DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

March 17, 2021

Melanie Sloan
American Oversight
1030 15th Street NW
Suite B255
Washington, District of Columbia 20005
Via email:

Dear Ms. Sloan:

This letter is regarding to your Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) Freedom of Information Act (FOIA) request of March 27, 2020, assigned #20-01072-FOIA.

We located 56 pages of responsive records (7 pages released in full; 35 released in part; 14 pages withheld in full). After a careful review of these pages, some information was withheld from release pursuant to 5 U.S.C. §552 Exemption(s) (b)(4) and (b)(6).

EXEMPTION 4
Exemption 4 protects trade secrets and commercial or financial information obtained from a person that is privileged or confidential. The information withheld is commercial or financial information, such as email and attachments that contained privileged and confidential commercial information, and we have determined that the individual/s to whom this information pertains have a substantial commercial or financial interest in withholding it.

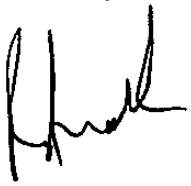
EXEMPTION 5
Exemption 5 protects inter-agency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency. Exemption 5 therefore incorporates the privileges that protect materials from discovery in litigation, including the deliberative process, attorney work-product, and attorney-client privileges. Information withheld under this exemption was protected under the deliberative process privilege. The deliberative process privilege protects the decision-making process of government agencies. The deliberative process privilege protects materials that are both predecisional and deliberative. The materials that have been withheld under the deliberative process privilege of Exemption 5 are both predecisional and deliberative, and do not contain or represent formal or informal agency policies or decisions. Examples of information withheld include emails which contain deliberative and pre-decisional information.

EXEMPTION 6
Exemption 6 protects information in personnel and medical files and similar files when disclosure would constitute a clearly unwarranted invasion of personal privacy. The information that has been withheld under Exemption 6 consists of personal information, such as names, email addresses, and phone numbers. We have determined that the individual(s) to whom this information pertains has a substantial privacy interest in withholding it.

You may contact our FOIA Public Liaison at 770-488-6277 for any further assistance and to discuss any aspect of your request. Additionally, you may contact the Office of Government Information Services (OGIS) at the National Archives and Records Administration to inquire about the FOIA mediation services they offer. The contact information for OGIS is as follows: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road-OGIS, College Park, Maryland 20740-6001, e-mail at ogis@nara.gov; telephone at 202-741-5770; toll free at 1-877-684-6448; or facsimile at 202-741-5769.

If you are not satisfied with the response to this request, you may administratively appeal by writing to the Deputy Agency Chief FOIA Officer, Office of the Assistant Secretary for Public Affairs, U.S. Department of Health and Human Services, Hubert H. Humphrey Building, 200 Independence Avenue, Suite 729H, Washington, D.C. 20201.You may also transmit your appeal via email to FOIARequest@psc.hhs.gov. Please mark both your appeal letter and envelope "FOIA Appeal." Your appeal must be postmarked or electronically transmitted by June 15, 2021.

Sincerely,



Roger Andoh
CDC/ATSDR FOIA Officer
Office of the Chief Operating Officer
(770) 488-6399
Fax: (404) 235-1852

Enclosures

20-01072-FOIA

From: (b)(6)
Sent: Wed, 11 Mar 2020 19:58:04 +0000
To: Messonnier, Nancy (CDC/DDID/NCIRD/OD)
Cc: Hamilton Bennett;MacNeil, Jessica R. (CDC/DDID/NCIRD/OD);Cohn, Amanda (CDC/DDID/NCIRD/OD);Weinbaum, Cindy (CDC/DDID/NCIRD/ISD)
Subject: RE: Moderna SARS-CoV-2 vaccine

Thanks Nancy. I'll reach out to Cindy. And keep you posted.

From: Messonnier, Nancy (CDC/DDID/NCIRD/OD) <nar5@cdc.gov>
Sent: Wednesday, March 11, 2020 3:11 PM
To: (b)(6) @modernatx.com>
Cc: (b)(6) @modernatx.com>; MacNeil, Jessica R. (CDC/DDID/NCIRD/OD) <aji8@cdc.gov>; Cohn, Amanda (CDC/DDID/NCIRD/OD) <anc0@cdc.gov>; Weinbaum, Cindy (CDC/DDID/NCIRD/ISD) <chw4@cdc.gov>
Subject: Re: Moderna SARS-CoV-2 vaccine

Hi (b)(6) We have stood up a vaccine task force as part of the response, led by Cindy Weinbaum, cced here. I'm also looping in Amanda and Jessica because of potential role of ACIP.

From (b)(6) @modernatx.com>
Sent: Wednesday, March 11, 2020 3:02:49 PM
To: Messonnier, Nancy (CDC/DDID/NCIRD/OD) <nar5@cdc.gov>
Cc: (b)(6) @modernatx.com>
Subject: Moderna SARS-CoV-2 vaccine

Dear Nancy,
I cannot imagine how busy you must be. After leaving FDA I joined Moderna, a firm developing a novel vaccine platform. In collaboration with NIAID our mRNA vaccine is about to be the first SARS-CoV-2 vaccine to be evaluated in human subjects in phase 1. We will be reaching out to Dr. Redfield on potential future use of the vaccine under Expanded Access or EUA, recognizing that we will have to partner with CDC given the evolving epidemiology of this outbreak if such use comes to pass. Would such effort be run out of NCIRD? If not any guidance on whom at CDC we should be involving early? Glad to discuss further if you have time.

Thanks in advance.

(b)(6)
(b)(6) | ModernaTX Inc
(b)(6) | modernatx.com
office (b)(6) (b)(6) | fax (617) 225-9093

Please consider the environment before printing this email

From: (b)(6)
Sent: Fri, 13 Mar 2020 18:31:00 +0000
To: Weinbaum, Cindy (CDC/DDID/NCIRD/ISD)
Cc: Hamilton Bennett;MacNeil, Jessica R. (CDC/DDID/NCIRD/OD);Cohn, Amanda (CDC/DDID/NCIRD/OD);Messonnier, Nancy (CDC/DDID/NCIRD/OD)
Subject: RE: Moderna SARS-CoV-2 vaccine

Dear Cindy,
We would like to have an introductory telecon to discuss the possible role for a SARS-CoV-2 vaccine in the current outbreak. Would you be able to provide some dates and available times?
Thanks,
(b)(6)

From: (b)(6)
Sent: Wednesday, March 11, 2020 3:58 PM
To: Messonnier, Nancy (CDC/DDID/NCIRD/OD) <nar5@cdc.gov>
Cc: (b)(6) @modernatx.com>; MacNeil, Jessica R. (CDC/DDID/NCIRD/OD) <aji8@cdc.gov>; Cohn, Amanda (CDC/DDID/NCIRD/OD) <anc0@cdc.gov>; Weinbaum, Cindy (CDC/DDID/NCIRD/ISD) <chw4@cdc.gov>
Subject: RE: Moderna SARS-CoV-2 vaccine

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Sent: Wednesday, March 11, 2020 3:11 PM
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Subject: Re: Moderna SARS-CoV-2 vaccine

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Sent: Wednesday, March 11, 2020 3:02:49 PM
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potential future use of the vaccine under Expanded Access or EUA, recognizing that we will have to partner with CDC given the evolving epidemiology of this outbreak if such use comes to pass. Would such effort be run out of NCIRD? If not any guidance on whom at CDC we should be involving early? Glad to discuss further if you have time.

Thanks in advance.

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| ModernaTX Inc
(b)(6) | modernatx.com
office (b)(6) mobile (b)(6) | fax (617) 225-9093

Please consider the environment before printing this email

From: (b)(6) [JRDUS]
Sent: Wed, 25 Mar 2020 15:00:53 +0000
To: Xia, Guo-liang (CDC/DDID/NCHHSTP/DVH);Messonnier, Nancy (CDC/DDID/NCIRD/OD)
Subject: RE: Contain Virus without Distancing People, idea for control of covid-19 epidemic in US

Dear Dr. Messonnier, our main concern is the spread caused by a great number of unidentifiable, asymptomatic, infected people in crowded communities like New York City. We suggest everyone in these communities to wear a mask when social distancing is impossible such as when riding subway in rush hours. We would be more than happy to discuss with you if you have any questions. Thanks.

(b)(6)

From: Xia, Guo-liang (CDC/DDID/NCHHSTP/DVH) <gax1@cdc.gov>
Sent: Tuesday, March 24, 2020 10:22 AM
To: Messonnier, Nancy (CDC/DDID/NCIRD/OD) <nar5@cdc.gov>
Cc: (b)(6) [JRDUS] <(b)(6)@its.jnj.com>
Subject: [EXTERNAL] Contain Virus without Distancing People, idea for control of covid-19 epidemic in US

Dear Dr Messonnier,

I am forwarding you an idea of **Everyone Wears a Face Mask** for control of covid-19 epidemic in US. Attached idea came from Dr. Songbai Wang, MD, MPH, Scientific Director at Johnson & Johnson, He is my classmate at medical school. I hope it works to slow covid-19 outbreaks and keep our **life as usual**.

Thank You!

Guo-Liang Xia, MD, MSc
Biologist, Laboratory Branch, Division of Viral Hepatitis (DVH)
National Center for HIV/AIDS, Viral Hepatitis, STD & TB Prevention (NCHHSTP)
Centers for Disease Control and Prevention (CDC)
MS-H18-4, 1600 Clifton Road N.E., Atlanta, GA 30333
Office: 404-639-2336 Email: GXIA@CDC.GOV

From: (b)(6)
Sent: Wed, 11 Mar 2020 19:02:49 +0000
To: Messonnier, Nancy (CDC/DDID/NCIRD/OD)
Cc: (b)(6)
Subject: Moderna SARS-CoV-2 vaccine

Dear Nancy,
I cannot imagine how busy you must be. After leaving FDA I joined Moderna, a firm developing a novel vaccine platform. In collaboration with NIAID our mRNA vaccine is about to be the first SARS-CoV-2 vaccine to be evaluated in human subjects in phase 1. We will be reaching out to Dr. Redfield on potential future use of the vaccine under Expanded Access or EUA, recognizing that we will have to partner with CDC given the evolving epidemiology of this outbreak if such use comes to pass. Would such effort be run out of NCIRD? If not any guidance on whom at CDC we should be involving early? Glad to discuss further if you have time.

Thanks in advance,

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(b)(6) | ModernaTX Inc
(b)(6) modernatx.com
office ((b)(6) mobile ((b)(6) | fax (617) 225-9093

moderna

Please consider the environment before printing this email

From: (b)(6) @bayer.com>
Sent: Wed, 15 Apr 2020 18:07:50 +0000
To: Butler, Jay C. (CDC/DDID/OD)
Subject: Accepted: COVID-19 CDC/Bayer Health Meeting

From: (b)(6)
Sent: Sun, 19 Apr 2020 21:10:08 +0000
To: Butler, Jay C. (CDC/DDID/OD)
Subject: Accepted: COVID-19 CDC/Bayer Health Meeting

From: (b)(6) /US
Sent: Tue, 18 Feb 2020 14:03:49 +0000
To: Messonnier, Nancy (CDC/DDID/NCIRD/OD);Grohskopf, Lisa A. (CDC/DDID/NCIRD/ID);Cohn, Amanda (CDC/DDID/NCIRD/OD);Pope, Kristin (CDC/DDID/NCIRD/OD)
Subject: Head's up on Sanofi / HHS coronavirus collaboration
Attachments: Sanofi Coronavirus Partnership[2].pdf

Dears -
I'm reaching out to provide you advance news of an announcement we will be making today regarding our engagement with BARDA to advance a new vaccine against COVID-19 using our baculovirus expression platform currently used to manufacture Flublok vaccine.

Please see the attached press release which will be made public at 10am ET today. I'm sharing this in advance with you for your awareness and information asking that you not publicize or distribute the information or release until after 10am ET.

I'd be interested to know any questions or thoughts you have on this and look forward to seeing you at ACIP next week.

(b)(6)

SANOFI

Press Release

Source: Sanofi (EURONEXT: SAN) (NASDAQ: SNY)

Sanofi joins forces with U.S. Department of Health and Human Services to advance a novel coronavirus vaccine

* Work with Biomedical Advanced Research and Development Authority (BARDA) will utilize Sanofi's well-established recombinant technology platform to expedite a potential COVID-19 vaccine

PARIS – February 18, 2020 – Sanofi Pasteur, the vaccines global business unit of Sanofi, will leverage previous development work for a SARS vaccine which may unlock a fast path forward for developing a COVID-19 vaccine. Sanofi will collaborate with the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response, expanding the company's long-standing partnership with BARDA.

COVID-19 belongs to a family of coronaviruses that can cause respiratory disease. In late 2002, the SARS (severe acute respiratory syndrome) coronavirus emerged and then largely disappeared by 2004. Sanofi plans to further investigate an advanced pre-clinical SARS vaccine candidate that could protect against COVID-19.

> *"Addressing a global health threat such as this newest coronavirus is going to take a collaborative effort, which is why we are working with BARDA to quickly advance a potential vaccine candidate,"* said David Loew, Global Head of Vaccines at Sanofi. *"While we are lending our expertise where possible, we believe the collaboration with BARDA may provide the most meaningful results in protecting the public from this latest outbreak."*

Sanofi to utilize innovative recombinant technology platform

Sanofi will use its recombinant DNA platform to produce a 2019 novel coronavirus vaccine candidate. The recombinant technology produces an exact genetic match to proteins found on the surface of the virus. The DNA sequence encoding this antigen will be combined into the DNA of the baculovirus expression platform, the basis of Sanofi's licensed recombinant influenza product, and used to rapidly produce large quantities of the coronavirus antigen which will be formulated to stimulate the immune system to protect against the virus.

> *"Emerging global health threats like the 2019 novel coronavirus require a rapid response,"* said BARDA Director Rick A. Bright, Ph.D. *"By expanding our partnership with Sanofi Pasteur and leveraging a licensed recombinant vaccine platform, we hope to speed development of a vaccine candidate to protect against a new virus."*

Sanofi uniquely positioned in search for a coronavirus vaccine

In non-clinical studies, the SARS vaccine candidate was immunogenic and afforded partial protection as assessed in animal challenge models. This development work by Protein Sciences (acquired by Sanofi in 2017) provides a head start in expediting a COVID-19 vaccine. Additionally, since there is a licensed vaccine based on this platform this will allow for research and materials to be produced relatively quickly for clinical testing. Sanofi's platform also has the potential to manufacture large quantities of the vaccine candidate.

Sanofi's long-standing commitment to protecting public health

This agreement with BARDA marks another milestone in Sanofi's ongoing contributions to help fight public health threats. Sanofi continues to actively explore potential opportunities where the company's deep vaccine experience and innovative technologies may contribute to addressing the coronavirus public health situation, including sharing Sanofi's vaccine research and development experience with the Coalition for Epidemic Preparedness Innovations.

In December 2019, Sanofi also entered into an agreement with BARDA to establish state of the art facilities in the U.S. for the sustainable production of an adjuvanted recombinant vaccine for use in the event of an influenza pandemic and based on the same technology platform that will be used for the COVID-19 program.

About Sanofi

Sanofi is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. We prevent illness with vaccines, provide innovative treatments to fight pain and ease suffering. We stand by the few who suffer from rare diseases and the millions with long-term chronic conditions.

With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.

Sanofi, Empowering Life

Media Relations Contact
Marion Breyer
Tel.: +33 (0)1 53 77 46 46
mr@sanofi.com

Investor Relations Contact
Felix Lauscher
Tel.: +33 (0)1 53 77 45 45
ir@sanofi.com

Forward-Looking Statements

This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified

by the words "expects", "anticipates", "believes", "intends", "estimates", "plans" and similar expressions. Although Sanofi's management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such product candidates, the absence of guarantee that the product candidates if approved will be commercially successful, the future approval and commercial success of therapeutic alternatives, Sanofi's ability to benefit from external growth opportunities, to complete related transactions and/or obtain regulatory clearances, risks associated with intellectual property and any related pending or future litigation and the ultimate outcome of such litigation, trends in exchange rates and prevailing interest rates, volatile economic conditions, the impact of cost containment initiatives and subsequent changes thereto, the average number of shares outstanding as well as those discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in Sanofi's annual report on Form 20-F for the year ended December 31, 2018. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

From: (b)(6)
Sent: Thu, 26 Mar 2020 19:02:49 +0000
To: Weinbaum, Cindy (CDC/DDID/NCIRD/ISD)
Cc: (b)(6) Wharton, Melinda (CDC/DDID/NCIRD/ISD);Messonnier, Nancy (CDC/DDID/NCIRD/OD)
Subject: (b)(4)

(b)(4)

Dear Cindy,

Thanks,
(b)(6)

Please consider the environment before printing this email

From: (b)(6) /US
Sent: Sat, 28 Mar 2020 18:25:21 +0000
To: Messonnier, Nancy (CDC/DDID/NCIRD/OD);Cohn, Amanda (CDC/DDID/NCIRD/OD);Grohskopf, Lisa A. (CDC/DDID/NCIRD/ID)
Subject: Sanofi and Translate Bio COVID-19 Collaboration Announcement

Dears –
Sharing the following to keep you informed of our latest effort in the fight against COVID-19. This is a second vaccine initiative for Sanofi Pasteur and additive to the therapeutic efforts going on through our Sanofi parent company related to sarilumab and hydroxycholorquine.

http://www.news.sanofi.us/2020-03-27-Sanofi-and-Translate-Bio-collaborate-to-develop-novel-mRNA-vaccine-candidate-against-COVID-19

On a more personal note…
I hope this finds you and your families well.
Thank you for your determination and resolve to follow the science versus the rhetoric in guiding the country through these unprecedented times. Though it may not always seem like it, most of us are very grateful for your work…and eventually, the rest of us will be.

Please let me / us know anything we can do to help –
(b)(6)

From: (b)(6) /US
Sent: Thu, 30 Apr 2020 14:44:51 +0000
To: Messonnier, Nancy (CDC/DDID/NCIRD/OD)
Subject: checking in

Yes – that would be most helpful.
At your convenience.
My cell: (b)(6)

From: "nar5@cdc.gov" <nar5@cdc.gov>
Date: Thursday, April 30, 2020 at 10:38 AM
To: "Ritchey, Julian /US" (b)(6) @sanofi.com>
Subject: [EXTERNAL] checking in

EXTERNAL : Real sender is nar5@cdc.gov

Do we need to check in before today's call?

From: (b)(6)
Sent: Tue, 5 May 2020 17:52:30 +0000
To: Messonnier, Nancy (CDC/DDID/NCIRD/OD)
Subject: RE: chat

That would be great Nancy; how does 3:30 pm today sound, I have 45 minutes before going into another call at 4:15pm. Alternatively later today. My cell phone is (b)(6) Best (b)(6)

From: Messonnier, Nancy (CDC/DDID/NCIRD/OD) (b)(5) @cdc.gov>
Sent: Tuesday, May 5, 2020 1:33 PM
To (b)(6) @pfizer.com>
Subject: [EXTERNAL] chat

Let me know if you have a few minutes to talk about COVID vaccines.
Nancy

From: (b)(6)
Sent: Tue, 5 May 2020 18:19:22 +0000
To: Messonnier, Nancy (CDC/DDID/NCIRD/OD)
Subject: RE: chat

Great looking forward to it

From: Messonnier, Nancy (CDC/DDID/NCIRD/OD) <nar5@cdc.gov>
Sent: Tuesday, May 5, 2020 2:16 PM
To: (b)(6)@pfizer.com>
Subject: [EXTERNAL] RE: chat

Yes, I can make that work. Just have to be done by 4. I'll call you.

From: (b)(6)@pfizer.com>
Sent: Tuesday, May 5, 2020 1:53 PM
To: Messonnier, Nancy (CDC/DDID/NCIRD/OD) <nar5@cdc.gov>
Subject: RE: chat

That would be great Nancy; how does 3:30 pm today sound, I have 45 minutes before going into another call at 4:15pm. Alternatively later today. My cell phone is (b)(6) Best (b)(6)

From: Messonnier, Nancy (CDC/DDID/NCIRD/OD) <nar5@cdc.gov>
Sent: Tuesday, May 5, 2020 1:33 PM
To: (b)(6)@pfizer.com>
Subject: [EXTERNAL] chat

Let me know if you have a few minutes to talk about COVID vaccines.
Nancy

From: Jansen, Kathrin
Sent: Sun, 10 May 2020 18:13:51 +0000
To: Messonnier, Nancy (CDC/DDID/NCIRD/OD);Santos, Michael (FNIH) [T];Lowy, Douglas (NIH/NCI) [E]
Cc: Schrag, Stephanie (CDC/DDID/NCIRD/DBD);Verani, Jennifer R. (CDC/DDID/NCIRD/DBD);Thornburg, Natalie (CDC/DDID/NCIRD/DVD);(b)(6) (NIH/NIAID) [E]
Subject: RE: Review requested: Human Challenge Model draft; notes from Vaccines Sub-Groups, ACTIV Leadership Team, and Preclinical WG

Thank you Nancy for your support and yes it would be great to have Stephanie, Natalie and Jennifer joining. Mike can provide you with all the communications as he has it all at his fingertips, no doubt. Best regards Kathrin

---

From: Messonnier, Nancy (CDC/DDID/NCIRD/OD) <nar5@cdc.gov>
Sent: Sunday, May 10, 2020 1:14 PM
To: Santos, Michael (FNIH) [T] <(b)(6)@fnih.org>; J(b)(6)@pfizer.com>
Cc: Schrag, Stephanie (CDC/DDID/NCIRD/DBD) <zha6@cdc.gov>; Verani, Jennifer R. (CDC/DDID/NCIRD/DBD) <qzr7@cdc.gov>; Thornburg, Natalie (CDC/DDID/NCIRD/DVD) <nax3@cdc.gov>; (b)(6) NIH/NIAID) (b)(6)@nih.gov>
Subject: [EXTERNAL] RE: Review requested: Human Challenge Model draft; notes from Vaccines Sub-Groups, ACTIV Leadership Team, and Preclinical WG

Michael and Kathrin
To ensure that CDC can provide the level of input which is being requested, please add Stephanie Schrag and Jennifer Verani, who are leading CDC coronavirus vaccine evaluation activities, and Natalie Thornburg, who leads COVID serology activities, to the overall ACTIV group. I think that Stephanie and Jennifer would be helpful additions to the subgroup considering the design of a phase III study. Kathrin has been asking for information about ongoing natural history and serology studies and Natalie would be well placed to discuss CDC's work.

I can send them some of the notes from the previous meetings so they can get caught up but I was wondering if you have that posted somewhere that they could access, if that's easier.

Thank you,
Nancy

From: Santos, Michael (FNIH) [T] <msantos@fnih.org>
Sent: Saturday, May 9, 2020 10:16 PM
To:(b)(6)@pfizer.com; L(b)(6)@mail.nih.gov>; (b)(6)@merck.com; A(b)(6)@stanford.edu>; (b)(6) (b)(6); (b)(6)@sfdph.org; (b)(6)@fredhutch.org; (b)(6)@stanford.edu; (b)(6)@gatesfoundation.org; (b)(6)@gsk.com; (b)(6) (b)(6)@mc.duke.edu>; (b)(6)@bcm.edu; I(b)(6)@irb.usi.ch; I(b)(6) (FDA/CBER) (b)(6)@fda.hhs.gov>; (b)(6) NIH/VRC) [E] <(b)(6)mail.nih.gov>; Messonnier, Nancy

(CDC/DDID/NCIRD/OD) <nar5@cdc.gov>; (b)(6) (b)(6) civ@mail.mil>; Offit, Paul (b)(6) @email.chop.edu>; (b)(6) @its.jnj.com; (b)(6) (b)(6) (OS/ASPR/BARDA) (b)(6) @hhs.gov>; (b)(6) @sanofi.com; (b)(6) (b)(6) modernatx.com>
C (b)(6) deloitte.com>; (b)(6) (NIH/NIAID) [E] (b)(6) @niaid.nih.gov>; (b)(6) @merck.com; (b)(6) @duke.edu; (b)(6) @pfizer.com; (b)(6) (NIH/NCI) [E] (b)(6) @dea.nci.nih.gov>; (b)(6) (NIH/NCI) [C] (b)(6) @nih.gov>; (b)(6) @fredhutch.org; (b)(6) @modernatx.com; (b)(6) @duke.edu; (b)(6) @bcm.edu; (b)(6) (NIH/VRC) [E] (b)(6) @mail.nih.gov>; (b)(6) @pfizer.com; (b)(6) @pfizer.com; Cohen, Myron (b)(6) @med.unc.edu>; (b)(6) [JRDUS] (b)(6) @its.jnj.com>; (b)(6) NIH/NIAID) [E] (b)(6) @nih.gov> (b)(6) @scharp.org>; (b)(6) (b)(6) @gsk.com>; (b)(6) @pfizer.com; (b)(6) (FDA/CBER) (b)(6) @fda.hhs.gov>; (b)(6) @sanofi.com>; (b)(6) o (b)(6) (OS/ASPR/BARDA) (b)(6) @hhs.gov>; (b)(6) @pfizer.com; (b)(6) (b)(6) @niaid.nih.gov>; (b)(6) @its.jnj.com>; (b)(6) (NIH/NIAID) (b)(6) n@nih.gov>; (b)(6) (b)(6) @som.umaryland.edu>; (b)(6) @hivresearch.org>; (b)(6) Michael Watson (x) <Mike.Watson@modernatx.com>; Parker, Ashley (NIH/OD) [E] (b)(6) @nih.gov>; Qashu, Felicia (NIH/OD) [E] (b)(6) @nih.gov>; (b)(6) (NIH/NCATS) [E] (b)(6) @nih.gov>; (b)(6) @merck.com; (b)(6) @novartis.com; (b)(6) (NIH/NCATS) [E] (b)(6) @nih.gov>; (b)(6) (NIH/NIAID) [E] <readsa@niaid.nih.gov>; john.young.jy3@roche.com; Menetski, Joseph (FNIH) [T] (b)(6) @fnih.org>; (b)(6) @deloitte.com>; (b)(6) (FNIH) [T] (b)(6) @fnih.org>; (b)(6) @deloitte.com>; (b)(6) (FNIH) [T] (b)(6) @fnih.org> (b)(6) @DELOITTE.com>; (b)(6) FNIH) [T] (b)(6) @fnih.org>; (b)(6) @deloitte.com>; (b)(6) (b)(6) @DELOITTE.com>

Subject: Review requested: Human Challenge Model draft; notes from Vaccines Sub-Groups, ACTIV Leadership Team, and Preclinical WG

Dear Vaccines Working Group members (and cc'ing others for awareness),

This note is an omnibus update for the Working Group: Sub-Group meeting notes, the human challenge model draft and agenda for the Working Group meeting, upcoming Vaccines Clinical Trial Sub-Group meetings and topics, and for awareness notes from the ACTIV Leadership Team meeting and Preclinical WG.

Sub-Group meeting notes

As a reminder, the Protective Immune Responses and Vaccine-associated Immune Enhancement Sub-Groups met since our last Working Group meeting (Thurs and Fri, respectively). Thank you to all who participated or sent input. **Attached are the notes and action items from each meeting**. The agendas and meeting materials and pre-reads are embedded in those documents. If anyone would like to be added to the lists for either Sub-Group, please let us know.

Review Controlled Human Infection Model outline in preparation for Monday's Working Group meeting

The main agenda item at the next Vaccines Working Group meeting, Monday, 12pm ET (9am PT / 6pm CEST), is a discussion of the Working Group's perspective on a CoV-2 controlled human infection model. Please review the attached outline to prepare for that discussion. If you cannot attend the meeting, feel free to send input via email that we can represent.

Vaccines Clinical Trial Sub-Group updates

Members of this Sub-Group are invited on Tuesday (11am ET) to join the Clinical Trial Capacity Working Group meeting, where Paula and Larry will share the plans of the Sub-Group and the CTC WG will share their activities and how they can work with us (e.g., inventory trial site capacity). **The Sub-Group meeting Wednesday (1pm ET) will focus on key protocol questions.**

ACTIV Leadership Team meeting notes

Last Wednesday, the ACTIV Leadership Team (the parent body above the Working Groups) met. Kathrin and Doug presented the progress and plans of the Working Group and answered questions. The meeting presentation and notes are attached. **Note: This is a good way to see a high-level summary of the activities of the other Working Groups, many of which are relevant to our work**; if you have specific questions, let us know and we can follow up.

Pre-clinical Working Group

Finally, as discussed last week we will continue to share notes from the Preclinical Working Group for awareness (attached zip file). **Note: a request to review the data collection fields for animal models will be coming to our group**, which we will circulate to the Protective Immune Responses and Vaccine-associated Immune Enhancement Sub-Groups.

As always, please don't hesitate to reach out with any questions or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science
Foundation for the National Institutes of Health
301-402-6917 | fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852

From: Jansen, Kathrin
Sent: Sat, 23 May 2020 14:05:04 +0000
To: Messonnier, Nancy (CDC/DDID/NCIRD/OD)
Subject: ACTIV vaccine working group meeting

Dear Nancy, as briefly discussed by phone, the ACTIV vaccine working group has made progress in defining the path forward for COVID19 vaccines to enter pivotal stages of vaccine clinical assessments which will be required (at least to have started before vaccine candidates can be made more widely available). For the next steps to be informed by the wealth of data the CDC has been and is collecting, we would be grateful if you could ask Stephanie Shrag and Jennifer Verani to share with the group how CDC is modeling the path of the current pandemic in the US and elsewhere and how CDC models can help predict the next hot spots in the US. Obviously these data would be of immense importance for vaccine developers to inform their ph3 trials. The working group meets on Thursday May 28th from 2 to 3 pm. Thank you for your help and I hope you can enjoy the holiday weekend. Stay well, best Kathrin

From: Jansen, Kathrin
Sent: Tue, 26 May 2020 10:26:21 +0000
To: Verani, Jennifer R. (CDC/DDID/NCIRD/DBD);Santos, Michael (FNIH) [T];Messonnier, Nancy (CDC/DDID/NCIRD/OD);Tolman, Brett;Lowy, Douglas (NIH/NCI) [E]
Cc: Schrag, Stephanie (CDC/DDID/NCIRD/DBD);Biggerstaff, Matthew (CDC/DDID/NCIRD/ID)
Subject: RE: ACTIV vaccine working group meeting

Thank you Nancy and Jennifer, much appreciated. Best regards Kathrin

---

From: Verani, Jennifer R. (CDC/DDID/NCIRD/DBD) <qzr7@cdc.gov>
Sent: Saturday, May 23, 2020 3:40 PM
To: Messonnier, Nancy (CDC/DDID/NCIRD/OD) <nar5@cdc.gov>; Jansen, Kathrin (b)(6)@pfizer.com>
Cc: Schrag, Stephanie (CDC/DDID/NCIRD/DBD) <zha6@cdc.gov>; Biggerstaff, Matthew (CDC/DDID/NCIRD/ID) <zmo2@cdc.gov>
Subject: [EXTERNAL] RE: ACTIV vaccine working group meeting

Kathrin,

Matt Biggerstaff (cc'd here) from the CDC modeling team has kindly offered to present at vaccine working group meeting this Thursday (May 28). Should he plan to present at the start of the meeting (2pm?)

Regards,
Jennifer

From: Messonnier, Nancy (CDC/DDID/NCIRD/OD) <nar5@cdc.gov>
Sent: Saturday, May 23, 2020 2:08 PM
To: Jansen, Kathrin <(b)(6)@pfizer.com>
Cc: Schrag, Stephanie (CDC/DDID/NCIRD/DBD) <zha6@cdc.gov>; Verani, Jennifer R. (CDC/DDID/NCIRD/DBD) <qzr7@cdc.gov>
Subject: RE: ACTIV vaccine working group meeting

We'd be happy to. Jennifer and Stephanie can help coordinate with the modelers.

From: Jansen, Kathrin (b)(6)@pfizer.com>
Sent: Saturday, May 23, 2020 10:05 AM
To: Messonnier, Nancy (CDC/DDID/NCIRD/OD) <nar5@cdc.gov>
Subject: ACTIV vaccine working group meeting

Dear Nancy, as briefly discussed by phone, the ACTIV vaccine working group has made progress in defining the path forward for COVID19 vaccines to enter pivotal stages of vaccine clinical assessments which will be required (at least to have started before vaccine candidates can be made more widely available). For the next steps to be informed by the wealth of data the CDC has been and is collecting, we would be grateful if you could ask Stephanie Shrag and Jennifer Verani to share with the group how CDC

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From: (b)(6)
Sent: Fri, 29 May 2020 21:22:08 +0000
To: Messonnier, Nancy (CDC/DDID/NCIRD/OD)
Cc: Hering, David;Snow, Vincenza T;Coen, Lisa;Jodar, Luis;Fox, Kimberley (CDC/DDID/NCIRD/DBD);MacNeil, Jessica R. (CDC/DDID/NCIRD/OD)
Subject: Contact from Pfizer

Dear Nancy,

I hope you and your family are all doing well.

Many thanks to you and your staff for your hard work and dedication to public health during these difficulty times. As was agreed at the meeting we had in person on February 3, we have been working closely with Jessica MacNeil and Noah Aleshire to update ACIP on our pipeline and approved vaccines. We are very grateful for their time and assistance in getting us in touch with all the relevant work groups.

(b)(4)

I know how incredibly busy you are but I was hoping you, Melinda Wharton, and Jessica might have a few minutes to spare to speak with us on these topics?

Thanks in advance for your time.

Best regards,

(b)(4)

Pfizer Biopharmaceuticals Group
Complejo Thames Office Park

Colectora Panamericana 1804, 1 Piso Sector "B" Lado Sur
Villa Adelina (CP 1607EEV) Pcia Buenos Aires-Argentina
Tel (b)(6)
Mobile: (b)(4)
e mail: (b)(4)

From: (b)(6)
Sent: Tue, 9 Jun 2020 19:39:28 +0000
To: Messonnier, Nancy (CDC/DDID/NCIRD/OD)
Subject: FW: Contact from Pfizer

Dear Nancy,

I hope you and your family are remaining safe and well

I´m so sorry to bothering you again. I can´t imagine how busy you are, and my intention is just to confirm you have received my previous contact.

I know these are not perfect times to ask for any kind of meeting but I was hoping you might have a few minutes to spare to speak on the topics listed in the email below

Thanks in advance for your time.

Best regards,

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Tel: (b)(6)
Mobile: (b)(6)
e mail: (b)(6)

Pfizer Vaccines
Pfizer Biopharmaceuticals Group

From: (b)(6)
Sent: Friday, May 29, 2020 6:22 PM
To: Messonnier, Nancy (CDC/DDID/NCIRD/OD) <nar5@cdc.gov>
Cc: (b)(6) @pfizer.com>; (b)(6) @pfizer.com>; (b)(6) @pfizer.com>; (b)(6) @pfizer.com>; Fox, Kimberley (CDC/DDID/NCIRD/DBD) <kaf6@cdc.gov>; MacNeil, Jessica R. (CDC/DDID/NCIRD/OD) <aji8@cdc.gov>
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Tel: + (b)(6)
Mobile: (b)(6)
e mail: (b)(6)

Pfizer Vaccines
Pfizer Biopharmaceuticals Group

From: (b)(6)
Sent: Wed, 10 Jun 2020 21:58:05 +0000
To: Messonnier, Nancy (CDC/DDID/NCIRD/OD)
Cc: Fox, Kimberley (CDC/DDID/NCIRD/DBD);Wharton, Melinda (CDC/DDID/NCIRD/ISD)
Subject: RE: Contact from Pfizer

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Kim and Melinda, it would be a pleasure to have a meeting (at least virtually) with you and your teams as Nancy has suggested. Please let me know who from your teams can help me with the organization of the call.

I also wanted to reinforce the fact that personally, but also for the entire Pfizer Vaccines team is critical to continue building a strong relationship as well as to maintain a very open and transparent channel of communication with you.

Looking forward to meet you soon

Best regards,

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Pfizer Vaccines
Pfizer Biopharmaceuticals Group

From: Messonnier, Nancy (CDC/DDID/NCIRD/OD) <nar5@cdc.gov>
Sent: Wednesday, June 10, 2020 6:07 PM
To: (b)(6) @pfizer.com>
Cc: Fox, Kimberley (CDC/DDID/NCIRD/DBD) <kaf6@cdc.gov>; Wharton, Melinda (CDC/DDID/NCIRD/ISD) <mew2@cdc.gov>
Subject: [EXTERNAL] RE: Contact from Pfizer

My apologies. As you can imagine, it is an unimaginably busy time here. I think the best next step would be for your team to talk to the combination of Kim Fox, who took over for Barb Mahon, and Melinda Wharton, who directs ISD. Kim's group at DBD is the group that writes the recommendations but then Melinda's group is translating it into CDSi. We worked so hard to build on the relationship between CDC and Pfizer and I definitely want to continue to build on that.

Nancy

From (b)(6) @pfizer.com>
Sent: Tuesday, June 9, 2020 3:39 PM
To: Messonnier, Nancy (CDC/DDID/NCIRD/OD) <nar5@cdc.gov>
Subject: FW: Contact from Pfizer

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e mail: (b)(6) @pfizer.com

Pfizer Vaccines Pfizer Biopharmaceuticals Group

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Sent: Friday, May 29, 2020 6:22 PM
To: Messonnier, Nancy (CDC/DDID/NCIRD/OD) <nar5@cdc.gov>
Cc: (b)(6) @pfizer.com>; (b)(6) @pfizer.com>; (b)(6) @pfizer.com>; (b)(6) @pfizer.com>; Fox, Kimberley (CDC/DDID/NCIRD/DBD) <kaf6@cdc.gov>; MacNeil, Jessica R. (CDC/DDID/NCIRD/OD) <aji8@cdc.gov>
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(b)(6)

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Tel: + (b)(6)
Mobile: (b)(6)
e mail: a

From: (b)(6)
Sent: Thu, 11 Jun 2020 13:47:43 +0000
To: Fox, Kimberley (CDC/DDID/NCIRD/DBD);Messonnier, Nancy (CDC/DDID/NCIRD/OD)
Cc: Wharton, Melinda (CDC/DDID/NCIRD/ISD)
Subject: RE: Contact from Pfizer

Dear Kim,

Thank you very much for your contact.
I think, if you are available, we can prepare a meeting for June 23rd at 3 pm , in order to avoid any potential conflict with the scheduled ACIP virtual meeting on June 24th.

Please let me know if you want me sending an appointment and, if this is the case, who from your team I should include as well as you and Melinda.
From the Pfizer side, the participants will be me, (b)(6) (as you know she is part of my team), (b)(6) (North America Vaccines Regional President) and (b)(6) (Vaccines Corporate Affairs)

Looking forward to talk with you

Best regards,

(b)(6)

From: Fox, Kimberley (CDC/DDID/NCIRD/DBD) <kaf6@cdc.gov>
Sent: Wednesday, June 10, 2020 9:15 PM
To: (b)(6) @pfizer.com>; Messonnier, Nancy (CDC/DDID/NCIRD/OD) <nar5@cdc.gov>
Cc: Wharton, Melinda (CDC/DDID/NCIRD/ISD) <mew2@cdc.gov>
Subject: [EXTERNAL] RE: Contact from Pfizer

Dear Ale,
I will follow up for the scheduling. Would late afternoon (between 3 and 5 PM) on either June 23 or June 24 work for you? If not, I will look for times later that same week.
I look forward to talking with you.
Regards,
Kim

Kimberley Fox, MD, MPH
Captain, USPHS
Acting Director, Division of Bacterial Diseases
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention
Atlanta, GA USA

Tel 404-718-1408
Cell (b)(6)

From: (b)(6) @pfizer.com>
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Cc: Fox, Kimberley (CDC/DDID/NCIRD/DBD) <kaf6@cdc.gov>; Wharton, Melinda (CDC/DDID/NCIRD/ISD) <mew2@cdc.gov>
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Thanks in advance for your time.

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Tel: + (b)(6)
Mobile: (b)(6)
e mail: (b)(6)

From: (b)(6) /US
Sent: Tue, 23 Jun 2020 21:26:06 +0000
To: Messonnier, Nancy (CDC/DDID/NCIRD/OD)
Subject: Routine Immunization Status by Age
Attachments: State Claims_External Parties v2[1].pptx

Dear Nancy –
Thank you for your time on the call today with the STOP Coalition.

I appreciate your continuing to share updates in various forums on how your teams are approaching the season. It's good to hear that the discussion on timing seems to have settled on keeping the Press Conference on 10/1. And I took from the call you feel as I do the quantity of doses (between new and in market) is sufficient to support significantly raising rates.

On the topic of routine immunization, I thought you might be interested in the attached. I have just been able to secure permission from IQVIA (the claims data people) to allow us to share these slides with public health partners such as yourself (b)(4) (b)(4)
Your point in the presentation today was spot on that rates are returning, but that is skewed toward the youngest ages. (b)(4)

I suspect this is more in Melinda's and Jeanne's courts, but after today's discussion, I thought I'd share with you first as I think this will be an important issue to identify and monitor going forward to ensure progress against it. We'd be happy to discuss this and provide this to your team each month if this is information you don't already have and/or a projection that helps visualize the data more clearly. I'd welcome any thoughts you have on this.

Good luck with ACIP tomorrow. The team has been doing a great job amid the practical challenges to assemble a strong program.

(b)(6)

(b)(4)

(b)(4)

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(b)(4)

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(b)(4)

(b)(4)

From: (b)(6) /US
Sent: Wed, 24 Jun 2020 02:30:01 +0000
To: Messonnier, Nancy (CDC/DDID/NCIRD/OD)
Subject: RE: Routine Immunization Status by Age

Please do.
I'm happy to discuss any questions with them, answer (or get answers) to source data questions, etc.
We'd love to compare observations on the data.
And yes, it needs to be for your internal use only per our IQVIA contract.

(b)(6)

From: "nar5@cdc.gov" <nar5@cdc.gov>
Date: Tuesday, June 23, 2020 at 5:41 PM
To: (b)(6) @sanofi.com>
Subject: [EXTERNAL] RE: Routine Immunization Status by Age

EXTERNAL : Real sender is nar5@cdc.gov

(b)(4)

We have been trying to get just like this. If its okay, I will share with Melinda, Jeanne, and Ram? Clearly for internal use only.
And thanks.

From: (b)(6) @sanofi.com>
Sent: Tuesday, June 23, 2020 5:26 PM
To: Messonnier, Nancy (CDC/DDID/NCIRD/OD) <nar5@cdc.gov>
Subject: Routine Immunization Status by Age

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On the topic of routine immunization, I thought you might be interested in the attached. I have just been able to secure permission from IQVIA (the claims data people) to allow us to share these slides with public health partners such as yourself
Your point in the presentation today was spot on that rates are returning, but that is skewed toward the

(b)(4)

youngest ages. (b)(4)

I suspect this is more in Melinda's and Jeanne's courts, but after today's discussion, I thought I'd share with you first as I think this will be an important issue to identify and monitor going forward to ensure progress against it. We'd be happy to discuss this and provide this to your team each month if this is information you don't already have and/or a projection that helps visualize the data more clearly. I'd welcome any thoughts you have on this.

Good luck with ACIP tomorrow. The team has been doing a great job amid the practical challenges to assemble a strong program.

(b)(6)

From: Butler, Jay C. (CDC/DDID/OD)
Sent: Wed, 15 Apr 2020 17:53:10 +0000
To: Butler, Jay C. (CDC/DDID/OD);(b)(6)
Cc: CDC IMS 2019 NCOV Response Policy Partnerships;Gunn, Janelle P. (CDC/DDNID/NCCDPHP/DNPAO);Hickner, Hadley (CDC/DDNID/NCCDPHP/DDT)
Subject: COVID-19 CDC/Bayer Health Meeting

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From: (b)(6)
Sent: Fri, 14 Feb 2020 09:30:00 -0600
To: Messonnier, Nancy (CDC/DDID/NCIRD/OD)
Subject: Roche Diagnostics Fix - CDC - 2019-nCoV Reagent Issue (GenomeWeb)

Hello Dr. Messonnier,
(b)(4)
I saw this "Reagent Issue" news article below regarding the CDC 2019-nCoV assay. Is there a contact you can share with me where Roche can assist in fixing the reagent issue? We have a few PhD scientists ready. (b)(4)

(b)(4)

Thanks,
(b)(6)

genomeweb

Business & Policy | Technology | Research | Diagnostics | Disease Areas

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New Reagent Needed

Feb 13, 2020

Save for later

Some testing kits for 2019-nCoV sent out by the US Centers for Disease Control and Prevention are giving inconclusive results during quality control checks, leading the agency to have to re-manufacture one of the kits' reagents, as GenomeWeb reports.

A positive result on the test, which is real-time RT-PCR based, indicates a likely infection with the 2019-nCoV coronavirus, though a negative result does not fully rule out possible infection. The Food and Drug Administration issued an Emergency Use Authorization for the test last week to enable other labs than the CDC in Atlanta to use it. According to the *New York Times*, the CDC began last week to ship about 200 kits to labs in the US — each kit can test about 700 to 800 patient samples — and a similar number internationally, though the international shipments were held as this issue was uncovered.

As GenomeWeb reports, when state labs were conducting quality assessment and validation checks of the test, they encountered inconclusive results. The CDC says it traced the issue to a reagent that wasn't working properly and will be re-manufacturing that reagent. "Obviously a state wouldn't want to be doing this test and using it to make clinical decisions if it isn't working as perfectly at state [labs] as it is at CDC," Nancy Messonnier, the director of the National Center for Immunization and Respiratory Diseases, said during a news conference.

(b)(6)

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