DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

Food and Drug Administration
Rockville, MD 20857

May 31, 2022

Via Email: mdiliberto@judicialwatch.org

Meredith Di Liberto
Judicial Watch, Inc.
425 Third Street, SW, Suite 800
Washington, DC 20024

Re: FDA FOIA Request 2021-5961; *Judicial Watch, Inc. v. HHS,* 22-cv-00293-APM

Dear Ms. Di Liberto,

Per the Joint Status Report dated March 25, 2022, attached please find our first partial response to the Freedom of Information Act (FOIA) request number **2020-5341** that is the subject of above-referenced matter.

Attached are 27 pages of records from the FDA's Center for Biologics Evaluation and Research (CBER) (Bates numbered FDA-CBER-2021-5961-0001 to -0027) some of which contain redactions.

We have withheld portions of pages under FOIA Exemption (b)(6), 5 U.S.C. § 522(b)(6). That exemption protects information from disclosure when its release would cause a clearly unwarranted invasion of personal privacy. FOIA Exemption 6 is available to protect information in personnel or medical files and similar files. This requires a balancing of the public's right to disclosure against the individual's right to privacy.

Please direct any questions regarding this response to Assistant United States Attorney Marcia Sowles of the Department of Justice, at (202) 514-4960 or Marcia.Sowles@usdoj.gov.

Sincerely,

Beth Brockner Ryan
Chief, Access Litigation and Freedom of Information Branch
Division of Disclosure and Oversight Management
Office of Communication Outreach and Development
Center for Biologics Evaluation and Research

Attachments

cc:

Marcia Sowles, Federal Programs Branch, USDOJ (By email)
Joshua Davenport, Office of the Chief Counsel, FDA (By email)

From: Gruber, Marion
To: Atreya, Prabhakara; Witten, Celia (CBER)
Cc: Hussey, Deirdre; Leary, Mary; Hayes, Kathleen E (CDC)
Subject: RE: VRBPAC team meeting tomorrow??
Date: Friday, September 3, 2021 5:15:00 PM

IF we even take the MODERNA submission to VRBPAC then it would need to be Oct 14. October 20 would not allow us to take regulatory action prior to end of October and that would be too late.
Marion

From: Atreya, Prabhakara <Prabhakara.Atreya@fda.hhs.gov>
Sent: Friday, September 3, 2021 1:18 PM
To: Witten, Celia (CBER) <Celia.Witten@fda.hhs.gov>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Cc: Hussey, Deirdre <Deirdre.Hussey@fda.hhs.gov>; Leary, Mary <Mary.Leary@fda.hhs.gov>; Hayes, Kathleen <Kathleen.Hayes@fda.hhs.gov>
Subject: RE: VRBPAC team meeting tomorrow??

Dear Dr. Witten and Gruber,

Please see availability data of VRBPAC members and consultants for Oct 14 and Oct 20, 2021 dates. We seem to have most members/consultants available for these two dates.

Please can you confirm if one of these two dates would work for Moderna booster topic meeting so that we can go ahead and confirm to the members and consultants. They ask for quick confirmation at the earliest so they can arrange their schedules and/or coverage for them when they attend our meeting(s).

Also if you anticipate other COVID topic meetings in Nov and Dec time frame, please let us know now so we can start polling members and the AV staff/BroadCasters. Sooner we know the better.

Thanks for your understanding.

Best,
Prabha

From: Atreya, Prabhakara
Sent: Thursday, September 2, 2021 3:59 PM
To: Witten, Celia (CBER) <Celia.Witten@fda.hhs.gov>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Cc: Hussey, Deirdre <Deirdre.Hussey@fda.hhs.gov>; Leary, Mary <Mary.Leary@fda.hhs.gov>; Hayes, Kathleen <Kathleen.Hayes@fda.hhs.gov>
Subject: RE: VRBPAC team meeting tomorrow??

Thanks Dr. Witten for the heads up on the need for additional dates in October.

We have polled members and consultants for Oct 14 and Oct 20 and their availability data was shared in our previous VRBPAC team meeting. We can send the updated list again tomorrow via e-mail.

Would one of these two October dates be suitable for taking the Moderna Vaccine booster topic to VRBPAC? If we get confirmation of the suitable Oct date now, we can start the preparations for that meeting as well.

I have just one question for my own understanding: with regards to the booster doses, what is the Agency's thinking- to using Pfizer booster dose just for prior Pfizer vaccinees only and using Moderna booster dose for only to prior Moderna vaccinees? Is cross boosters are also being considered across Pfizer, Moderna or J & J vaccines?

Thanks
Prabha

From: Witten, Celia (CBER) <Celia.Witten@fda.hhs.gov>
Sent: Thursday, September 2, 2021 2:38 PM
To: Atreya, Prabhakara <Prabhakara.Atreya@fda.hhs.gov>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Cc: Hussey, Deirdre <Deirdre.Hussey@fda.hhs.gov>; Leary, Mary <Mary.Leary@fda.hhs.gov>; Hayes, Kathleen <Kathleen.Hayes@fda.hhs.gov>
Subject: RE: VRBPAC team meeting tomorrow??

Its fine to cancel for tomorrow, but can you please send us all a reminder of the dates we have in October—I believe we are going to take the Moderna to the AC also, and we need to pick a date. If you send the dates you have in October, the perhaps Marion can let you know the choice of dates, because I think planning will need to start for that one also.

Celia M.Witten, Ph.D., M.D.
Deputy Director
Center for Biologics Evaluation and Research
Food and Drug Administration
240-402-8351

From: Atreya, Prabhakara <Prabhakara.Atreya@fda.hhs.gov>
Sent: Thursday, September 2, 2021 12:12 PM

To: Witten, Celia (CBER) <Celia.Witten@fda.hhs.gov>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Cc: Hussey, Deirdre <Deirdre.Hussey@fda.hhs.gov>; Leary, Mary <Mary.Leary@fda.hhs.gov>; Hayes, Kathleen <Kathleen.Hayes@fda.hhs.gov>
Subject: VRBPAC team meeting tomorrow??

Dear Drs. Witten and Gruber,

Both Kathleen and I are attending and supporting the CTGTAC meeting taking place between today and tomorrow; so we would like to know whether we can cancel the big VRBPAC team meeting tomorrow?

The following are the updates as of today related to Sept 17 VRBPAC:

- FRN submitted and undergone review by IOD/OCC and currently being prepared for publication by RPMS staff – date of publication to be determined but anticipated for early next week
- Received the list of Affected Firms from OVRR, and COI screening forms containing this information were sent and are being received from the Members/consultants; COI analysis is being conducted as we write this e-mail
- Timelines for receiving the Sponsor and FDA Briefing Documents were proposed by DSAC via e-mail yesterday and pending confirmation by OVRR; OCOD reviewed these timelines and indicated their availability for FOIA review/clearance of these documents.
- Items pending from OVRR:
    - Draft Agenda with possible presentation slots being planned
    - Speakers information – if there are from other Agencies such as CDC/NIH – need to be COI screened
    - Guest Speakers names, contact information – for COI disclosures and confirm their presentations

In view of the above updates, we may perhaps cancel tomorrow's meeting if we can exchange needed information via e-mail communications.

Thanks and let me know if you all agree.

Prabha

From: Krause, Philip
To: Gruber, Marion
Subject: WHO paper was accepted by Lancet this morning
Date: Thursday, September 2, 2021 11:27:41 AM
Attachments: Lancet 2 sept2021.docx

The current version is attached, but will likely still change after their editor gets to it and the table gets updated.

From: Krause, Philip
To: Gruber, Marion
Subject: WHO paper was accepted by Lancet this morning
Date: Thursday, September 2, 2021 11:27:00 AM
Attachments: Lancet 2 sept2021.docx

The current version is attached, but will likely still change after their editor gets to it and the table gets updated.

From: Gruber, Marion
To: Cohn, Amanda (CDC/DDID/NCIRD/OD)
Subject: RE: [EXTERNAL] Re: VRBPAC Sep 17 to discuss booster doses
Date: Tuesday, August 31, 2021 4:38:00 PM
Attachments: image001.png

Sure thing!

From: Cohn, Amanda (CDC/DDID/NCIRD/OD) <anc0@cdc.gov>
Sent: Tuesday, August 31, 2021 3:58 PM
To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Subject: [EXTERNAL] Re: VRBPAC Sep 17 to discuss booster doses

Hi Marion,

While you will be missed greatly, congratulations on your retirement, I can not imagine how challenging the last year has been but your leadership has been greatly appreciated.

Before we commit to a speaker, we would like to resolve the issue of ACIP meeting prior to the FDA decision. Can we talk about this maybe tomorrow during our Wed time?

Thanks,
Amanda

Get Outlook for iOS

From: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Sent: Monday, August 30, 2021 2:46:13 PM
To: Cohn, Amanda (CDC/DDID/NCIRD/OD) <anc0@cdc.gov>
Subject: VRBPAC Sep 17 to discuss booster doses

Hi Amanda,
We will convene a Sep 17 VRBPAC to discuss considerations for a (homologous) booster dose following the primary series of Pfizer's COVID-19 vaccine. We are looking for a CDC speaker who can talk about the current trajectory of the pandemic, the delta variant and evidence/or not for breakthrough infections in individuals who have completed the primary vaccination series. Can you help, please? Timelines are insane but hey, what's new!
Marion

Marion F. Gruber, Ph.D
Director

Office of Vaccines Research & Review
Center for Biologics Evaluation & Research
Food & Drug Administration, DHHS
10903 New Hampshire Ave.
Building 71, Rm. 3230
Silver Spring, Maryland 20993

Tel.: (301) 796 1856
Email: marion.gruber@fda.hhs.gov

From: Gruber, Marion
To: Cohn, Amanda C (CDC)
Subject: VRBPAC Sep 17 to discuss booster doses
Date: Monday, August 30, 2021 2:46:00 PM
Attachments: image001.png

Hi Amanda,
We will convene a Sep 17 VRBPAC to discuss considerations for a (homologous) booster dose following the primary series of Pfizer's COVID-19 vaccine. We are looking for a CDC speaker who can talk about the current trajectory of the pandemic, the delta variant and evidence/or not for breakthrough infections in individuals who have completed the primary vaccination series. Can you help, please? Timelines are insane but hey, what's new!
Marion

Marion F. Gruber, Ph.D
Director

Office of Vaccines Research & Review
Center for Biologics Evaluation & Research
Food & Drug Administration, DHHS
10903 New Hampshire Ave.
Building 71, Rm. 3230
Silver Spring, Maryland 20993

Tel.: (301) 796 1856
Email: marion.gruber@fda.hhs.gov

From: Krause, Philip
To: Gruber, Marion
Subject: RE: Briefing document
Date: Thursday, September 2, 2021 11:53:26 AM
Attachments: Booster BD pk.docx

Hi Marion,

Sorry this took so long. I thought everything you wrote was excellent. For this version, I moved things around with track changes off (so that everything didn't just turn red) to make it flow a bit better , but after that turned track changes on so you could see where I changed or added language.

This afternoon and evening, I'm going to dig into the BLA to start looking at which tables we need to include, but will also be preparing for tomorrow's WHO meeting. I expect to make a lot more progress over the weekend with some of these other things out of the way.

Phil

From: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Sent: Saturday, August 28, 2021 6:53 PM
To: Krause, Philip <Philip.Krause@fda.hhs.gov>
Subject: Briefing document

Dear Phil,
I hand the draft BD over to you at this stage. Please pay close attention to section 3 (Considerations for booster doses) and Section10 (data needed to support booster), revisions welcome. Note that I tried to keep a neutral position (Section 3) whether boosters are needed. I also had to modify previous sections on data needed to support licensure or EUA of COVID-19 vaccines as the current guidance document that describes data needed for development and licensure of COVID-19 vaccine does not address immune-bridging studies and the EUA guidance discusses them in the context of modified vaccines against VOCs. I started an executive summary (that will need to be modified, I am sure) and section 11 needs to be populated by the MOs. I am glad that Pfizer submitted at least the 508 compliant tables which the clinical team can copy into this document. I told Peter that this document cannot be finished by next weekend as the clinical teams needs time to review the data.

I am copying Doran so that he knows that we are working on this document but he should probably not look at it/work on it prior to you reviewing, editing and revising it. Call me if you need to talk tomorrow.

Marion

From: Gruber, Marion
To: Krause, Philip
Subject: Briefing document
Date: Saturday, August 28, 2021 6:52:00 PM
Attachments: Booster BD.docx

Dear Phil,
I hand the draft BD over to you at this stage. Please pay close attention to section 3 (Considerations for booster doses) and Section10 (data needed to support booster), revisions welcome. Note that I tried to keep a neutral position (Section 3) whether boosters are needed. I also had to modify previous sections on data needed to support licensure or EUA of COVID-19 vaccines as the current guidance document that describes data needed for development and licensure of COVID-19 vaccine does not address immune-bridging studies and the EUA guidance discusses them in the context of modified vaccines against VOCs. I started an executive summary (that will need to be modified, I am sure) and section 11 needs to be populated by the MOs. I am glad that Pfizer submitted at least the 508 compliant tables which the clinical team can copy into this document. I told Peter that this document cannot be finished by next weekend as the clinical teams needs time to review the data.

I am copying Doran so that he knows that we are working on this document but he should probably not look at it/work on it prior to you reviewing, editing and revising it. Call me if you need to talk tomorrow.

Marion

From:	Gruber, Marion
To:	Marks, Peter
Subject:	FW: Clinical Memo ready for upload!
Date:	Monday, August 23, 2021 8:37:00 AM
Attachments:	STN 125742.0 Pfizer BioNTech clinical review.final.signed ATSMApdf.pdf

From: Wollersheim, Susan <Susan.Wollersheim@fda.hhs.gov>
Sent: Monday, August 23, 2021 8:32 AM
To: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>; Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>
Cc: Allende, Maria <Maria.Allende@fda.hhs.gov>; Lee, Lucia <Lucia.Lee@fda.hhs.gov>; Schwartz, Ann T <Ann.Schwartz@fda.hhs.gov>; Fink, Doran <Doran.Fink@fda.hhs.gov>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Krause, Philip <Philip.Krause@fda.hhs.gov>; Yang, Ye <Ye.Yang@fda.hhs.gov>; Huang, Lei <Lei.Huang@fda.hhs.gov>
Subject: Clinical Memo ready for upload!

Hi Ram, Mike & Laura,

Please upload our clinical memo!

Thanks so so much,
Susan

Please note: I am working on Hawaii Standard Time (HST), so my morning start times may be mid-day for you, on East Coast time (currently in EDT).
-M/T/Th: noon (EDT)
-Wed: 10am (EDT)
-Fri: 2pm (EDT)
Many thanks for your understanding Will begin my mornings responding to pending e-mails.

Susan Wollersheim, MD, FAAP
Medical Officer

Center for Biologics Evaluation and Research
Office of Vaccines Research and Review
U.S. Food and Drug Administration
Cell: 240-506-6674

From:	Gruber, Marion
To:	Krause, Philip; Farizo, Karen; Finn, Theresa; Marshall, Valerie (OS); Hess, Maureen
Subject:	FW: [EXTERNAL] BLA Approval Press Release
Date:	Monday, August 23, 2021 9:05:00 AM
Attachments:	BLA Approval Press Release_DRAFT 08.22.21_11PM.docx

From: Boyce, Donna <Donna.Boyce@pfizer.com>
Sent: Sunday, August 22, 2021 11:16 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Subject: [EXTERNAL] BLA Approval Press Release

Hi Peter and Marion,
A copy of our press release (current draft) regarding the BLA approval is attached for your information.
Best regards,
Donna

From: Krause, Philip
To: henaorestrepoa@who.int
Subject: Lancet
Date: Sunday, August 22, 2021 3:17:00 PM
Attachments: Boosting Lancet.docx

Hi Ana Maria,

Here is the article. Obviously it may require different formatting and shortening for Lancet (though I did put the references in Lancet format).

Phil

From:	Krause, Philip
To:	Gruber, Marion
Subject:	RE: boosters
Date:	Monday, August 23, 2021 3:52:44 PM
Attachments:	Boosting Lancet.pdf Lancet Fig 1.pdf Lancet Fig 2.pdf

Hi Marion, Just to let you know, the New England Journal decided not to accept this, because despite early very strong interest they don't think they can publish it quickly. It's now been submitted to Lancet, who seem very eager to accept and publish it quickly. Here is the version that was submitted to Lancet. Phil

From: Krause, Philip
Sent: Friday, August 20, 2021 5:01 PM
To: Gruber, Marion (Marion.Gruber@fda.hhs.gov) <Marion.Gruber@fda.hhs.gov>
Subject: boosters

From:	Krause, Philip
To:	"Gruber, Marion
Subject:	RE: boosters
Date:	Monday, August 23, 2021 3:52:00 PM
Attachments:	Boosting Lancet.pdf Lancet Fig 1.pdf Lancet Fig 2.pdf

Hi Marion, Just to let you know, the New England Journal decided not to accept this, because despite early very strong interest they don't think they can publish it quickly. It's now been submitted to Lancet, who seem very eager to accept and publish it quickly. Here is the version that was submitted to Lancet. Phil

From: Krause, Philip
Sent: Friday, August 20, 2021 5:01 PM
To: Gruber, Marion (Marion.Gruber@fda.hhs.gov) <Marion.Gruber@fda.hhs.gov>
Subject: boosters

From: Krause, Philip
To: Gruber, Marion
Subject: boosters
Date: Friday, August 20, 2021 5:01:02 PM
Attachments: Boosting NEJM.docx

From: Krause, Philip
To: Gruber, Marion
Subject: boosters
Date: Friday, August 20, 2021 5:01:00 PM
Attachments: Boosting NEJM.docx

From: Krause, Philip
To: HENAO RESTREPO, Ana Maria
Subject: RE: [EXTERNAL] Fw: [EXT] Further revised figures 1 & 2 of the Lancet article
Date: Thursday, September 2, 2021 12:13:00 AM
Attachments: Lancet 2 sept.docx

Hi Ana Maria, here is the manuscript file with new references added and now properly numbered. I left out the Chile reference since they didn't specify any information about variants, but added more references from your list and entered Hongchao's corrections. For now, I still left out those expressed as odds ratios.
Phil

From: HENAO RESTREPO, Ana Maria <henaorestrepoa@who.int>
Sent: Wednesday, September 1, 2021 7:56 PM
To: Krause, Philip <Philip.Krause@fda.hhs.gov>
Subject: [EXTERNAL] Fw: [EXT] Further revised figures 1 & 2 of the Lancet article

From: Hongchao Pan <hongchao.pan@ndph.ox.ac.uk>
Sent: Thursday, September 2, 2021 1:31 AM
To: HENAO RESTREPO, Ana Maria <henaorestrepoa@who.int>
Cc: Richard Peto Personal <rpeto@ndph.ox.ac.uk>
Subject: [EXT] Further revised figures 1 & 2 of the Lancet article

Dear Ana Maria,

I have spent hours going through references of tables 1 & 2 (or figures 1 & 2). I have made some corrections in the tables (track-changed), where possible, I extracted the missing 95% CIs from figures and tables of the relevant references.

The track-changed tables are attached, together with the updated figures 1 & 2.

Best wishes,

Hongchao

From: Krause, Philip
To: HENAO RESTREPO, Ana Maria; Longini,Ira M; Thomas R. Fleming; Richard Peto Personal
Subject: RE: [EXTERNAL] For the proposed call on the Lancet article tonight at 23:30 Geneva time
Date: Wednesday, September 1, 2021 3:23:00 PM
Attachments: Boosting Lancet revision 1sep2021 clean.docx
Boosting Lancet revision 1sep2021.docx
WHO COVID booster VP Reviews.docx

The discussion will include this Israeli study: https://www.gov.il/BlobFolder/reports/vaccine-efficacy-safety-follow-up-committee/he/files_publications_corona_booster-27082021.pdf and how it should be discussed in the manuscript.

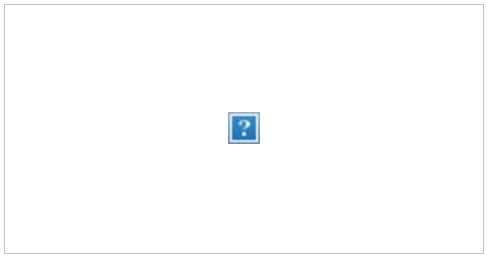
I've also attached tracked and clean copies of the manuscript, and the response to reviewers.

From: HENAO RESTREPO, Ana Maria <henaorestrepoa@who.int>
Sent: Wednesday, September 1, 2021 3:03 PM
To: Krause, Philip <Philip.Krause@fda.hhs.gov>; Longini,Ira M <ilongini@ufl.edu>; Thomas R. Fleming (tfleming@uw.edu) <tfleming@uw.edu>; Richard Peto Personal <rpeto@ndph.ox.ac.uk>
Subject: [EXTERNAL] For the proposed call on the Lancet article tonight at 23:30 Geneva time

Dear All,

We will be discussing with Phil and Richard and hope you will also be able to join us. Let us use this link please. Just copy and past in goggle chrome

https://solidaritytrial.whereby.com/core



Whereby

Easy video meetings with no login or downloads. Video conferencing with screen sharing, recording and much more.

solidaritytrial.whereby.com

Kind regards,

Ana Maria

Sent from my iPhone

From: Gruber, Marion
To: Arnold Monto; Krause, Philip
Subject: RE: [EXTERNAL] VRBPAC and boosters
Date: Monday, August 23, 2021 7:54:00 PM

Hi Arnolds,
We will be discussing the "booster question" and related submissions including whether a VRBPAC should be held. We do not know yet and you are right that timing will be an issue once again.
Marion

From: Arnold Monto <asmonto@umich.edu>
Sent: Monday, August 23, 2021 3:31 PM
To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Krause, Philip <Philip.Krause@fda.hhs.gov>
Subject: [EXTERNAL] VRBPAC and boosters

The Surgeon General last night made a statement that the FDA and CDC advisory committees would be reviewing Hope that he misspoke about the VRBPAC Doesn't seem to be enough time to get it organized

Just got asked about flu vaccination and Covid boosters being given at the same time. Gave my personal information, don't

Arnold

--

Arnold S. Monto, M.D.
Thomas Francis Collegiate Professor
Department of Epidemiology
School of Public Health
University of Michigan

1415 Washington Heights
Ann Arbor, MI 48109-2029
Tel: (734) 764-5453
Fax: (734) 764-3192
asmonto@umich.edu

From: Krause, Philip
To: HENAO RESTREPO, Ana Maria
Subject: RE: [EXT] RE: [EXTERNAL] Corrected version....
Date: Monday, August 23, 2021 2:29:00 PM
Attachments: Boosting Lancet.pdf
Lancet Fig 1.pdf
Lancet Fig 2.pdf

Here it is!

From: HENAO RESTREPO, Ana Maria <henaorestrepoa@who.int>
Sent: Monday, August 23, 2021 2:05 PM
To: Julian Higgins <Julian.Higgins@bristol.ac.uk>; isabelle.boutron <isabelle.boutron@aphp.fr>; KAZI, Fatema <kazif@who.int>
Cc: Krause, Philip <Philip.Krause@fda.hhs.gov>
Subject: Re: [EXT] RE: [EXTERNAL] Corrected version....

Super ! Thanks !

Ana Maria

From: Julian Higgins <Julian.Higgins@bristol.ac.uk>
Sent: Monday, August 23, 2021 8:01 PM
To: HENAO RESTREPO, Ana Maria <henaorestrepoa@who.int>; isabelle.boutron <isabelle.boutron@aphp.fr>; KAZI, Fatema <kazif@who.int>
Cc: Krause, Philip <philip.krause@fda.hhs.gov>
Subject: RE: [EXT] RE: [EXTERNAL] Corrected version....

Hi Ana Maria,

Some amendments to address Philip's comments. The one thing I have not had time to do is to pull out the confidence intervals from the last slide of the Israel study presentation.

Best wishes,
Julian

From: HENAO RESTREPO, Ana Maria <henaorestrepoa@who.int>
Sent: 23 August 2021 18:38
To: Julian Higgins <Julian.Higgins@bristol.ac.uk>; BOUTRON Isabelle <isabelle.boutron@aphp.fr>; KAZI, Fatema <kazif@who.int>
Cc: Krause, Philip <philip.krause@fda.hhs.gov>

Subject: Fw: [EXT] RE: [EXTERNAL] Corrected version....

From: Krause, Philip <Philip.Krause@fda.hhs.gov>
Sent: Monday, August 23, 2021 7:35 PM
To: HENAO RESTREPO, Ana Maria <henaorestrepoa@who.int>
Subject: [EXT] RE: [EXTERNAL] Corrected version....

Hi Ana Maria, I made some comments for corrections to the figures—though these might not any longer be the most recent version. Can you share with Julian? Thanks! Phil

---

From: HENAO RESTREPO, Ana Maria <henaorestrepoa@who.int>
Sent: Monday, August 23, 2021 1:00 PM
To: Krause, Philip <Philip.Krause@fda.hhs.gov>
Cc: Longini,Ira M <ilongini@ufl.edu>; Thomas R. Fleming (tfleming@uw.edu) <tfleming@uw.edu>
Subject: [EXTERNAL] Corrected version....

From: Krause, Philip
To: HENAO RESTREPO, Ana Maria
Subject: RE: [EXTERNAL] VE tables... we are finalizing and will try with Richard"s help to do a forest plot instead...
Date: Friday, August 20, 2021 2:23:00 PM
Attachments: WHO Boosting Strategies 20aug2021b.docx

Here is current version intended for submission.

From: HENAO RESTREPO, Ana Maria <henaorestrepoa@who.int>
Sent: Friday, August 20, 2021 8:31 AM
To: Krause, Philip <Philip.Krause@fda.hhs.gov>
Subject: [EXTERNAL] VE tables... we are finalizing and will try with Richard's help to do a forest plot instead...

Kind regards,

Ana Maria

From: Gruber, Marion
To: Krause, Philip
Subject: FW: [EXTERNAL] Friday WHO call
Date: Tuesday, August 31, 2021 5:09:00 PM
Attachments: Submitted Manuscript combined 210821.pdf

From: Donna Ambrosino (b) (6)
Sent: Tuesday, August 31, 2021 4:28 PM
To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Cc: George Siber (b) (6); Goldblatt, David <d.goldblatt@ucl.ac.uk>
Subject: [EXTERNAL] Friday WHO call

Dear Marion,

First, I am really sad to hear you will be leaving the FDA (although these last months must have been gruesome). The entire community will greatly miss your wisdom.

Second (and far less important)
I am attaching a pre-print that is now on the Research Square pre- print server and it will be presented by David Goldblatt on the WHO WG Friday call. George Siber and I thought if you had a chance to read this before the panel discussion, it might be helpful. Please feel free to ashare with Phil Krause as well (and of course interested in any of your thoughts).

Best regards
Donna

Donna M Ambrosino MD
(b) (6)

From: Krause, Philip
To: (b) (6) ; HENAO RESTREPO, Ana Maria
Subject: FW: [EXT] RE: [EXTERNAL] Corrected version....
Date: Monday, August 23, 2021 2:35:00 PM
Attachments: Boosting Lancet.pdf
Lancet Fig 1.pdf
Lancet Fig 2.pdf

From: Krause, Philip
Sent: Monday, August 23, 2021 2:30 PM
To: HENAO RESTREPO, Ana Maria <henaorestrepoa@who.int>
Subject: RE: [EXT] RE: [EXTERNAL] Corrected version....

Here it is!

From: HENAO RESTREPO, Ana Maria <henaorestrepoa@who.int>
Sent: Monday, August 23, 2021 2:05 PM
To: Julian Higgins <Julian.Higgins@bristol.ac.uk>; isabelle.boutron <isabelle.boutron@aphp.fr>; KAZI, Fatema <kazif@who.int>
Cc: Krause, Philip <Philip.Krause@fda.hhs.gov>
Subject: Re: [EXT] RE: [EXTERNAL] Corrected version....

Super ! Thanks !

Ana Maria

From: Julian Higgins <Julian.Higgins@bristol.ac.uk>
Sent: Monday, August 23, 2021 8:01 PM
To: HENAO RESTREPO, Ana Maria <henaorestrepoa@who.int>; isabelle.boutron <isabelle.boutron@aphp.fr>; KAZI, Fatema <kazif@who.int>
Cc: Krause, Philip <philip.krause@fda.hhs.gov>
Subject: RE: [EXT] RE: [EXTERNAL] Corrected version....

Hi Ana Maria,

Some amendments to address Philip's comments. The one thing I have not had time to do is to pull out the confidence intervals from the last slide of the Israel study presentation.

Best wishes,

Julian

From: HENAO RESTREPO, Ana Maria <henaorestrepoa@who.int>
Sent: 23 August 2021 18:38
To: Julian Higgins <Julian.Higgins@bristol.ac.uk>; BOUTRON Isabelle <isabelle.boutron@aphp.fr>; KAZI, Fatema <kazif@who.int>
Cc: Krause, Philip <philip.krause@fda.hhs.gov>
Subject: Fw: [EXT] RE: [EXTERNAL] Corrected version....

From: Krause, Philip <Philip.Krause@fda.hhs.gov>
Sent: Monday, August 23, 2021 7:35 PM
To: HENAO RESTREPO, Ana Maria <henaorestrepoa@who.int>
Subject: [EXT] RE: [EXTERNAL] Corrected version....

Hi Ana Maria, I made some comments for corrections to the figures—though these might not any longer be the most recent version. Can you share with Julian? Thanks! Phil

---

From: HENAO RESTREPO, Ana Maria <henaorestrepoa@who.int>
Sent: Monday, August 23, 2021 1:00 PM
To: Krause, Philip <Philip.Krause@fda.hhs.gov>
Cc: Longini,Ira M <ilongini@ufl.edu>; Thomas R. Fleming (tfleming@uw.edu) <tfleming@uw.edu>
Subject: [EXTERNAL] Corrected version....

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

Food and Drug Administration
Rockville, MD 20857

June 30, 2022

Via Email: mdiliberto@judicialwatch.org

Meredith Di Liberto
Judicial Watch, Inc.
425 Third Street, SW, Suite 800
Washington, DC 20024

Re: FDA FOIA Request 2021-5961; *Judicial Watch, Inc. v. HHS,* 22-cv-00293-APM

Dear Ms. Di Liberto,

Per the Joint Status Report dated March 25, 2022, attached please find our second partial response to the Freedom of Information Act (FOIA) request number **2020-5341** that is the subject of above-referenced matter.

Attached are 85 pages of records from the FDA's Center for Biologics Evaluation and Research (CBER) (Bates numbered FDA-CBER-2021-5961-0028 to -0112) some of which contain redactions.

We have withheld portions of pages under FOIA Exemption (b)(6), 5 U.S.C. § 522(b)(6). That exemption protects information from disclosure when its release would cause a clearly unwarranted invasion of personal privacy. FOIA Exemption 6 is available to protect information in personnel or medical files and similar files. This requires a balancing of the public's right to disclosure against the individual's right to privacy.

Please direct any questions regarding this response to Assistant United States Attorney Marcia Sowles of the Department of Justice, at (202) 514-4960 or Marcia.Sowles@usdoj.gov.

Sincerely,

Beth A. Brockner Ryan -S
Digitally signed by Beth A. Brockner Ryan -S
Date: 2022.06.30 11:48:23 -04'00'

Beth Brockner Ryan
Chief, Access Litigation and Freedom of Information Branch
Division of Disclosure and Oversight Management
Office of Communication Outreach and Development
Center for Biologics Evaluation and Research

Attachments

cc:

Marcia Sowles, Federal Programs Branch, USDOJ (By email)
Joshua Davenport, Office of the Chief Counsel, FDA (By email)

From: Gruber, Marion
To: Forshee, Richard; Anderson, Steven
Cc: Krause, Philip
Subject: Sep 17 VRBPAC to discuss booster doses
Date: Monday, August 30, 2021 4:16:00 PM
Attachments: image001.png

Hi Steven and Rich,

As you know we will convene a Sep 17 VRBPAC to discuss considerations for a (homologous) booster dose following the primary series of Pfizer's COVID-19 vaccine, more specifically " to discuss Pfizer-BioNTech's supplemental Biologics License Application for administration of a third dose, or "booster" dose, of the COVID-19 vaccine, Comirnaty, in individuals 16 years of age and older."

We have reached out to the CDC for a speaker who can talk about the current trajectory of the pandemic, the delta variant and evidence or lack thereof of breakthrough infections/breakthrough disease in individuals who have completed the primary vaccination series. There are of course, various published studies on this topic but the committee would benefit from a presentation that would put this all together. I am reaching out to you to see whether you are doing work in this space and/or would be interested to present at this upcoming VRBPAC. If so, let me know. Timelines are insane but hey, what's new!

Marion

Marion F. Gruber, Ph.D
Director

Office of Vaccines Research & Review
Center for Biologics Evaluation & Research
Food & Drug Administration, DHHS
10903 New Hampshire Ave.
Building 71, Rm. 3230
Silver Spring, Maryland 20993

Tel.: (301) 796 1856
Email: marion.gruber@fda.hhs.gov

From: Gruber, Marion
To: Hess, Maureen; Krause, Philip; Finn, Theresa; Farizo, Karen; Fink, Doran
Subject: RE: Communication to announce Comirnaty VRBPAC
Date: Monday, August 30, 2021 1:37:00 PM
Attachments: image001.png

Hi Maureen,
From my perspective this is as good as it can get. Obviously, this statements puts us into a real bind but the damage is already done.
Marion

From: Hess, Maureen <Maureen.Hess@fda.hhs.gov>
Sent: Monday, August 30, 2021 1:20 PM
To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Krause, Philip <Philip.Krause@fda.hhs.gov>; Finn, Theresa <Theresa.Finn@fda.hhs.gov>; Farizo, Karen <Karen.Farizo@fda.hhs.gov>; Fink, Doran <Doran.Fink@fda.hhs.gov>
Subject: RE: Communication to announce Comirnaty VRBPAC

Just a note to follow-up, wondering if you like this version any better?

Maureen

From: Hess, Maureen
Sent: Friday, August 27, 2021 6:06 PM
To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Krause, Philip <Philip.Krause@fda.hhs.gov>; Finn, Theresa <Theresa.Finn@fda.hhs.gov>; Farizo, Karen <Karen.Farizo@fda.hhs.gov>; Fink, Doran <Doran.Fink@fda.hhs.gov>
Subject: RE: Communication to announce Comirnaty VRBPAC

I made some additional edits- see if you like it any better.

Maureen

From: Hess, Maureen
Sent: Friday, August 27, 2021 5:54 PM
To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Krause, Philip <Philip.Krause@fda.hhs.gov>; Finn, Theresa <Theresa.Finn@fda.hhs.gov>; Farizo, Karen <Karen.Farizo@fda.hhs.gov>; Fink, Doran <Doran.Fink@fda.hhs.gov>
Subject: RE: Communication to announce Comirnaty VRBPAC

Okay, I'll make some additional edits (but JW was included on this statement- https://www.cdc.gov/media/releases/2021/s0818-covid-19-booster-shots.html) so our edits may be rejected above us.

Maureen

From: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Sent: Friday, August 27, 2021 5:51 PM
To: Hess, Maureen <Maureen.Hess@fda.hhs.gov>; Krause, Philip <Philip.Krause@fda.hhs.gov>; Finn, Theresa <Theresa.Finn@fda.hhs.gov>; Farizo, Karen <Karen.Farizo@fda.hhs.gov>; Fink, Doran <Doran.Fink@fda.hhs.gov>
Subject: RE: Communication to announce Comirnaty VRBPAC

Well, the message appears to be "total buy-in in the need for boosters," this is not how I am writing the BD, I am trying to take a more neutral approach. This piece sounds as if we already decided to approve this supplement.

From: Hess, Maureen <Maureen.Hess@fda.hhs.gov>
Sent: Friday, August 27, 2021 5:18 PM
To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Krause, Philip <Philip.Krause@fda.hhs.gov>; Finn, Theresa <Theresa.Finn@fda.hhs.gov>; Farizo, Karen <Karen.Farizo@fda.hhs.gov>; Fink, Doran <Doran.Fink@fda.hhs.gov>
Subject: Communication to announce Comirnaty VRBPAC

Greetings,

I received this a little while ago- Comirnaty VRBPAC. If you have any additional edits, please send to me on Monday.

Thanks,
Maureen

From: Gruber, Marion
To: Krause, Philip; Fink, Doran; McVittie, Loris; Farizo, Karen; Finn, Theresa; Prutzman, Kirk C; Reindel, Rebecca
Subject: FW: [EXTERNAL] sBLA for a Booster Dose - Press Release
Date: Wednesday, August 25, 2021 12:03:00 PM
Attachments: Booster sBLA press release_FINAL.docx

-----Original Message-----
From: Boyce, Donna <Donna.Boyce@pfizer.com>
Sent: Wednesday, August 25, 2021 11:38 AM
To: Marks, Peter <Peter.Marks@fda hhs.gov>; Gruber, Marion <Marion.Gruber@fda hhs.gov>
Subject: RE: [EXTERNAL] sBLA for a Booster Dose - Press Release

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Peter and Marion,
Attached please find the press release to be issued by Pfizer later today.
Kind regards,
Donna

-----Original Message-----
From: Marks, Peter <Peter.Marks@fda hhs.gov>
Sent: Tuesday, August 24, 2021 8:25 PM
To: Boyce, Donna <Donna.Boyce@pfizer.com>; Gruber, Marion <Marion.Gruber@fda hhs.gov>
Subject: RE: [EXTERNAL] sBLA for a Booster Dose

Dear Donna,

Thanks so much for letting us know.

Congratulations on yesterday's approval.

Best Regards,
Peter

-----Original Message-----
From: Boyce, Donna <Donna.Boyce@pfizer.com>
Sent: Tuesday, August 24, 2021 6:12 PM
To: Marks, Peter <Peter.Marks@fda hhs.gov>; Gruber, Marion <Marion.Gruber@fda hhs.gov>
Subject: [EXTERNAL] sBLA for a Booster Dose

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Peter and Marion,
Just heads up…As discussed with Peter last week, we plan to submit our sBLA for a booster dose tomorrow. Pfizer will issue a press release to announce the filing.
Best regards,
Donna

From: Krause, Philip
To: HENAO RESTREPO, Ana Maria
Cc: Longini, Ira M; Thomas R. Fleming
Subject: RE: [EXTERNAL] Fw: [EXT] RE: List of PDFs_data extraction for manuscript
Date: Monday, August 23, 2021 1:52:00 PM
Attachments: Boosting Lancet.docx

Hi Ana Maria, et al.,

Here is (I hope) the final text. I will still need to add the references to the figures, and delete the tables from this version (they are retained in this copy to keep the reference list in shape). Any comments still welcome!

Phil

From: HENAO RESTREPO, Ana Maria <henaorestrepoa@who.int>
Sent: Monday, August 23, 2021 1:13 PM
To: Krause, Philip <Philip.Krause@fda.hhs.gov>
Cc: Longini,Ira M <ilongini@ufl.edu>; Thomas R. Fleming (tfleming@uw.edu) <tfleming@uw.edu>
Subject: [EXTERNAL] Fw: [EXT] RE: List of PDFs_data extraction for manuscript

From: BOUTRON Isabelle <isabelle.boutron@aphp.fr>
Sent: Monday, August 23, 2021 7:09 PM
To: HENAO RESTREPO, Ana Maria <henaorestrepoa@who.int>; Julian Higgins <Julian.Higgins@bristol.ac.uk>
Cc: KAZI, Fatema <kazif@who.int>
Subject: Re: [EXT] RE: List of PDFs_data extraction for manuscript

The comments related the remaining studies. I believe we checked all.
Overall, as the data of the CI interval were rounded by Fatema, I think it may be better to keep it rounded for all otherwise it will be inconsistent
Happy to discuss quickly if needed but I have to leave in 15 minutes

From: Julian Higgins <Julian.Higgins@bristol.ac.uk>
Sent: Monday, August 23, 2021 7:05 PM
To: HENAO RESTREPO, Ana Maria <henaorestrepoa@who.int>
Cc: KAZI, Fatema <kazif@who.int>; isabelle.boutron <isabelle.boutron@aphp.fr>
Subject: RE: [EXT] RE: List of PDFs_data extraction for manuscript

Oh sorry – here's one with the Israel confidence intervals added as per recent email…
J

From: HENAO RESTREPO, Ana Maria <henaorestrepoa@who.int>
Sent: 23 August 2021 17:59
To: Julian Higgins <Julian.Higgins@bristol.ac.uk>
Cc: KAZI, Fatema <kazif@who.int>; isabelle.boutron <isabelle.boutron@aphp.fr>
Subject: Re: [EXT] RE: List of PDFs_data extraction for manuscript

Thanks... now it works for me....

From: Julian Higgins <Julian.Higgins@bristol.ac.uk>
Sent: Monday, August 23, 2021 6:57 PM
To: HENAO RESTREPO, Ana Maria <henaorestrepoa@who.int>
Cc: KAZI, Fatema <kazif@who.int>; isabelle.boutron <isabelle.boutron@aphp.fr>
Subject: RE: [EXT] RE: List of PDFs_data extraction for manuscript

I'm puzzled – mine is editable just like the first one. Sending again in case something got corrupted…
J

From: HENAO RESTREPO, Ana Maria <henaorestrepoa@who.int>
Sent: 23 August 2021 17:56
To: Julian Higgins <Julian.Higgins@bristol.ac.uk>; isabelle.boutron <isabelle.boutron@aphp.fr>
Cc: KAZI, Fatema <kazif@who.int>
Subject: Re: [EXT] RE: List of PDFs_data extraction for manuscript

Hi can we have an editable version like teh first one, please?

Thnaks,

Ana Maria

From: Julian Higgins <Julian.Higgins@bristol.ac.uk>
Sent: Monday, August 23, 2021 6:54 PM
To: isabelle.boutron <isabelle.boutron@aphp.fr>
Cc: HENAO RESTREPO, Ana Maria <henaorestrepoa@who.int>; KAZI, Fatema <kazif@who.int>
Subject: RE: [EXT] RE: List of PDFs_data extraction for manuscript

Here's a version with some corrections to the data after Isabelle's email.

Best wishes,
Julian

From: BOUTRON Isabelle <isabelle.boutron@aphp.fr>
Sent: 23 August 2021 17:53
To: Julian Higgins <Julian.Higgins@bristol.ac.uk>
Cc: HENAO RESTREPO, Ana Maria <henaorestrepoa@who.int>; KAZI, Fatema <kazif@who.int>
Subject: Re: [EXT] RE: List of PDFs_data extraction for manuscript

Yes it should be 75.0 (70.5-78.9)
The easiest would probably to round up all numbers effect estimates and CI

De : Julian Higgins <Julian.Higgins@bristol.ac.uk>
Date : lundi 23 août 2021 à 18:48
À : BOUTRON Isabelle <isabelle.boutron@aphp.fr>
Cc : "HENAO RESTREPO, Ana Maria" <henaorestrepoa@who.int>, "KAZI, Fatema" <kazif@who.int>
Objet : RE: [EXT] RE: List of PDFs_data extraction for manuscript

Hi Isabelle,

I see you have a comment for Pfizer - Qatar - Alpha saying "75.0 (75.5-78.9)" – should that be "75.0 (70.5-78.9)"?

Best wishes,
Julian

From: BOUTRON Isabelle <isabelle.boutron@aphp.fr>
Sent: 23 August 2021 17:41
To: KAZI, Fatema <kazif@who.int>; Julian Higgins <Julian.Higgins@bristol.ac.uk>; HENAO RESTREPO, Ana Maria <henaorestrepoa@who.int>
Subject: Re: [EXT] RE: List of PDFs_data extraction for manuscript

Ok, in attached an update of our notes
We still have 2 to check

- Tenforde MW, Self WH, Naioti EA, et al. Sustained Effectiveness of Pfizer-BioNTech and Moderna Vaccines Against COVID-19 Associated Hospitalizations Among Adults — United States, March–July 2021. MMWR Morb Mortal Wkly Rep 2021; ePub: 18 August 2021. DOI: https://www.cdc.gov/mmwr/volumes/70/wr/mm7034e2.htm?s_cid=mm7034e2_w.
- Nanduri S, Pilishvili T, Derado G, et al. Effectiveness of Pfizer-BioNTech and Moderna Vaccines in Preventing SARS-CoV-2 Infection Among Nursing Home Residents Before and During Widespread Circulation of the SARS-CoV-2 B.1.617.2 (Delta) Variant — National Healthcare Safety Network, March 1–August 1, 2021. . MMWR Morb Mortal Wkly Rep 2021; ePub: 18 August 2021. https://www.cdc.gov/mmwr/volumes/70/wr/mm7034e3.htm?s_cid=mm7034e3_w.

And one we cant check as not in English

- https://www.gov.il/BlobFolder/reports/vaccine-efficacy-safety-follow-up-committee/he/files_publications_corona_two-dose-vaccination-data.pdf

De : "KAZI, Fatema" <kazif@who.int>
Date : lundi 23 août 2021 à 18:29
À : BOUTRON Isabelle <isabelle.boutron@aphp.fr>, Julian Higgins <Julian.Higgins@bristol.ac.uk>, "HENAO RESTREPO, Ana Maria" <henaorestrepoa@who.int>
Objet : RE: [EXT] RE: List of PDFs_data extraction for manuscript

Hi

This was one my questions too (in blue), I chose to go for the data related to "All variants" = VE = 70.8 (50.0-83.8), as the data is available.
Best
fatema

Vaccine developer		Study Location	Variant addressed	Effectiveness vs. severe disease or hospitalization	Effectiveness vs. symptomatic disease or infection (i)	
Bharat BBV152		India [12]*	All Delta	93.4% (57-100) 93.4% (57.1-99.8)	77.8% (50-84) 70.8% (50.0-83.8) 65.2% (33-83) 65.2% (33.1-83.0)	Format of data (decimal places) adjusted for consistency Table 2 (pg 25) reports 'Symptomatic COVID-19' VE = 77.8 (65.2–86.4). There is also 'Symptomatic or asymptomatic COVID-19' VE = 68.8 (46.7–82.5) which may be more appropriate. However, if by 'All' under 'variant addressed' you mean 'All variant related COVID-19' then in Table 3 (pg 26) the VE = 70.8 (50.0-83.8)

-----Original Message-----
From: BOUTRON Isabelle <isabelle.boutron@aphp.fr>
Sent: Monday, August 23, 2021 5:54 PM
To: KAZI, Fatema <kazif@who.int>; Julian Higgins <Julian.Higgins@bristol.ac.uk>; HENAO RESTREPO, Ana Maria <henaorestrepoa@who.int>
Subject: Re: [EXT] RE: List of PDFs_data extraction for manuscript

Actually only 1-2 issues to check for the first slot We are checking the full text of the others and will come back to you Fatema, we can discuss the points we identified if needed

Le 23/08/2021 17:34, « KAZI, Fatema » <kazif@who.int> a écrit :

Dear Isabelle,

If there is anything I can help with checking let me know, for instance you can give me some instructions to look for specific data in selected studies for you.

Best
Fatema

-----Original Message-----
From: Julian Higgins <Julian.Higgins@bristol.ac.uk>
Sent: Monday, August 23, 2021 5:31 PM
To: isabelle.boutron <isabelle.boutron@aphp.fr>; HENAO RESTREPO, Ana Maria <henaorestrepoa@who.int>
Cc: KAZI, Fatema <kazif@who.int>
Subject: [EXT] RE: List of PDFs_data extraction for manuscript

Here's one with the data in Table 2 too. I may have been wasting some of my time if there are lots of corrections to make...!
Julian

-----Original Message-----
From: BOUTRON Isabelle <isabelle.boutron@aphp.fr>
Sent: 23 August 2021 16:16
To: Julian Higgins <Julian.Higgins@bristol.ac.uk>; HENAO RESTREPO, Ana Maria <henaorestrepoa@who.int>
Cc: KAZI, Fatema <kazif@who.int>
Subject: Re: List of PDFs_data extraction for manuscript

We did find some discrepancies in the first studies for which we have the data, we had to go back to the papers for some as the timepoints were not exactly the same I will send an annotated document within 20 minutes.
However, the one that were not extracted will still have to be checked

Le 23/08/2021 17:13, « Julian Higgins » <Julian.Higgins@bristol.ac.uk> a écrit :

Here is a quick forest plot of the data currently in Table 1. I'm not sure there will be time to do a corrected version or a plot for Table 2 before 6pm Geneva time...

Best wishes,
Julian

-----Original Message-----
From: KAZI, Fatema <kazif@who.int>
Sent: 23 August 2021 16:10
To: Julian Higgins <Julian.Higgins@bristol.ac.uk>
Cc: BOUTRON Isabelle <isabelle.boutron@aphp.fr>; HENAO RESTREPO, Ana Maria <henaorestrepoa@who.int>
Subject: List of PDFs_data extraction for manuscript
Importance: High

Dear Julian,
I have added the studies from which data was extracted to the drop box:
https://www.dropbox.com/sh/la4codxsd4258vc/AADOSKuomuv7q8RRdmMWArika?dl=0

Hope you can access them.

Best
Fatema

From:	Gruber, Marion
To:	Fink, Doran; Krause, Philip; Finn, Theresa; McVittie, Loris
Subject:	RE: **UPDATE TO MANAGEMENT_ Moderna IND 19745 -- Request for TC re: EUA boost; Response to Feedback and additional questions**
Date:	Friday, August 20, 2021 1:01:00 PM
Attachments:	image001.png image002.png image003.jpg image004.jpg image005.jpg image006.jpg image007.jpg image008.jpg

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He keeps on telling me that following this approval, he will sit down with us to hammer out a plan to get on top of the workload because "while I was gone he actually did an inventory and determined that our workload is no longer manageable"……at the same time he encourages sponsors to send in submissions and I am sure promises fast turn-around.

From: Fink, Doran <Doran.Fink@fda.hhs.gov>
Sent: Friday, August 20, 2021 12:46 PM
To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Krause, Philip <Philip.Krause@fda.hhs.gov>; Finn, Theresa <Theresa.Finn@fda.hhs.gov>; McVittie, Loris <Loris.McVittie@fda.hhs.gov>
Subject: RE: **UPDATE TO MANAGEMENT_ Moderna IND 19745 -- Request for TC re: EUA boost; Response to Feedback and additional questions**

I had to bite my tongue when Peter mentioned this morning we wouldn't be doing rushed reviews anymore so as not to ask about the booster doses that the administration promised to everyone by Sept 20!

FYI, the ACIP WG is thinking there is some merit to targeted booster doses for certain populations (e.g., HCW to avoid loss of workforce to illness, and elderly who are most at risk for hospitalization/death due to diminished response to primary series, subsequent waning, and dependence on neutralizing antibodies because of immunosenescence). However, that would be a complicated set of recommendations, and because those populations were targeted for primary series first, a broader recommendation based on time since primary series (e.g., at least 8 months) may accomplish the same thing.

And then there is the question of the data that will support these booster doses – maybe I'm wrong, but my understanding is that Pfizer is proposing that their sBLA include the Phase 1 booster data from a grand total of 23 subjects. I'm not sure what Moderna will have, but the data Fauci presented in the press conference was from NIAID studies, which was ~25 subjects per treatment arm.

From: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Sent: Friday, August 20, 2021 12:40 PM
To: Krause, Philip <Philip.Krause@fda.hhs.gov>; Fink, Doran <Doran.Fink@fda.hhs.gov>; Finn, Theresa <Theresa.Finn@fda.hhs.gov>; McVittie, Loris <Loris.McVittie@fda.hhs.gov>
Subject: RE: **UPDATE TO MANAGEMENT_ Moderna IND 19745 -- Request for TC re: EUA boost; Response to Feedback and additional questions**

"They also noted that they have been encouraged by CBER leadership to amend the EUA for booster dose as soon as possible. "

From: Agnihothram, Sudhakar <Sudhakar.Agnihothram@fda.hhs.gov>
Sent: Friday, August 20, 2021 12:36 PM
To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Krause, Philip <Philip.Krause@fda.hhs.gov>; Izurieta, Hector <Hector.Izurieta@fda.hhs.gov>; Pratt, Douglas R. <Douglas.Pratt@fda.hhs.gov>; McVittie, Loris <Loris.McVittie@fda.hhs.gov>; Prutzman, Kirk C <Kirk.Prutzman@fda.hhs.gov>
Cc: Fink, Doran <Doran.Fink@fda.hhs.gov>; Zhang, Rachel <Rachel.Zhang@fda.hhs.gov>; Rastogi, Anuja <Anuja.Rastogi@fda.hhs.gov>; Allende, Maria <Maria.Allende@fda.hhs.gov>; Dabrazhynetskaya, Alena <Alena.Dabrazhynetskaya@fda.hhs.gov>; Levis, Robin <Robin.Levis@fda.hhs.gov>; Weir, Jerry P. <Jerry.Weir@fda.hhs.gov>; Yang, Ye <Ye.Yang@fda.hhs.gov>; Huang, Lei <Lei.Huang@fda.hhs.gov>; Lin, Tsai-Lien <Tsai-Lien.Lin@fda.hhs.gov>; Farizo, Karen <Karen.Farizo@fda.hhs.gov>; Finn, Theresa <Theresa.Finn@fda.hhs.gov>; Pandey, Rakesh <Rakesh.Pandey@fda.hhs.gov>; Fritz, Timothy <Timothy.Fritz@fda.hhs.gov>; Elekwachi, Oluchi <Oluchi.Elekwachi@fda.hhs.gov>; Stockbridge, Lisa L <Lisa.Stockbridge@fda.hhs.gov>; Gagneten, Sara <Sara.Gagneten@fda.hhs.gov>; Verma, Swati <Swati.Verma@fda.hhs.gov>
Subject: **UPDATE TO MANAGEMENT_ Moderna IND 19745 -- Request for TC re: EUA boost; Response to Feedback and additional questions**

Dear all,

I am writing to update you that Moderna reached out with responses to our comments (communicated August 11, 2021) on the P201 Part B data (immunogenicity data from 50mcg of booster dose of mRNA-1273 against prototype strain, submitted to IND 19745.196) and outlines for their submission plans for an EUA to support a booster dose of 50µg mRNA-1273. Please see the attached word document "RTQ From CBER Comments Received July 2 and Aug 11, 2021.docx" and the accompanying literature submitted by Moderna. Moderna initially reached out to me via phone to give a heads up that the email below will be forthcoming.

In addition, they have also included 4 questions at the end of the document regarding fact sheet updates, labeling, packaging, presentation etc.., . They also noted that they have been encouraged by CBER leadership to amend the EUA for booster dose as soon as possible.

Moderna is requesting a telecon next week to discuss responses to these questions.

We understand that management is extremely busy with Pfizer BLA. We will await directions from management on granting a telecon/responding to Moderna and meanwhile will work on review of the submitted information.

Thanks,
Sudhakar Agnihothram

PS: Related Documents:

IND19745.182 CBER Feedback on Moderna's Response to CBER Comments on Prototype Booster Study.pdf- Communicated July 2, 2021.

IND 19745.196 CBER feedback on Booster EUA Strategy.pdf- Communicated August 11, 2021.

Sudhakar Agnihothram, B.Pharm., Ph.D
Biologist (Primary Reviewer)
Center for Biologics Evaluation and Research
Office of Vaccines Research and Review
U.S. Food and Drug Administration
Tel: 301-348-3056 (Off)
202-870-6949 (Cell)
Fax: 301-827-3532
Email: Sudhakar.Agnihothram@fda.hhs.gov

From: Michelle Olsen <Michelle.Olsen@modernatx.com>
Sent: Friday, August 20, 2021 11:30 AM
To: Agnihothram, Sudhakar <Sudhakar.Agnihothram@fda.hhs.gov>
Cc: Carla Vinals <Carla.Vinals@modernatx.com>
Subject: [EXTERNAL] Moderna IND 19745 -- Request for TC re: EUA boost; Response to Feedback and additional questions

Dear Sudhakar,

Please find attached a courtesy copy of files that will be submitted through the gateway today to the **IND**. The document attached contains our responses to FDA comments received on 11Aug2021 with regards to the P201 Part B data (submitted IND 19745 SN 0176) and outlines our submission plans for an EUA to support a booster dose of 50µg mRNA-1273. In addition, there are a few questions

also included at the end of the document. Also attached are two supportive manuscripts cited in the document that are currently under peer review (NEJM, Nature Medicine) [please keep confidential].

In a phone conversation between Stephen Hoge and Peter Marks, Dr. Marks encouraged Moderna to submit an EUA amendment for the booster dose as soon as possible. We were also encourage to request a TC between Moderna and CBER next week in an effort to expedite this EUA amendment.

We therefore respectfully request to have a teleconference with CBER next week at the Division's earliest convenience, taking into account the discussion between Dr. Marks and Stephen Hoge and also the recent Joint Statement from HHS Public Health and Medical Experts on COVID-19 Booster Shots. We'd like to discuss the proposed EUA submission plans and supporting data presented in the response document attached.

Best regards,
Michelle

Michelle Olsen, PhD
Associate Director, Regulatory Strategy – Infectious Diseases | Moderna
Mobile (617) 417-4428 | modernatx.com

From:	Gruber, Marion
To:	Cavaleri Marco
Subject:	Gilbert CoP paper
Date:	Friday, August 20, 2021 8:25:00 AM
Attachments:	Gilbert CoP COVID analysis 8 2021.pdf image001.png

Here it is.

Marion F. Gruber, Ph.D
Director

Office of Vaccines Research & Review
Center for Biologics Evaluation & Research
Food & Drug Administration, DHHS
10903 New Hampshire Ave.
Building 71, Rm. 3230
Silver Spring, Maryland 20993

Tel.: (301) 796 1856
Email: marion.gruber@fda.hhs.gov

From: Gruber, Marion
To: Krause, Philip
Subject: FW: Clinical Review memo for Pfizer COVID-19 BLA in progress
Date: Thursday, August 19, 2021 7:00:00 AM
Attachments: _BLA 125742 Pfizer BioNTech covid Clinical 8-19-21 DRAFT.docx
image001.jpg
image002.jpg
image003.jpg
image004.jpg
image005.jpg
image006.jpg

….

From: Allende, Maria <Maria.Allende@fda.hhs.gov>
Sent: Thursday, August 19, 2021 6:53 AM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Witten, Celia (CBER) <Celia.Witten@fda.hhs.gov>
Cc: Fink, Doran <Doran.Fink@fda.hhs.gov>; Lee, Lucia <Lucia.Lee@fda.hhs.gov>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Subject: RE: Clinical Review memo for Pfizer COVID-19 BLA in progress

Dear Peter, thank you so much, yes, our team is wonderful. Attached please find a more updated version of our memo in progress.
Best regards,
Maria

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Thursday, August 19, 2021 4:33 AM
To: Allende, Maria <Maria.Allende@fda.hhs.gov>; Witten, Celia (CBER) <Celia.Witten@fda.hhs.gov>
Cc: Fink, Doran <Doran.Fink@fda.hhs.gov>; Lee, Lucia <Lucia.Lee@fda.hhs.gov>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Subject: RE: Clinical Review memo for Pfizer COVID-19 BLA in progress

Dear Maria,

Thank you so much for sending this along. All of the work of your team is incredibly appreciated.

Best Regards,
Peter

From: Allende, Maria <Maria.Allende@fda.hhs.gov>
Sent: Wednesday, August 18, 2021 10:40 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Witten, Celia (CBER) <Celia.Witten@fda.hhs.gov>
Cc: Fink, Doran <Doran.Fink@fda.hhs.gov>; Lee, Lucia <Lucia.Lee@fda.hhs.gov>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Subject: Clinical Review memo for Pfizer COVID-19 BLA in progress

Hello Dr. Marks and Dr. Witten,

I am attaching the current version of our in-progress memo “as is” pulled from the SP folder of our review team.
Most comments from supervisors have been addressed.
Thank you,
Best regards
Maria

María C. Allende, M.D.
Chief, Clinical Review Branch I

Division of Vaccines and Related Products Applications
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration
Tel: 301-796-2952 (office)
240-478-8025 (cell)
maria.allende@fda.hhs.gov

From:	Gruber, Marion
To:	Agnihothram, Sudhakar; Krause, Philip; Izurieta, Hector; Pratt, Douglas R.; McVittie, Loris; Prutzman, Kirk C
Cc:	Fink, Doran; Zhang, Rachel; Rastogi, Anuja; Allende, Maria; Huang, Lei; Xiang, Ruoxuan; Lin, Tsai-Lien; Pandey, Rakesh; Fritz, Timothy
Subject:	Re: **EUA 27205/IND 22657_ Janssen COVID 19 Vaccine_ Requesting Management Input_Update From Janssen on Data for Booster Dose**
Date:	Wednesday, August 18, 2021 9:02:34 PM
Attachments:	image002.png image003.jpg image004.jpg image005.jpg image006.jpg image007.jpg image008.jpg

No time for t- con, I am afraid, I think written response more efficient.
Marion

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From: Agnihothram, Sudhakar <Sudhakar.Agnihothram@fda.hhs.gov>
Sent: Wednesday, August 18, 2021 8:59:15 PM
To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Krause, Philip <Philip.Krause@fda.hhs.gov>; Izurieta, Hector <Hector.Izurieta@fda.hhs.gov>; Pratt, Douglas R. <Douglas.Pratt@fda.hhs.gov>; McVittie, Loris <Loris.McVittie@fda.hhs.gov>; Prutzman, Kirk C <Kirk.Prutzman@fda.hhs.gov>
Cc: Fink, Doran <Doran.Fink@fda.hhs.gov>; Zhang, Rachel <Rachel.Zhang@fda.hhs.gov>; Rastogi, Anuja <Anuja.Rastogi@fda.hhs.gov>; Allende, Maria <Maria.Allende@fda.hhs.gov>; Huang, Lei <Lei.Huang@fda.hhs.gov>; Xiang, Ruoxuan <Ruoxuan.Xiang@fda.hhs.gov>; Lin, Tsai-Lien <Tsai-Lien.Lin@fda.hhs.gov>; Pandey, Rakesh <Rakesh.Pandey@fda.hhs.gov>; Fritz, Timothy <Timothy.Fritz@fda.hhs.gov>
Subject: RE: **EUA 27205/IND 22657_ Janssen COVID 19 Vaccine_ Requesting Management Input_Update From Janssen on Data for Booster Dose**

Thanks, Dr. Gruber.

I can let Janssen know that we prefer a meeting package and will respond in writing. I think they probably were planning on a slide set submission to engage in a telecon discussion with us.

Thanks,
Sudhakar Agnihothram

Sudhakar Agnihothram, B.Pharm., Ph.D
Biologist (Primary Reviewer)
Center for Biologics Evaluation and Research
Office of Vaccines Research and Review
U.S. Food and Drug Administration
Tel: 301-348-3056 (Off)
202-870-6949 (Cell)
Fax: 301-827-3532
Email: Sudhakar.Agnihothram@fda.hhs.gov

From: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Sent: Wednesday, August 18, 2021 8:56 PM
To: Agnihothram, Sudhakar <Sudhakar.Agnihothram@fda.hhs.gov>; Krause, Philip <Philip.Krause@fda.hhs.gov>; Izurieta, Hector <Hector.Izurieta@fda.hhs.gov>; Pratt, Douglas R. <Douglas.Pratt@fda.hhs.gov>; McVittie, Loris <Loris.McVittie@fda.hhs.gov>; Prutzman, Kirk C <Kirk.Prutzman@fda.hhs.gov>
Cc: Fink, Doran <Doran.Fink@fda.hhs.gov>; Zhang, Rachel <Rachel.Zhang@fda.hhs.gov>; Rastogi, Anuja <Anuja.Rastogi@fda.hhs.gov>; Allende, Maria <Maria.Allende@fda.hhs.gov>; Huang, Lei <Lei.Huang@fda.hhs.gov>; Xiang, Ruoxuan <Ruoxuan.Xiang@fda.hhs.gov>; Lin, Tsai-Lien <Tsai-Lien.Lin@fda.hhs.gov>; Pandey, Rakesh <Rakesh.Pandey@fda.hhs.gov>; Fritz, Timothy <Timothy.Fritz@fda.hhs.gov>
Subject: Re: **EUA 27205/IND 22657_ Janssen COVID 19 Vaccine_ Requesting Management Input_Update From Janssen on Data for Booster Dose**

Why can't they submit a meeting package instead of a slide set and yes, we respond in writing.
Marion

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From: Agnihothram, Sudhakar <Sudhakar.Agnihothram@fda.hhs.gov>
Sent: Wednesday, August 18, 2021 8:47:55 PM
To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Krause, Philip <Philip.Krause@fda.hhs.gov>; Izurieta, Hector <Hector.Izurieta@fda.hhs.gov>; Pratt, Douglas R. <Douglas.Pratt@fda.hhs.gov>; McVittie, Loris <Loris.McVittie@fda.hhs.gov>; Prutzman, Kirk C <Kirk.Prutzman@fda.hhs.gov>
Cc: Fink, Doran <Doran.Fink@fda.hhs.gov>; Zhang, Rachel <Rachel.Zhang@fda.hhs.gov>; Rastogi, Anuja <Anuja.Rastogi@fda.hhs.gov>; Allende, Maria <Maria.Allende@fda.hhs.gov>; Huang, Lei <Lei.Huang@fda.hhs.gov>; Xiang, Ruoxuan <Ruoxuan.Xiang@fda.hhs.gov>; Lin, Tsai-Lien <Tsai-Lien.Lin@fda.hhs.gov>; Pandey, Rakesh <Rakesh.Pandey@fda.hhs.gov>; Fritz, Timothy <Timothy.Fritz@fda.hhs.gov>
Subject: **EUA 27205/IND 22657_ Janssen COVID 19 Vaccine_ Requesting Management Input_Update From Janssen on Data for Booster Dose**

Dear IND 22657 Review Team and Management,

Janssen reached out to share the immunogenicity results from studies VAC31518COV1001 and VAC31518COV2001 regarding:

- the durability of the immune response from the primary dose of Janssen COVID-19 Vaccine
- 6-month booster in individuals 18-55 and ≥65 years of age

They are also sharing these results with ACIP.

Sometime between Aug-Sep 2021 timeframe, Janssen hopes to have additional immunogenicity data from COV1001 and COV2001), and the efficacy results from the double-blind phase of our pivotal Phase 3 studies COV3001 (1-dose) and COV3009 (2-dose), to support their discussion on the booster dose.

They would like an opportunity to discuss the potential data package that would support the amendment request for addition of a booster dose under EUA 27205. Instead of submitting a pre EUA meeting package for this purpose, Janssen is proposing to submit a slide deck with questions for our feedback. Although the format of the material of the Pre-EUA (slide set Vs meeting package) seems to be agreeable, my two cents are that we can provide written responses to their questions instead of engaging in a discussion (they are possibly referring to a telecon here) with them.

Q to management: If Management agrees, I can let Janssen know the following:

'When available, please submit your outline of the potential data package to support the booster dose as a slide set with your questions for FDA feedback as an amendment to IND 22657. We will review the data and provide written responses to your questions'.

Thanks,
Sudhakar Agnihothram,

Sudhakar Agnihothram, B.Pharm., Ph.D
Biologist (Primary Reviewer)
Center for Biologics Evaluation and Research
Office of Vaccines Research and Review
U.S. Food and Drug Administration
Tel: 301-348-3056 (Off)
202-870-6949 (Cell)
Fax: 301-827-3532
Email: Sudhakar.Agnihothram@fda.hhs.gov

From: Walawalkar, Ruta [JRDUS] <RWalawal@its.jnj.com>
Sent: Wednesday, August 18, 2021 3:57 PM
To: Agnihothram, Sudhakar <Sudhakar.Agnihothram@fda.hhs.gov>
Cc: Obiozo, Mirian [JRDUS J&J] <MObiozo@ITS.JNJ.com>
Subject: [EXTERNAL] Communication from Janssen (EUA 027205)

Dear Dr. Agnihothram,

With this message Janssen would like to share the available results on the immune response to Ad26.COV2.S in terms of durability and 6-month booster in individuals 18-55 and ≥65 years of age from studies COV1001 and COV2001. The data are provided in the attached document.
This data is also being shared with the Advisory Committee on Immunization Practices (ACIP) Working Group.

With data accrual and the evolving pandemic situation, Janssen is requesting for an opportunity to have a discussion with the Agency on a potential data package that could support a booster submission as an EUA Amendment.

- Proposed supportive material: To expedite this engagement, Janssen proposes to submit a slide presentation with data and questions to the Agency to support the meeting and forego submission of a formal briefing document. Would this be agreeable?
- Proposed timeline: Additional immunogenicity data from COV1001 and COV2001 will become available in the next weeks (August-September 2021). Furthermore, the readouts for the end of the double-blind phase of our pivotal Phase 3 studies COV3001 (1-dose efficacy) and COV3009 (2-dose efficacy) are expected in the same timeframe and will further support discussion on potential booster strategies. Janssen suggests to have the meeting once these data have become available (exact date to be determined).

Please acknowledge receipt of this email and attached document.

Kind Regards,
Ruta Walawalkar ,MSc. M.S.

US Vaccines Regulatory Affairs

Global Regulatory Affairs
Janssen Research and Development
Tel: +1 908 927 3237, Mobile: +1 732 586 3995
rwalawal@its.jnj.com

From:	Gruber, Marion
To:	Agnihothram, Sudhakar; Krause, Philip; Izurieta, Hector; Pratt, Douglas R.; McVittie, Loris; Prutzman, Kirk C
Cc:	Fink, Doran; Zhang, Rachel; Rastogi, Anuja; Allende, Maria; Huang, Lei; Xiang, Ruoxuan; Lin, Tsai-Lien; Pandey, Rakesh; Fritz, Timothy
Subject:	Re: **EUA 27205/IND 22657_ Janssen COVID 19 Vaccine_ Requesting Management Input_Update From Janssen on Data for Booster Dose**
Date:	Wednesday, August 18, 2021 8:56:00 PM
Attachments:	image001.jpg image002.png image003.jpg image004.jpg image005.jpg image006.jpg image007.jpg

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From: Agnihothram, Sudhakar <Sudhakar.Agnihothram@fda.hhs.gov>
Sent: Wednesday, August 18, 2021 8:47:55 PM
To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Krause, Philip <Philip.Krause@fda.hhs.gov>; Izurieta, Hector <Hector.Izurieta@fda.hhs.gov>; Pratt, Douglas R. <Douglas.Pratt@fda.hhs.gov>; McVittie, Loris <Loris.McVittie@fda.hhs.gov>; Prutzman, Kirk C <Kirk.Prutzman@fda.hhs.gov>
Cc: Fink, Doran <Doran.Fink@fda.hhs.gov>; Zhang, Rachel <Rachel.Zhang@fda.hhs.gov>; Rastogi, Anuja <Anuja.Rastogi@fda.hhs.gov>; Allende, Maria <Maria.Allende@fda.hhs.gov>; Huang, Lei <Lei.Huang@fda.hhs.gov>; Xiang, Ruoxuan <Ruoxuan.Xiang@fda.hhs.gov>; Lin, Tsai-Lien <Tsai-Lien.Lin@fda.hhs.gov>; Pandey, Rakesh <Rakesh.Pandey@fda.hhs.gov>; Fritz, Timothy <Timothy.Fritz@fda.hhs.gov>
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Thanks,
Sudhakar Agnihothram,

Sudhakar Agnihothram, B.Pharm., Ph.D
Biologist (Primary Reviewer)
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Tel: 301-348-3056 (Off)
202-870-6949 (Cell)
Fax: 301-827-3532
Email: Sudhakar.Agnihothram@fda.hhs.gov

From: Walawalkar, Ruta [JRDUS] <RWalawal@its.jnj.com>
Sent: Wednesday, August 18, 2021 3:57 PM
To: Agnihothram, Sudhakar <Sudhakar.Agnihothram@fda.hhs.gov>
Cc: Obiozo, Mirian [JRDUS J&J] <MObiozo@ITS.JNJ.com>
Subject: [EXTERNAL] Communication from Janssen (EUA 027205)

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With data accrual and the evolving pandemic situation, Janssen is requesting for an opportunity to have a discussion with the Agency on a potential data package that could support a booster submission as an EUA Amendment.

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Please acknowledge receipt of this email and attached document.

Kind Regards,

Ruta Walawalkar ,MSc. M.S.
US Vaccines Regulatory Affairs

Janssen_Hor_RGB

Global Regulatory Affairs
Janssen Research and Development
Tel: +1 908 927 3237, Mobile: +1 732 586 3995
rwalawal@its.jnj.com

From: Gruber, Marion
To: Fink, Doran; Krause, Philip
Subject: FW: Your Question to Doran
Date: Tuesday, August 17, 2021 8:55:00 PM
Attachments: BLA 125742 Pfizer BioNTech covid clin rev template.docx

FYI

From: Gruber, Marion
Sent: Tuesday, August 17, 2021 8:55 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: Your Question to Doran

Dear Peter,
Doran has shared the email string below with me. I am attaching, for you review, the current draft of the clinical review memo. You will see that this memo still needs a lot of work and that Doran's summary of sections that will still need to be populated, revised and reviewed is an accurate and comprehensive account of the work that is still outstanding. Please also note that OVRR has not received OBE's B/R summary document and the information and the assessment included in that document will also need to be captured in the clinical review memo. In addition, as mentioned by Doran in his summary the B/R table that is part of the clinical review memo still needs significant revisions and updates as per his extensive feedback to the team, which was provided to them separate from this document.
I am concerned and disappointed about the apparent lack of confidence and trust that Dr. Woodcock has in the OVRR team and that she has asked you to verify the information that we have provided to you in today's meeting and in the email sent to you by Doran this afternoon. However, I understand that you do not have a choice as she directed you to personally assess and verify the work on the clinical memo that has been done so far.
I trust that, following your assessment of the attached draft clinical memo, you will come to the same conclusion about work that still needs to be completed as stated in Doran's email below and thus, an ADD of August 20 is not possible. Therefore, feel free to borrow from that summary in your response to Dr. Woodcock.
Please do not hesitate to call me this evening if you want to discuss further. As Doran's supervisor, I feel strongly that I need to provide him with some downtime at least this evening. I am confident that under Doran's guidance and leadership, the clinical team will conclude its work on this memo as soon as possible. They fully understand that the Acting Commissioner would like to approve this product very soon and are trying their best to complete their review and assessment while at the same time, maintaining our high standards and scientific and clinical integrity. Another document that is at a very early draft stage is the SBRA and that has not even been shared with me. We have assigned this to Kirk Prutzmann who is not part of the team but capable of doing this work. We are doing what we can to accelerate the approval of this BLA.
Thank you for your understanding,
Marion

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Tuesday, August 17, 2021 6:32 PM
To: Fink, Doran <Doran.Fink@fda.hhs.gov>
Subject: RE: Question

Dear Doran,

Dr. Woodcock has directed me to personally review and assess what we have so far before I go back to her tomorrow for a conversation about moving the action date later. Could you please point me to the Sharepoint or other site where these documents are? Thanks very much.

You are doing an amazing job and I very much appreciate the sacrifices that you have made to get this and everything else done.

Best Regards,
Peter

From: Fink, Doran <Doran.Fink@fda.hhs.gov>
Sent: Tuesday, August 17, 2021 3:52 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: RE: Question

Hi Peter,

Over the weekend I reviewed and provided feedback on the following clinical memo sections:

2- Clinical and regulatory background
3 – Submission quality and good clinical practices
4 – Significant efficacy/safety issues related to other review disciplines (still need to add summary of benefit/risk analyses from Rich Forshee's group, which they are working providing)
5 – Sources of clinical data and other information considered in the review
6 – Discussion of individual studies (The part that was ready for my review included study design, statistical considerations, demographics and disposition, and efficacy analyses; subsections on safety analyses and study conclusions were still in process)
11 – benefit/risk considerations table (there is more to this section, but the table is a key component that provides the framework for the benefit/risk discussion)

This week the clinical team has been working on finishing the remaining sections and responding to my feedback so far. I looked in on the memo, and many of my comments are satisfactorily addressed, but more work needed on some.

Sections that are well on their way in drafting but remaining to be completed include:

1 – Executive summary
6 – Discussion of individual studies (safety analyses and study conclusions, as mentioned above)

9 – Additional clinical considerations not covered elsewhere (e.g., specific populations, PREA)
10 – Overall conclusions
11 – Benefit/risk considerations and recommendations (in addition to the table completed this weekend)

*for anyone following along at home, sections 7 (integrated summary of efficacy) and 8 (integrated summary of safety) are not applicable for this memo.

In particular, the benefit/risk considerations are complex, and the team is doing their best to complete it along with the rest of the sections, and respond to my feedback, and resolve remaining labeling issues. They are hopeful to have a complete document for my further review by the end of this week (which I would consider a minor miracle based on how the document looks to me now), though I will continue to check in on it and check in with the team daily (or rather throughout each day) as parts are completed and as they respond to my feedback.

In addition to finishing drafting and incorporating feedback from myself, Marion, and Phil, the document will need substantial clean-up from the medical editors, which we are very happy to have at our disposal.

Thanks,
Doran

Doran L. Fink, MD, PhD
Deputy Director – Clinical
Division of Vaccines and Related Products Applications
FDA/CBER, Office of Vaccines Research and Review
(301) 796-2640

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Tuesday, August 17, 2021 3:25 PM
To: Fink, Doran <Doran.Fink@fda.hhs.gov>
Subject: Question

Dear Doran,

As I go to speak to Dr. Woodcock, it would be helpful to know where you are with the clinical review, as I know that she will ask that (that is what got you invited to the last meeting with her). According to the last update that I wrote down, my understanding was that you have been reviewing the sections as they were ready and that the safety section was pending yesterday. Can you let me know where you are right now, and when you anticipate being done? Thanks so much.

And my apologies, I was wrong to be short about CDC. They are trying their hardest – I will make sure that they are properly informed on the status of things.

Best Regards,

Peter

From: Gruber, Marion
To: Marks, Peter
Subject: Your Question to Doran
Date: Tuesday, August 17, 2021 8:55:00 PM
Attachments: BLA 125742 Pfizer BioNTech covid clin rev template.docx

Dear Peter,
Doran has shared the email string below with me. I am attaching, for you review, the current draft of the clinical review memo. You will see that this memo still needs a lot of work and that Doran's summary of sections that will still need to be populated, revised and reviewed is an accurate and comprehensive account of the work that is still outstanding. Please also note that OVRR has not received OBE's B/R summary document and the information and the assessment included in that document will also need to be captured in the clinical review memo. In addition, as mentioned by Doran in his summary the B/R table that is part of the clinical review memo still needs significant revisions and updates as per his extensive feedback to the team, which was provided to them separate from this document.
I am concerned and disappointed about the apparent lack of confidence and trust that Dr. Woodcock has in the OVRR team and that she has asked you to verify the information that we have provided to you in today's meeting and in the email sent to you by Doran this afternoon. However, I understand that you do not have a choice as she directed you to personally assess and verify the work on the clinical memo that has been done so far.
I trust that, following your assessment of the attached draft clinical memo, you will come to the same conclusion about work that still needs to be completed as stated in Doran's email below and thus, an ADD of August 20 is not possible. Therefore, feel free to borrow from that summary in your response to Dr. Woodcock.
Please do not hesitate to call me this evening if you want to discuss further. As Doran's supervisor, I feel strongly that I need to provide him with some downtime at least this evening. I am confident that under Doran's guidance and leadership, the clinical team will conclude its work on this memo as soon as possible. They fully understand that the Acting Commissioner would like to approve this product very soon and are trying their best to complete their review and assessment while at the same time, maintaining our high standards and scientific and clinical integrity. Another document that is at a very early draft stage is the SBRA and that has not even been shared with me. We have assigned this to Kirk Prutzmann who is not part of the team but capable of doing this work. We are doing what we can to accelerate the approval of this BLA.
Thank you for your understanding,
Marion

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Tuesday, August 17, 2021 6:32 PM
To: Fink, Doran <Doran.Fink@fda.hhs.gov>
Subject: RE: Question

Dear Doran,

Dr. Woodcock has directed me to personally review and assess what we have so far before I go back to her tomorrow for a conversation about moving the action date later. Could you please point me to the Sharepoint or other site where these documents are? Thanks very much.

You are doing an amazing job and I very much appreciate the sacrifices that you have made to get this and everything else done.

Best Regards,
Peter

From: Fink, Doran <Doran.Fink@fda.hhs.gov>
Sent: Tuesday, August 17, 2021 3:52 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: RE: Question

Hi Peter,

Over the weekend I reviewed and provided feedback on the following clinical memo sections:

2- Clinical and regulatory background
3 – Submission quality and good clinical practices
4 – Significant efficacy/safety issues related to other review disciplines (still need to add summary of benefit/risk analyses from Rich Forshee's group, which they are working providing)
5 – Sources of clinical data and other information considered in the review
6 – Discussion of individual studies (The part that was ready for my review included study design, statistical considerations, demographics and disposition, and efficacy analyses; subsections on safety analyses and study conclusions were still in process)
11 – benefit/risk considerations table (there is more to this section, but the table is a key component that provides the framework for the benefit/risk discussion)

This week the clinical team has been working on finishing the remaining sections and responding to my feedback so far. I looked in on the memo, and many of my comments are satisfactorily addressed, but more work needed on some.

Sections that are well on their way in drafting but remaining to be completed include:

1 – Executive summary
6 – Discussion of individual studies (safety analyses and study conclusions, as mentioned above)
9 – Additional clinical considerations not covered elsewhere (e.g., specific populations, PREA)
10 – Overall conclusions
11 – Benefit/risk considerations and recommendations (in addition to the table completed this weekend)

*for anyone following along at home, sections 7 (integrated summary of efficacy) and 8 (integrated summary of safety) are not applicable for this memo.

In particular, the benefit/risk considerations are complex, and the team is doing their best to complete it along with the rest of the sections, and respond to my feedback, and resolve remaining labeling issues. They are hopeful to have a complete document for my further review by the end of this week (which I would consider a minor miracle based on how the document looks to me now), though I will continue to check in on it and check in with the team daily (or rather throughout each day) as parts are completed and as they respond to my feedback.

In addition to finishing drafting and incorporating feedback from myself, Marion, and Phil, the document will need substantial clean-up from the medical editors, which we are very happy to have at our disposal.

Thanks,
Doran

Doran L. Fink, MD, PhD
Deputy Director – Clinical
Division of Vaccines and Related Products Applications
FDA/CBER, Office of Vaccines Research and Review
(301) 796-2640

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Subject: Question

Dear Doran,

As I go to speak to Dr. Woodcock, it would be helpful to know where you are with the clinical review, as I know that she will ask that (that is what got you invited to the last meeting with her). According to the last update that I wrote down, my understanding was that you have been reviewing the sections as they were ready and that the safety section was pending yesterday. Can you let me know where you are right now, and when you anticipate being done? Thanks so much.

And my apologies, I was wrong to be short about CDC. They are trying their hardest – I will make sure that they are properly informed on the status of things.

Best Regards,
Peter

From: Gruber, Marion
To: Fink, Doran; Krause, Philip
Subject: FW: Question
Date: Tuesday, August 17, 2021 8:33:00 PM
Attachments: BLA 125742 Pfizer BioNTech covid clin rev template.docx

Dear Doran/Phil,

As discussed earlier, here is the draft of an email I want to sent to Peter tonight.

Dear Peter,
Doran has shared the email string below with me. I am attaching, for you review, the current draft of the clinical review memo. You will see that this memo still needs a lot of work and that Doran's summary of sections that will still need to be populated, revised and reviewed is an accurate and comprehensive account of the work that is still outstanding. Please also note that OVRR has not received OBE's B/R summary document and the information and the assessment included in that document will also need to be captured in the clinical review memo. In addition, the B/R table that is part of the clinical review memo needs significant revisions and updates.
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Thanks,
Doran

Doran L. Fink, MD, PhD
Deputy Director – Clinical
Division of Vaccines and Related Products Applications
FDA/CBER, Office of Vaccines Research and Review
(301) 796-2640

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Sent: Tuesday, August 17, 2021 3:25 PM
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Subject: Question

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And my apologies, I was wrong to be short about CDC. They are trying their hardest – I will make sure that they are properly informed on the status of things.

Best Regards,
Peter

From:	Krause, Philip
To:	SCHWARTZ, Lauren
Cc:	HENAO RESTREPO, Ana Maria
Subject:	FW: [EXTERNAL] NMPA to join the regulatory session: WHO Consultation, 13 August 13h-18h CET
Date:	Friday, August 13, 2021 6:48:00 AM
Attachments:	Agenda_COVID19 Vaccine Research.pdf Resume LIU Bo-NMPA.docx

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From: MIYAZAKI-KRAUSE, Ryoko <miyazakikrauser@who.int>
Sent: Thursday, August 12, 2021 4:18 PM
To: liub (liub@cde.org.cn) <liub@cde.org.cn>; MAFUNGA, Neddy <mafungan@who.int>
Cc: Krause, Philip <Philip.Krause@fda.hhs.gov>; HENAO RESTREPO, Ana Maria <henaorestrepoa@who.int>
Subject: [EXTERNAL] NMPA to join the regulatory session: WHO Consultation, 13 August 13h-18h CET

Dear Mr Liu Bo,
Thank you for agreeing to join the regulatory session on boosters tomorrow.
Attached is the updated agenda for information.

As you have been informed by our colleagues from WHO County office, could you please kindly prepare **a 2 minute talk** on agency's perspective around major issues, data or evidence gaps to justify needs for boosters?

Phil Krause, Cced here, will be moderating the discussion on next steps and identifying data/research needs in the second half of this session.

Confirmation request: recording and presentation (if relevant):
Could you please kindly confirm if WHO can share the recording of the consultation and your presentation (if relevant)?

Neddy, could you please send a panellist Zoom link?
Neddy, Phil and Ana Maria, Mr Bo Liu's CV is attached for information.
Mr Liu Bo is Lead Clinical Reviewer from Center for Drug Evaluation at NMPA.

Best regards,
Ryoko

Dr Ryoko Miyazaki-Krause
Project Officer, Office of Director
Regulation and Prequalification (PRQ)
Access to Medicines and Health Products (MHP)

From: MIYAZAKI-KRAUSE, Ryoko
To: liub; MAFUNGA, Neddy
Cc: Krause, Philip; HENAO RESTREPO, Ana Maria
Subject: [EXTERNAL] NMPA to join the regulatory session: WHO Consultation, 13 August 13h-18h CET
Date: Thursday, August 12, 2021 4:18:29 PM
Attachments: Agenda_COVID19 Vaccine Research.pdf
Resume LIU Bo-NMPA.docx

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Mr Liu Bo is Lead Clinical Reviewer from Center for Drug Evaluation at NMPA.

Best regards,
Ryoko

Dr Ryoko Miyazaki-Krause
Project Officer, Office of Director
Regulation and Prequalification (PRQ)
Access to Medicines and Health Products (MHP)

From: Krause, Philip
To: Longini,Ira M; Thomas R. Fleming; Richard Peto Personal; HENAO RESTREPO, Ana Maria
Subject: RE: [EXTERNAL] RE: boosting
Date: Thursday, August 19, 2021 11:25:00 AM
Attachments: WHO Boosting Strategies 19aug2021.docx

Here is a new version, which I think is better because it includes a more comprehensive review of the currently existing data. This will be submitted as a "Sounding Board" which doesn't limit references and actually gives us up to 2000 words.

I would love to send this to NEJM tomorrow—but would like to allow our group another round of comments and Ana Maria will need to also get other authors on board. Any chance you could provide comments by 5 pm US Eastern today (or sooner)?

Thanks!
Phil

From: Longini,Ira M <ilongini@ufl.edu>
Sent: Monday, August 16, 2021 2:16 PM
To: Thomas R. Fleming <tfleming@uw.edu>; Krause, Philip <Philip.Krause@fda.hhs.gov>; Richard Peto Personal <rpeto@ndph.ox.ac.uk>; HENAO RESTREPO, Ana Maria <henaorestrepoa@who.int>
Subject: RE: [EXTERNAL] RE: boosting

Dear all, I think that is excellent, and it would be good to publish it as soon as possible. I have added a few minor corrections and additions in addition to Tom's. Cheers, Ira

Ira Longini, Ph.D.
Professor of Biostatistics

Department of Biostatistics
22 Buckman Drive, 452 Dauer Hall
University of Florida
Gainesville, FL 32611

Phone: 404-275-5156 (cell), 352-294-1938 (office)
email: ilongini@ufl.edu

From: Thomas R. Fleming <tfleming@uw.edu>
Sent: Monday, August 16, 2021 1:18 PM
To: Krause, Philip <Philip.Krause@fda.hhs.gov>; Longini,Ira M <ilongini@ufl.edu>; Richard Peto Personal <rpeto@ndph.ox.ac.uk>; HENAO RESTREPO, Ana Maria <henaorestrepoa@who.int>
Subject: RE: [EXTERNAL] RE: boosting

[External Email]
Colleagues,

This version from Phil is even better than the previous draft. It provides substantive scientific context for the important guidance from WHO in final paragraph that there should be a moratorium on boosting until the benefits of primary vaccination have been made available to more people around the world.

If this manuscript could be submitted to a front-line journal like NEJM within the next couple days and then be published soon thereafter, it could meaningfully influence evidence-based decision-makers.

The attached document provides some suggested revisions made using the tracking feature.

Best wishes,
Tom

From: Krause, Philip <Philip.Krause@fda.hhs.gov>
Sent: Sunday, August 15, 2021 10:43 PM
To: Longini,Ira M <ilongini@ufl.edu>; Thomas R. Fleming <tfleming@uw.edu>; Richard Peto Personal <rpeto@ndph.ox.ac.uk>; HENAO RESTREPO, Ana Maria <henaorestrepoa@who.int>
Subject: RE: [EXTERNAL] RE: boosting

Here is an updated version of the manuscript that takes into consideration some of the discussion on Friday. I've also added some (but not all) references.

From: Longini,Ira M <ilongini@ufl.edu>
Sent: Wednesday, August 11, 2021 12:51 PM
To: Thomas R. Fleming <tfleming@uw.edu>; Krause, Philip <Philip.Krause@fda.hhs.gov>; Richard Peto Personal <rpeto@ndph.ox.ac.uk>; HENAO RESTREPO, Ana Maria <henaorestrepoa@who.int>
Subject: [EXTERNAL] RE: boosting

Hi all, This is looking good to me. I think we should propose the following, based on our NEJM variant commentary and fig. 1 on large-scale simple randomized studies. I have add the short paragraph "The effectiveness of booster doses could be assessed during deployment via large- scale randomization allocating the order of booster vaccinations over time to groups of people. The effectiveness could be assessed by comparing the rates of illness, hospitalizations and deaths in those who have already received the booster doses to that among those who have not yet received booster doses (ref)." We could add a bit to that plus a figure for the idea. Cheers, Ira

Ira Longini, Ph.D.
Professor of Biostatistics

Department of Biostatistics
22 Buckman Drive, 452 Dauer Hall
University of Florida
Gainesville, FL 32611

Phone: 404-275-5156 (cell), 352-294-1938 (office)
email: ilongini@ufl.edu

From: Thomas R. Fleming <tfleming@uw.edu>
Sent: Wednesday, August 11, 2021 1:30 AM
To: Krause, Philip <Philip.Krause@fda.hhs.gov>; Richard Peto Personal <rpeto@ndph.ox.ac.uk>; Longini,Ira M <ilongini@ufl.edu>; HENAO RESTREPO, Ana Maria <henaorestrepoa@who.int>
Subject: RE: boosting

[External Email]

The content of this draft by Phil is compelling and timely. Leaders who are evidence based, such as Biden, need these insights now.

The attachment provides suggested revisions to the wording and to the ordering of paragraphs to enhance clarity.

I look forward to your thoughts.

Best wishes,
Tom

From: Krause, Philip <Philip.Krause@fda.hhs.gov>
Sent: Tuesday, August 10, 2021 3:25 PM
To: Thomas R. Fleming <tfleming@uw.edu>; Richard Peto Personal <rpeto@ndph.ox.ac.uk>; Longini,Ira M <ilongini@ufl.edu>; HENAO RESTREPO, Ana Maria <henaorestrepoa@who.int>
Subject: boosting

Hi Ana Maria, Ira, Tom and Richard,

Motivated by the crazy controversy and very strong push towards boosting vaccinees that I am seeing here in the US, the EU, and a few other countries, I tried to put some of my thoughts about this issue in writing. I mentioned that I am working on this to Ana Maria, and not surprisingly, WHO has a strong interest in this. I am also missing our late night editing sessions (though Corina is not!), so am hoping that you will all take a look at this and we might be able to move forward with a viewpoint type article with the goal of sharing with potential co-authors this weekend.

WHO is also having a meeting on this topic this Friday, and we could incorporate some of the outcomes if anything unexpected comes out of that—but I think it is unlikely that much would change.

I have not added references yet—but wanted to give you more time to provide comments.

Many thanks,

Phil

From: MIYAZAKI-KRAUSE, Ryoko
To: Krause, Philip; Boitumelo.Semete@sahpra.org.za; Marks, Peter; Bielsky, Marie-Christine; Cavaleri Marco; PINTO DE SÁ GASPAR, Rogerio Paulo; HENAO RESTREPO, Ana Maria; WOOD, David John
Subject: [EXTERNAL] Preparatory call for the Regulatory session on boosters - WHO Consultation on 13 Aug
Attachments: image001.jpg
image002.jpg
image001.jpg
Agenda_COVID19 Vaccine Research_13Aug2021 public version_10Aug_11pm.docx

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CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear colleagues,

Apologies for scheduling this meeting in your extremely busy schedules (and additional apologies to Phil and Peter for selecting early morning hour..)

Draft agenda is attached and the regulatory session is planned from 16:00 to 16:30 CET (for now).

For information, Alejandro Cravioto (SAGE Chair) will touch on data needed for boosters.

Please note that WHO SAGE statements on boosters, fractioned doses and heterologous priming were published today (these are not policy recommendations, but points to consider & data/research need).

COVID-19 vaccine booster doses

https://www.who.int/news/item/10-08-2021-interim-statement-on-covid-19-vaccine-booster-doses

fractionated doses:

https://www.who.int/news/item/10-08-2021-interim-statement-on-dose-sparing-strategies-for-covid-19-vaccines-(fractionated-vaccine-doses)

heterologous priming for COVID-19 vaccines

https://www.who.int/news/item/10-08-2021-interim-statement-on-heterologous-priming-for-covid-19-vaccines

We will follow up with email in case you are unable to join this call.

Sincerely,

Ryoko on behalf of Rogerio and his team

Microsoft Teams meeting

Join on your computer or mobile app

Click here to join the meeting <https://teams.microsoft.com/l/meetup-join/19%3ameeting_YjlkMTgyMDQtMzk1MC00ZDI5LThiNTgtNDlmZTQ1OGExODE1%40thread.v2/0?context=%7b%22Tid%22%3a%22f610c0b7-bd24-4b39-810b-3dc280afb590%22%2c%22Oid%22%3a%22460796a0-961c-4da2-822c-2caac616936a%22%7d>

Join with a video conferencing device

who2@m.webex.com <mailto:who2@m.webex.com>

Video Conference ID: 127 895 352 8

Alternate VTC instructions <https://www.webex.com/msteams?confid=1278953528&tenantkey=who2&domain=m.webex.com>

Learn More <https://aka.ms/JoinTeamsMeeting> | Meeting options <https://teams.microsoft com/meetingOptions/?organizerId=460796a0-961c-4da2-

822c-2caac616936a&tenantId=f610c0b7-bd24-4b39-810b-3dc280afb590&threadId=19_meeting_YjlkMTgyMDQtMzk1MC00ZDI5LThiNTgtNDlmZTQ1OGExODE1@thread.v2&messageId=0&language=en-US>

From: Krause, Philip
To: Gruber, Marion; Fink, Doran
Subject: RE: [EXTERNAL] Invitation: Aug. 14th CDC/IDSA COVID-19 Clinician Call
Date: Tuesday, August 10, 2021 4:01:35 PM
Attachments: image001.png

It sounds like Peter thinks he has taken over all vaccine operations, not just the Pfizer BLA…

From: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Sent: Tuesday, August 10, 2021 4:00 PM
To: Fink, Doran <Doran.Fink@fda.hhs.gov>; Krause, Philip <Philip.Krause@fda.hhs.gov>
Subject: RE: [EXTERNAL] Invitation: Aug. 14th CDC/IDSA COVID-19 Clinician Call

Well, wrapping this up by Friday is certainly news to me and I guess, I can enjoy my Saturday rather than calling into that meeting as Saturday's call may not discuss this issue if ACIP does not meet. CBER IOD not informing us of communications with our sister agencies is really unsettling!
Marion

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To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Krause, Philip <Philip.Krause@fda.hhs.gov>
Subject: RE: [EXTERNAL] Invitation: Aug. 14th CDC/IDSA COVID-19 Clinician Call

FWIW, I heard from the ACIP lead Sara Oliver just a few hours ago (this is how I get my news about goings-on at FDA) that Peter told Amanda Cohn he is aiming to have EUA amendments for 3rd doses of Pfizer and Moderna in IC populations wrapped up by Friday this week! She told me that if there will be a substantial delay beyond Friday (and we heard from Peter this morning that David Cho assessed CDC's initial proposal for a submission to be deficient), then ACIP may postpone their discussion so as not to get peoples' hopes up but then not be able to deliver.

From: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Sent: Tuesday, August 10, 2021 3:46 PM
To: Fink, Doran <Doran.Fink@fda.hhs.gov>; Krause, Philip <Philip.Krause@fda.hhs.gov>
Subject: FW: [EXTERNAL] Invitation: Aug. 14th CDC/IDSA COVID-19 Clinician Call
Importance: High

I think I should not decline but it will be difficult to present a perspective as all of us agree that 3rd doses in IC persons make sense but that short if an IND or an approved BLA there is not a regulatory mechanism to allow for 3rd doses. Peter talked this am about amending the EUAs to include certain IC populations. I am afraid if I decline this invite, they will ask Peter and then all bets are off (again).
Marion

From: Wollins, Dana <dwollins@idsociety.org>

Sent: Tuesday, August 10, 2021 1:16 PM
To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Subject: [EXTERNAL] Invitation: Aug. 14th CDC/IDSA COVID-19 Clinician Call
Importance: High

Dear Dr. Gruber:

My name is Dana Wollins from the Infectious Diseases Society of America (IDSA). John Farley gave me your name and contact information and suggested I get in touch. I'm writing to ask if you would be available to join our upcoming CDC/IDSA COVID-19 Clinician Call, to be held Saturday, 8/14 from 3-4 PM Eastern Time. ACIP has just announced it will be meeting this Friday to discuss additional doses of COVID-19 for immunocompromised individuals in addition to booster doses of COVID-19 vaccine more generally. On Saturday's call, we're planning to have ACIP members share a re-cap of the meeting discussion and any recommendations that are made. We are hoping you would be willing to join as well to provide an update and answer questions from the FDA perspective.

About the Clinician Calls: The CDC and IDSA have been holding COVID-19 Clinician Calls each Saturday for the past year. Delivered via Zoom webinar, the calls are intended for clinicians on the front lines caring for patients with COVID-19. We are routinely drawing 700+ attendees each week from a variety of backgrounds—about 2/3 are ID physicians, and the rest are composed of specialists in pulmonary/critical care, emergency medicine, internal medicine/ primary care, pediatrics, cardiology, rheumatology, hematology, pharmacology and others. Most who attend are physicians, although we do have some participation from nurses and physician assistants as well. The calls are recorded and available for later viewing on the IDSA website.

Thanks so much for considering.

Best,
Dana

Dana S. Wollins, DrPH, MGC
Vice President, Clinical Affairs & Practice Guidelines
Infectious Diseases Society of America
4040 Wilson Blvd. Suite 300
Arlington, VA 22203
Tel: 703-299-5146
www.idsociety.org

From: Gruber, Marion
To: Fink, Doran; Krause, Philip
Subject: RE: [EXTERNAL] Invitation: Aug. 14th CDC/IDSA COVID-19 Clinician Call
Date: Tuesday, August 10, 2021 3:59:00 PM
Attachments: image001.png

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Sent: Tuesday, August 10, 2021 3:52 PM
To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Krause, Philip <Philip.Krause@fda.hhs.gov>
Subject: RE: [EXTERNAL] Invitation: Aug. 14th CDC/IDSA COVID-19 Clinician Call

FWIW, I heard from the ACIP lead Sara Oliver just a few hours ago (this is how I get my news about goings-on at FDA) that Peter told Amanda Cohn he is aiming to have EUA amendments for 3rd doses of Pfizer and Moderna in IC populations wrapped up by Friday this week! She told me that if there will be a substantial delay beyond Friday (and we heard from Peter this morning that David Cho assessed CDC's initial proposal for a submission to be deficient), then ACIP may postpone their discussion so as not to get peoples' hopes up but then not be able to deliver.

From: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Sent: Tuesday, August 10, 2021 3:46 PM
To: Fink, Doran <Doran.Fink@fda.hhs.gov>; Krause, Philip <Philip.Krause@fda.hhs.gov>
Subject: FW: [EXTERNAL] Invitation: Aug. 14th CDC/IDSA COVID-19 Clinician Call
Importance: High

I think I should not decline but it will be difficult to present a perspective as all of us agree that 3rd doses in IC persons make sense but that short if an IND or an approved BLA there is not a regulatory mechanism to allow for 3rd doses. Peter talked this am about amending the EUAs to include certain IC populations. I am afraid if I decline this invite, they will ask Peter and then all bets are off (again).
Marion

From: Wollins, Dana <dwollins@idsociety.org>
Sent: Tuesday, August 10, 2021 1:16 PM
To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Subject: [EXTERNAL] Invitation: Aug. 14th CDC/IDSA COVID-19 Clinician Call
Importance: High

Dear Dr. Gruber:

My name is Dana Wollins from the Infectious Diseases Society of America (IDSA). John Farley gave me your name and contact information and suggested I get in touch. I'm writing to ask if you would be available to join our upcoming CDC/IDSA COVID-19 Clinician Call, to be held Saturday, 8/14 from 3-4 PM Eastern Time. ACIP has just announced it will be meeting this Friday to discuss additional doses of COVID-19 for immunocompromised individuals in addition to booster doses of COVID-19 vaccine more generally. On Saturday's call, we're planning to have ACIP members share a re-cap of the meeting discussion and any recommendations that are made. We are hoping you would be willing to join as well to provide an update and answer questions from the FDA perspective.

About the Clinician Calls: The CDC and IDSA have been holding COVID-19 Clinician Calls each Saturday for the past year. Delivered via Zoom webinar, the calls are intended for clinicians on the front lines caring for patients with COVID-19. We are routinely drawing 700+ attendees each week from a variety of backgrounds—about 2/3 are ID physicians, and the rest are composed of specialists in pulmonary/critical care, emergency medicine, internal medicine/ primary care, pediatrics, cardiology, rheumatology, hematology, pharmacology and others. Most who attend are physicians, although we do have some participation from nurses and physician assistants as well. The calls are recorded and available for later viewing on the IDSA website.

Thanks so much for considering.

Best,
Dana

Dana S. Wollins, DrPH, MGC
Vice President, Clinical Affairs & Practice Guidelines
Infectious Diseases Society of America
4040 Wilson Blvd. Suite 300
Arlington, VA 22203
Tel: 703-299-5146
www.idsociety.org

From: Gruber, Marion
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Subject: FW: [EXTERNAL] Invitation: Aug. 14th CDC/IDSA COVID-19 Clinician Call
Date: Tuesday, August 10, 2021 3:46:00 PM
Attachments: image001.png
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From: MIYAZAKI-KRAUSE, Ryoko
To: Adam Hacker; Ajoy Chakrabarti; brett.barnett@cepi.net; Ann Ottosen; Bielsky, Marie-Christine; Daniel Brasseur; David Robinson; debra.yeskey@cepi.net; Elwyn Griffiths; flavia.sobral@anvisa.gov.br; Ingrid Kromann; Jakob Cramer; Jose Luis Di Fabio; Julia Kuhn; Kira Lee Skolas; Kristine Rose; TOMAS, Kristy; Laurent Mallet; Cavaleri Marco; Gruber, Marion; Matthew Downham; Choong May Ling; Melanie Saville; Michael Wiseman; Mrs D.M. Darko; Nicolas Havelange; Noyen, Benjamin; Olga Rovira; Patricia Aprea; Paul Kristiansen; Peter Dull; raimonda.viburiene@cepi.net; Shivji Ragini; dean.smith; Sonja Henne; Titilayo Majekodunmi; titilayo.majekodunmi@cepi.net; Tiziana Scarna; Udell, Michael; Yasuhiro Araki
Cc: PINTO DE SÁ GASPAR, Rogerio Paulo; MUBANGIZI, Deusdedit; SILLO, Hiiti Baran; WOOD, David John; BROWN, Laura Kay
Subject: [EXTERNAL] 37th WHO Regulatory Update on COVID-19
Date: Tuesday, August 10, 2021 3:18:25 AM
Attachments: image001.png
image002.png
37th WHO Regulatory Update on COVID-19_09Aug2021.pdf

Message sent on behalf of Dr Rogério Gaspar,

Dear Colleagues,

Please find the latest version of the Regulatory Update with the following highlights:

Key Messages

The WHO Emergency Committee on COVID-19 in its latest meeting expressed concern that the pandemic is being mischaracterized as coming to an end even though it is nowhere near finished. It also warned about the strong likelihood for the emergence and global spread of new and possibly more dangerous variants of concern that may be even more challenging to control.

As stated by Dr Tedros on 4th August, WHO is calling for a moratorium on boosters to enable at least 10% of the population of every country to be vaccinated and all countries are asked to support this effort.

Highlights and main issues

- To increase awareness and to assist healthcare providers, WHO published an interim guidance for clinical case management of thrombosis with thrombocytopenia syndrome (TTS) in individuals vaccinated with COVID-19 non-replicant adenovirus vector-based vaccines. Knowledge about TTS following vaccination is rapidly evolving. WHO will continue to monitor the situation closely for update as needed.
- SAGE published its updated Roadmap that offers recommendations on how vaccines should be prioritized for maximum public health impact in countries with limited supply, considering the most recent evidence on COVID-19 vaccines and on the ongoing supply constraint issues faced by the COVAX Facility.
- An ICMRA workshop reached consensus that immunogenicity bridging studies may be needed if an assessment of effectiveness of 2nd generation COVID-19 vaccines in clinical endpoint efficacy studies are no longer feasible. These could be designed as non-inferiority immunogenicity studies if the comparator vaccine has demonstrated high efficacy in clinical diseases endpoint efficacy trials and/or superiority designs if the comparator vaccine has demonstrated modest efficacy.

- A milestone meeting between ICMRA and industry associations discussed enabling manufacturing capacity in the COVID-19 pandemic. Most regulatory agencies have adopted the use of regulatory flexibilities for Covid-19 products. The workshop was an opportunity for an exchange of views on what changes have worked well, what were less effective, what future changes should be prioritized, what are the major challenges over the next 12 months, and where are the regulatory bottlenecks.
- WHO has launched an expression of interest for prequalification of manufacturers of interleukin-6 (IL-6) receptor blockers. Global demand for IL-6 receptor blockers for the treatment of severe COVID-19 has been soaring since the WHO's treatment recommendation on 6 July. Prequalification of innovator and its biosimilar products aims to expand the availability of quality-assured products with reduced prices to meet urgent public health needs through increased market competition.

Two workshops are coming up as follows:

WHO Consultation on COVID-19 vaccine research: 13 August, 13:00 - 17:00 CET

The objectives of this consultation will be to review the available evidence on the efficacy and effectiveness of vaccines being deployed in terms of:

- Emerging variants effect on protection levels
- Duration of protection
- Safety of booster vaccines
- Research to evaluate various delivery strategies

During the consultation, experts will debate the methodological strength and limitations of existing data and the potential designs to generate additional data leading to evidence-based decisions.

Registration at https://www.who.int/news-room/events/detail/2021/08/13/default-calendar/who-consultation-on-covid-19-vaccines-research-13-august-2021

COVAX Enabling Sciences: Standardization of Immune Response Assays to COVID-19 Vaccines, A Year's Experience Transferring Assays to a Global Laboratory Network: 31 August, 15:30 – 19:30 CET

Brochure

Registration

Please use COVAX-Reg@who.int for regulatory related questions on COVAX and COVID-related products.

WHO Regulatory updates are published at: https://www.who.int/teams/regulation-prequalification

Best wishes,
Rogério

Rogério Gaspar
Director
Regulation and Prequalification Department (RPQ)

Access to Medicines and Health Products Division (MHP)
World Health Organization
Geneva, Switzerland

Office: +41 (0)22 791 5531
Mobile: +41 (0)79 364 1485
Email: gasparr@who.int
Web: http://www.who.int/medicines/en/
Follow WHO on Facebook, Twitter, YouTube, Instagram

From:	Gruber, Marion
To:	Fink, Doran; Agnihothram, Sudhakar; Krause, Philip
Subject:	FW: [EXTERNAL] RE: Janssen COVID Vaccine - recent conversations with HHS - upcoming public statements
Date:	Wednesday, August 25, 2021 9:24:00 AM
Attachments:	image001.png

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Wednesday, August 25, 2021 9:20 AM
To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: Janssen COVID Vaccine - recent conversations with HHS - upcoming public statements

Dear Marion,

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Best Regards,
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Thanks for all of this information. Given these issues and some of the emerging issues with Moderna that I need to fill you in on, it might be good to catch up live today so that we can be sure that we are in synch. Unfortunately, I don't have time open until after 5 PM. Could that time work for you (or 5:30?) . Thanks.

Best Regards,

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Sent: Wednesday, August 25, 2021 9:03 AM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: FW: [EXTERNAL] RE: Janssen COVID Vaccine - recent conversations with HHS - upcoming public statements

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Over the last couple of days, Janssen has bombarded us with emails regarding their booster dose studies. Karin van Baelen emailed me, Ruta Walawalkar emailed Sudhakar and also, Karin informed me that Mathai Mammen has spoken to you August 23. I have discussed the requests (copied below) Jansen made with DVRPA leadership and my response to Karin van Baelen is stated in red:

Janssen is requesting for an opportunity to have a discussion with the Agency on a potential data package that could support a booster submission as an EUA Amendment.

- Proposed supportive material: To expedite this engagement, Janssen proposes to submit a slide presentation with data and questions to the Agency to support the meeting and forego submission of a formal briefing document. Would this be agreeable?
  No, please submit a formal briefing document for our review that contains updated immunogenicity data from COV1001 and COV2001. We are also interested in the data from COV3009 (2-dose efficacy) as these data will further inform the need for a booster dose with your vaccine.

- Proposed timeline: Additional immunogenicity data from COV1001 and COV2001 will become available in the next weeks (August-September 2021). Furthermore, the readouts for the end of the double-blind phase of our pivotal Phase 3 studies COV3001 (1-dose efficacy) and COV3009 (2-dose efficacy) are expected in the same timeframe and will further support discussion on potential booster strategies. Janssen suggests to have the meeting once these data have become available (exact date to be determined).
  We agree that a meeting can take place once these data are available.

Peter, I want to make sure (in case you talked to Mathai) that our messages are aligned.

I am also very concerned that companies (such as Pfizer and Janssen) are trying to put pressure on OVRR by way of PR. We need to be given time to consider their data and cannot be pushed by these companies and, for that matter the Administration, who try to impose timeless that make no sense (e.g., Sep 20).

Also, I need to let you know that OVRR, for homologous booster studies, will apply the same criteria as for the heterologous booster studies (i.e., as per our guidance regarding VOCs). I also discussed this approach with colleagues at EMA and HC and there is agreement. It appears that at least Pfizer's data will not be aligned with this approach and the "n" they have is grossly insufficient. Obviously, we have to review the data but we have taken a peak and have serious concerns.

Lastly, and this is my personal opinion, data we have seen so far from various companies (Pfizer, Janssen, Moderna) appear to suggest that boosters are not needed.
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Sent: Tuesday, August 24, 2021 4:16 PM
To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Subject: [EXTERNAL] RE: Janssen COVID Vaccine - recent conversations with HHS - upcoming public statements

Dear Marion,

As promised, I am sharing the manuscript that was submitted today and the press release. We plan to issue it on the newswire at 6:45 am ET tomorrow morning (Wed, August 25). Thanks for keeping this confidential until posted.

We are sharing the same information with the RPM.
I am looking forward to our discussion.

Kind regards
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To: Van Baelen, Karin [JRDBE] <KVBAELEN@its.jnj.com>
Subject: RE: [EXTERNAL] Janssen COVID Vaccine - recent conversations with HHS - upcoming public statements

Dear Karin,
Thank you for the update. I will discuss with my team and will be in touch. Give me a couple of days, please.

Sincerely,
Marion

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Sent: Monday, August 23, 2021 5:04 PM
To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Subject: [EXTERNAL] Janssen COVID Vaccine - recent conversations with HHS - upcoming public statements

Dear dr Gruber,
Dear Marion,

Mathai Mammen, the head of R&D Janssen, is speaking with Peter Marks tonight. I wanted to provide you with the context of their conversation.

As you know, earlier this week, a Joint Statement from HHS Public Health and Medical Experts was issued related to the need for Booster Shots of COVID-19 vaccines, focusing on subjects having received EUA authorized mRNA vaccines. The Joint statement also provided that they anticipated that booster shots will likely be needed for people who received the Janssen vaccine, and that more data is expected in the coming weeks. This announcement has triggered a lot of questions related to the need for a booster dose of subjects who received the Janssen vaccine, and if so, which booster could be given. We received similar questions from vaccination policy decision makers in the US.

In this context, we have brought together and presented to Dr. F. Collins (NIH), Dr. Fauci (NIAID) and members of their staff, the data generated to date on the topic of durability of immunity elicited by our single dose vaccination regimen and the impact of homologous (late) boosting on antibody levels. This included:

- Data from our ongoing phase 1/2a and phase 2 studies describing the kinetics over time of the immune responses (up to 8 months in 18–55-year-old participants and 9 months in >65 year old participants) after a single dose of JnJ vaccine, reactogenicity and immunogenicity of a booster dose of the JnJ vaccine, when given 6 months after the single dose primary regimen on August 18, 2021 at 3:57 p.m.
- The data show persistence of binding and neutralizing antibodies up to at least 8 months (18-55 years old adults) and 9 months (≥65 years old adults) post single dose vaccination, with a slight decline in the older adults as compared to antibody levels on day 29 post vaccination. This was observed for both binding antibody levels (ELISA) as for neutralizing antibody titers (wild-type VNA) against

the reference strain. Neutralizing titers after the booster dose against Variants of Concern (VOC) are currently being determined but in a recent publication (Barouch et al. NEJM 2021) we already demonstrated the increasing neutralizing activity against variants of concern (VOC), likely reflecting antibody maturation over time after single dose JnJ vaccine. Results from post dose 2 sera (2^{nd} dose given with 2 months interval) have shown that a rise in ELISA titers also resulted in a proportional increase in neutralizing antibodies against VOC (including B.1.351 – the strain known to be most resistant to neutralization).

- Following a booster dose of $5x10^{10}$vp at 6 months post primary vaccination in 18–55-year-olds, a strong rise of antibodies was detected 7 days after administration of the booster shot, reflective of a strong anamnestic response. More specifically: at 7 days post boost, binding antibody levels were 9-fold higher than the level at day 29 post single dose primary vaccination.
- In addition, following a booster dose of $1.25x10^{10}$vp at 6 months post primary vaccination in 18-55 and $\geq$ 65 year old adults, again a strong rise of antibodies was already detected 7 days after administration of the booster shot, reflecting a strong anamnestic response also in older adults, including in the few older adults in whom a trend for declining neutralizing titers has been seen by month 6. More specifically: at 29 days post boost, binding antibody levels were 6-7-fold higher than the level at day 29 post single dose primary vaccination.
- Post-boost neutralizing antibody titers are currently being measured. However, based on the strong correlation between binding and neutralizing antibodies, it is expected that boosting will also result in a proportional increase in neutralizing titer (both against reference virus and VOC).
- As to the safety of a second dose, it is important to note that to date > 9,000 subjects have received a second dose at 2-3 months after the first dose in context of our COV3009 phase 3 efficacy study. This, in our view, provides considerable safety information. Janssen will be able to share Top Line Safety Results of Study C3009 by early Sept.

In view of the urgency created by the recent joint announcement by HHS and Medical Experts, we consider it important to be able to address the questions raised related to US citizens who received the Janssen vaccine single dose regimen earlier this year as soon as possible.

Therefore, we wish to inform you that we will submit a paper describing the data mentioned above, to MedRxiv on Tuesday August 24 (actual publication likely within 2-48 hrs. after submission). This publication will be preceded by a press release on August 24 early AM EST. We will share the manuscript and press release with you ahead of time.

Finally, we would welcome a meeting with the Division to align on Janssen's EUA

amendment approach allowing the use of the JnJ vaccine as a booster dose to subjects who received the Janssen vaccines as a primary regimen.
Personally, I would appreciate if I could speak with you to exchange thoughts about the EUA amendment priorities and BLA strategy in a 1-1 so I can better guide my team.
Thanks for considering this request.

Sincerely,
Karin

Karin Van Baelen
Head Global Regulatory Affairs

Turnhoutseweg 30 2340 Beerse, Belgium Office Tel +32 14 64 12 36

920 US Highway 202, Raritan New Jersey, USA Office Tel +1 908 927 2664

Mobile: +32 479 66 91 55

kvbaelen@its.jnj.com
www.janssen.com

We are sending this email also to the RPM.

Sincerely

From:	Gruber, Marion
To:	Marks, Peter
Subject:	RE: [EXTERNAL] RE: Janssen COVID Vaccine - recent conversations with HHS - upcoming public statements
Date:	Wednesday, August 25, 2021 9:23:00 AM
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- Following a booster dose of $5x10^{10}$vp at 6 months post primary vaccination in 18–55-year-olds, a strong rise of antibodies was detected 7 days after administration of the booster shot, reflective of a strong anamnestic response. More specifically: at 7 days post boost, binding antibody levels were 9-fold higher than the level at day 29 post single dose primary vaccination.
- In addition, following a booster dose of $1.25x10^{10}$vp at 6 months post primary vaccination in 18-55 and $\geq$ 65 year old adults, again a strong rise of antibodies was already detected 7 days after administration of the booster shot, reflecting a strong anamnestic response also in older adults, including in the few older adults in whom a trend for declining neutralizing titers has been seen by month 6. More specifically: at 29 days post boost, binding antibody levels were 6-7-fold higher than the level at day 29 post single dose primary vaccination.
- Post-boost neutralizing antibody titers are currently being measured. However, based on the strong correlation between binding and neutralizing antibodies, it is expected that boosting will also result in a proportional increase in neutralizing titer (both against reference virus and VOC).
- As to the safety of a second dose, it is important to note that to date > 9,000 subjects have received a second dose at 2-3 months after the first dose in context of our COV3009 phase 3 efficacy study. This, in our view, provides considerable safety information. Janssen will be able to share Top Line Safety Results of Study C3009 by early Sept.

In view of the urgency created by the recent joint announcement by HHS and Medical Experts, we consider it important to be able to address the questions raised related to US citizens who received the Janssen vaccine single dose regimen earlier this year as soon as possible.

Therefore, we wish to inform you that we will submit a paper describing the data mentioned above, to MedRxiv on Tuesday August 24 (actual publication likely within 2-48 hrs. after submission). This publication will be preceded by a press release on August 24 early AM EST. We will share the manuscript and press release with you ahead of time.

Finally, we would welcome a meeting with the Division to align on Janssen's EUA

amendment approach allowing the use of the JnJ vaccine as a booster dose to subjects who received the Janssen vaccines as a primary regimen.
Personally, I would appreciate if I could speak with you to exchange thoughts about the EUA amendment priorities and BLA strategy in a 1-1 so I can better guide my team.
Thanks for considering this request.

Sincerely,
Karin

Karin Van Baelen
Head Global Regulatory Affairs

Turnhoutseweg 30 2340 Beerse, Belgium Office Tel +32 14 64 12 36

920 US Highway 202, Raritan New Jersey, USA Office Tel +1 908 927 2664

Mobile: +32 479 66 91 55

kvbaelen@its.jnj.com
www.janssen.com

We are sending this email also to the RPM.

Sincerely

From: Gruber, Marion
To: Krause, Philip; Fink, Doran; Agnihothram, Sudhakar; McVittie, Loris
Subject: FW: [EXTERNAL] RE: Janssen COVID Vaccine - recent conversations with HHS - upcoming public statements
Date: Wednesday, August 25, 2021 9:17:00 AM
Attachments: image001.png

….something is up…

From: Gruber, Marion
Sent: Wednesday, August 25, 2021 9:15 AM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: Janssen COVID Vaccine - recent conversations with HHS - upcoming public statements

Dear Peter,
Today, 5:30 pm is perfect. Let me know if it is ok to also invite Doran, Sudhakar and Phil to this discussion? By the way, I will have to miss the call with the CDC this afternoon.
Marion

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Wednesday, August 25, 2021 9:09 AM
To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: Janssen COVID Vaccine - recent conversations with HHS - upcoming public statements

Dear Marion,

Thanks for all of this information. Given these issues and some of the emerging issues with Moderna that I need to fill you in on, it might be good to catch up live today so that we can be sure that we are in synch. Unfortunately, I don't have time open until after 5 PM. Could that time work for you (or 5:30?) . Thanks.

Best Regards,
Peter

From: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Sent: Wednesday, August 25, 2021 9:03 AM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: FW: [EXTERNAL] RE: Janssen COVID Vaccine - recent conversations with HHS - upcoming public statements

Dear Peter,

Over the last couple of days, Janssen has bombarded us with emails regarding their booster dose studies. Karin van Baelen emailed me, Ruta Walawalkar emailed Sudhakar and also, Karin informed me that Mathai Mammen has spoken to you August 23. I have discussed the

requests (copied below) Jansen made with DVRPA leadership and my response to Karin van Baelen is stated in red:

Janssen is requesting for an opportunity to have a discussion with the Agency on a potential data package that could support a booster submission as an EUA Amendment.

- Proposed supportive material: To expedite this engagement, Janssen proposes to submit a slide presentation with data and questions to the Agency to support the meeting and forego submission of a formal briefing document. Would this be agreeable?
  No, please submit a formal briefing document for our review that contains updated immunogenicity data from COV1001 and COV2001. We are also interested in the data from COV3009 (2-dose efficacy) as these data will further inform the need for a booster dose with your vaccine.

- Proposed timeline: Additional immunogenicity data from COV1001 and COV2001 will become available in the next weeks (August-September 2021). Furthermore, the readouts for the end of the double-blind phase of our pivotal Phase 3 studies COV3001 (1-dose efficacy) and COV3009 (2-dose efficacy) are expected in the same timeframe and will further support discussion on potential booster strategies. Janssen suggests to have the meeting once these data have become available (exact date to be determined).
  We agree that a meeting can take place once these data are available.

Peter, I want to make sure (in case you talked to Mathai) that our messages are aligned.

I am also very concerned that companies (such as Pfizer and Janssen) are trying to put pressure on OVRR by way of PR. We need to be given time to consider their data and cannot be pushed by these companies and, for that matter the Administration, who try to impose timeless that make no sense (e.g., Sep 20).

Also, I need to let you know that OVRR, for homologous booster studies, will apply the same criteria as for the heterologous booster studies (i.e., as per our guidance regarding VOCs). I also discussed this approach with colleagues at EMA and HC and there is agreement. It appears that at least Pfizer's data will not be aligned with this approach and the "n" they have is grossly insufficient. Obviously, we have to review the data but we have taken a peak and have serious concerns.

Lastly, and this is my personal opinion, data we have seen so far from various companies (Pfizer, Janssen, Moderna) appear to suggest that boosters are not needed.
Marion

From: Van Baelen, Karin [JRDBE] <KVBAELEN@its.jnj.com>
Sent: Tuesday, August 24, 2021 4:16 PM
To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Subject: [EXTERNAL] RE: Janssen COVID Vaccine - recent conversations with HHS - upcoming public statements

Dear Marion,

As promised, I am sharing the manuscript that was submitted today and the press release. We plan to issue it on the newswire at 6:45 am ET tomorrow morning (Wed, August 25). Thanks for keeping this confidential until posted.

We are sharing the same information with the RPM.
I am looking forward to our discussion.

Kind regards
Karin

From: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Sent: dinsdag 24 augustus 2021 1:38
To: Van Baelen, Karin [JRDBE] <KVBAELEN@its.jnj.com>
Subject: RE: [EXTERNAL] Janssen COVID Vaccine - recent conversations with HHS - upcoming public statements

Dear Karin,
Thank you for the update. I will discuss with my team and will be in touch. Give me a couple of days, please.
Sincerely,
Marion

From: Van Baelen, Karin [JRDBE] <KVBAELEN@its.jnj.com>
Sent: Monday, August 23, 2021 5:04 PM
To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Subject: [EXTERNAL] Janssen COVID Vaccine - recent conversations with HHS - upcoming public statements

Dear dr Gruber,

Dear Marion,

Mathai Mammen, the head of R&D Janssen, is speaking with Peter Marks tonight. I wanted to provide you with the context of their conversation.

As you know, earlier this week, a Joint Statement from HHS Public Health and Medical Experts was issued related to the need for Booster Shots of COVID-19 vaccines, focusing on subjects having received EUA authorized mRNA vaccines. The Joint statement also provided that they anticipated that booster shots will likely be needed for people who received the Janssen vaccine, and that more data is expected in the coming weeks. This announcement has triggered a lot of questions related to the need for a booster dose of subjects who received the Janssen vaccine, and if so, which booster could be given. We received similar questions from vaccination policy decision makers in the US.

In this context, we have brought together and presented to Dr. F. Collins (NIH), Dr. Fauci (NIAID) and members of their staff, the data generated to date on the topic of durability of immunity elicited by our single dose vaccination regimen and the impact of homologous (late) boosting on antibody levels. This included:

- Data from our ongoing phase 1/2a and phase 2 studies describing the kinetics over time of the immune responses (up to 8 months in 18–55-year-old participants and 9 months in >65 year old participants) after a single dose of JnJ vaccine, reactogenicity and immunogenicity of a booster dose of the JnJ vaccine, when given 6 months after the single dose primary regimen on August 18, 2021 at 3:57 p.m.
- The data show persistence of binding and neutralizing antibodies up to at least 8 months (18-55 years old adults) and 9 months (≥65 years old adults) post single dose vaccination, with a slight decline in the older adults as compared to antibody levels on day 29 post vaccination. This was observed for both binding antibody levels (ELISA) as for neutralizing antibody titers (wild-type VNA) against the reference strain. Neutralizing titers after the booster dose against Variants of Concern (VOC) are currently being determined but in a recent publication (Barouch et al. NEJM 2021) we already demonstrated the increasing neutralizing activity against variants of concern (VOC), likely reflecting antibody maturation over time after single dose JnJ vaccine. Results from post dose 2 sera (2^{nd} dose given with 2 months interval) have shown that a rise in ELISA titers also resulted in a proportional increase in neutralizing antibodies against VOC (including B.1.351 – the strain known to be most resistant to neutralization).
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fold higher than the level at day 29 post single dose primary vaccination.

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In view of the urgency created by the recent joint announcement by HHS and Medical Experts, we consider it important to be able to address the questions raised related to US citizens who received the Janssen vaccine single dose regimen earlier this year as soon as possible.

Therefore, we wish to inform you that we will submit a paper describing the data mentioned above, to MedRxiv on Tuesday August 24 (actual publication likely within 2-48 hrs. after submission). This publication will be preceded by a press release on August 24 early AM EST. We will share the manuscript and press release with you ahead of time.

Finally, we would welcome a meeting with the Division to align on Janssen's EUA amendment approach allowing the use of the JnJ vaccine as a booster dose to subjects who received the Janssen vaccines as a primary regimen.
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Thanks for considering this request.

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Karin

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Mobile: +32 479 66 91 55

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www.janssen.com

We are sending this email also to the RPM.

Sincerely

Madalis, Rebecca

Subject: [EXTERNAL] Preparatory call for the Regulatory session on boosters - WHO Consultation on 13 Aug
Location: Microsoft Teams Meeting

Start: Wed 8/11/2021 6:00 AM
End: Wed 8/11/2021 7:00 AM
Show Time As: Tentative

Recurrence: (none)

Meeting Status: Not yet responded

Organizer: MIYAZAKI-KRAUSE, Ryoko

Dear colleagues,
Apologies for scheduling this meeting in your extremely busy schedules (and additional apologies to Phil and Peter for selecting early morning hour..)
Draft agenda is attached and the regulatory session is planned from 16:00 to 16:30 CET (for now).

For information, Alejandro Cravioto (SAGE Chair) will touch on data needed for boosters.
Please note that WHO SAGE statements on boosters, fractioned doses and heterologous priming were published today (these are not policy recommendations, but points to consider & data/research need).

COVID-19 vaccine booster doses
https://www.who.int/news/item/10-08-2021-interim-statement-on-covid-19-vaccine-booster-doses

fractionated doses:
https://www.who.int/news/item/10-08-2021-interim-statement-on-dose-sparing-strategies-for-covid-19-vaccines-(fractionated-vaccine-doses)

heterologous priming for COVID-19 vaccines
https://www.who.int/news/item/10-08-2021-interim-statement-on-heterologous-priming-for-covid-19-vaccines

15:20 – 15:50	How much safety data are needed to support benefit-risk assessment of booster doses?	Panel Discussion **Marco Cavaleri** (moderator); Biological Heal and Vaccines Strategy, EMA **Rita Helfand**; Centers for Disease Control and Prevention, USA; Chair of the WHO Global Ad Committee on Vaccine Safety **Dror Mevorach**; Department of Internal Medi Jerusalem's Hadassah Medical Center, Israel **Raina MacIntyre**; Biosecurity Program, Kirby I University of New South Wales, Australia
15:50 – 16:00	What should a booster dose achieve from the public health perspective and what data is needed?	**Alejandro Cravioto** Faculty of Medicine of the Universidad Nacio Autónoma de México, Mexico Chairperson of the WHO Strategic Advisory G Experts on Immunization
16:00 – 16:30	What additional research is needed to support informed regulatory decision-making about the benefits and risks of booster doses?	Panel Discussion **Philip Krause** (moderator) **Marie-Christine Bielsky**; Medicines and Healt products, Regulatory Agency (**MHRA**), UK **Tumi (Boitumelo) Semete-Makokotlela**; South Health Products Regulatory Authority, South A **Peter Marks**; Center for Biologics Evaluation a Research (CBER), FDA, USA **Representative of NMPA**, China And the Moderators of previous panels: **David Montefiori** (TBC) & **Marco Cavaleri** (TBC

We will follow up with email in case you are unable to join this call.

Sincerely,
Ryoko on behalf of Rogerio and his team

Microsoft Teams meeting

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who2@m.webex.com
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From: Gruber, Marion
To: Krause, Philip
Subject: FW: [EXTERNAL] VRBPAC, boosters and variants
Date: Friday, September 3, 2021 4:37:00 PM
Attachments: image004.png

From: Norman Baylor <nbaylor@biologicsconsulting.com>
Sent: Friday, September 3, 2021 4:36 PM
To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Subject: RE: [EXTERNAL] VRBPAC, boosters and variants

Glad to hear this, Marion. (b) (6) has been in discussions with Marco, and it didn't appear from their conversation that the WHO has been very forthcoming with what they have in the works. As an aside, you are probably aware that some folks are hesitant about WHO coordinating anything these days! That being said, I will circle back with (b) (6) because he is supposed to reach out to some of his WHO colleagues. We definitely don't want to reinvent the wheel! Thanks

-Norman

From: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Sent: Friday, September 3, 2021 4:24 PM
To: Norman Baylor <nbaylor@biologicsconsulting.com>
Subject: RE: [EXTERNAL] VRBPAC, boosters and variants

Dear Norman,
There have been actually a lot of discussions regarding modified vaccines against VOC and who will make a decision whether a switch is needed. The WHO is developing a framework borrowing from the flu experience. It is my understanding that a working group has been formed within WHO. The decision whether a change in vaccine is needed will definitely not be

up to the companies and it will involve a global discussion aka flu strain change. If you want to convene an IABS meeting you should talk to WHO first. I can see if I can get you the right contact. Pfizer can include in their presentation (or just tell the committee verbally) an update on where they stand with their modified vaccines at the upcoming VRBPAC, I can ask them to do that.
Marion

Happy Labor day!

From: Norman Baylor <nbaylor@biologicsconsulting.com>
Sent: Friday, September 3, 2021 2:40 PM
To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Subject: [EXTERNAL] VRBPAC, boosters and variants

Hi Marion,

With the upcoming FDA VRBPAC on the 17th to discuss Pfizer's request to include a third dose booster of their vaccine against COVID19, I wanted to put in a plug for bringing up the subject at the VRBPAC of progress on the development of vaccines against the variants. I know the companies and NIH are doing this research, but we've heard very little about what is going on. Further, it would be important to know what is the process, if any, of determining when a decision would be made and by who to change the vaccines. Is this decision up to the companies alone or would this be a global discussion between regulators, industry, CDC, WHO, etc. such as what occurs with influenza vaccines? I know there is a September 30 VRBPAC to discuss and make recommendations on the selection of strains to be included in the influenza virus vaccines for the 2021 to 2022 southern hemisphere influenza season. BTW, I have had preliminary discussions with (b) (6) and others about arranging an international meeting to discuss how and who should coordinate a "strain change" of the COVID19 vaccines. We have reached out to IABS to determine if they would take something like this on. Thanks

Best,
Norman

From: Gruber, Marion
To: Norman Baylor
Subject: RE: [EXTERNAL] VRBPAC, boosters and variants
Date: Friday, September 3, 2021 4:23:00 PM
Attachments: image001.png

Dear Norman,
There have been actually a lot of discussions regarding modified vaccines against VOC and who will make a decision whether a switch is needed. The WHO is developing a framework borrowing from the flu experience. It is my understanding that a working group has been formed within WHO. The decision whether a change in vaccine is needed will definitely not be up to the companies and it will involve a global discussion aka flu strain change. If you want to convene an IABS meeting you should talk to WHO first. I can see if I can get you the right contact. Pfizer can include in their presentation (or just tell the committee verbally) an update on where they stand with their modified vaccines at the upcoming VRBPAC, I can ask them to do that.
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Best,
Norman

From: Gruber, Marion
To: McNeill, Lorrie
Subject: Fwd: [EXTERNAL] Covid 19 Vaccines- The Need for More Investigation- Cessation of EUA"s
Date: Monday, August 23, 2021 6:12:23 AM

Get Outlook for iOS

From: Carol Brouillet (b) (6)
Sent: Monday, August 23, 2021 12:48:00 AM
To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Krause, Philip <Philip.Krause@fda.hhs.gov>; Bridgewater, Jennifer <Jennifer.Bridgewater@fda.hhs.gov>; Cheung, Anissa <Anissa.Cheung@fda.hhs.gov>; Dickerson, David <David.Dickerson@fda.hhs.gov>; Shelia.Dreher-Lesnick@fda.hhs.gov Helen.Gemignani@fda.hhs.gov <Shelia.Dreher-Lesnick@fda.hhs.gov Helen.Gemignani@fda.hhs.gov>; Houck, Christina M <Christina.Houck@fda.hhs.gov>; Norris, Scott <Scott.Norris@fda.hhs.gov>; Overking, Cassandra <Cassandra.Overking@fda.hhs.gov>; Stewart, Daphne <Daphne.Stewart@fda.hhs.gov>; Wagner, Leslie <Leslie.Wagner@fda.hhs.gov>
Subject: [EXTERNAL] Covid 19 Vaccines- The Need for More Investigation- Cessation of EUA's

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

To all of you at the FDA,

I believe the FDA should not prematurely grant a license to any COVID-19 vaccine until all bioweapon violations and antitrust violations have been fully investigated. I have grave concern that the premature licensure of a COVID-19 vaccine can seriously undermine public confidence in regulatory authorities, if the following entities are found to be complicit in antitrust violations and domestic terrorism: FDA, CDC, NIH, NIAID, Vaccines and Related Biological Products Advisory Committee (VRBPAC), Office of Vaccines Research and Review Center for Biologics Evaluation and Research (OVRR) and other government agencies.

Since April 2020, the DOJ, FTC, Office of Inspector General at HHS, U.S. legal attorneys, congressional representatives and others were notified of the violations by Dr. David Martin. Congressional representative, Rand Paul's office, was sent notices of these violations several times over the course of the last 18 months.

The spike protein has been documented as a known toxin. Injection of a bioweapon is a violation of Section 802 of the Patriot Act according to U.S. code. The SPIKE PROTEIN in the injection is a bioweapon defined under U.S. Law:

18 U.S. Code § 175 - Prohibitions with respect to biological weapons

(a)In General.-

Whoever knowingly develops, produces, stockpiles, transfers, acquires, retains, or possesses any biological agent, toxin, or delivery system for use as a weapon, or knowingly assists a foreign state or any organization to do so, or attempts, threatens, or conspires to do the same, shall be fined under this title or imprisoned for life or any term of years, or both. There is extraterritorial Federal jurisdiction over an offense under this section committed by or against a national of the United States.

27 clinicians and researchers filed an urgent Citizen Petition with the U.S. Food and Drug Administration (FDA) on June 1, 2021 urging the agency not to prematurely grant full approval to any COVID vaccine citing a Pfizer Bio-Distribution Study submitted to the Japanese Government which found that the spike protein is indeed a toxin. https://www.regulations.gov/document/FDA-2021-P-0521-0001

Also, the International Journal of Vaccine Theory, Practice, and Research (IJVTPR) lists Antibody-Dependent Enhancement (ADE) as a possible unintended consequence of vaccine-induced coronavirus spike protein antibodies against COVID-19 in which case would make the cure worse than the disease:

"With tens of millions of young adults and even children now with vaccine-induced coronavirus spike protein antibodies, there exists the possibility of triggering ADE related to either future SARS-CoV-2 infection or booster injection among this younger population. Time will tell."
https://ijvtpr.com/index.php/IJVTPR/article/view/23/51

Furthermore, there is an abundance of documentation of COVID-19 biological weapon violations and antitrust violations:

*Dr. David Martin's Fauci/COVID-19 Dossier documents bioweapons violations, racketeering, collusion, market manipulation, interlocking directorates and other antitrust violations:
https://www.davidmartin.world/wp-content/uploads/2021/01/The_Fauci_COVID-19_Dossier.pdf
*NIH and NIAID funded and imported a biological weapon:
https://shermanclay.blogspot.com/2021/08/gain-of-function-biological-weapons.html

*Bioweapons and RICO: Dr. David Martin's legal discovery interview with Attorney Reiner Füllmich of the Germany Corona Virus Investigative Committee documenting antitrust violations-collusion, racketeering, market manipulations-bioweapon violations and more: https://shermanclay.blogspot.com/2021/08/reiner-fuellmich-david-martin-legal.html
*The spike protein in the injection is a bioweapon and the injection of a bioweapon is a violation of Section 802 of the Patriot Act: https://shermanclay.blogspot.com/2021/08/david-martin-and-stew-peters-there-is.html
*COVID-19 Antitrust Violations: Racketeering, Collusion, Interlocking Directorates, Market Manipulation involving Anthony Fauci, Bill Gates, China's CDC director, Dr. Gao, and others: https://shermanclay.blogspot.com/2021/08/the-silver-bullet-dr.html#more

The FDA should immediately revoke EUAs for COVID-19 vaccines due to antitrust violations which void the vaccine liability protection afforded to those entities.

The FDA, VRBPAC, and OVRR should immediately cease any approval or recommendations of COVID-19 vaccines until current congressional investigations are completed and other agencies' such as, but not limited to, the DOJ, FTC, Office of Inspector General at HHS, and U.S. legal attorneys' investigations are complete.

Respectfully Submitted,

Carol Brouillet
A Concerned American Citizen

From: Gruber, Marion
To: McNeill, Lorrie
Subject: FW: [EXTERNAL] Covid 19 experimental vaccine
Date: Sunday, August 22, 2021 8:23:00 PM

…sigh

From: John Hish (b) (6)
Sent: Sunday, August 22, 2021 7:39 PM
To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Subject: [EXTERNAL] Covid 19 experimental vaccine

Dear Public Servant,

I believe the FDA should not prematurely grant a license to any COVID-19 vaccine until all bioweapon violations and antitrust violations have been fully investigated. I have grave concern that the premature licensure of a COVID-19 vaccine can seriously undermine public confidence in regulatory authorities, if the following entities are found to be complicit in antitrust violations and domestic terrorism: FDA, CDC, NIH, NIAID, Vaccines and Related Biological Products Advisory Committee (VRBPAC), Office of Vaccines Research and Review Center for Biologics Evaluation and Research (OVRR) and other government agencies.

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27 clinicians and researchers filed an urgent Citizen Petition with the U.S. Food and Drug Administration (FDA) on June 1, 2021 urging the agency not to prematurely grant full approval to any COVID vaccine citing a Pfizer Bio-Distribution Study submitted to the Japanese Government which found that the spike protein is indeed a toxin. https://www.regulations.gov/document/FDA-2021-P-0521-0001

Also, the International Journal of Vaccine Theory, Practice, and Research (IJVTPR) lists Antibody-Dependent Enhancement (ADE) as a possible unintended consequence of vaccine-induced coronavirus spike protein antibodies against COVID-19 in which case would make the cure worse than the disease:

"With tens of millions of young adults and even children now with vaccine-induced coronavirus spike protein antibodies, there exists the possibility of triggering ADE related to either future SARS-CoV-2 infection or booster injection among this younger population. Time will tell." https://ijvtpr.com/index.php/IJVTPR/article/view/23/51

Furthermore, there is an abundance of documentation of COVID-19 biological weapon violations and antitrust violations:

- Dr. David Martin's Fauci/COVID-19 Dossier documents bioweapons violations, racketeering, collusion, market manipulation, interlocking directorates and other antitrust violations: https://www.davidmartin.world/wp-content/uploads/2021/01/The_Fauci_COVID-19_Dossier.pdf
- NIH and NIAID funded and imported a biological weapon: https://shermanclay.blogspot.com/2021/08/gain-of-function-biological-weapons.html
- Bioweapons and RICO: Dr. David Martin's legal discovery interview with Attorney Reiner Füllmich of the Germany Corona Virus Investigative Committee documenting antitrust violations—collusion, racketeering, market manipulations—bioweapon violations and more: https://shermanclay.blogspot.com/2021/08/reiner-fuellmich-david-martin-legal.html
- The spike protein in the injection is a bioweapon and the injection of a bioweapon is a violation of Section 802 of the Patriot Act: https://shermanclay.blogspot.com/2021/08/david-martin-and-stew-peters-there-is.html
- COVID-19 Antitrust Violations: Racketeering, Collusion, Interlocking Directorates, Market Manipulation involving Anthony Fauci, Bill Gates, China's CDC director, Dr. Gao, and others: https://shermanclay.blogspot.com/2021/08/the-silver-bullet-dr.html#more

ACTIONS REQUESTED:

The FDA completely follow through with the actions requested in the following Citizen Petition: https://www.regulations.gov/document/FDA-2021-P-0521-0001

The FDA to immediately revoke EUAs for COVID-19 vaccines due to antitrust violations which void the vaccine liability protection afforded to those entities.

The FDA, VRBPAC, and OVRR to immediately cease any approval or recommendations of COVID-19 vaccines until current congressional investigations are completed and other agencies' such as, but not limited to, the DOJ, FTC, Office of Inspector General at HHS, and U.S. legal attorneys' investigations are complete.

Respectfully Submitted,

John Hish

A Concerned American Citizen