Memmoli and Hoft:

Each of your names was referenced in a New York Times article written by Carl Zimmer a few days ago. The article suggests that each of you has a strong professional desire to ensure the development of a single solution that can protect against Covid-19, its variants and the next pathogenic coronavirus to emerge.

I have invented technology that I have good reason to believe will do each of those things and clear an early infection with SARS-CoV-2 within about a day. This technology is described in a pending patent entitled "Cytolytic T Cell Immunotherapy for Highly Pathogenic Coronaviruses." Please allow me the opportunity to explain the reason for my email.

As a virologist at Johns Hopkins, I have focused much of my research on human papillomavirus and polyomaviruses. My interests also cover seroepidemiological studies of human coronaviruses, and development of a SARS-CoV-1 coronavirus subunit vaccine. About 10 years ago I began the research that culminated in a Patent being issued for "Polyionic Papilloma Virus-Like Particle (VLP) Vaccines."

In May 2020 I invented a way to use the VLPs to induce a T cell-mediated immune response to coronaviruses. The pending patent embodies that invention. Briefly, the self-adjuvanting VLP delivers strategically selected antigens that, through a reversible disulfide bond, are released within the endosome to induce a CD8+ T cell-mediated immune response through cross presentation. The construct is designed to include SARS-CoV-2-specific antigens to induce CD8+ T cells intended to provide long-term protection from future infection. In addition, immune escape concerns are reduced because these strategically selected antigens target multiple proteins of the virus.

But, as important, my VLP construct for pathogenic coronaviruses targets antigenic regions shared by endemic coronaviruses. Using this strategy to treat infection with SARS-CoV-2, the VLP construct targets antigenic regions shared by the endemic OC43 and HKU12 and SARS-CoV-2. This stimulates pre-existing OC43 and HKU1 tissue-resident CD8+ memory T cells that will attack cells infected with SARS-CoV-2. As described in the attached summary written for the pharmaceutical industry, a blitz of CD8+ tissue-resident memory T cells can clear infection in a day. This strategy can be an on-the-shelf product and ready immediately upon emergence of any new coronavirus that shares antigenic regions with one or more of the 4 endemic coronaviruses. The VLP is intended for intranasal delivery (directly to the site of endemic coronavirus tissue-resident memory T cells). By administering the VLPs through this route, the immune response is designed to be immediate.

Since October, I and my partner have worked diligently to expose my invention to the pharmaceutical industry and the Biden administration. The attached summary has, with other data, been provided to the FDA and NIH. Despite these efforts and the strong support for my strategy found in academic literature, it has been seemingly impossible to convince anyone to show an interest in my approach.

If you each are interested in a single technology that can clear early infection with SARS-CoV-2, prevent consequential future infection, and be available on the shelf to treat and provide long-term protection against new coronaviruses, then I would like to enlist your assistance. I

understand you each have your own interests and pursuits; by no means is this an attempt to divert your attention. I also understand that you may be invested in the notion that antibodies are the best avenue to address the pandemic and future risk. And I understand that without data, what I have invented remains theoretical for the most part. But I appeal to you to review the attached with an open mind and apply scientific logic to appreciate the potential of my technology as one we owe society a duty to put to the test. At the very least, in case variants, disease enhancement and/or other concerns prevent a successful antibody solution, it would be more than just prudent that my technology be fully developed and available as a back-up.

Time is too short for our venture to be a start-up. We need to acquire a qualified pharmaceutical partner immediately. Without support from you and others like you, and without government encouragement we hope your support might garner, we fear we will be unable to convince a qualified company to do what is required to get my technology to clinical trials expeditiously. Like any such solution, studies and/or trials may prove it to be ineffective. But based on existing science, there is no reason to believe, without testing, it will not achieve its intended benefit. You may see reasons, on the face of it, for skepticism, but I am confident that a dialogue with me will be able to address any such skepticism and convince you that we would be remiss not to exhaust my invention as a way to meet society's goals as outlined in Carl Zimmer's article. Thus, I welcome the opportunity to discuss my technology with any or all of you at your convenience. Thank you for your time and consideration.

Yours,

Raphael Viscidi

Professor of Pediatrics and Infectious Diseases Johns Hopkins University School of Medicine

As an aside to Dr. Modjarrad, I have known Nelson Michael for a long time, and I recently worked with Diane Bolton and Gordon Joyce on ideas for an HIV vaccine based on the VLP technology.

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