Obtained via FOIA by Judicial Watch, Inc.



August 31, 2022

Via Email: lburke@judicialwatch.org

Lauren Burke
Judicial Watch, Inc.
425 Third Street, SW, Suite 800
Washington, DC 20024

Re: FDA FOIA Request 2021-5762; *Judicial Watch, Inc. v. HHS,* 22-cv-00660-FYP

Dear Ms. Burke,

Per the Joint Status Report dated May 27, 2022, attached please find our first partial response to the Freedom of Information Act (FOIA) request number **2021-5762** that is the subject of above-referenced matter.

Attached are 1,062 pages of records from the FDA's Center for Biologics Evaluation and Research (CBER) (Bates numbered FDA-CBER-2021-5762-00001 to -01062) some of which contain redactions and native Windows Media Audio (MWA), Excel, and PowerPoint file(s).

We have withheld portions of pages under Exemption (b)(5), 5 U.S.C. § 552(b)(5). Exemption (b)(5) permits the withholding of inter-agency or intra-agency communications or records which are part of the deliberative process and pre-decisional. Disclosure of such material could inhibit the open and candid expression of opinions and diminish the quality of the decision-making process. In addition, this exemption permits the withholding of materials subject to the attorney-client privilege and/or attorney work product doctrine.

In addition, we have withheld portions of pages under Exemption (b)(6), 5 U.S.C. § 552(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 Jody D. Lowenstein of the Department of Justice, at (202) 598-9280 or jody.d.lowenstein@usdoj.gov.

Sincerely,

Beth A. Brockner Ryan -S
Digitally signed by Beth A. Brockner Ryan -S
Date: 2022.08.31 09:04:52 -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:
Jody D. Lowenstein, Federal Programs Branch, USDOJ (By email)
Seth Heller, Office of the Chief Counsel, FDA (By email)

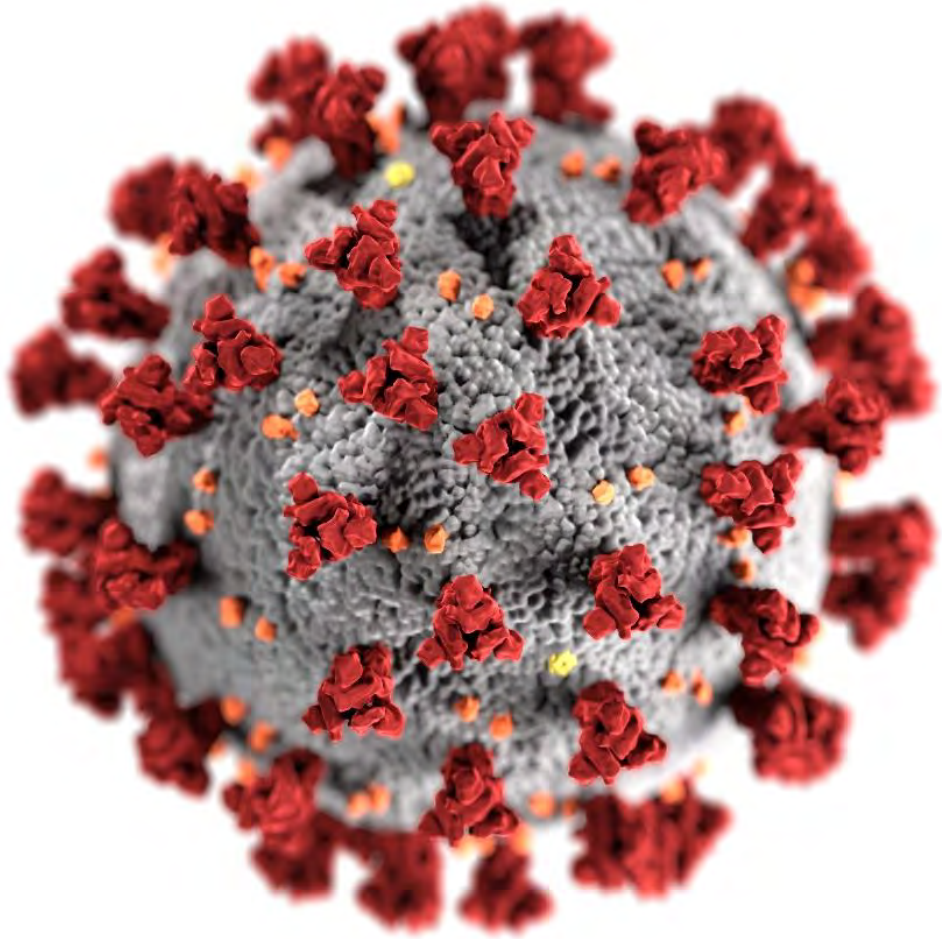
U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

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	Series 1	Series 2
Fully vaccina	59.6%	40.4%
At least one	68.3%	31.7%

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Benefits and Risks of COVID-19 Vaccines: Work Group Interpretation



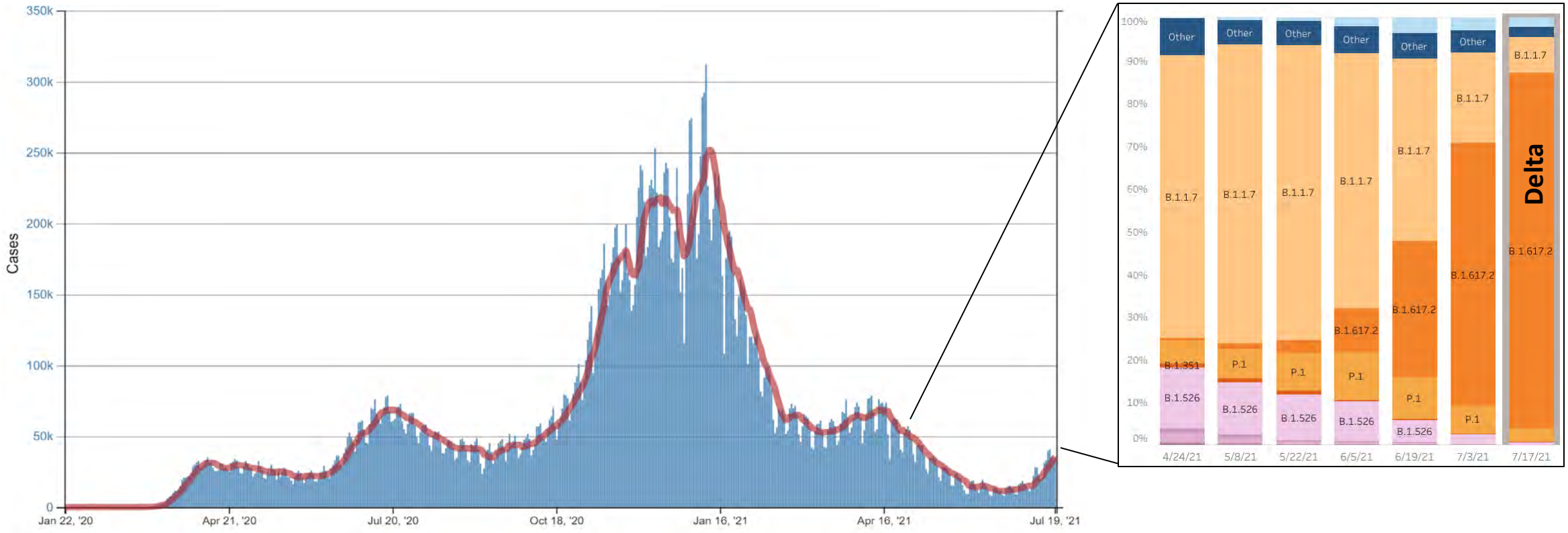
Sarah Mbaeyi, MD MPH
Centers for Disease Control and Prevention
July 22, 2021

cdc.gov/coronavirus

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After a period of decline, COVID-19 cases rising again

Majority of cases due to Delta variant



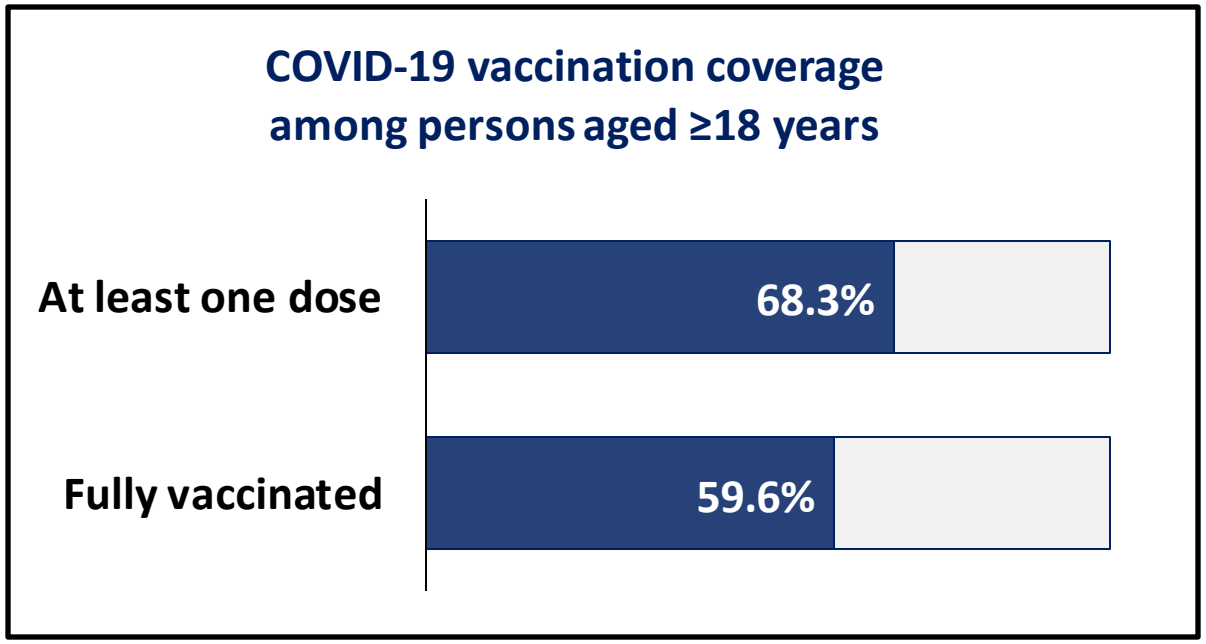
As of July 20, 2021

https://covid.cdc.gov/covid-data-tracker/#trends_dailytrendscases

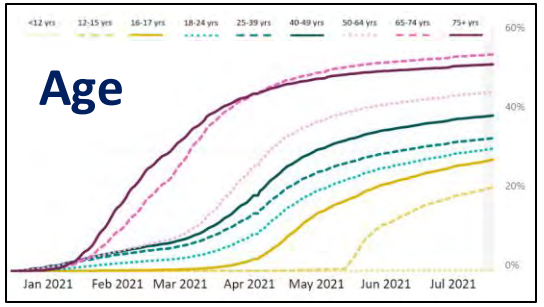
https://covid.cdc.gov/covid-data-tracker/#variant-proportions

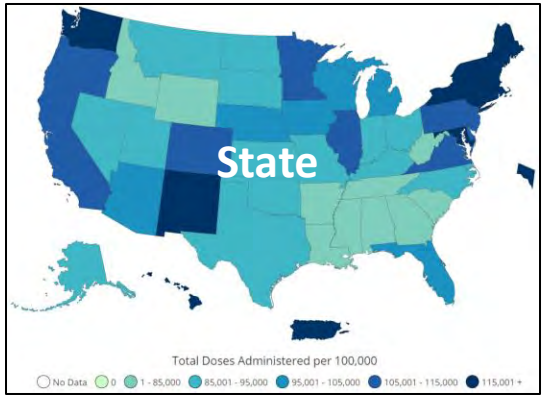
Over two-thirds of U.S. adults have received at least one COVID-19 vaccine dose

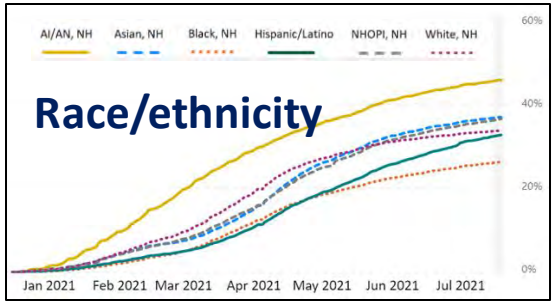
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Coverage varies by



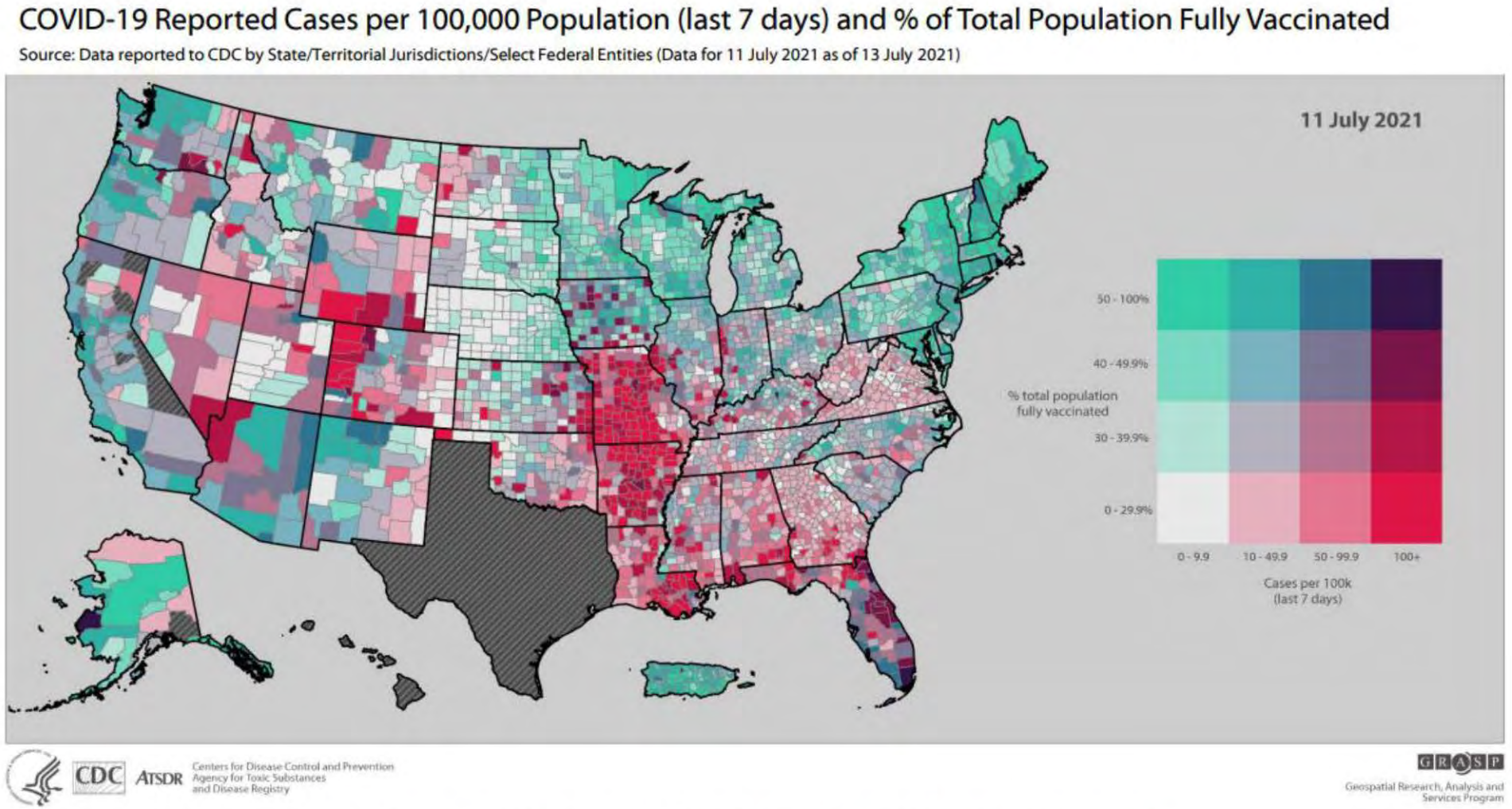




As of July 20, 2021
https://covid.cdc.gov/covid-data-tracker/#vaccinations

Low COVID-19 vaccination coverage puts individuals and communities at risk

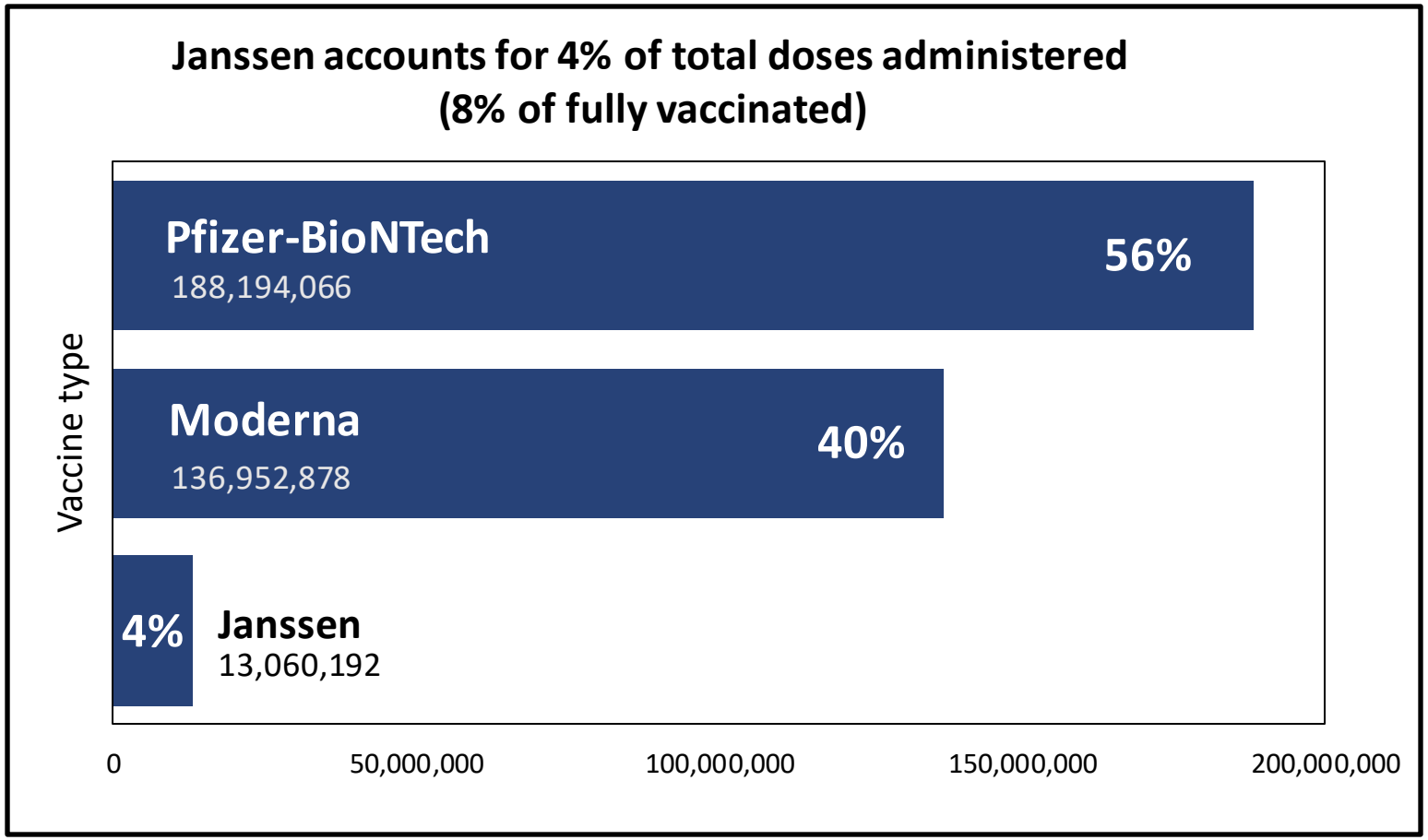
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https://www.cdc.gov/coronavirus/2019-ncov/images/communication/covid-data-tracker/Vaccinations_By_Case_Rate_FINAL_07072021.pdf

mRNA vaccines account for majority of doses administered in the United States

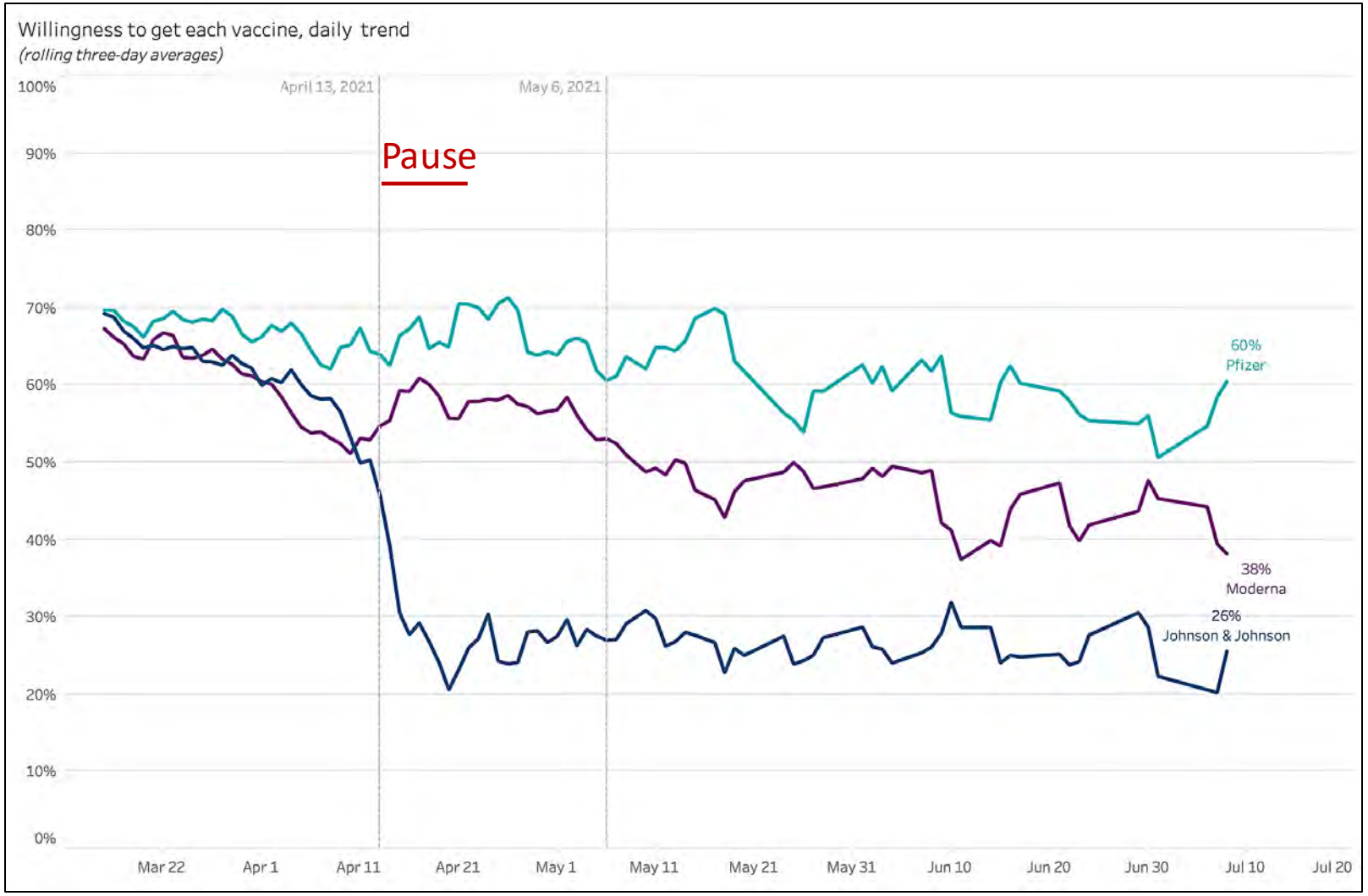
Obtained via FOIA by Judicial Watch, Inc.



As of July 20, 2021.
https://covid.cdc.gov/covid-data-tracker/#vaccinations

Willingness to receive Janssen vaccine remains lower since the April pause

Obtained via FOIA by Judicial Watch, Inc.



Results shown are among those who haven't received a vaccine but plan to get one

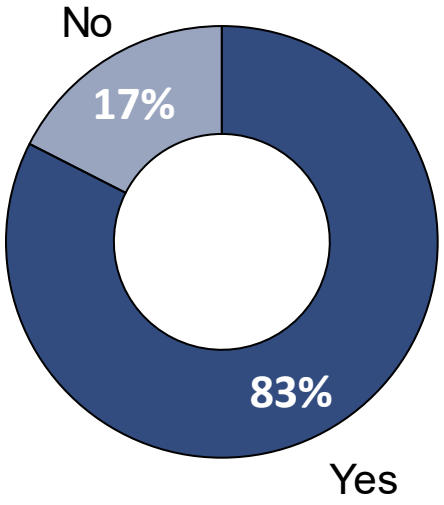
Outbreaks Near Me | Boston Children's Hospital | momentive

Obtained via FOIA by Judicial Watch, Inc.

Janssen vaccine: Patient choice, access, and vaccine equity

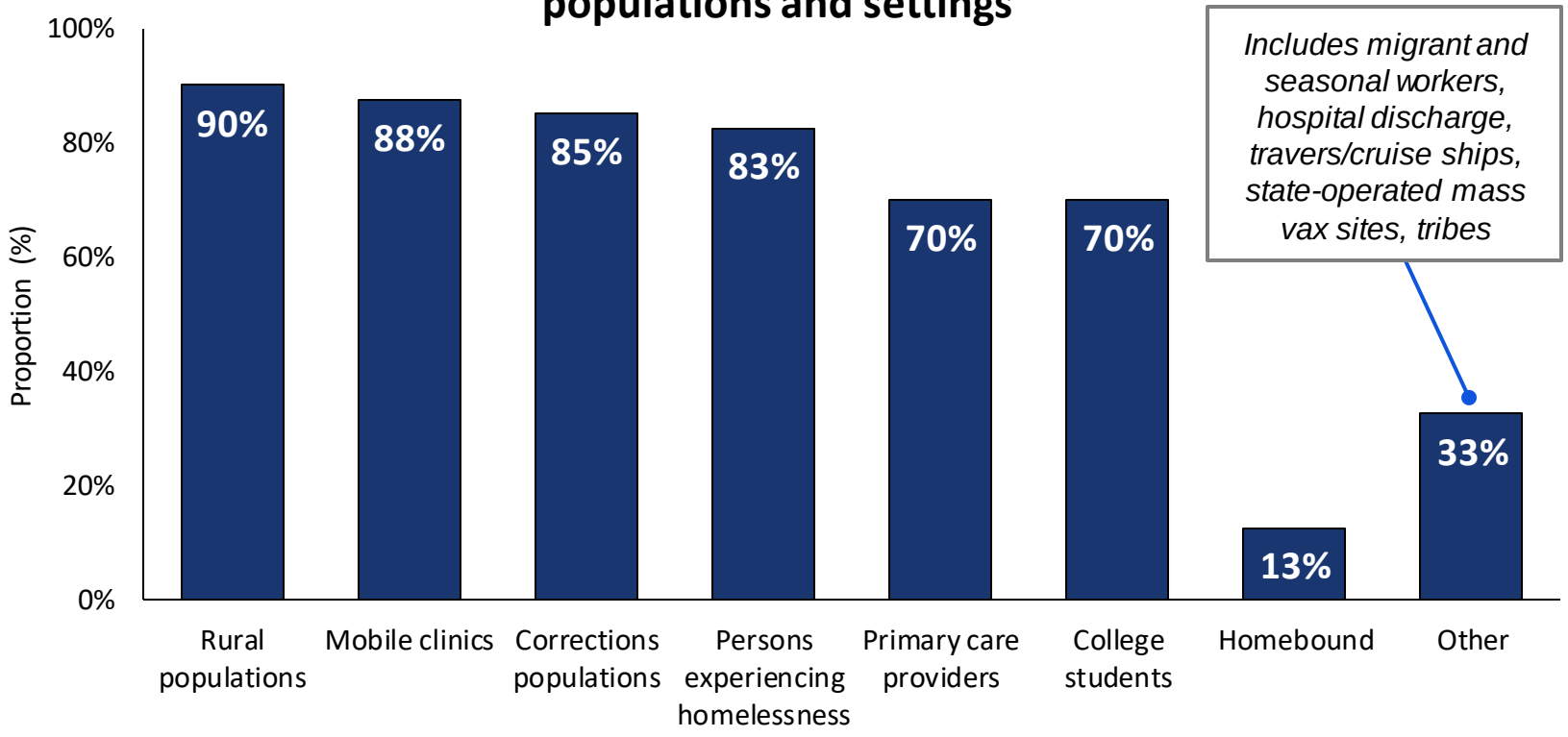
Findings from survey of jurisdictions – July 16, 2021

Most vaccination sites offer more than one type of vaccine



Responding to question: Do most of the vaccinations sites in your jurisdiction offer more than one type (Pfizer, Moderna, Janssen) of COVID vaccine?

Most jurisdictions report Janssen vaccine used in a variety of populations and settings



Responding to question: Which populations or settings in your jurisdiction are utilizing the Janssen vaccine?

Source: CDC Jurisdictional Pulse Survey 07/16-2021 1700, N=40

Obtained via FOIA by Judicial Watch, Inc.

Benefits of COVID-19 vaccines are unequivocal

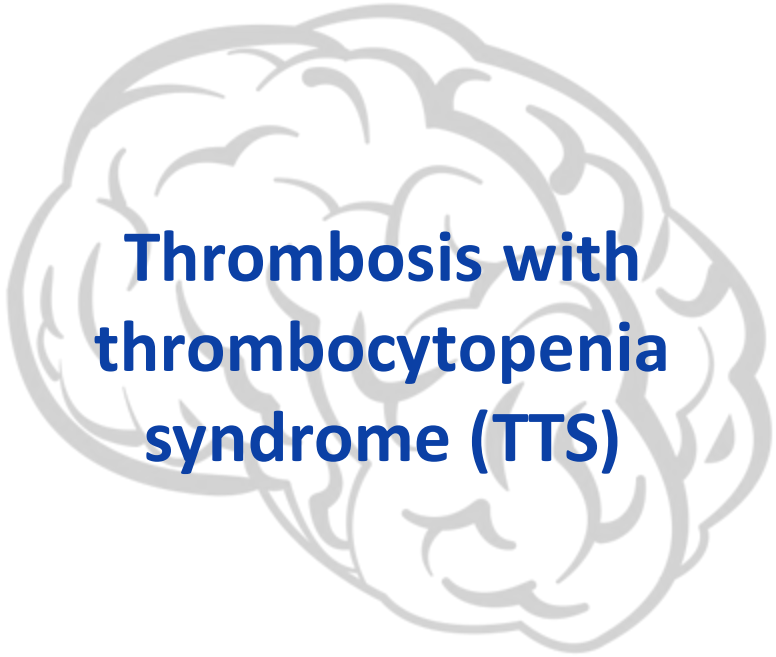
- All COVID-19 vaccines currently authorized in the United States are effective against COVID-19, including serious outcomes like severe disease, hospitalization, and death
- Available evidence suggests that currently authorized vaccines offer protection against known circulating variants, including the Delta variant
- A growing body of evidence indicates that people fully vaccinated with an mRNA vaccine are less likely to have asymptomatic infection or to transmit SARS-CoV-2 to others

https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html
Nasreen S, et al. "Effectiveness of COVID-19 vaccines against variants of concern, Canada." *medRxiv* (2021).
Stowe J, et al. "Effectiveness of COVID-19 vaccines against hospital admission with the Delta (B.1.617.2) variant." Public Health England. 2021.
Sheikh A, et al. "SARS-CoV-2 Delta VOC in Scotland: demographics, risk of hospital admission, and vaccine effectiveness." *The Lancet* (2021).

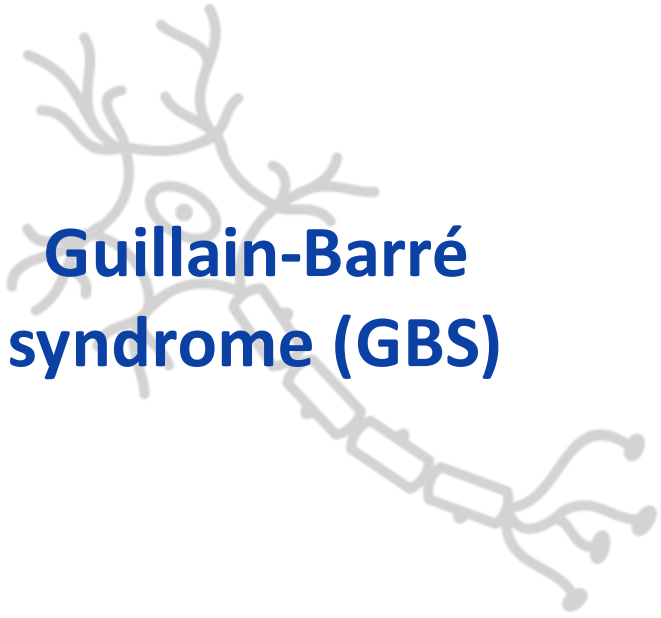
Rare serious adverse events have been reported after COVID-19 vaccination

Obtained via FOIA by Judicial Watch, Inc.

Janssen

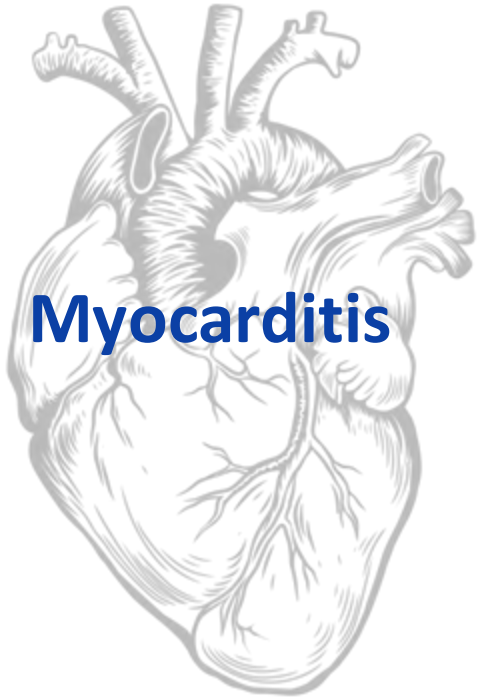


Thrombosis with thrombocytopenia syndrome (TTS)



Guillain-Barré syndrome (GBS)

mRNA



Myocarditis

Obtained via FOIA by Judicial Watch, Inc.

Benefits of vaccination continue to outweigh risks

For every million doses of vaccine given with U.S. exposure risk and hospitalization rates from June 19, 2021

	Janssen COVID-19 vaccine					mRNA COVID-19 vaccine			
Age	Prevented COVID-19 hospitalizations/ ICU admissions/deaths			GBS Cases	TTS Cases	Prevented COVID-19 hospitalizations/ ICU admissions/deaths			Myocarditis Cases
FEMALES									
18-29 years	700	50	5	1	4-5	750	50	5	3-4
30-49 years	900	140	20	6-7	8-10	950	140	20	1-2
50-64 years	1600	350	120	7-8	3-4	1,700	375	125	1
65+ years	5,900	1250	840	8-10	0	6,200	1300	900	<1
MALES									
18-29 years	300	60	3	2	2-3	300	60	3	22-27
30-49 years	650	150	25	7-8	1-2	700	160	25	5-6
50-64 years	1,800	480	140	14-17	1-2	1,900	500	150	1
65+ years	11,800	3300	2300	7-8	0	12,500	3500	2400	<1

Obtained via FOIA by Judicial Watch, Inc.

Work Group interpretation

Benefits and risks of COVID-19 vaccination

- Vaccination continues to be critical during this period of rapidly increasing cases and spread of variants of concern
- The reported adverse events (TTS, GBS, and myocarditis) are potentially serious and should be transparently communicated with the public
- Even with new GBS safety signal, benefits of Janssen vaccination continue to outweigh risks

Obtained via FOIA by Judicial Watch, Inc.

Work Group interpretation

Additional considerations for use of Janssen COVID-19 Vaccine

- In addition to benefit-risk profile, the Work Group discussed:
  - Importance of patient choice in vaccine product
  - Access to vaccines for disproportionately affected populations
  - Confidence in patients and providers to understand benefits and risks of vaccines and make informed decisions
  - Need for communication and educational materials
  - Implications of any change in vaccine recommendations on global vaccine confidence and use

Obtained via FOIA by Judicial Watch, Inc.

Work Group interpretation

Use of Janssen COVID-19 Vaccine after reports of GBS in vaccine recipients

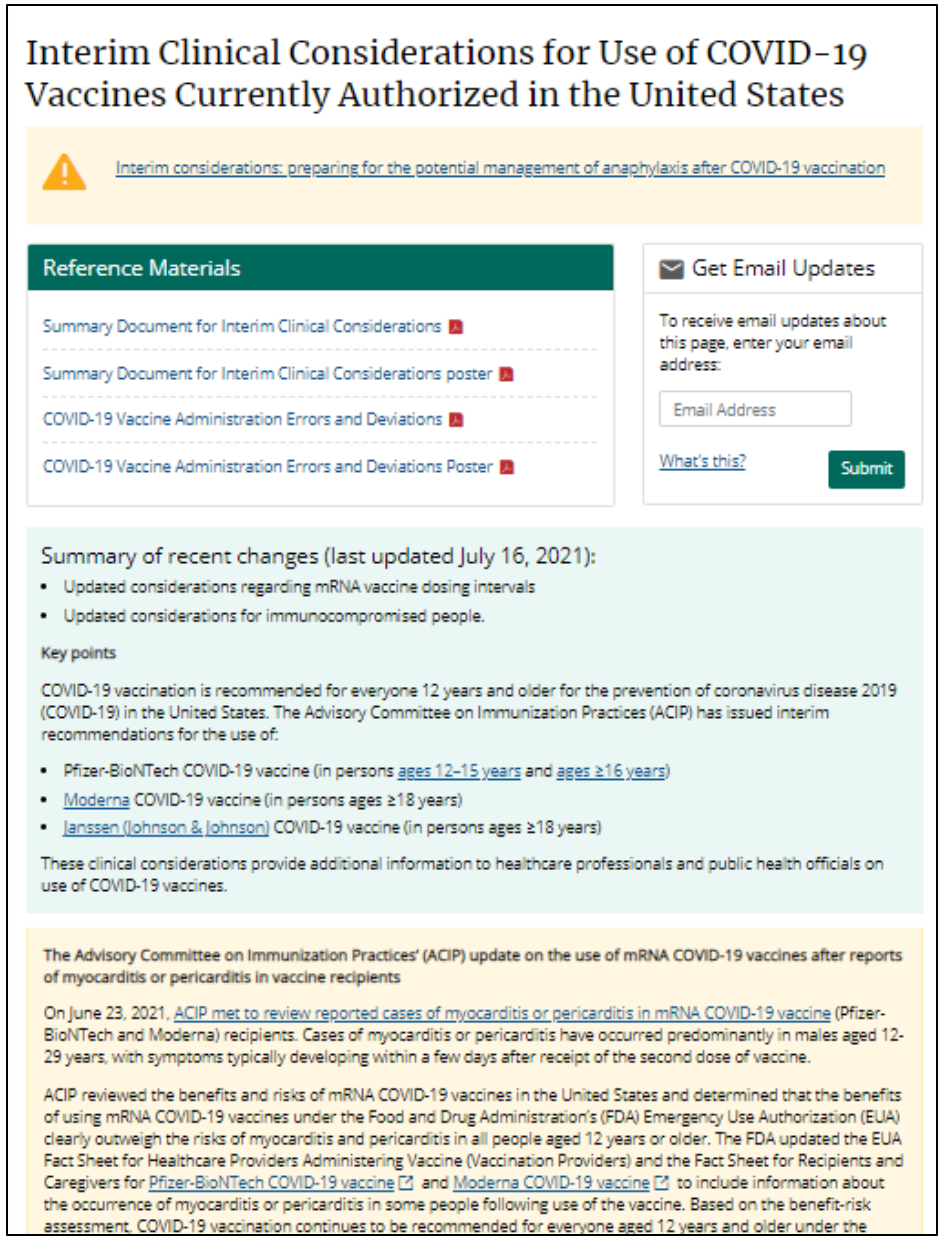
- Work Group reaffirms that all eligible persons should receive a COVID-19 vaccine
- Patients and providers should be aware of both the benefits and risks of COVID-19 vaccination when choosing a vaccine product
- **Work Group members expressed strong support for continued use of Janssen vaccine according to the current recommendations**

Updates to CDC Clinical Considerations

Obtained via FOIA by Judicial Watch, Inc.

- Persons with a prior history of GBS:
  - Can receive any of the authorized vaccines
  - Given possible association between Janssen vaccine and GBS, **patients with a history of GBS and their clinical team should discuss the availability of mRNA vaccines**.

- Information on signs and symptoms of GBS



Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States

Interim considerations: preparing for the potential management of anaphylaxis after COVID-19 vaccination

Reference Materials

Summary Document for Interim Clinical Considerations

Summary Document for Interim Clinical Considerations poster

COVID-19 Vaccine Administration Errors and Deviations

COVID-19 Vaccine Administration Errors and Deviations Poster

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Summary of recent changes (last updated July 16, 2021):

- Updated considerations regarding mRNA vaccine dosing intervals
- Updated considerations for immunocompromised people.

Key points

COVID-19 vaccination is recommended for everyone 12 years and older for the prevention of coronavirus disease 2019 (COVID-19) in the United States. The Advisory Committee on Immunization Practices (ACIP) has issued interim recommendations for the use of:

- Pfizer-BioNTech COVID-19 vaccine (in persons ages 12–15 years and ages ≥16 years)
- Moderna COVID-19 vaccine (in persons ages ≥18 years)
- Janssen (Johnson & Johnson) COVID-19 vaccine (in persons ages ≥18 years)

These clinical considerations provide additional information to healthcare professionals and public health officials on use of COVID-19 vaccines.

The Advisory Committee on Immunization Practices' (ACIP) update on the use of mRNA COVID-19 vaccines after reports of myocarditis or pericarditis in vaccine recipients

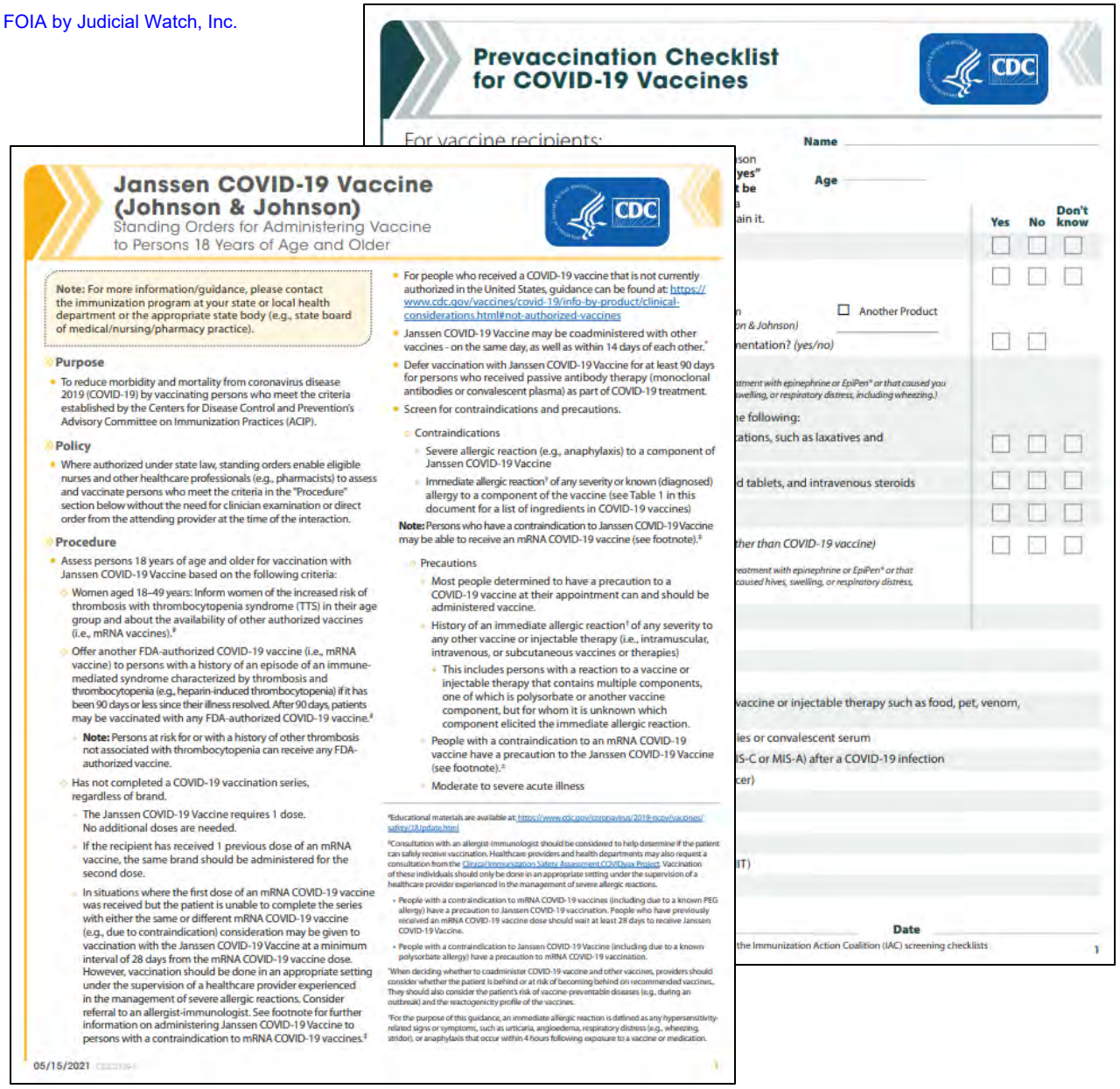
On June 23, 2021, ACIP met to review reported cases of myocarditis or pericarditis in mRNA COVID-19 vaccine (Pfizer-BioNTech and Moderna) recipients. Cases of myocarditis or pericarditis have occurred predominantly in males aged 12-29 years, with symptoms typically developing within a few days after receipt of the second dose of vaccine.

ACIP reviewed the benefits and risks of mRNA COVID-19 vaccines in the United States and determined that the benefits of using mRNA COVID-19 vaccines under the Food and Drug Administration's (FDA) Emergency Use Authorization (EUA) clearly outweigh the risks of myocarditis and pericarditis in all people aged 12 years or older. The FDA updated the EUA Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and the Fact Sheet for Recipients and Caregivers for Pfizer-BioNTech COVID-19 vaccine and Moderna COVID-19 vaccine to include information about the occurrence of myocarditis or pericarditis in some people following use of the vaccine. Based on the benefit-risk assessment, COVID-19 vaccination continues to be recommended for everyone aged 12 years and older under the

Updates will be posted at: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

Obtained via FOIA by Judicial Watch, Inc.

Updates to additional clinical resources



Prevaccination Checklist for COVID-19 Vaccines

For vaccine recipients:

Name

Age

Yes No Don't know

Another Product

Janssen COVID-19 Vaccine (Johnson & Johnson)

Standing Orders for Administering Vaccine to Persons 18 Years of Age and Older

Note: For more information/guidance, please contact the immunization program at your state or local health department or the appropriate state body (e.g., state board of medical/nursing/pharmacy practice).

Purpose

- To reduce morbidity and mortality from coronavirus disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy

- Where authorized under state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess and vaccinate persons who meet the criteria in the "Procedure" section below without the need for clinician examination or direct order from the attending provider at the time of the interaction.

Procedure

- Assess persons 18 years of age and older for vaccination with Janssen COVID-19 Vaccine based on the following criteria:
  - Women aged 18–49 years: Inform women of the increased risk of thrombosis with thrombocytopenia syndrome (TTS) in their age group and about the availability of other authorized vaccines (i.e., mRNA vaccines).[#]
  - Offer another FDA-authorized COVID-19 vaccine (i.e., mRNA vaccine) to persons with a history of an episode of an immune-mediated syndrome characterized by thrombosis and thrombocytopenia (e.g., heparin-induced thrombocytopenia) if it has been 90 days or less since their illness resolved. After 90 days, patients may be vaccinated with any FDA-authorized COVID-19 vaccine.[#]
    - **Note:** Persons at risk for or with a history of other thrombosis not associated with thrombocytopenia can receive any FDA-authorized vaccine.
  - Has not completed a COVID-19 vaccination series, regardless of brand.
    - The Janssen COVID-19 Vaccine requires 1 dose. No additional doses are needed.
    - If the recipient has received 1 previous dose of an mRNA vaccine, the same brand should be administered for the second dose.
    - In situations where the first dose of an mRNA COVID-19 vaccine was received but the patient is unable to complete the series with either the same or different mRNA COVID-19 vaccine (e.g., due to contraindication) consideration may be given to vaccination with the Janssen COVID-19 Vaccine at a minimum interval of 28 days from the mRNA COVID-19 vaccine dose. However, vaccination should be done in an appropriate setting under the supervision of a healthcare provider experienced in the management of severe allergic reactions. Consider referral to an allergist-immunologist. See footnote for further information on administering Janssen COVID-19 Vaccine to persons with a contraindication to mRNA COVID-19 vaccines.[‡]
- For people who received a COVID-19 vaccine that is not currently authorized in the United States, guidance can be found at: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#not-authorized-vaccines
- Janssen COVID-19 Vaccine may be coadministered with other vaccines - on the same day, as well as within 14 days of each other.[*]
- Defer vaccination with Janssen COVID-19 Vaccine for at least 90 days for persons who received passive antibody therapy (monoclonal antibodies or convalescent plasma) as part of COVID-19 treatment.
- Screen for contraindications and precautions.
  - Contraindications
    - Severe allergic reaction (e.g., anaphylaxis) to a component of Janssen COVID-19 Vaccine
    - Immediate allergic reaction[†] of any severity or known (diagnosed) allergy to a component of the vaccine (see Table 1 in this document for a list of ingredients in COVID-19 vaccines)

Note: Persons who have a contraindication to Janssen COVID-19 Vaccine may be able to receive an mRNA COVID-19 vaccine (see footnote).[‡]

  - Precautions
    - Most people determined to have a precaution to a COVID-19 vaccine at their appointment can and should be administered vaccine.
    - History of an immediate allergic reaction[†] of any severity to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies)
      - This includes persons with a reaction to a vaccine or injectable therapy that contains multiple components, one of which is polysorbate or another vaccine component, but for whom it is unknown which component elicited the immediate allergic reaction.
    - People with a contraindication to an mRNA COVID-19 vaccine have a precaution to the Janssen COVID-19 Vaccine (see footnote).[‡]
    - Moderate to severe acute illness

[#]Educational materials are available at: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/JJUpdate.html

[‡]Consultation with an allergist-immunologist should be considered to help determine if the patient can safely receive vaccination. Healthcare providers and health departments may also request a consultation from the Clinical Immunization Safety Assessment COVIDvax Project. Vaccination of these individuals should only be done in an appropriate setting under the supervision of a healthcare provider experienced in the management of severe allergic reactions.

- People with a contraindication to mRNA COVID-19 vaccines (including due to a known PEG allergy) have a precaution to Janssen COVID-19 vaccination. People who have previously received an mRNA COVID-19 vaccine dose should wait at least 28 days to receive Janssen COVID-19 Vaccine.
- People with a contraindication to Janssen COVID-19 Vaccine (including due to a known polysorbate allergy) have a precaution to mRNA COVID-19 vaccination.

[*]When deciding whether to coadminister COVID-19 vaccine and other vaccines, providers should consider whether the patient is behind or at risk of becoming behind on recommended vaccines. They should also consider the patient's risk of vaccine-preventable diseases (e.g., during an outbreak) and the reactogenicity profile of the vaccines.

[†]For the purpose of this guidance, an immediate allergic reaction is defined as any hypersensitivity-related signs or symptoms, such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within 4 hours following exposure to a vaccine or medication.

05/15/2021

Date

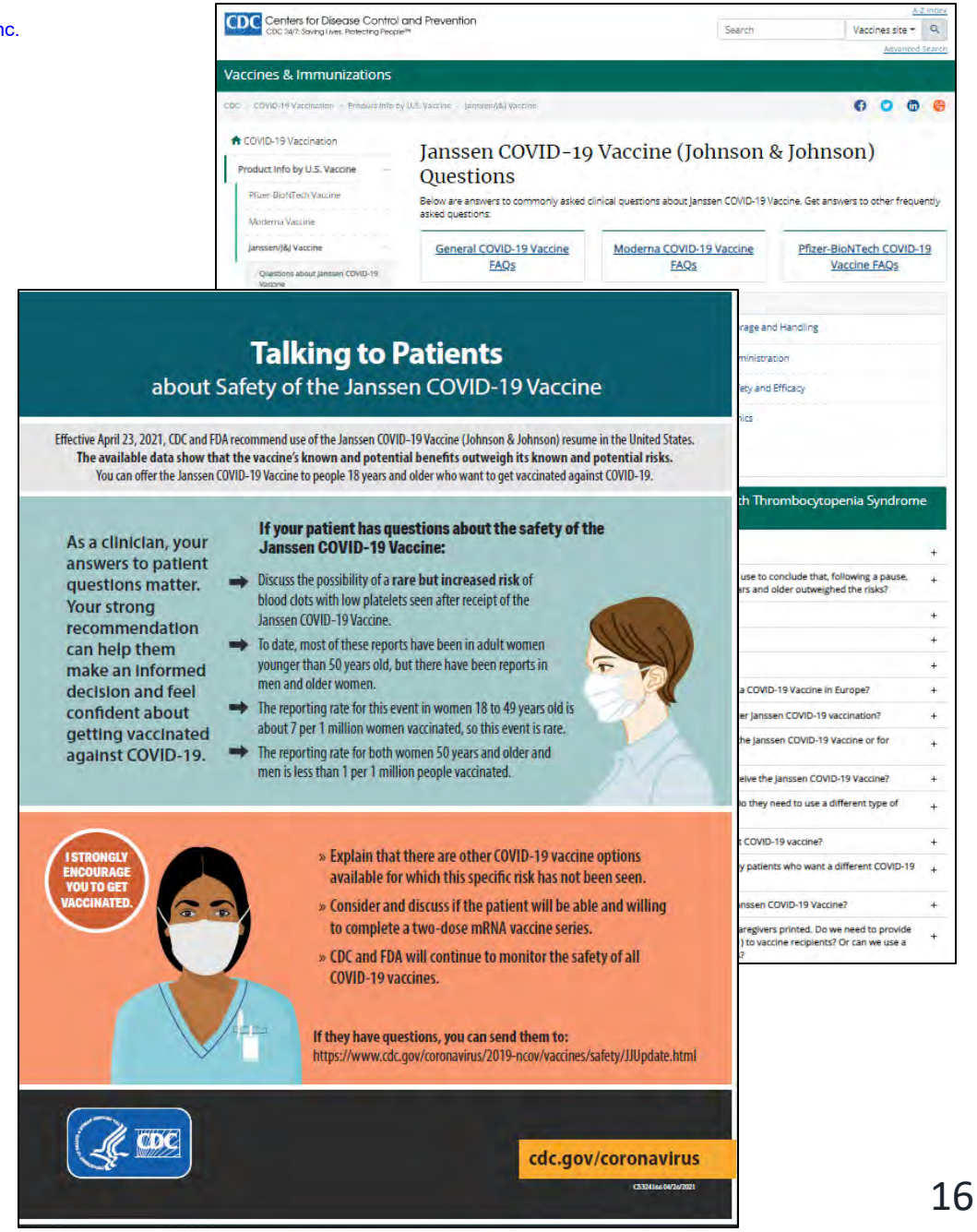
the Immunization Action Coalition (IAC) screening checklists

Updates will be posted at: https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/index.html

Planned CDC communication materials

Obtained via FOIA by Judicial Watch, Inc.

- Updated materials for providers on talking to patients about Janssen vaccine safety
- Updated frequently asked questions



Obtained via FOIA by Judicial Watch, Inc.

Discussion

- What is the ACIP's interpretation of the benefits and risks of COVID-19 vaccines?

- Does ACIP agree with the Work Group's interpretation that Janssen COVID-19 Vaccine should continue to be used according to the current recommendations?

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From: Cohn, Amanda (CDC/DDID/NCIRD/OD) [anc0@cdc.gov]
Sent: 12/17/2020 2:14:29 PM
To: Allende, Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3eb3dba5ebf44aabac32aa1a5b58d83-ALLENDEM]; Anderson, Steven [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c0c242feba45fa954f4f9b05eb3557-AndersonSt]; Clark, Thomas A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7654dd7010c34f819e1e2eb29bcc86d1-HHS-tnc4-cd]; Cohn, Amanda C (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4cbff30d34c4611a2e973fcb192de37-HHS-anc0-cd]; Farizo, Karen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4e44a6d3b754a66ad321c00f9b1debd-Farizo]; Fink, Doran [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b3bfbf3e7bea40b1b726937796eba4e8-FinkDo]; Forshee, Richard [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc6a16c85d124b81893beb85a6929867-Forshee]; Goud, Ravi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1b7603ba94e24c089ab4f83e09bcd3c4-Ravi.Goud]; Gruber, Marion [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=019cd2669c7048f7a116d72b7682de44-gruber]; Hess, Maureen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=23ed9c01196f4765b89921c357f855f9-Hessma]; Krause, Philip [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00c6330fea0042fdb5571c3fdef792ed-krause]; Lee, Lucia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c2d89bf8adec408fb3dd10c29d63d0fc-LeeL]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Martin, Stacey (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=75d5b37f96474b98892a56a967a0f55b-HHS-zmt0-cd]; Messonnier, Nancy E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3db273e5a524ff690738a633d2c15de-HHS-nar5-cd]; Nair, Narayan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=debe49605be845e5a44d59cf099b8cb8-Narayan.Nai]; Nordlund, Kristen (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9fdfd41389a645ca9fa28bed63d860c8-HHS-hok4-cd]; Pratt, Douglas R. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=682a5e028a4e428aa16bc3c206518d81-prattd]; Shimabukuro, Tom (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8313741a075c4f3d8d8351e106d1ffbc-HHS-ayv6-cd]; Welsh, Kerry [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=39b32156b8d34975a1093048aa852589-Kerry.Welsh]; Wollersheim, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00541f26747c48c09d7b38f8968d3e0e-Susan.Wolle]
Subject: COVID-19 CDC and FDA Coms list
Attachments: COVID-19 CDC and FDA Coms

Hi everyone,

Attached is a group contact list for discussion of communications between CDC and FDA on adverse events and/or communications alignment. To save, open the attachment and click “save and close”.

Thank you all,

Amanda

Obtained via FOIA by Judicial Watch, Inc.

Amanda Cohn, MD
CAPT, USPHS
Lead, Vaccine Planning Unit
CDC COVID-19 Response

Obtained via FOIA by Judicial Watch, Inc.

From: Cohn, Amanda (CDC/DDID/NCIRD/OD) [anc0@cdc.gov]
Sent: 12/17/2020 1:42:51 PM
Subject: COVID-19 CDC and FDA Coms

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From: Haynes, Leslie (CBER) [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02015880B0CE4A78953D370750FD4748-LESLIE.HAYN]
Sent: 1/22/2021 11:15:28 AM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Slaoui, Moncef (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=927359946fba418bbe88165cbde8d8ad-HHS-Moncef.]; Messonnier, Nancy E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3db273e5a524ff690738a633d2c15de-HHS-nar5-cd]; Hepburn, Matt (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=68c7e72407d94642b6e0761db3088888-HHS-Matt.He]; Runstrom, Mark (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87730c0209a340f1b779812822b74f70-HHS-Mark.Ru]; Johnson, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c7eb3a419464ea2917f9d1e3f6e57a4-HHS-Robert.]; Disbrow, Gary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-HHS-Gary.Di]; Clark, Matthew (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7016989d4b7e476781fe395661cbead4-HHS-Matthew]; Gorman, Richard (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60cb802883ef4f29aa00909646b6ab97-HHS-Richard]; Hamilton, Holli (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d9dd10bd6974f7f82128d5f9b193722-HHS-Holli.H]; Horwith, Gary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d6472efbb7f4130b46287660c7db94a-HHS-Gary.Ho]; Mcqueen, Anthony (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e76ec4716deb491ea440f22bb0baffbd-HHS-Anthony]; 'Ake, Julie (mail.mil)' [julie.a.ake.mil@mail.mil]; Anderson, Steven [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c0c242feba45fa954f4f9b05eb3557-AndersonSt]; Gruber, Marion [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=019cd2669c7048f7a116d72b7682de44-gruber]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Martin, Stacey (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=75d5b37f96474b98892a56a967a0f55b-HHS-zmt0-cd]; Cohn, Amanda C (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4cbff30d34c4611a2e973fcb192de37-HHS-anc0-cd]; Wharton, Melinda (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=20ac94633baa479e8282a619f083bbfb-HHS-mew2-cd]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Atalla, Mark (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=06877c4bc1c64f56961e4cce41bdc5aa-HHS-Mark.At]; 'Harjivan, Chandresh (US SCA) (Harjivan.Chan@bcgfed.com)' [Harjivan.Chan@bcgfed.com]; 'tian.kathy@bcg.com' [tian.kathy@bcg.com]; 'alhassani.ali@bcg.com' [alhassani.ali@bcg.com]; 'Choy, Michael' [Choy.Michael@bcg.com]; Kelman, Jeffrey A (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bcbadfaf1f347738e547528d0cd214e-HHS-Jeffrey]; Perez-Rivera, Diana (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c224eebfa1e4624b0c22b3b343fe6c7-HHS-Diana.P]; Good-Cohn, Meredith (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e06154b83bb4cb8a7b01816905e1300-HHS-Meredit]; Blackford, Carol W (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7dc338b24154229bd381935f207cb43-HHS-Carol.B]; Clark, Thomas A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7654dd7010c34f819e1e2eb29bcc86d1-HHS-tnc4-cd]; Shimabukuro, Tom (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8313741a075c4f3d8d8351e106d1ffbc-HHS-ayv6-cd]; Forshee, Richard

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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc6a16c85d124b81893beb85a6929867-Forshee]; Nair, Narayan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=debe49605be845e5a44d59cf099b8cb8-Narayan.Nai]; McNeill, Lorrie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77b0b352c9c24851bf0c7330f53e00d9-McNeill]; Frantz-Bohn, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c4a10821c774ffa9c5cf59bda6bcf75-frantz_bohn]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Krause, Philip [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00c6330fea0042fdb5571c3fdef792ed-krause]; Farizo, Karen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4e44a6d3b754a66ad321c00f9b1debd-Farizo]; Fink, Doran [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b3bfbf3e7bea40b1b726937796eba4e8-FinkDo]; Izurieta, Hector [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2dde96468af24b2d9ef03b853eeb3af9-Izurieta]; Roberts, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f99ba866ca234f6d826007b9f1429e8e-RobertsJ]; Witten, Celia (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc08ebb3ac61486da9f1b4046757c5cf-Witten]; Kessler, David A (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=efb6a7c634694533833de5d2f4beaee3-HHS-David.K]

Subject: Additional resource link - Jan 25 mtg, Coordination of COVID-19 Vaccine Safety Surveillance Efforts (4)

Please see below an additional resource link for the CDC presentation, during the discussion meeting being held on Jan 25, 2021, 12:30pm.

- Global Advisory Committee on Vaccine Safety Vaccine Safety subcommittee meeting review
https://www.who.int/news/item/22-01-2021-gacvs-review-deaths-pfizer-biontech-covid-19-vaccine-bnt162b2

Thank you.

Leslie Haynes, RD
Program Manager (PDUFA Oversight)
Immediate Office of the Director
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration

10903 New Hampshire Avenue
WO Bldg 71, Room 7222
Silver Spring, MD 20993-0002
Tel: 1-240-402-8074; Fax: 1-301-595-1310
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From: Haynes, Leslie (CBER) [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02015880B0CE4A78953D370750FD4748-LESLIE.HAYN]
Sent: 1/22/2021 10:54:21 AM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Slaoui, Moncef (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=927359946fba418bbe88165cbde8d8ad-HHS-Moncef.]; Messonnier, Nancy E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3db273e5a524ff690738a633d2c15de-HHS-nar5-cd]; Hepburn, Matt (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=68c7e72407d94642b6e0761db3088888-HHS-Matt.He]; Runstrom, Mark (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87730c0209a340f1b779812822b74f70-HHS-Mark.Ru]; Johnson, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c7eb3a419464ea2917f9d1e3f6e57a4-HHS-Robert.]; Disbrow, Gary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-HHS-Gary.Di]; Clark, Matthew (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7016989d4b7e476781fe395661cbead4-HHS-Matthew]; Gorman, Richard (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60cb802883ef4f29aa00909646b6ab97-HHS-Richard]; Hamilton, Holli (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d9dd10bd6974f7f82128d5f9b193722-HHS-Holli.H]; Horwith, Gary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d6472efbb7f4130b46287660c7db94a-HHS-Gary.Ho]; Mcqueen, Anthony (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e76ec4716deb491ea440f22bb0baffbd-HHS-Anthony]; 'Ake, Julie (mail.mil)' [julie.a.ake.mil@mail.mil]; Anderson, Steven [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c0c242feba45fa954f4f9b05eb3557-AndersonSt]; Gruber, Marion [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=019cd2669c7048f7a116d72b7682de44-gruber]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Martin, Stacey (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=75d5b37f96474b98892a56a967a0f55b-HHS-zmt0-cd]; Cohn, Amanda C (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4cbff30d34c4611a2e973fcb192de37-HHS-anc0-cd]; Wharton, Melinda (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=20ac94633baa479e8282a619f083bbfb-HHS-mew2-cd]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Atalla, Mark (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=06877c4bc1c64f56961e4cce41bdc5aa-HHS-Mark.At]; 'Harjivan, Chandresh (US SCA) (Harjivan.Chan@bcgfed.com)' [Harjivan.Chan@bcgfed.com]; 'tian.kathy@bcg.com' [tian.kathy@bcg.com]; 'alhassani.ali@bcg.com' [alhassani.ali@bcg.com]; 'Choy, Michael' [Choy.Michael@bcg.com]; Kelman, Jeffrey A (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bcbadfaf1f347738e547528d0cd214e-HHS-Jeffrey]; Perez-Rivera, Diana (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c224eebfa1e4624b0c22b3b343fe6c7-HHS-Diana.P]; Good-Cohn, Meredith (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e06154b83bb4cb8a7b01816905e1300-HHS-Meredit]; Blackford, Carol W (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7dc338b24154229bd381935f207cb43-HHS-Carol.B]
CC: Clark, Thomas A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7654dd7010c34f819e1e2eb29bcc86d1-HHS-tnc4-cd]; Shimabukuro, Tom (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8313741a075c4f3d8d8351e106d1ffbc-HHS-ayv6-cd]; Forshee, Richard

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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc6a16c85d124b81893beb85a6929867-Forshee]; Nair, Narayan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=debe49605be845e5a44d59cf099b8cb8-Narayan.Nai]; McNeill, Lorrie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77b0b352c9c24851bf0c7330f53e00d9-McNeill]; Frantz-Bohn, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c4a10821c774ffa9c5cf59bda6bcf75-frantz_bohn]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Krause, Philip [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00c6330fea0042fdb5571c3fdef792ed-krause]; Farizo, Karen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4e44a6d3b754a66ad321c00f9b1debd-Farizo]; Fink, Doran [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b3bfbf3e7bea40b1b726937796eba4e8-FinkDo]; Izurieta, Hector [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2dde96468af24b2d9ef03b853eeb3af9-Izurieta]; Roberts, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f99ba866ca234f6d826007b9f1429e8e-RobertsJ]; Witten, Celia (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc08ebb3ac61486da9f1b4046757c5cf-Witten]; Kessler, David A (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=efb6a7c634694533833de5d2f4beaee3-HHS-David.K]

Subject: AGENDA attached :: Coordination of COVID-19 Vaccine Safety Surveillance Efforts (4)
Attachments: Agenda - COVID-19 Vaccine Safety Surveillance Efforts 1-25-21 (final).pdf
Location: WebEx (shown below)

Start: 1/25/2021 12:30:00 PM
End: 1/25/2021 1:00:00 PM
Show Time As: Tentative

Required Attendees: Marks, Peter; Slaoui, Moncef (OS); Messonnier, Nancy E (CDC); Hepburn, Matt (OS); Runstrom, Mark (OS); Johnson, Robert (OS); Disbrow, Gary (OS); Clark, Matthew (OS); Gorman, Richard (OS); Hamilton, Holli (OS); Horwith, Gary (OS); Mcqueen, Anthony (OS); 'Ake, Julie (mail.mil)'; Anderson, Steven; Gruber, Marion; Cho, David S (CBER); Martin, Stacey (CDC); Cohn, Amanda C (CDC); Wharton, Melinda (CDC); Abernethy, Amy; Atalla, Mark (CMS); 'Harjivan, Chandresh (US SCA) (Harjivan.Chan@bcgfed.com)'; 'tian.kathy@bcg.com'; 'alhassani.ali@bcg.com'; 'Choy, Michael'; Kelman, Jeffrey A (CMS); Perez-Rivera, Diana (CMS); Good-Cohn, Meredith (CMS); Blackford, Carol W (CMS)
Optional Attendees: Clark, Thomas A (CDC); Shimabukuro, Tom (CDC); Forshee, Richard; Nair, Narayan; McNeill, Lorrie; Frantz-Bohn, Susan; Tierney, Julia; Krause, Philip; Farizo, Karen; Fink, Doran; Izurieta, Hector; Roberts, Jeff; Witten, Celia (CBER); Kessler, David (HHS/IOS)

This meeting will be used to discuss the efforts of FDA, CDC, and other government agencies to follow the safety of COVID-19 vaccines that are deployed for use.

Mtg 1: 12/16/20, 4-4:30pm
Mtg 2: 12/28/20, 12:30-1pm
Mtg 3: 1/11/21, 12:30-1pm
Mtg 4: 1/25/21, 12:30-1pm

Please refer to your principals within your organizations, prior to forwarding this calendar invitation.

With questions, please contact below, or send email to the FDA Covid-19 Vaccine Pharmacovigilance Coordination Team at Covid19VaccinePV@fda.hhs.gov.

Obtained via FOIA by Judicial Watch, Inc.

Thank you.

On behalf of Peter Marks, MD, PhD, Director, FDA Center for Biologics Evaluation and Research

Leslie Haynes, RD
Program Manager (PDUFA Oversight)
Immediate Office of the Director
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration

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Coordination of COVID-19 Vaccine Safety Surveillance Efforts Meeting
Monday, January 25, 2021
12:30 – 1:00 PM EST

Dial-in Number: 1-877-465-7975
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Meeting Topic	Presenter
Anaphylaxis and allergic reactions	CDC and FDA
San Diego small cluster of allergic reactions	Narayan Nair/FDA
Reports of death and post-vaccination mortality Update on Norway cases (in > 80 yrs of age)	Tom Shimabukuro/CDC FDA
Counts of vaccination in databases - Preparation for large-scale safety monitoring	CDC and FDA
UPDATES: • Bell's Palsy case reports	Narayan Nair/FDA
Other Topics	All

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Other Topics	All

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CC: Clark, Thomas A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7654dd7010c34f819e1e2eb29bcc86d1-HHS-tnc4-cd]; Shimabukuro, Tom (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8313741a075c4f3d8d8351e106d1ffbc-HHS-ayv6-cd]; Forshee, Richard

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Optional Attendees: Clark, Thomas A (CDC); Shimabukuro, Tom (CDC); Forshee, Richard; Nair, Narayan; McNeill, Lorrie; Frantz-Bohn, Susan; Tierney, Julia; Krause, Philip; Fink, Doran; Farizo, Karen; Roberts, Jeff; Izurieta, Hector; Wasley, Annemarie (CDC)

This meeting will be used to discuss the efforts of FDA, CDC, and other government agencies to follow the safety of COVID-19 vaccines that are deployed for use.

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Mtg 2: 12/28/20, 12:30-1pm
Mtg 3: 1/11/21, 12:30-1pm
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With questions, please contact below, or send email to the FDA Covid-19 Vaccine Pharmacovigilance Coordination Team at Covid19VaccinePV@fda.hhs.gov.

Thank you.

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On behalf of Peter Marks, MD, PhD, Director, FDA Center for Biologics Evaluation and Research

Leslie Haynes, RD
Program Manager (PDUFA Oversight)
Immediate Office of the Director
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration

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Summary review of anaphylactic reactions	All
Review of reports of Bell's palsy	Narayan Nair/FDA
Review of deaths in close proximity to vaccination	Tom Shimabukuro/CDC
UPDATES: • MMWR published this week • Posting of background rates Protocol	 CDC FDA
Other Topics	All

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Other Topics	All

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Subject: [EXTERNAL] Fwd: J&J Ad26 vaccine efficacy; Al Kapikian's 1975 coronavirus review and baseball comments
Attachments: J&J-02.26.21-Ad26FDA brfng doc.pdf; Kapikian Dev Biol Stand 1975.pdf; 01 Track 1.wma

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Dr Davidson found my home phone number and called I had not responded to his emails I said I would forward this to you I explained how things work to him and even tried to explain the numbers issue that concerned him to no avail. This gets me off the hook, and I told him you would not be able to respond. Turns out he knew Al Kapikian at NIH and the rotavirus vaccine stories, which explain the attachments

Regards

Arnold

---------- Forwarded message ---------
From: **Bruce Davidson** <(b) (6)>
Date: Wed, Mar 10, 2021 at 7:50 PM
Subject: J&J Ad26 vaccine efficacy; Al Kapikian's 1975 coronavirus review and baseball comments
To: <asmonto@umich.edu>

Thanks for speaking with me, Dr Monto. If FDA provides the data, I hope you'll forward it. I've tried FDA, 4 different people, at least 7 emails and 4 or 5 phone calls--no answer. None from CDC either.

To be most helpful, additional data should describe, for the 28-day outcome, for the per-protocol patient set (not the safety set, not the enrolled ITT set) both the 18 cases among 1624 vaccinees and 26 cases among 1604 placebo recipients by these descriptors:

	Ad26 cases n=18	Ad26 non-cases n=1610	Placebo cases n=26	Placebo non-cases n=1578
US-resident American Indians				
US-resident Alaska Natives				
Non-US resident American Indians				
Non-US resident Alaska Natives				
Totals	18	1610	26	1578

--

If you look at Table 12 page 28 in the FDA briefing document I've attached for your convenience, you'll see that with 1/3 fewer patients in the "Multiple (mixed) Race" group, the efficacy was just fine, with 95% confidence

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limits nowhere near zero, let alone into negative numbers, and without a significant p-value for being different from efficacy in the rest of study subjects.

I've also attached Al Kapikian's coronavirus review (he devised the nomenclature for classifying rhinoviruses, he told me) and his great phone call to the baseball radio station about not allowing blocking home plate. That rule was passed shortly after he died.

Sincerely,

Bruce

--
Bruce L Davidson MD MPH

Email (b) (6)
Tel

--
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Vaccines and Related Biological Products Advisory Committee Meeting
February 26, 2021

FDA Briefing Document

Janssen Ad26.COV2.S Vaccine for the Prevention of COVID-19

Sponsor:
Janssen Biotech, Inc.

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Glossary

Ad26	adenovirus type 26
AE	adverse event
AR	adverse reaction
AESI	adverse event of special interest
ARDS	acute respiratory distress syndrome
CBRN	chemical, biological, radiological, or nuclear
CDC	Centers for Disease Control and Prevention
CMC	chemistry, manufacturing and control
CT	computed tomography
ECMO	extracorporeal membrane oxygenation
EUA	Emergency Use Authorization
FAS	full analysis set
FDA	Food and Drug Administration
FD&C	Federal Food, Drug, and Cosmetic Act
hACE2	human angiotensin converting enzyme 2
HHS	Health and Human Services
LMP	last menstrual period
MAAE	medically attended adverse event
MERS-CoV	Middle Eastern respiratory syndrome
MedDRA	Medical Dictionary for Regulatory Activities
MRU	Medical Resource Utilization
PT	preferred term
RT-PCR	reverse transcription-polymerase chain reaction
SAE	serious adverse event
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2
SMQ	standard MedDRA query
SAP	statistical analysis plan
VAERS	Vaccine Adverse Event Reporting System
VE	vaccine efficacy
vp	viral particles
VRBPAC	Vaccines and Related Biological Products Advisory Committee

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1. Executive Summary

On February 4, 2021, Janssen Biotech, Inc. (the Sponsor) submitted an Emergency Use Authorization (EUA) request to FDA for an investigational vaccine intended to prevent COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The vaccine, known as Ad26.COV2.S, is a replication-incompetent adenovirus type 26 (Ad26) vectored vaccine encoding a stabilized variant of the SARS-CoV-2 S protein. The proposed use under an EUA is for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older. The proposed dosing regimen is a single intramuscular injection at the dose level of 5×10^{10} viral particles (vp).

In support of their EUA request, Janssen has submitted safety and efficacy data from an ongoing multi-national Phase 3 randomized, double-blind and placebo-controlled trial of a single dose ($5x10^{10}$ vp) of Ad26.COV2.S in approximately 40,000 participants. The EUA request followed a successful protocol-specified primary analysis that evaluated co-primary efficacy endpoints of molecularly confirmed, moderate to severe/critical COVID-19 with onset at least 14 and 28 days, respectively, after vaccination in participants without evidence of SARS-CoV-2 infection prior to vaccination. The co-primary efficacy analysis (data cutoff of January 22, 2021) included 39,321 randomized (1:1) participants with a median follow-up time of 2 months post-vaccination. These participants were included in the per-protocol efficacy analysis population.

Vaccine efficacy (VE) against central laboratory-confirmed moderate to severe/critical COVID-19 across all geographic areas in which the trial was conducted was 66.9% (95% CI 59.0, 73.4) when considering cases occurring at least 14 days after the single-dose vaccination and 66.1% (55.0, 74.8) when considering cases occurring at least 28 days after vaccination. For the vaccine and placebo groups, respectively, there were 116 and 348 COVID-19 cases that occurred at least 14 days after vaccination, and 66 and 193 cases that occurred at least 28 days after vaccination. Analyses of secondary endpoints demonstrated vaccine efficacy against central laboratory confirmed and blind-adjudicated severe/critical COVID-19 occurring at least 14 days and at least 28 days after vaccination of 76.7% (54.6, 89.1) and 85.4% (54.2, 96.9), respectively. VE estimates for prevention of moderate to severe/critical COVID-19 and for prevention of severe/critical COVID-19 including positive PCR results still awaiting confirmation by the central laboratory were similar (but with narrower confidence intervals) to the VE estimates that included only centrally-confirmed cases. In a post hoc analysis of all COVID-19 related hospitalizations starting 14 days after vaccination, including non-centrally confirmed cases, there were 2 cases in the vaccine group (with no cases after 28 days) compared with 29 cases in the placebo group (with 16 cases after 28 days). As of February 5, 2021, there were 7 COVID-19 related deaths in the study in the placebo group and no COVID-19 related deaths in the vaccine group.

In general, VE among the subgroups (age, comorbidity, race, ethnicity) appears to be similar to the VE in the overall study population. A lower VE estimate was observed for the subgroup of participants 60 years of age and older with comorbidities compared with the overall population, but with an observed trend of increasing VE with narrower confidence intervals as numbers of cases included in the analysis increased (i.e., counting cases from 14 days rather than 28 days and including cases not yet centrally confirmed). There were no COVID-19-related deaths and no COVID-19 cases requiring medical intervention occurring 28 days or more post-vaccination among participants age 60 years or older with medical comorbidities in the vaccine group. The VE results for some other subgroups with small numbers of participants (≥75 years of age, certain racial subgroups) have limited interpretability. Data were insufficient to assess VE in participants with evidence of prior SARS-CoV-2 infection.

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There was country-to-country variation in VE estimates for the prevention of moderate to severe/critical COVID-19 and severe/critical COVID-19, but the confidence intervals were overlapping. Predominant strains among those sequenced were Wuhan-H1 variant D614G in the U.S. (96.4% of sequenced cases), 20H/501Y.V2 variant (B.1.351) in South Africa (94.5% of sequenced cases), and variant of the P.2 lineage in Brazil (69.4% of sequenced cases, with the remaining 30.6% Wuhan-H1 variant D614G). There were no cases identified as B.1.1.7 or P1 lineages as of February 12, 2021.

Safety analysis through the January 22, 2021 data cutoff included 43,783 randomized (1:1) participants ≥18 years of age with 2-month median follow-up. The analysis supported a favorable safety profile with no specific safety concerns identified that would preclude issuance of an EUA.

A subset of participants (N=6,736) was followed for solicited reactions within 7 days following vaccination and unsolicited reactions within 28 days following vaccination. The most common solicited adverse reactions associated with Ad26.COV2.S were injection site pain (48.6%), headache (38.9%), fatigue (38.2%), and myalgia (33.2%); these were predominately mild and moderate, with 0.7% and 1.8% of local and systemic solicited adverse reactions, respectively, reported as grade 3. Reports of solicited reactions were less common among participants ≥60 years of age. Reactogenicity to Ad26.COV2.S in adults ≥18 years of age was demonstrated to be transient, and most solicited adverse events (AEs) generally resolved in 1 to 2 days post-vaccination. There were no meaningful imbalances between vaccine and placebo recipients in unsolicited adverse events reported during the 28 days following vaccination.

Among all adverse events collected through the January 22, 2021 data cutoff, a numerical imbalance was seen in non-serious urticaria events reported in the vaccine group (n=5) compared to placebo group (n=1) within 7 days following vaccination which is possibly related to the vaccine. Numerical imbalances were observed between vaccine and placebo recipients for thromboembolic events (15 versus 10) and tinnitus (6 versus 0). Data at this time are insufficient to determine a causal relationship between these events and the vaccine. There were no other notable patterns or numerical imbalances in the available data as of the cutoff date between treatment groups for specific categories of adverse events that would suggest a causal relationship to Ad26.COV2.S.

Non-fatal serious adverse events, excluding those attributed to COVID-19, were infrequent and balanced between study groups with respect to rates and types of events (0.4% in both groups). One serious event of a hypersensitivity reaction, not classified as anaphylaxis, beginning two days following vaccination was likely related to receipt of the vaccine.

There was more frequent, generally mild to moderate reactogenicity in participants 18 to 59 years of age compared to older participants. There were no specific safety concerns identified in subgroup analyses by age, race, ethnicity, medical comorbidities, or prior SARS-CoV-2 infection. Occurrence of solicited, unsolicited, and serious adverse events in these subgroups was generally consistent with the overall study population.

This meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) is being convened to discuss and provide recommendations whether, based on the totality of scientific evidence available, the benefits of the Ad26.COV2.S vaccine outweigh its risks for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older.

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2. Background

2.1 SARS-CoV-2 Pandemic

The SARS-CoV-2 pandemic presents an extraordinary challenge to global health and, as of February 17, 2021, has caused more than 110 million cases of COVID-19 and claimed the lives of more than 2.4 million people worldwide. In the United States, more than 27 million cases and 486,000 deaths have been reported to the Centers for Disease Control and Prevention (CDC). On January 31, 2020, the U.S. Secretary of Health and Human Services (HHS) declared a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS. Following the World Health Organization's declaration of the novel coronavirus pandemic on March 11, 2020, the U.S. President declared a national emergency in response to COVID-19 on March 13, 2020. Vaccines to protect against COVID-19 are critical to mitigate the current SARS-CoV-2 pandemic and to prevent future disease outbreaks.

SARS-CoV-2 is a novel, zoonotic coronavirus that emerged in late 2019 in patients with pneumonia of unknown cause.[1] The virus was named SARS-CoV-2 because of its similarity to the coronavirus responsible for severe acute respiratory syndrome (SARS-CoV, a lineage B betacoronavirus).[2] SARS-CoV-2 is an enveloped, positive sense, single stranded RNA virus sharing more than 70% of its sequence with SARS-CoV, and ~50% with the coronavirus responsible for Middle Eastern respiratory syndrome (MERS-CoV).[3] The SARS-CoV-2 spike glycoprotein (S), which is the main target for neutralizing antibodies, binds to its receptor human angiotensin converting enzyme 2 (hACE2) to initiate infection.[4] SARS-CoV-2 is the cause of COVID-19, an infectious disease with respiratory and systemic manifestations. Disease symptoms vary, with many persons presenting with asymptomatic or mild disease and some progressing to severe respiratory tract disease including pneumonia and acute respiratory distress syndrome (ARDS), leading to multiorgan failure and death.

In an attempt to prevent the spread of disease and to control the pandemic, numerous COVID-19 vaccine candidates are in development. FDA issued emergency use authorizations for two mRNA vaccines, developed by Pfizer and Moderna, respectively, in December 2020. Other COVID-19 vaccines currently in development are based on various platforms and include mRNA, DNA, viral vectored, subunit, inactivated, and live-attenuated vaccines. Most COVID-19 candidate vaccines express the spike protein or parts of the spike protein, i.e., the receptor binding domain, as the immunogenic determinant.

2.2 EUA Request for the Janssen Ad26.COV2.S Vaccine

Janssen Biotech, Inc. is developing a replication-incompetent adenovirus type 26 (Ad26)-vectored vaccine encoding a stabilized variant of the SARS-CoV-2 S protein, to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older. The Ad26.COV2.S vaccine is administered as a single intramuscular injection of $5x10^{10}$ vp. The vaccine is supplied as a multidose vial (5 doses) containing a refrigerated suspension with a shelf life of 3 months when stored at 2° to 8° C. The vaccine does not contain a preservative.

A Phase 3 randomized and placebo-controlled trial of the single-dose Ad26.COV2.S in approximately 40,000 participants is currently ongoing to evaluate the vaccine's safety and efficacy. The primary analysis of 39,321 participants using a data cutoff date of January 22, 2021 demonstrated vaccine efficacy (VE) of 66.9% (adjusted 95% CI 59.0%, 73.4%) for the prevention of moderate to severe/critical COVID-19 occurring at least 14 days vaccination, and

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66.1% (adjusted 95% CI 55.0%, 74.8%) for the prevention of cases occurring at least 28 days after vaccination. Safety data from a January 22, 2021 data cutoff with a median of 58 days follow-up after vaccination were reported to demonstrate an acceptable tolerability profile with no significant safety concerns. On February 4, 2021, Janssen Biotech, Inc. submitted an EUA request to FDA, based on the primary analyses described above, for Ad26.COV2.S for active immunization for the prevention of COVID-19 in adults 18 years of age and older.

2.3 U.S. Requirements to Support Issuance of an EUA for a Biological Product

Based on the declaration by the Secretary of HHS that the COVID-19 pandemic constitutes a public health emergency with a significant potential to affect national security or the health and security of United States citizens living abroad, FDA may issue an EUA after determining that certain statutory requirements are met (section 564 of the FD&C Act (21 U.S.C. 360bbb-3)).[5]

- The chemical, biological, radiological, or nuclear (CBRN) agent referred to in the March 27, 2020 EUA declaration by the Secretary of HHS (SARS-CoV-2) can cause a serious or life-threatening disease or condition.
- Based on the totality of scientific evidence available, including data from adequate and well-controlled trials, if available, it is reasonable to believe that the product may be effective to prevent, diagnose, or treat such serious or life-threatening disease or condition that can be caused by SARS-CoV-2, or to mitigate a serious or life-threatening disease or condition caused by an FDA-regulated product used to diagnose, treat, or prevent a disease or condition caused by SARS-CoV-2.
- The known and potential benefits of the product, when used to diagnose, prevent, or treat the identified serious or life-threatening disease or condition, outweigh the known and potential risks of the product.
- There is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating the disease or condition.

If these criteria are met, under an EUA, FDA can allow unapproved medical products (or unapproved uses of approved medical products) to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by threat agents. FDA has been providing regulatory advice to COVID-19 vaccine manufacturers regarding the data needed to determine that a vaccine's benefit outweigh its risks. This includes demonstrating that manufacturing information ensures product quality and consistency along with data from at least one Phase 3 clinical trial demonstrating a vaccine's safety and efficacy in a clear and compelling manner.

In the event an EUA is issued for this product, it would still be considered unapproved and would continue under further investigation (under an Investigational New Drug Application). Licensure of a COVID-19 vaccine will be based on review of additional manufacturing, efficacy, and safety data, providing greater assurance of the comparability of licensed product to product tested in the clinical trials, greater assurance of safety based on larger numbers of vaccine recipients who have been followed for a longer period of time, and additional information about efficacy that addresses, among other questions, the potential for waning of protection over time.

2.4 Available Vaccines and Therapies for COVID-19

No vaccine or other medical product is FDA approved for prevention of COVID-19. On October 22, 2020, FDA approved remdesivir for use in adult and pediatric patients 12 years of age and

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older and weighing at least 40 kilograms for the treatment of COVID-19 requiring hospitalization. Several other therapies are currently available under EUA, but not FDA approved, for treatment of COVID-19. On December 11, 2020, FDA issued an EUA for the Pfizer-BioNTech COVID-19 vaccine for active immunization for prevention of COVID-19 due to SARS-CoV-2 in individuals 16 years of age and older, administered as 2 doses 3 weeks apart. On December 18, 2020, FDA issued an EUA for the Moderna COVID-19 vaccine for use in individuals 18 years of age and older, administered as 2 doses 4 weeks apart. These COVID-19 vaccines are considered unapproved products, and current supplies are insufficient to vaccinate all persons in the U.S. for whom use of the vaccines are authorized. Thus, there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating the disease or condition.

2.5 Applicable Guidance for Industry

An EUA for a COVID-19 vaccine allows for the rapid and widespread deployment for administration to millions of individuals, including healthy people and thus, data are needed demonstrating that the known and potential benefits of the vaccine outweigh its known and potential risks. FDA published guidance for industry Emergency Use Authorization for Vaccines to Prevent COVID-19 (October 2020) describing FDA's current recommendations regarding the manufacturing, nonclinical, and clinical data and information needed under section 564 of the FD&C Act to support the issuance of an EUA for an investigational vaccine to prevent COVID-19, including a discussion of FDA's current thinking regarding the circumstances under which an EUA for a COVID-19 vaccine would be appropriate.[6]

2.6 Safety and Effectiveness Information Needed to Support an EUA

Effectiveness data

Issuance of an EUA requires a determination that the known and potential benefits of the vaccine outweigh the known and potential risks. Data adequate to inform an assessment of the vaccine's benefits and risks, and thus support issuance of an EUA, would include meeting the prespecified success criteria for the study's primary efficacy endpoint, as described in the guidance for industry Development and Licensure of Vaccines to Prevent COVID-19 (June 2020) (i.e., a point estimate for a placebo-controlled efficacy trial of at least 50%, with a lower bound of the appropriately alpha-adjusted confidence interval around the primary efficacy endpoint point estimate of >30%).[6]

Safety data

An EUA request for a COVID-19 vaccine should include all safety data accumulated from studies conducted with the vaccine, with data from Phase 1 and 2 focused on serious adverse events, adverse events of special interest, and cases of severe COVID-19 among study participants. Phase 3 safety data should include characterization of reactogenicity (common and expected adverse reactions shortly following vaccination) in a sufficient number of participants from relevant age groups and should include a high proportion of enrolled participants (numbering well over 3,000) followed for serious adverse events and adverse events of special interest for at least one month after completion of the full vaccination regimen. The Phase 1 and 2 safety data likely will be of a longer duration than the available safety data from the Phase 3 trial at the time of submission of an EUA request and thus, are intended to complement the available data from safety follow-up from ongoing Phase 3 studies.

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Phase 3 Follow-up

Data from Phase 3 studies should include a median follow-up duration of at least 2 months after completion of the full vaccination regimen to provide adequate information to assess a vaccine's benefit-risk profile. From a safety perspective, a 2-month median follow-up following completion of the full vaccination regimen will allow identification of potential adverse events that were not apparent in the immediate postvaccination period. Adverse events considered plausibly linked to vaccination generally start within 6 weeks of vaccine receipt.[7] From the perspective of vaccine efficacy, a 2-month median follow-up is the shortest follow-up period to achieve some confidence that any protection against COVID-19 is likely to be more than short-lived. The EUA request should include a plan for active follow-up for safety (including deaths, hospitalizations, and other serious or clinically significant adverse events) among individuals administered the vaccine under an EUA in order to inform ongoing benefit-risk determinations to support continuation of the EUA.

2.7 Continuation of Clinical Trials Following Issuance of an EUA for a COVID-19 Vaccine

FDA does not consider availability of a COVID-19 vaccine under EUA, in and of itself, as grounds for immediately stopping blinded follow-up in an ongoing clinical trial or grounds for offering vaccine to all placebo recipients. To minimize the risk that use of an unapproved vaccine under EUA will interfere with long-term assessment of safety and efficacy in ongoing trials, it is critical to continue to gather data about the vaccine even after it is made available under EUA. An EUA request should therefore include strategies that will be implemented to ensure that ongoing clinical trials of the vaccine are able to assess long-term safety and efficacy (including evaluating for vaccine-associated enhanced respiratory disease and decreased effectiveness as immunity wanes over time) in sufficient numbers of participants to support vaccine licensure. These strategies should address how ongoing trial(s) will handle requests for unblinding and crossover of placebo recipients to receive vaccine in the trial and loss of follow-up information for study participants who choose to withdraw from the study in order to receive the vaccine under an EUA.

2.8 Previous Meetings of the VRBPAC to Discuss Vaccines to Prevent COVID-19

On October 22, 2020, the VRBPAC met in open session to discuss, in general, the development, authorization, and/or licensure of vaccines to prevent COVID-19. No specific application was discussed at this meeting. Topics discussed at the meeting included:

- FDA's approach to safety and effectiveness, and chemistry, manufacturing and control (CMC) data as outlined in the respective guidance documents
- Considerations for continuation of blinded Phase 3 clinical trials if an EUA has been issued for an investigational COVID-19 vaccine
- Studies following licensure and/or issuance of an EUA for COVID-19 vaccines to:
  - Further evaluate safety, effectiveness and immune markers of protection
  - Evaluate the safety and effectiveness in specific populations.

On December 10, 2020, the VRBPAC met in open session to discuss the EUA request of the Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 in individuals 16 years of age older. Topics discussed at the meeting but not voted upon included Pfizer's plan for continuation of blinded, placebo-controlled follow-up in ongoing trials in the event that the vaccine is made available under EUA and gaps in plans for further evaluation of vaccine safety and effectiveness in populations that receive the Pfizer-BioNTech Vaccine under an EUA. The committee voted in favor of a determination that, based on the totality of scientific evidence

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available, the benefits of the proposed vaccine outweigh its risks for use in individuals 16 years of age and older.

On December 17, 2020, the VRBPAC met to discuss the EUA request of the Moderna COVID-19 Vaccine for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older. Committee members discussed but did not vote on whether the ongoing Phase 3 trial should be continued using a blinded cross-over design or an open-label design as proposed by Moderna. The committee suggested the conduct of additional studies to obtain data, including data on vaccine effectiveness in the elderly, immunogenicity in immunocompromised subpopulations, effectiveness of the vaccine following one dose, and the vaccine's duration of protection. The committee voted in favor of a determination that, based on the totality of scientific evidence available, the benefits of the proposed vaccine outweigh its risks for use in individuals 18 years of age and older.

3. Topics for VRBPAC Discussion

The Vaccines and Related Biological Products Advisory Committee will convene on February 26, 2021, to discuss and provide recommendations on whether based on the totality of scientific evidence available, the benefits of the Janssen Ad26.COV2.S vaccine outweigh its risks for use in individuals 18 years of age and older.

4. Janssen Ad26.COV2.S (COVID-19) Vaccine

4.1 Vaccine Composition, Dosing Regimen

The Janssen Ad26.COV2.S vaccine is a colorless to slightly yellow, clear to very opalescent sterile suspension for intramuscular injection. The vaccine consists of a replication-incompetent recombinant adenovirus type 26 (Ad26) vector expressing the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) spike (S) protein in a stabilized conformation. The vaccine also contains the following inactive ingredients: citric acid monohydrate, trisodium citrate dihydrate, ethanol, 2-hydroxypropyl-β-cyclodextrin (HBCD), polysorbate 80, sodium chloride, sodium hydroxide, and hydrochloric acid.

The Ad26 vector expressing the SARS-CoV-2 S protein is grown in PER.C6® TetR Cell Line, in media containing amino acids and no animal-derived proteins. After propagation, the vaccine is processed through several purification steps, formulated with inactive ingredients and filled into vials.

The Ad26.COV2.S vaccine is provided as a refrigerated suspension [stored at 2°C to 8°C (36°F to 46°F)] in a multi-dose vial containing 5 doses (0.5 mL each). The vials should be protected from light. Unpunctured vials may be stored between 9°C to 25°C (47°F to 77°F) for up to 12 hours. After the first dose has been withdrawn, the vial should be held between 2° to 8°C (36° to 46°F) for up to 6 hours or at room temperature (maximally 25°C/77°F) for up to 2 hours. The vial should be discarded if the vaccine is not used within these times.

Ad26.COV2.S (5×10^{10} vp) is administered as a single intramuscular injection (0.5 mL dose).

FDA has reviewed the CMC data submitted to date for this vaccine and has determined that the CMC information is consistent with the recommendations set forth in FDA's guidance Emergency Use Authorization for Vaccines to Prevent COVID-19 (October 2020). As such, FDA

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has determined that the Sponsor has provided adequate information to ensure the vaccine's quality and consistency for authorization of the product under an EUA.

4.2 Safety Experience of Ad26-based Vaccines

The Ad26.COV2.S (COVID-19) vaccine is based on the Ad26 vector platform. Clinical experience with the Ad26 platform consists of the Ad26.ZEBOV/MVA-BN-Filo Ebola vaccine regimen (approved by the European Medicines Agency on July 1, 2020) and investigational vaccines against Zika, filovirus, HIV, HPV, malaria, and respiratory syncytial virus. As of 31 December 2020, Ad26-based vaccines have been used to vaccinate 193,831 participants in clinical studies and vaccination programs. Overall, these vaccines have been shown to have an acceptable clinical safety profile to date.

4.3 Proposed Use Under EUA

The proposed use of the Ad26.COV2.S vaccine under an EUA is for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older.

5. FDA Review of Clinical Safety and Effectiveness Data

5.1 Overview of Clinical Studies

There are five ongoing clinical studies with Ad26.COV2.S, which are summarized in Table 1 below. All listed trials are randomized, double-blind, and placebo-controlled. Study VAC31518COV3001 (Study 3001) is a Phase 3 efficacy and safety study with a single-dose regimen and is the focus of the EUA review. Study 3009 is a Phase 3 efficacy and safety study with a 2-dose regimen than began in November 2020, for which only blinded safety data was available at the time of the EUA request. Study 2001 is a Phase 2a dose-ranging study exploring 4 dose levels and 1-dose and 2-dose regimens in adults and adolescents and will not be discussed in detail. Studies 1002 and 1001 are Phase 1 dose-ranging studies and will also not be discussed in detail. Summaries of the designs and results to date of Studies 1001, 1002, 2001, and 3009 may be found in Appendix A, page 60.

Table 1. Clinical Trials Submitted in Support of Efficacy and Safety Determinations of the Janssen Ad26.COV2.S (COVID-19) Vaccine

Study Number	Phase Type (Efficacy, Safety)	Participants Planned (N)	Test Product(s); Dosing Regimens	Study Status
3001	Phase 3 efficacy, safety	40,000 adults	Ad26.COV2.S $5x10^{10}$ vp 1-dose regimen	Enrollment complete
3009	Phase 3, efficacy, safety	30,000 adults	Ad26.COV2.S $5×10^{10}$ vp 2-dose regimen	Enrollment ongoing
2001	Phase 2a safety, immunogenicity	550 adults 660 adolescents	Ad26.COV2.S $1×10^{11}$ vp $5×10^{10}$ vp $2.5x10^{10}$ vp $1.25x10^{10}$ vp; 1-dose and 2-dose regimens	Enrollment of adults ongoing; enrollment of adolescents not started

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Study Number	Phase Type (Efficacy, Safety)	Participants Planned (N)	Test Product(s); Dosing Regimens	Study Status
1002	Phase 1 safety, immunogenicity	250 adults	Ad26.COV2.S 5×10^{10} vp, 1×10^{11} vp; 2-dose regimen	Enrollment complete
1001	Phase 1/2a safety, immunogenicity	1045 adults	Ad26.COV2.S 5×10^{10} vp and 1×10^{11} vp; 1-dose and 2-dose regimens, with booster in 1 cohort	Enrollment complete

5.2 Study 3001

5.2.1 Design

Study 3001 is an ongoing randomized, double-blind, placebo-controlled study to evaluate the efficacy, safety and immunogenicity of Ad26.COV2.S administered as a single dose in adults ≥18 years of age. A target of 40,000 adults were to be randomized 1:1 to receive intramuscular injections of either vaccine ($5x10^{10}$ vp) or placebo. At least 30% of the total study population was to consist of participants ≥60 years of age, and enrollment of participants 18 to 40 years of age was limited to approximately 20% of the total study population.

A staged enrollment strategy was specified in the protocol. Following acceptable safety and immunogenicity data from Study 1001 to support the dosing regimen, Study 3001 enrolled approximately 2000 participants 18 to 59 years of age without comorbidities (stage 1a). As no safety issues were identified during the Data Safety Monitoring Board's examination of safety data through Day 3 post-vaccination, participants 18 to 59 years with and without co-morbidities were enrolled (stage 1b). In parallel, approximately 2000 participants ≥60 years of age without comorbidities were enrolled (stage 2a) followed by a pause in vaccination for evaluation safety data through Day 3 post-vaccination prior to enrollment of ≥60-year-olds with and without comorbidities (stage 2b).

Symptoms of COVID-19 experienced by participants during post-vaccination follow-up prompted an unscheduled illness visit and nasopharyngeal swab. For the initial diagnosis of SARS-CoV-2 infection, FDA-authorized PCR tests were used, irrespective whether the test was performed locally at study sites or at the central laboratory (University of Washington [UW Virology laboratory]). Samples from locally diagnosed COVID-19 cases were to be sent to the central laboratory for confirmatory testing. Molecular confirmation of SARS-CoV-2 infection (using the Abbott Real Time SARS-CoV-2 RT-PCR assay) by the central laboratory was required to meet the co-primary and secondary efficacy endpoint case definitions.

The co-primary endpoints were efficacy of a single dose of vaccine to prevent centrally confirmed, moderate to severe/critical COVID-19 occurring (1) at least 14 days after vaccination and (2) at least 28 days after vaccination in study participants without evidence of prior SARS-CoV-2 infection at baseline. Evaluation of the co-primary endpoints was triggered by prespecified criteria:

1. The first 50% of participants have at least 2 months of follow-up after vaccination
2. At least 42 moderate to severe/critical cases of COVID-19 with onset at least 28 days after vaccination

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3. At least 6 cases of COVID-19 among participants ≥60 years of age (onset ≥28 days after vaccination)
4. At least 5 severe/critical cases of COVID-19 in the placebo group (onset ≥28 days after vaccination) with a favorable vaccine-to-placebo split for both co-primary endpoints.

The protocol-specified "final analysis" will be performed when the last participant completes the visit 12 months post-vaccination or discontinues earlier. The end-of-study analysis will be performed when all participants have completed the visit 24 months post-vaccination or discontinued earlier. The expected duration of study participation is approximately 25 months.

Case Definitions

The case definition for moderate COVID-19 was a SARS-CoV-2 positive RT-PCR or molecular test result from any available respiratory tract sample (e.g., nasal, throat, sputum, saliva) or other sample, **and** at any time during the course of observation:

Any 1 of the following new or worsening signs or symptoms:

- Respiratory rate ≥20 breaths/minute
- Abnormal saturation of oxygen (SpO_2) but still >93% on room air at sea level
- Clinical or radiologic evidence of pneumonia
- Radiologic evidence of deep vein thrombosis
- Shortness of breath or difficulty breathing

OR

Any 2 of the following new or worsening signs or symptoms:

- Fever (≥38.0°C or ≥100.4°F)
- Heart rate ≥90 beats/minute
- Shaking chills or rigors
- Sore throat
- Cough
- Malaise as evidenced by loss of appetite, fatigue, physical weakness, and/or feeling unwell
- Headache
- Muscle pain (myalgia)
- Gastrointestinal symptoms (diarrhea, vomiting, nausea, abdominal pain)
- New or changing olfactory or taste disorders
- Red or bruised looking feet or toes

The case definition for severe/critical COVID-19 was a RT-PCR or molecular test result from samples described above **and** any one of the following at any time during the course of observation:

- Clinical signs at rest indicative of severe systemic illness (respiratory rate ≥30 breaths/minute, heart rate ≥125 beats/minute, oxygen saturation (SpO_2) ≤93% on room air at sea level, or partial pressure of oxygen/fraction of inspired oxygen (PaO_2/FiO_2) <300 mmHg)
- Respiratory failure (defined as needing high-flow oxygen, non-invasive ventilation, mechanical ventilation, or extracorporeal membrane oxygenation [ECMO])
- Evidence of shock (defined as systolic blood pressure <90 mmHg, diastolic blood pressure <60 mmHg, or requiring vasopressors)
- Significant acute renal, hepatic, or neurologic dysfunction
- Admission to the ICU
- Death

All cases meeting the severe/critical criteria were adjudicated by a blinded clinical severity adjudication committee to determine if the case was severe/critical in their judgement.

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Additionally, all cases meeting the moderate case definition and that included >3 signs and/or symptoms from the list of signs and symptoms were evaluated by the clinical severity adjudication committee to determine if the case was severe/critical in their judgement.

Primary Efficacy Endpoint

The originally specified primary endpoint was efficacy of the vaccine to prevent centrally confirmed, moderate to severe/critical COVID-19 occurring at least 14 days post-vaccination in SARS-CoV-2 seronegative adults (with "seronegative" defined as negative RT-PCR and negative serology against SARS-CoV-2 nucleocapsid on Day 1). Study protocol amendment 3 (December 14, 2020) added a co-primary endpoint counting COVID-19 cases from 28 days post-vaccination.

The primary analysis was based on the per-protocol set defined as those participants in the full analysis set (FAS) who received study vaccine, were seronegative at the time of vaccination, and had no major protocol deviations that were judged to possibly impact the efficacy of the vaccine.

A successful primary efficacy conclusion required two conditions:

1. Rejecting the null hypothesis H_0: VE ≤30% for each co-primary endpoint at a 2.5% one-sided significance level and a VE point estimate ≥50% for each co-primary endpoint;

   and

2. A favorable split vaccine:placebo for the subset of primary endpoints meeting the severe/critical COVID-19 case definition (expressed as a VE point estimate against severe/critical COVID-19 molecularly confirmed endpoints ≥50%) and a minimum of 5 events in the placebo group. This requirement needed to be met for severe/critical events with onset at least 14 days after vaccination and 28 days after vaccination.

Both conditions 1 and 2 simultaneously had to be met for both co-primary endpoints at the same calendar timepoint. Exact Poisson regression was used to estimate VE and associated confidence intervals taking into account the follow-up time.

Secondary Efficacy Endpoints

Secondary endpoints included vaccine efficacy to prevent or vaccine impact on:

- Severe/critical COVID-19
- COVID-19 requiring medical intervention
- COVID-19-related death
- Any symptomatic COVID-19
- Asymptomatic COVID-19 as inferred through seroconversion
- COVID-19 per the FDA harmonized COVID-19 case definition

Vaccine efficacy of selected secondary endpoints was evaluated against a null hypothesis employing a lower limit VE >0% once hypothesis testing met the respective success criteria and data requirements for both co-primary endpoints. The case definition for mild COVID-19 (included in any symptomatic disease) and the FDA harmonized COVID-19 case definition may be found in Appendix B, page 62.

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Evaluation of Safety

In Study 3001, the safety objective was evaluation of the safety of Ad26.COV2.S following vaccination. In a subset of participants (n=6736), local and systemic reactions were recorded from for 7 days following vaccination, and unsolicited AEs were collected from vaccination to day 28 after vaccination. In all participants, medically attended adverse events (MAAEs) were collected from vaccination to 6 months after vaccination, and MAAEs leading to study discontinuation and serious AEs (SAEs) were collected from vaccination to the end of the study.

Safety assessments included the following:

- Solicited local and systemic adverse reactions (ARs) that occurred during the 7 days following vaccination. Solicited ARs were recorded daily using eDiaries
- Unsolicited AEs observed or reported during the 28 days following vaccination. Unsolicited AEs are those not included in the protocol-defined solicited ARs
- Medically attended adverse events (MAAEs) from Day 1 through 6 months after vaccination
- MAAEs leading to discontinuation from study participation from Day 1 through 104 weeks following vaccinations
- SAEs from Day 1 through 104 weeks following vaccination or withdrawal from the study
- Vital sign measurements
- Physical examination findings
- Pregnancy and accompanying outcomes

AEs, including SAEs, associated with molecularly confirmed SARS-CoV-2 infection were removed from the analysis of adverse events.

Monitoring for risk of vaccine-enhanced disease was performed by an unblinded team supporting the Data Monitoring Committee that reviewed cases of severe COVID-19 as they were received and reviewed AEs at least weekly for additional potential cases of severe COVID-19. A stopping rule would be triggered if the 1-sided probability of observing the same or a more extreme case split was 5% or less when the true incidence of severe disease was the same for vaccine and placebo participants.

Analysis Populations

For the purposes of analysis, the following populations are defined:

Table 2. Analysis Populations

Population	Description
Randomized	All participants who are randomized, regardless of the treatment status during the study.
Full analysis set	All randomized participants with a documented study vaccine administration. The FAS was used for all analyses of safety except solicited adverse reactions.
Per-protocol set	All participants in the FAS who had no immunologic or virologic evidence of prior COVID-19 at the time of vaccination and no major protocol deviations that were judged to possibly impact the efficacy of the vaccine.
Safety Subset	Subset of the full analysis set for the analysis of solicited and unsolicited AEs.

5.2.2 FDA Assessment of Phase 3 Follow-Up Duration

At the time of the primary analysis, the median follow-up duration for participants in the efficacy and safety analysis populations was 8 weeks after vaccination, which FDA considers to be

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equivalent to 2 months and which meets the FDA expectation for follow-up after completion of the full vaccination regimen. Phased enrollment by age group and comorbidity risk resulted in slight differences in follow-up time between participants in these groups, with an approximately 2-week difference in the median follow up time between the first group enrolled (18-59 without comorbidities) and last group enrolled (60 years and older with comorbidities). Table 3 shows the median follow-up time by age and comorbidities in the FAS. Follow-up time in the per-protocol set is similar (data not shown).

Table 3. Participant Disposition by Age Group and Comorbidities, Full Analysis Set, Study 3001

Participant Group Follow-up	Ad26.COV2.S N=21895	Placebo N=21888	All Participants N=43783
18-59 overall	14564	14547	29111
Participants with at least 8 weeks follow-up	62.8%	63.1%	63.0%
Median follow-up after vaccination in days	61.0	61.0	61.0
18-59, no comorbidities	9332	9371	18703
Participants with at least 8 weeks follow-up	70.0%	69.9%	70.0%
Median follow-up after vaccination in days	64.0	64.0	64.0
18-59, with comorbidities	5232	5176	10408
Participants with at least 8 weeks follow-up	49.9%	50.8%	50.4%
Median follow-up after vaccination in days	56.0	57.0	57.0
≥60 years overall	7331	7341	14672
Participants with at least 8 weeks follow-up	38.2%	37.8%	38.0%
Median follow-up after vaccination in days	52.0	52.0	52.0
≥60 years, no comorbidities	3627	3595	7222
Participants with at least 8 weeks follow-up	47.6%	49.0%	48.3%
Median follow-up after vaccination in days	54.0	55.0	54.0
≥60 years, with comorbidities	3704	3746	7450
Participants with at least 8 weeks follow-up	29.0%	27.1%	28.0%
Median follow-up after vaccination in days	50.0	50.0	50.0

Source:Sponsor table TSIDS08

5.2.3 Participant Disposition and Inclusion in Analysis Populations

The tables below show the disposition of participants in the efficacy analysis population (Table 4) and safety analysis population (Table 5). The proportions of participants excluded from the

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per-protocol set were balanced between treatment groups, with the majority of those excluded due to positive baseline SARS-CoV-2 status. Overall, few participants were discontinued or lost to follow-up, and these and other analysis population exclusions were generally balanced between treatment groups. In the per-protocol set, 54.6% of vaccine recipients and 54.7% of placebo recipients completed at least 8 weeks follow-up after vaccination. As of the data cutoff date, 5.3% of participants in the vaccine group and 5.8% of participants in the placebo group in the per-protocol set were unblinded by request after they became eligible to receive an authorized COVID-19 vaccine under EUA. A slightly greater proportion of participants ≥60 years of age were unblinded (6.6%) compared to those 18 to 59 years of age (4.4%). The vast majority (93.0%) of participants who were unblinded were from US study sites. These participants were included in the per-protocol set until the time of the unblinding.

Table 4. Disposition[a], Efficacy Analysis Population, Study 3001

Disposition	Ad26.COV2.S n (%)	Placebo n (%)	Total n (%)
Randomized	22174	22151	44325
Vaccinated[a]	21895	21888	43783
Full analysis set	21895 (100.0)	21888 (100.0)	43783 (100.0)
Participants excluded from per-protocol set	2265 (10.3)	2197 (10.0)	4462 (10.2)
Positive SARS-CoV-2 status at time of vaccination based on serology and/or PCR	2233 (10.2)	2166 (9.9)	4399 (10.0)
Major protocol deviation evaluated to possibly impact efficacy	33 (0.2)	36 (0.2)	69 (0.2)
In/exclusion criteria	18 (0.1)	23 (0.1)	41 (0.1)
Received wrong treatment or incorrect dose	9 (<0.1)	11 (0.1)	20 (<0.1)
Received a disallowed concomitant medication	2 (<0.1)	2 (<0.1)	4 (<0.1)
Other	4 (<0.1)	1 (<0.1)	5 (<0.1)
Per-protocol set	19630 (89.7)	19691 (90.0)	39321 (89.8)
Participants with at least 8 weeks follow-up[b]	10715 (54.6)	10776 (54.7)	21491 (54.7)
Discontinued from study[b]	41 (0.2)	89 (0.5)	130 (0.3)
Reason for discontinuation[b]			
Withdrawal by participant	30 (0.2)	62 (0.3)	92 (0.2)
Death	1 (<0.1)	11 (0.1)	12 (<0.1)
Lost to follow-up	6 (<0.1)	4 (<0.1)	10 (<0.1)
Physician decision	2 (<0.1)	1 (<0.1)	3 (<0.1)
Protocol deviation	0	1 (<0.1)	1 (<0.1)
Other	2 (<0.1)	10 (0.1)	12 (<0.1)
Participants included in per-protocol set until treatment unblinding[b]	1046 (5.3)	1138 (5.8)	2184 (5.6)

Source: Sponsor table TSIDS02_A
[a] These values are denominators for the percentage calculations
[b] Based on the per protocol set

The table below summarizes the disposition of the safety analysis population. In the FAS, 54.6% of participants completed at least 8 weeks follow-up. The proportion of participants who discontinued from the study was 0.3% (n=145) across study groups, with a greater number in the placebo group (n=96) compared with the vaccine group (n=49). The most frequently

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reported reason was withdrawal by participant. In the safety subset, almost all (99.9%) participants completed assessments through 29 days post-vaccination. As of the data cutoff date of January 22, 2021, in the FAS, 4.9% of participants in the vaccine group and 5.4% of participants in the placebo group were unblinded due to request by participant after the participant became eligible to receive an authorized COVID-19 vaccine under EUA.

Table 5. Disposition, Safety Analysis Population, Study 3001

Disposition	Ad26.COV2.S n (%)	Placebo n (%)	Total n (%)
Randomized	22174	22151	44325
Vaccinated[a]	21895	21888	43783
Vaccinated with incorrect vaccine	6	5	11
Full analysis set	21895 (100.0)	21888 (100.0)	43783 (100.0)
Participants with at least 8 weeks follow-up	11948 (54.6)	11955 (54.6)	23903 (54.6)
Participants unblinded to treatment	1080 (4.9)	1177 (5.4)	2257 (5.2)
Discontinued from study	49 (0.2%)	96 (0.4%)	145 (0.3)
Reason for discontinuation			
Withdrawal by participant	35 (0.2)	66 (0.3)	101 (0.2)
Death	2 (<0.1)	12 (0.1)	14 (<0.1)
Lost to follow-up	6 (<0.1)	5 (<0.1)	11 (<0.1)
Physician decision	2 (<0.1)	1 (<0.1)	3 (<0.1)
Protocol deviation	0	1 (<0.1)	1 (<0.1)
Other	4 (<0.1)	11 (0.1)	15 (<0.1)
Safety subset	3356 (15.3)	3380 (15.4)	6736 (15.4)
Completed post-vaccination (Day 1-29)[b]	3354 (99.9)	3376 (99.9)	6730 (99.9)

[a] These values are denominators for the percentage calculations
[b] Percentage based on Safety subset

5.2.4 Demographics and Other Baseline Characteristics

In the per-protocol set, 44.5% of participants were female and 20.4% were ≥65 years of age. Overall, 62.1% of participants were white, 17.2% Black or African American, 8.3% American Indian or Alaska Native, 3.5% Asian, 0.3% Native Hawaiian or other Pacific Islander, and 5.4% multiracial; 45.1% of participants were Hispanic/Latino. At least one comorbidity was present for 39.9% of participants. Geographically, 46.7% of subjects participated in the United States, 17.3% in Brazil, 12.7% in South Africa, and the remaining 23.3% in 5 different countries in Latin America. Baseline demographics in US participants included in the study were similar to that of the global demographics, with the exception of lower percentages of subjects who were American Indian or Alaska Native (1.0%) and subjects who identified as Hispanic or Latino (14.2%). There was a similar distribution of demographic characteristics between the treatment groups.

Table 6. Demographic Characteristics, Per-Protocol Set, Study 3001

Subgroup	Ad26.COV2.S	Placebo	All Participants
Per-protocol set	**19630**	**19691**	**39321**
Age (years)			
Mean (SD)	51.1 (15.0)	51.2 (15.0)	51.1 (15.0)
Median	52.0	53.0	53.0
Range	(18, 100)	(18, 94)	(18, 100)

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Subgroup	Ad26.COV2.S	Placebo	All Participants
Per-protocol set	**19630**	**19691**	**39321**
Age group (years)			
18-59	12830 (65.4%)	12881 (65.4%)	25711 (65.4%)
≥60	6800 (34.6%)	6810 (34.6%)	13610 (34.6%)
≥65	3984 (20.3%)	4018 (20.4%)	8002 (20.4%)
≥75	755 (3.8%)	693 (3.5%)	1448 (3.7%)
Sex			
Female	8702 (44.3%)	8777 (44.6%)	17479 (44.5%)
Male	10924 (55.6%)	10910 (55.4%)	21834 (55.5%)
Undifferentiated	2 (<0.1%)	4 (<0.1%)	6 (<0.1%)
Unknown	2 (<0.1%)	0	2 (<0.1%)
Race			
American Indian or Alaska Native	1643 (8.4%)	1628 (8.3%)	3271 (8.3%)
Asian	720 (3.7%)	663 (3.4%)	1383 (3.5%)
Black or African American	3374 (17.2%)	3390 (17.2%)	6764 (17.2%)
Native Hawaiian or other Pacific Islander	54 (0.3%)	45 (0.2%)	99 (0.3%)
White	12200 (62.1%)	12216 (62.0%)	24416 (62.1%)
Multiple	1036 (5.3%)	1087 (5.5%)	2123 (5.4%)
Unknown	603 (3.1%)	662 (3.4%)	1265 (3.2%)
Ethnicity			
Hispanic or Latino	8793 (44.8%)	8936 (45.4%)	17729 (45.1%)
Not Hispanic or Latino	10344 (52.7%)	10259 (52.1%)	20603 (52.4%)
Unknown	493 (2.5%)	496 (2.5%)	989 (2.5%)
Region and Country			
Latin America	7967 (40.6%)	8014 (40.7%)	15981 (40.6%)
Brazil	3399 (17.3%)	3390 (17.2%)	6789 (17.3%)
Chile	531 (2.7%)	540 (2.7%)	1071 (2.7%)
Argentina	1402 (7.1%)	1414 (7.2%)	2816 (7.2%)
Colombia	1858 (9.5%)	1869 (9.5%)	3727 (9.5%)
Peru	571 (2.9%)	581 (3.0%)	1152 (2.9%)
Mexico	206 (1.0%)	220 (1.1%)	426 (1.1%)
Northern America	9185 (46.8%)	9171 (46.6%)	18356 (46.7%)
United States	9185 (46.8%)	9171 (46.6%)	18356 (46.7%)
Southern Africa	2478 (12.6%)	2506 (12.7%)	4984 (12.7%)
South Africa	2478 (12.6%)	2506 (12.7%)	4984 (12.7%)
Presence of baseline comorbidity			
One or more	7830 (39.9%)	7867 (40.0%)	15697 (39.9%)
None	11800 (60.1%)	11824 (60.0%)	23624 (60.1%)

Source: Sponsor table TSIDEM01_A

The demographic characteristics among vaccine and placebo participants in the FAS were similar. There were no significant imbalances in demographic or other baseline characteristics between the per-protocol set and FAS. Overall, 9.6% of vaccinated participants in the study had evidence of previous infection with SARS-CoV-2 at baseline, as assessed by serology prior to vaccination.

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Table 7. Demographic Characteristics, Full Analysis Set, Study 3001

Subgroup	Ad26.COV2.S	Placebo	All Participants
Full analysis set	**21895**	**21888**	**43783**
Age (years)			
Mean (SD)	50.7 (15.1)	50.7 (15.0)	50.7 (15.1)
Median	52.0	52.0	52.0
Range	(18, 100)	(18, 94)	(18, 100)
Age group			
18-59	14564 (66.5%)	14547 (66.5%)	29111 (66.5%)
≥60	7331 (33.5%)	7341 (33.5%)	14672 (33.5%)
≥65	4259 (19.5%)	4302 (19.7%)	8561 (19.6%)
≥75	809 (3.7%)	732 (3.3%)	1541 (3.5%)
Sex			
Female	9820 (44.9%)	9902 (45.2%)	19722 (45.0%)
Male	12071 (55.1%)	11982 (54.7%)	24053 (54.9%)
Undifferentiated	2 (<0.1%)	4 (<0.1%)	6 (<0.1%)
Unknown	2 (<0.1%)	0	2 (<0.1%)
Race			
American Indian or Alaska Native	2083 (9.5%)	2060 (9.4%)	4143 (9.5%)
Asian	743 (3.4%)	687 (3.1%)	1430 (3.3%)
Black or African American	4251 (19.4%)	4264 (19.5%)	8515 (19.4%)
Native Hawaiian or other Pacific Islander	58 (0.3%)	48 (0.2%)	106 (0.2%)
White	12858 (58.7%)	12838 (58.7%)	25696 (58.7%)
Multiple	1204 (5.5%)	1245 (5.7%)	2449 (5.6%)
Unknown	308 (1.4%)	315 (1.4%)	623 (1.4%)
Ethnicity			
Hispanic or Latino	9874 (45.1%)	9963 (45.5%)	19837 (45.3%)
Not Hispanic or Latino	11472 (52.4%)	11362 (51.9%)	22834 (52.2%)
Unknown	197 (0.9%)	199 (0.9%)	396 (0.9%)
Region and country			
Latin America	8954 (40.9%)	8951 (40.9%)	17905 (40.9%)
Argentina	1498 (6.8%)	1498 (6.8%)	2996 (6.8%)
Brazil	3644 (16.6%)	3634 (16.6%)	7278 (16.6%)
Chile	563 (2.6%)	570 (2.6%)	1133 (2.6%)
Colombia	2125 (9.7%)	2123 (9.7%)	4248 (9.7%)
Mexico	238 (1.1%)	241 (1.1%)	479 (1.1%)
Peru	886 (4.0%)	885 (4.0%)	1771 (4.0%)
Northern America	9655 (44.1%)	9647 (44.1%)	19302 (44.1%)
United States	9655 (44.1%)	9647 (44.1%)	19302 (44.1%)
Southern Africa	3286 (15.0%)	3290 (15.0%)	6576 (15.0%)
South Africa	3286 (15.0%)	3290 (15.0%)	6576 (15.0%)
SARS-CoV-2 serostatus status at baseline			
Positive	2151 (9.8%)	2066 (9.4%)	4217 (9.6%)
Negative	19104 (87.3%)	19191 (87.7%)	38295 (87.5%)
Missing	640 (2.9%)	631 (2.9%)	1271 (2.9%)
Presence of baseline comorbidity			
One or more	8936 (40.8%)	8922 (40.8%)	17858 (40.8%)
None	12959 (59.2%)	12966 (59.2%)	25925 (59.2%)

Source: Sponsor table TSIDEM01_B

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The following table provides the proportions of participants with one or more comorbidities associated with an increased risk of progression to severe COVID-19. In the FAS, 40.8% of participants had one or more comorbidities at baseline. The most common comorbidities were obesity (28.5%) and hypertension (10.3%). The study also included participants who were HIV positive (2.8%). The proportions of individuals with comorbidities were similar between the vaccine and placebo groups and between the FAS and per-protocol set.

Table 8. Participants With Comorbidities, Full Analysis Set, Study 3001

Baseline Comorbidity Category	Ad26.COV2.S (N=21895) n (%)	Placebo (N=21888) n (%)	Total (N=43783) n (%)
No comorbidity	12959 (59.2)	12966 (59.2)	25925 (59.2)
With one or more comorbidity	8936 (40.8)	8922 (40.8)	17858 (40.8)
Asthma	262 (1.2)	300 (1.4)	562 (1.3)
Cancer	112 (0.5)	114 (0.5)	226 (0.5)
Cerebrovascular disease	78 (0.4)	80 (0.4)	158 (0.4)
Cystic fibrosis	1 (<0.1)	3 (<0.1)	4 (<0.1)
Chronic kidney disease	112 (0.5)	118 (0.5)	230 (0.5)
COPD	231 (1.1)	206 (0.9)	437 (1.0)
Serious heart conditions	497 (2.3)	511 (2.3)	1008 (2.3)
HIV infection[a]	601 (2.7)	617 (2.8)	1218 (2.8)
Hypertension[b]	2225 (10.2)	2296 (10.5)	4521 (10.3)
Immunocompromised state from blood transplant	43 (0.2)	36 (0.2)	79 (0.2)
Immunocompromised state from organ transplant	7 (<0.1)	3 (<0.1)	10 (<0.1)
Liver disease	103 (0.5)	103 (0.5)	206 (0.5)
Neurologic conditions	82 (0.4)	125 (0.6)	207 (0.5)
Obesity[c]	6277 (28.7)	6215 (28.4)	12492 (28.5)
Pulmonary fibrosis	10 (<0.1)	9 (<0.1)	19 (<0.1)
Sickle cell disease	13 (0.1)	5 (<0.1)	18 (<0.1)
Type 1 diabetes mellitus	105 (0.5)	90 (0.4)	195 (0.4)
Type 2 diabetes mellitus	1600 (7.3)	1594 (7.3)	3194 (7.3)
Thalassemia	16 (0.1)	30 (0.1)	46 (0.1)

Source: Sponsor table TSIDEM01_B
[a] HIV status not collected for participants with no-comorbidities and no medical history of HIV
[b] >150 mm Hg systolic and/or >95 mm Hg diastolic
[c] body mass index >30 kg/m^2

Subjects in the safety subset were enrolled from 45 sites in 3 Tier 1 countries (US, Brazil and South Africa). The Tier 1 countries were selected based on rapid start-up capacity and projected incidence rates for COVID-19 that would allow for rapid efficacy signal detection. At the site level, investigators questioned participants on their willingness to be part of the safety subset. Selection and randomization of the participants was then completed through a web-based randomization system. In safety subset, 48.3% of participants were female, and 23.0% were ≥65 years of age, which is similar to the FAS. A larger percentage of participants in the safety subset were white (83.4%) compared to the FAS (58.7%). Geographically, the safety subset was limited to participants in the United States (51.4%), South Africa (10.2%), and Brazil (38.5%). Fewer participants in the safety subset compared to the FAS were seropositive at baseline (4.5% versus 9.6%) and had a least one comorbidity (34.1% versus 40.8%).

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Table 9. Demographic Characteristics, Safety Subset, Study 3001

Subgroup	Ad26.COV2.S	Placebo	Total
Safety Subset	**3356**	**3380**	**6736**
Age (years)			
Mean (SD)	51.4 (15.9)	51.1 (16.1)	51.2 (16.0)
Median	54.0	54.0	54.0
Range	(18, 90)	(18, 91)	(18, 91)
Age group (years)			
18-59	2036 (60.7%)	2049 (60.6%)	4085 (60.6%)
≥60	1320 (39.3%)	1331 (39.4%)	2651 (39.4%)
≥65	763 (22.7%)	786 (23.3%)	1549 (23.0%)
≥75	150 (4.5%)	138 (4.1%)	288 (4.3%)
Sex			
Female	1637 (48.8%)	1615 (47.8%)	3252 (48.3%)
Male	1719 (51.2%)	1765 (52.2%)	3484 (51.7%)
Undifferentiated	0	0	0
Unknown	0	0	0
Race			
American Indian or Alaska Native	9 (0.3%)	9 (0.3%)	18 (0.3%)
Asian	114 (3.4%)	105 (3.1%)	219 (3.3%)
Black or African American	267 (8.0%)	260 (7.7%)	527 (7.8%)
Native Hawaiian or other Pacific Islander	9 (0.3%)	10 (0.3%)	19 (0.3%)
White	2798 (83.4%)	2823 (83.5%)	5621 (83.4%)
Multiple	97 (2.9%)	112 (3.3%)	209 (3.1%)
Unknown	20 (0.6%)	17 (0.5%)	37 (0.5%)
Ethnicity			
Hispanic or Latino	1284 (38.3%)	1287 (38.1%)	2571 (38.2%)
Not Hispanic or Latino	2024 (60.3%)	2038 (60.3%)	4062 (60.3%)
Unknown	12 (0.4%)	14 (0.4%)	26 (0.4%)
Region and country			
Latin America	1291 (38.5%)	1299 (38.4%)	2590 (38.5%)
Argentina	0	0	0
Brazil	1291 (38.5%)	1299 (38.4%)	2590 (38.5%)
Chile	0	0	0
Colombia	0	0	0
Mexico	0	0	0
Peru	0	0	0
Northern America	1727 (51.5%)	1735 (51.3%)	3462 (51.4%)
United States	1727 (51.5%)	1735 (51.3%)	3462 (51.4%)
Southern Africa	338 (10.1%)	346 (10.2%)	684 (10.2%)
South Africa	338 (10.1%)	346 (10.2%)	684 (10.2%)
SARS-CoV-2 serostatus status at baseline			
Positive	154 (4.6%)	147 (4.3%)	301 (4.5%)
Negative	3117 (92.9%)	3129 (92.6%)	6246 (92.7%)
Missing	85 (2.5%)	104 (3.1%)	189 (2.8%)
Presence of baseline comorbidity			
One or more	1135 (33.8%)	1164 (34.4%)	2299 (34.1%)
None	2221 (66.2%)	2216 (65.6%)	4437 (65.9%)

Source: Sponsor table TSIDEM01_D

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5.2.5 Vaccine Efficacy

Primary Efficacy Analysis

The primary efficacy analysis was based on the per-protocol set, which consisted of all vaccinated participants who were SARS-CoV-2 seronegative at time of vaccination and who had no major protocol deviations. The co-primary efficacy endpoints were vaccine efficacy (VE) in preventing protocol-defined moderate to severe/critical COVID-19, confirmed by the central laboratory, occurring at least 14 days and at least 28 days after vaccination, respectively. The primary efficacy success criterion would be met if the null hypothesis of VE ≤30% is rejected and the VE point estimate is ≥50% for both co-primary endpoints at the primary analysis. As shown in Table 10, in participants ≥18 years of age, VE against moderate to severe/critical COVID-19 with onset at least 14 days after vaccination was 66.9% (a lower bound of the 95% CI of 59.03), and VE against moderate to severe/critical COVID-19 with onset at least 28 days after vaccination was 66.1% (a lower bound of 95% CI of 55.01), which together met the pre-specified success criteria. Vaccine efficacy was similar between the two age groups of participants 18 to 59 and ≥60 years of age.

Table 10. Vaccine Efficacy Against Centrally Confirmed Moderate to Severe/Critical COVID-19 With Onset at Least 14 and at Least 28 Days After Vaccination, Per-Protocol Set, Study 3001

	Onset at Least 14 Days			Onset at Least 28 Days		
Co-primary Endpoint Subgroup	**Ad26.COV2.S Cases (N)[a] Person-yrs[b]**	**Placebo Cases (N) Person-yrs**	**VE% (95% CI)**	**Ad26.COV2.S Cases (N) Person-yrs**	**Placebo Cases (N) Person-yrs**	**VE% (95% CI)**
All participants	116 (19514) 3116.6	348 (19544) 3096.1	66.9% (59.0, 73.4)	66 (19306) 3102.0	193 (19178) 3070.7	66.1% (55.0, 74.8)
Age 18-59 years	95 (12750) 2106.8	260 (12782) 2095.0	63.7% (53.9, 71.6)	52 (12617) 2097.6	152 (12527) 2077.0	66.1% (53.3, 75.8)
Age ≥60 years	21 (6764) 1009.8	88 (6762) 1001.2	76.3% (61.6, 86.0)	14 (6689) 1004.4	41(6651) 993.6	66.2% (36.7, 83.0)

Source: Sponsor tables GEFPE02_A and GEFPE02_C
[a] N=Total number of participants at risk per category
[b] Person-years include time from vaccination to the onset of moderate to severe/critical COVID-19, discontinuation from study, major protocol deviation, unblinding to receive alternative vaccine, or data cutoff, whichever comes first.

Due to the high incidence rate of COVID-19 during the study, not all positive PCR tests had been confirmed by the central laboratory at the time of data cutoff. Of 682 primary endpoint cases with positive PCR from any lab accrued at the time of the data cutoff date, 464 were centrally confirmed. The statistical analysis plan specified that the primary and secondary endpoints would be based on centrally confirmed COVID-19, and thus only centrally confirmed cases were included in analyses of vaccine efficacy. For the subgroup analyses for the primary and secondary endpoints, positive PCR results from any source were used to increase the number of cases and the precision of the estimate. At the time of the data cutoff, there was high concordance between all local and central laboratory PCR results (90.3%). Evaluation of the primary efficacy endpoint including non-centrally-confirmed cases yielded results similar to those reported above (66.3% and 65.5% for onset at least 14 days and at least 28 days after vaccination, respectively). On February 12, the Sponsor submitted an update on centrally confirmed cases as an amendment to the EUA request; based on cases accrued by the time of the data cutoff and analyzed by the central laboratory by February 8, 582 primary endpoint cases were centrally confirmed. Vaccine efficacy based on this updated dataset was similar to that reported above (67.4% and 66.2% for onset at least 14 days and at least 28 days after vaccination, respectively). The high rate of concordance between local and central lab PCR tests and similar co-primary analysis results regardless of inclusion or exclusion of non-centrally

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confirmed cases support the inclusion of cases awaiting central laboratory confirmation in subgroup analyses to increase their robustness and improve interpretability.

The demographics of participants with moderate to severe/critical COVID-19, including non-centrally confirmed cases, with onset at least 14 days after vaccination are displayed below. The majority of COVID-19 cases were among participants in the United States, South Africa, and Brazil. Study participants with comorbidities were not over-represented among COVID-19 cases as compared to the overall study population.

Table 11. Demographic Characteristics of Participants With Moderate to Severe/Critical COVID-19, Including Non-centrally Confirmed Cases, With Onset at Least 14 days After Vaccination, Per-Protocol Set

Subgroup	Ad26.COV2.S N (%)	Placebo N (%)	All Participants N (%)
All participants	**173**	**509**	**682**
Age group (years)			
18-59	137 (79.2%)	389 (76.4%)	526 (77.1%)
≥60	36 (20.8%)	120 (23.6%)	156 (22.9%)
Sex			
Female	88 (50.9%)	240 (47.2%)	328 (48.1%)
Male	85 (49.1%)	269 (52.9%)	354 (51.9%)
Race			
American Indian or Alaska Native	21 (12.1%)	41 (8.1%)	62 (9.1%)
Asian	6 (3.5%)	12 (2.4%)	18 (2.6%)
Black or African American	37 (21.4%)	101 (19.8%)	138 (20.2%)
Native Hawaiian or other Pacific Islander	1 (0.6%)	0 (0.0%)	1 (0.2%)
White	94 (54.3%)	288 (56.6%)	382 (56.0%)
Multiple	10 (5.8%)	48 (9.4%)	58 (8.5%)
Unknown/ not reported	4 (2.3%)	19 (3.7%)	23 (3.4%)
Ethnicity			
Hispanic or Latino	81 (46.8%)	237 (46.6%)	318 (46.6%)
Not Hispanic or Latino	88 (50.9%)	257 (50.5%)	345 (50.6%)
Unknown/ not reported	4 (2.3%)	15 (3.0%)	19 (2.8%)
Country			
United States	51 (29.5%)	196 (38.5%)	247 (36.2%)
South Africa	43 (24.9%)	90 (17.7%)	133 (19.5%)
Brazil	39 (22.5%)	114 (22.4%)	153 (22.4%)
Colombia	22 (12.7%)	62 (12.2%)	84 (12.3%)
Argentina	8 (4.6%)	30 (5.9%)	38 (5.6%)
Peru	7 (4.1%)	13 (2.6%)	20 (2.9%)
Chile	2 (1.2%)	4 (0.8%)	6 (0.9%)
Mexico	1 (0.6%)	0 (0.0%)	1 (0.2%)

Obtained via FOIA by Judicial Watch, Inc.

Subgroup	Ad26.COV2.S N (%)	Placebo N (%)	All Participants N (%)
All participants	**173**	**509**	**682**
Presence of baseline comorbidity			
None	103 (59.5%)	315 (61. 9%)	418 (61.3%)
One or more	70 (40.5%)	194 (38.1%)	264 (38.7%)
Obesity	51 (29.5%)	151 (29.7%)	202 (29.6%)
Hypertension	14 (8.1%)	38 (7.5%)	52 (7.6%)
Type 2 diabetes mellitus	15 (8.7%)	32 (6.3%)	47 (6.9%)
Serious heart condition	3 (1.7%)	13 (2.6%)	16 (2.4%)
Asthma	1 (0.6%)	9 (1.8%)	10 (1.5%)
HIV infection	5 (2.9%)	5 (1.0%)	10 (1.5%)
COPD	1 (0.6%)	5 (1.0%)	6 (0.9%)
Liver disease	1 (0.6%)	2 (0.4%)	3 (0.4%)
Cancer	0 (0.0%)	2 (0.4%)	2 (0.3%)
Immunocompromised from blood transplant	2 (1.2%)	0 (0.0%)	2 (0.3%)
Neurologic conditions	0 (0.0%)	1 (0.2%)	1 (0.2%)

Source: Sponsor response to IR 17

Subgroup Analyses of Vaccine Efficacy

Subgroup analyses for the co-primary efficacy endpoints provide additional information on the applicability of these results across the general population. For the subgroup analyses, cases with any positive PCR, including those still awaiting confirmation by the central laboratory, were included. In general, VE among the subgroups are similar to the VE in the overall study population. The VE results for subgroups with small numbers of participants (e.g., participants ≥75 years of age, certain racial subgroups) have limited interpretability but are displayed for completeness.

Table 12. Vaccine Efficacy of First Occurrence of Moderate to Severe/Critical COVID-19, Including Non-centrally Confirmed Cases, With Onset at Least 14 or at Least 28 Days After Vaccination, by Demographic Characteristics, Per-Protocol Set, Study 3001

	Onset at Least 14 Days			Onset at Least 28 Days		
Subgroup	Ad26.COV2.S Cases (N) Person-yrs	Placebo Cases (N) Person-yrs	VE%[a] (95% CI)	Ad26.COV2.S Cases (N) Person-yrs	Placebo Cases (N) Person-yrs	VE%[a] (95% CI)
Sex						
Male	85 (10861) 1739.0	269 (10832) 1715.9	68.8% (60.1, 75.9)	54 (10764) 1732.4	176 (10649) 1704.2	69.8% (58.9, 78.2)
Female	88 (8649) 1374.2	240 (8708) 1372.6	63.4% (53.1, 71.7)	59 (8538) 1367.1	148 (8525) 1361.1	60.3% (46.0, 71.2)
Age group (yrs)						
18-64	157 (15544) 2527.8	441 (15552) 2504.8	64.7% (57.6, 70.8)	101 (15378) 2517.1	286 (15253) 2485.9	65.1% (56.1, 72.5)
≥65	16 (3970) 586.1	68 (3992) 584.3	76.5% (59.1, 87.3)	12 (3928) 583.1	38 (3925) 580.0	68.6% (38.6, 85.1)
≥75	1 (751) 107.3	9 (690) 99.1	89.7% (26.0, 99.8)	0 (740) 106.4	4 (673) 98.0	
Race						
Amer. Indian/ Alaskan	21 (1634) 279.0	41 (1621) 275.4	49.4% (12.4, 71.6)	18 (1628) 278.4	26 (1604) 274.4	31.7% (-29.4, 64.8)

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Subgroup	Onset at Least 14 Days			Onset at Least 28 Days		
	Ad26.COV2.S Cases (N) Person-yrs	Placebo Cases (N) Person-yrs	VE%[a] (95% CI)	Ad26.COV2.S Cases (N) Person-yrs	Placebo Cases (N) Person-yrs	VE%[a] (95% CI)
Asian	6 (714) 99.5	12 (649) 90.6	54.4% (-31.1, 86.0)	2 (689) 97.9	7 (626) 89.1	74.0% (-36.5, 97.4)
Black or African Amer.	37 (3362) 495.7	101 (3361) 491.4	63.7% (46.6, 75.8)	21 (3330) 493.7	66 (3300) 487.3	68.6% (48.0, 81.8)
Native Hawaiian/ Other	1 (54) 8.0	0 (44) 6.6		1 (54) 8.0	0 (43) 6.6	
White	94 (12123) 1975.4	288 (12133) 1958.3	67.6% (59.0, 74.6)	64 (11994) 1967.0	187 (11912) 1944.4	66.2% (54.8, 74.9)
Multiple	10 (1028) 166.6	48 (1080) 170.8	78.6% (57.3, 90.4)	4 (1018) 166.0	28 (1055) 169.2	85.4% (58.4, 96.3)
Ethnicity						
Hispanic/ Latino	81 (8733) 1418.6	237 (8869) 1429.3	65.6% (55.5, 73.6)	59 (8688) 1415.7	153 (8741) 1421.4	61.3% (47.4, 71.8)
Not Hispanic/ Latino	88 (10289) 1620.3	257 (10184) 1587.7	66.4% (57.1, 74.0)	52 (10131) 1610.1	163 (9957) 1573.1	68.8% (57.2, 77.6)
Region						
Northern America (U.S.)	51 (9119) 1414.0	196 (9086) 1391.3	74.4% (65.0, 81.6)	32 (8958) 1403.4	112 (8835) 1375.6	72.0% (58.2, 81.7)
Southern Africa (South Africa)	43 (2473) 377.6	90 (2496) 379.2	52.0% (30.3, 67.4)	23 (2449) 376.1	64 (2463) 376.9	64% (41.2, 78.7)
Latin America	79 (7922) 1322.2	223 (7962) 1318.5	64.7% (54.1, 73.0)	58 (7899) 1320.8	148 (7880) 1313.3	61.0% (46.9, 71.8)

N=Total number of participants at risk per category
[a] If fewer than 6 cases are observed for an endpoint then the VE is not shown.
Source: Sponsor tables GEFPE09A, GEFPE09C

Additional subgroup analyses were conducted to evaluate vaccine efficacy by risk factor for severe COVID-19. Vaccine efficacy against moderate to severe/critical COVID-19 with onset at least 28 days after vaccination was lower for individuals with comorbid conditions than for those without such conditions, especially in the subgroup of participants ≥60 years of age. However, the confidence intervals are wide, and the uncertainty of the point estimate is large, as shown in Table 13. The wide confidence intervals for the ≥28 days endpoint are attributable to lower numbers of cases due to the relatively shorter follow up duration (median of approximately 7 weeks) and with a greater proportion of participants in this subgroup who were unblinded (6.0% compared to 4.4% for 18-59 years cohort overall) due to eligibility for authorized COVID-19 vaccine under EUA, smaller number of participants, and lower incidence of COVID-19 in the cohort of those ≥60 years with comorbidities. For this and several other subgroups, the VE estimate increased and the confidence interval narrowed as the number of cases included in the analysis increased (with inclusion of non-centrally confirmed cases and with cases starting after 14 days), indicating that the apparent lower VE estimates in certain analyses potentially reflect imprecision associated with smaller numbers of cases. For a majority of individual comorbid conditions, interpretation of the results is limited by small sample size and low incidence of

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COVID-19. However, for subgroups with higher incidence of COVID-19, such as participants with obesity, the VE was similar to the VE estimate in the overall study population.

Table 13. Vaccine Efficacy of First Occurrence of Moderate to Severe/Critical COVID-19, Including Non-centrally Confirmed Cases, With Onset at Least 14 or at Least 28 Days After Vaccination, by Risk Factors for Severe COVID-19, Per-Protocol Set, Study 3001

	Onset at Least 14 Days			Onset at Least 28 Days		
Subgroup	Ad26.COV2.S Cases (N) Person-yrs	Placebo Cases (N) Person-yrs	VE%[a] (95% CI)	Ad26.COV2.S Cases (N) Person-yrs	Placebo Cases (N) Person-yrs	VE%[a] (95% CI)
Comorbidity, presence						
Yes	70 (7777) 1138.8	194 (7798) 1130.9	64.2% (52.7, 73.1)	44 (7684) 1133.0	105 (7626) 1120.0	58.6% (40.6, 71.6)
No	103 (11737) 1975.1	315 (11746) 1958.2	67.6% (59.4, 74.3)	69 (11622) 1967.3	219 (11552) 1945.9	68.8% (59.0, 76.6)
Age group and comorbidity presence						
18-59, no	89 (8346) 1433.5	258 (8411) 1428.2	65.6% (56.1, 73.3)	58 (8267) 1428.2	180 (8254) 1418.3	68.0% (56.8, 76.6)
18-59, yes	48 (4404) 671.5	131 (4371) 661.0	63.9% (49.4, 74.7)	29 (4350) 668.1	79 (4273) 654.8	64.0% (44.3, 77.3)
≥60, no	14 (3391) 541.6	57 (3335) 530.0	76.0% (56.3, 87.6)	11 (3355) 539.0	39 (3298) 527.6	72.4% (45.0, 87.3)
≥60, yes	22 (3373) 467.4	63 (3427) 469.9	64.9% (42.2, 79.4)	15 (3334) 464.9	26 (3353) 465.2	42.3% (-13.1, 71.6)
Comorbidity, type[b]						
Asthma	1 (238) 34.3	9 (278) 39.5	87.2% (7.6, 99.7)	0 (235) 34.1	4 (270) 38.9	
Cancer	0 (104) 14.2	2 (108) 15.0		0 (102) 14.1	0 (105) 14.8	
Chronic kidney disease	0 (106) 15.1	1 (109) 15.3		0 (102) 14.8	0 (106) 15.1	
COPD	1 (213) 30.2	5 (195) 28.0	81.5% (-65.2, 99.6)	1 (211) 30.1	3 (192) 27.8	
Serious heart conditions	3 (460) 65.3	13 (487) 67.7	76.1% (12.9, 95.6)	1 (455) 64.9	5 (472) 66.8	79.4% (-83.7, 99.6)
HIV infection	5 (467) 69.1	5 (498) 72.4	-4.8% (-355.2, 75.9)	2 (461) 68.7	4 (493) 72.2	47.5% (-266.0, 95.3)
Hypertension	14 (1999) 283.3	38 (2019) 282.8	63.2% (30.6, 81.6)	11 (1978) 281.9	17 (1977) 280.2	35.7% (-45.6, 72.8)
Immuno-compromised from blood transplant	2 (38) 4.9	0 (33) 4.6		1 (35) 4.7	0 (32) 4.5	
Liver disease	1 (97) 14.5	2 (100) 14.7		1 (96) 14.4	0 (98) 14.6	
Neurologic conditions	0 (77) 11.1	1 (115) 16.5		0 (77) 11.1	1 (114) 16.5	
Obesity	51 (5383) 794.1	151 (5352) 780.3	66.8% (54.1, 76.3)	30 (5318) 790.0	86 (5223) 772.0	65.9% (47.8, 78.3)

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	Onset at Least 14 Days			Onset at Least 28 Days		
Subgroup	Ad26.COV2.S Cases (N) Person-yrs	Placebo Cases (N) Person-yrs	VE%[a] (95% CI)	Ad26.COV2.S Cases (N) Person-yrs	Placebo Cases (N) Person-yrs	VE%[a] (95% CI)
Type 2 diabetes mellitus	15 (1399) 198.7	32 (1410) 199.5	52.9% (10.5, 76.3)	10 (1380) 197.5	13 (1378) 197.7	23.0% (-90.1, 69.8)

Source: Sponsor tables GEFPE09A, GEFPE09C
N=Total number of participants at risk per category
[a] If fewer than 6 cases are observed for an endpoint then the VE is not shown.
[b] Results not shown for comorbidities which did not have any cases in either arm for either of the two time periods

Among the 4,156 participants with positive baseline SARS-CoV-2 status who would have otherwise fulfilled the criteria for the Per Protocol Set, there were 7 moderate to severe/critical COVID-19 cases which occurred at least 14 days post-vaccination (3 in vaccine group, 4 in placebo group), of which 3 cases occurred at least 28 days post-vaccination (1 in vaccine group, 2 in placebo group). One case, in a participant in the vaccine group, was assessed as severe. Of the 7 cases, only one case was centrally confirmed at the time of the data cutoff. There is insufficient data at this time to evaluate vaccine efficacy in previously infected individuals.

Table 14. Vaccine Efficacy of First Occurrence of Moderate to Severe/Critical COVID-19, Including Non-centrally Confirmed Cases, With Onset at Least 14 or at Least 28 Days After Vaccination, by Baseline SARS-CoV-2 Status[a], Per Protocol Set

	Onset at Least 14 Days			Onset at Least 28 Days		
Baseline SARS-CoV-2 Serostatus[a]	Ad26.COV2.S Cases (N) Person-yrs	Placebo Cases (N) Person-yrs	VE% (95% CI)	Ad26.COV2.S Cases (N) Person-yrs	Placebo Cases (N) Person-yrs	VE%[b] (95% CI)
Regardless of baseline SARS-CoV-2 status	176 (21636) 3450.2	513 (21574) 3409.8	66.1% (59.7, 71.6)	114 (21424) 3436.3	326 (21199) 3385.9	65.5% (57.2, 72.4)
Positive	3 (2122) 336.3	4 (2030) 320.8	28.5% (-322.8, 89.5)	1 (2118) 336.1	2 (2021) 320.0	
Negative	173 (19514) 3113.9	509 (19544) 3089.1	66.3% (59.9, 71.8)	113 (19306) 3100.3	324 (19178) 3065.9	65.5% (57.2, 72.4)

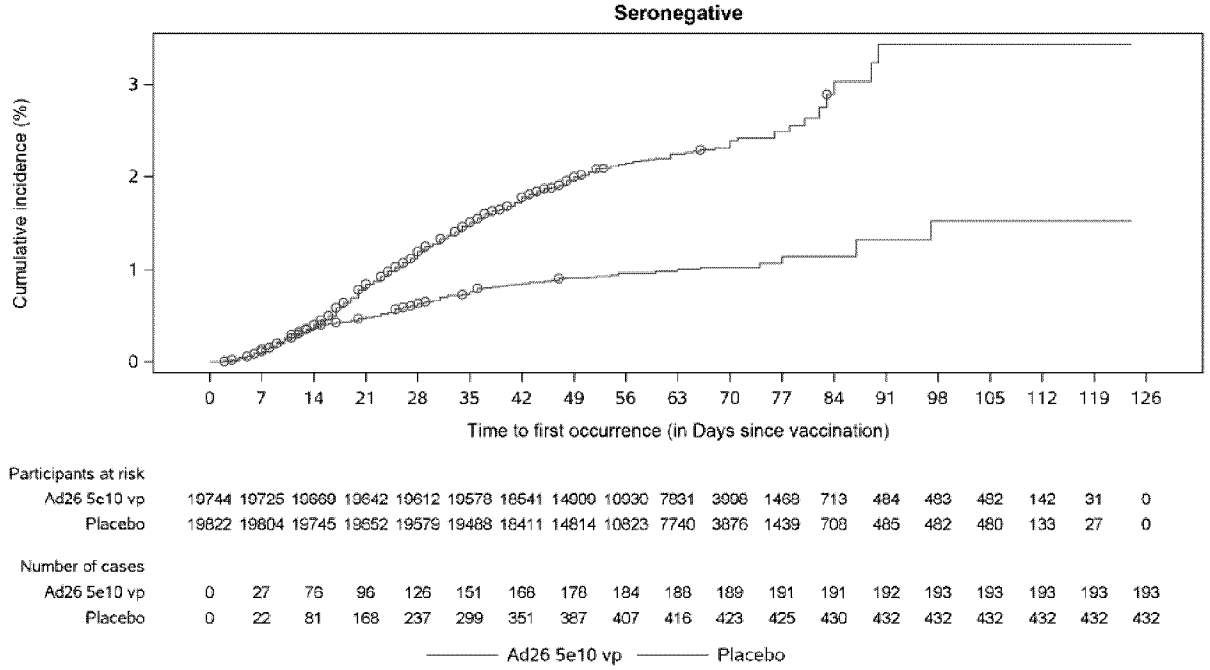
Source: Sponsor tables GEFPE07A, GEFPE07C
N=Total number of participants at risk per category
[a] Based on serological test at baseline
[b] If fewer than 6 cases are observed for an endpoint then the VE is not shown

Cumulative Incidence Curves –Primary Efficacy Analysis

Cumulative incidence of moderate to severe/critical COVID-19 in the FAS was similar in both the vaccine and placebo groups until around Day 14, following which the curves diverge, with more cases accumulating in the placebo group than the vaccine group.

Obtained via FOIA by Judicial Watch, Inc.

Figure 1. Cumulative Incidence Curve of Centrally Confirmed Moderate to Severe/Critical COVID-19 Cases With Onset at Least 1 Day After Vaccination, Full Analysis Set



Secondary Efficacy Analyses

Efficacy Against Any Symptomatic COVID-19

Efficacy against any symptomatic COVID-19 (including mild disease) and efficacy based on a less restrictive case definition (FDA harmonized case definition), with onset at least 14 days or 28 days after vaccination, were overall similar to results obtained for the primary efficacy endpoint of efficacy against moderate to severe/critical COVID-19. There were only 4 centrally confirmed mild COVID-19 cases (1 in vaccine group, 3 in placebo group) with onset ≥14 days post-vaccination, indicating that the moderate to severe/critical primary efficacy endpoint definition captured almost all cases of symptomatic COVID-19.

Table 15. Vaccine Efficacy Against Centrally Confirmed COVID-19[a] With Onset at Least 14 or at Least 28 Days After Vaccination, Per-Protocol Set, Study 3001

	Onset at Least 14 Days			Onset at Least 28 Days		
	Ad26.COV2.S Cases (N) Person-yrs	Placebo Cases (N) Person-yrs	VE% (95% CI)	Ad26.COV2.S Cases (N) Person-yrs	Placebo Cases (N) Person-yrs	VE% (95% CI)
Symptomatic COVID-19, any severity[a]	117 (19514) 3116.5	351 (19544) 3095.9	66.9% (59.1, 73.4)	66 (19306) 3102.0	195 (19178) 3070.5	66.5% (55.5, 75.1)
FDA harmonized COVID-19 cases	114 (19514) 3116.6	345 (19544) 3096.3	67.2% (59.3, 73.7)	65 (19306) 3102.0	193 (19178) 3070.6	66.7% (55.6, 75.2)

Source: Sponsor tables TEFSUM01_A, TEMSUM01_C
N=Total number of participants at risk per category
[a] Includes mild, moderate, and severe/critical cases

Obtained via FOIA by Judicial Watch, Inc.

Severe COVID-19 Cases

All COVID-19 cases which met the severe/critical definition as specified by the study protocol and all moderate cases with a total of 3 or more signs and/or symptoms were assessed independently by a clinical severity adjudication committee. Only cases classified as severe/critical by the adjudication committee are included in the severe/critical endpoint. Table 16 shows efficacy against severe/critical COVID-19 including only centrally confirmed cases and efficacy against severe/critical COVID-19 when non-centrally confirmed cases are also included.

As of the cutoff date for adjudication (January 19, 2021), there were 74 centrally confirmed, adjudicated severe/critical COVID-19 cases with an onset at least 14 days after vaccination and 39 cases with an onset at least 28 days after vaccination. Efficacy against severe disease appears to be greater when cases that occurred before 28 days are excluded. Point estimates of efficacy were lower in participants ≥60 years of age compared to participants 18 to 59 years-old when evaluating only centrally confirmed cases; however, the confidence intervals are wide. When non-centrally confirmed cases were included, the VE estimate for participants ≥60 years of age increased (and the confidence interval narrowed) and was more similar to the VE estimates for 18 to 59 year-olds and the overall population.

Table 16. Vaccine Efficacy Against Adjudicated Severe/Critical COVID-19 With Onset at Least 14 or at Least 28 Days After Vaccination, Per-Protocol Set, Study 3001

	Onset at Least 14 Days			Onset at Least 28 Days		
	Ad26.COV2.S Cases (N) Person-yrs	Placebo Cases (N) Person-yrs	VE% (95% CI)	Ad26.COV2.S Cases (N) Person-yrs	Placebo Cases (N) Person-yrs	VE% (95% CI)
Centrally confirmed cases[a]						
Overall	14 (19514) 3125.1	60 (19544) 3122.0	76.7% (54.6, 89.1)[b]	5 (19306) 3106.2	34 (19178) 3082.6	85.4% (54.2, 96.9)[b]
18-59 years	8 (12750) 2114.3	41 (12782) 2115.1	80.5% (57.8, 92.1)	2 (12617) 2101.0	24 (12527) 2086.7	91.7% (66.7, 99.1)
≥60	6 (6764) 1010.7	19 (6762) 1006.9	68.5% (18.1, 89.7)	3 (6689) 1005.1	10 (6651) 995.9	70.3% (-15.5, 94.7)
Including non-centrally confirmed cases						
Overall	19 (19514) 3124.7	80 (19544) 3121.0	76.3% (57.9, 87.5)	8 (19306) 3106.0	48 (19178) 3082.0	83.5% (54.2, 96.9)
18-59 years	12 (12750) 2114.0	52 (12782) 2114.5	76.9% (56.2, 88.8)	5 (12617) 2100.9	33 (12527) 2086.3	85.0% (61.2, 95.4)
≥60 years	7 (6764) 1010.7	28 (6762) 1006.4	75.1% (41.7, 90.8)	3 (6689) 1005.1	15 (6651) 995.7	80.2% (30.0, 96.3)

Source: Sponsor tables GEFBO06_A, GEFBO06_C, GEFBO05NC_A, GEFBO05NC_C
N=Total number of participants at risk per category
[a] Endpoint for severe/critical disease as specified in SAP
[b] Adjusted 95% CI

Severe cases which occurred after the cutoff date for adjudication were included in the primary

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efficacy analysis but were not included as severe/critical cases, which is based on adjudicated cases only.

COVID-19 Requiring Medical Intervention

The endpoint of COVID-19 requiring medical intervention is defined as participant requiring hospitalization, ICU admission, mechanical ventilation, and/or ECMO, linked to objective measures such as decreased oxygenation, X-ray or computed tomography (CT) findings, and linked to any molecularly confirmed, COVID-19 with onset at least 14 days and at least 28 days post-vaccination. This endpoint was collected using the Medical Resource Utilization (MRU) form to be completed by the investigator on Days 3 through 5 and/or Day 29 of the COVID-19 episode. The vaccine appears to offer protection against COVID-19 requiring medical intervention starting at least 14 days post-vaccination. In the vaccine group, there were no COVID-19 cases requiring medical intervention, per MRU forms, after 28 days post-vaccination, compared to 5 such cases in the placebo group counting only centrally confirmed cases (7 cases in the placebo group counting any positive PCR).

Table 17. Vaccine Efficacy of First Occurrence COVID-19 Requiring Medical Intervention Based on MRU, With Onset at Least 14 or at Least 28 Days After Vaccination, Per-Protocol Set, Study 3001

	Onset at Least 14 Days			Onset at Least 28 Days		
	Ad26.COV2.S Cases (N) Person-yrs	Placebo Cases (N) Person-yrs	VE% (95% CI)	Ad26.COV2.S Cases (N) Person-yrs	Placebo Cases (N) Person-yrs	VE%[a] (95% CI)
Centrally Confirmed	2 (19514) 3126.9	8 (19544) 3126.1	75.0% (-25.3, 97.4)	0 (19306) 3106.4	5 (19178) 3084.4	
Any positive PCR	2 (19514) 3125.9	14 (19544) 3125.8	85.7% (37.8, 98.4)	0 (19306) 3106.4	7 (19178) 3084.4	100% (31.1, 100.0)

Source: Sponsor tables GEFMI03, GEFMI01, GEFMI01NCA, GEFMI01NCC
N=Total number of participants at risk per category
[a] If fewer than 6 cases are observed for an endpoint then the VE is not shown.
Abbreviation: MRU, Medical Resource Utilization

The Day 29 timepoint included in the MRU forms resulted in some cases requiring medical intervention not having MRU forms returned by the data cutoff date, and these cases were not included in the analysis above. A post hoc analysis of all COVID-19 hospitalizations was performed by counting all hospitalizations recorded in MRU forms, SAEs, and clinical event listings (e.g., during a severe/critical COVID-19 episode), in the setting of a positive PCR at the onset of the COVID-19 episode or onset of the AE. In total, 48 COVID-19 hospitalizations were identified among participants without evidence of SARS-CoV-2 PCR infection at baseline. The totality of these data indicates vaccine efficacy in the prevention of severe COVID-19 requiring hospitalization, with no COVID-19 related hospitalizations in the vaccine group following 28 days after vaccination.

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Table 18. Vaccine Efficacy of First Occurrence COVID-19 Requiring Hospitalization, With Onset at Least 14 or at Least 28 Days After Vaccination, Per Protocol Set, Study 3001 (Post Hoc Analysis)

Onset After Vaccination	Ad26.COV2.S No. of Cases (Person-yrs)	Placebo No. of Cases (Person-yrs)	VE% (95% CI)
At least 1 day (FAS-seronegative at baseline)			
Centrally confirmed	6 (3202.8)	18 (3213.1)	66.6% (12.1, 89.1)
Any positive PCR	6 (3202.8)	42 (3211.6)	85.7% (66.1, 95.0)
At least 14 days			
Centrally confirmed	2 (3125.8)	11 (3125.9)	81.8% (16.7, 98.0)
Any positive PCR	2 (3125.8)	29 (3125.1)	93.1% (72.7, 99.2)
At least 28 days			
Centrally confirmed	0 (3106.3)	6 (3084.4)	100% (15.7, 100.0)
Any positive PCR	0 (3106.3)	16 (3083.9)	100% (74.3, 100.0)

Source: TEFMI04

The 2 COVID-19 related hospitalizations that occurred at least 14 days after vaccination in the vaccine group were both participants ≥60 years of age with comorbidities (obesity and hypertension). In the subgroup of participants ≥60 years with comorbidities, 2 of 22 total moderate to severe/critical COVID-19 cases in vaccine recipients resulted in hospitalization (both prior to 28 days) compared to 11 of 63 moderate to severe/critical cases in placebo recipients (with 5 occurring after 28 days).

COVID-19 Related Deaths

As of February 5, 2021, there were 7 COVID-19-related deaths reported in the study. All participants had a documented positive SARS-CoV-2 RT-PCR around the time of the event, but not all have been centrally confirmed to date. All 7 deaths occurred in the placebo group and were in study sites in South Africa. All of these participants had one or more comorbidities which placed them at higher risk for severe COVID-19. One death was in a participant PCR positive at baseline, who had onset of illness 10 days after vaccination. These results suggest that the vaccine is efficacious against mortality associated with COVID-19. Outcomes related to an exploratory all-cause mortality endpoint are discussed in a separate section below.

Table 19. COVID-19 Related Deaths

Arm	Study Day[c]	Age	Comorbidity
Placebo	15	63	Obesity, Hypertension
Placebo	18[a]	52	Obesity, Diabetes
Placebo	31	54	Obesity, Hypertension, Diabetes, Heart failure
Placebo	38	49	Obesity, Hypertension
Placebo	39	68	Obesity
Placebo	49[b]	60	Obesity
Placebo	55	60	Asthma

[a] Participant with positive SARS-CoV-2 PCR at baseline
[b] Reported after the primary analysis cutoff date of January 22, 2021
[c] Study day of death

Vaccine Efficacy Against Asymptomatic Infections

The secondary endpoint for asymptomatic infection was defined in the protocol as a participant who does not fulfill the criteria for suspected COVID-19 based on signs and symptoms (further specified as no symptoms on the day preceding, the day of, or any time after the positive PCR test) AND has a SARS-CoV-2 positive RT-PCR test result OR develops a positive serology

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based on a SARS-CoV-2 N-specific immunoglobulin assay (Elecsys®, Roche) during the study. SARS CoV-2 seropositivity by non-S protein was assessed at Day 1 (pre-vaccination), Day 29 (28 days post-vaccination), and Day 71. On manual review of the cases included in this endpoint, the Sponsor identified multiple cases in which the participants were symptomatic 2 days or more prior to the positive PCR or serology test. Manual review identified 2 centrally-confirmed cases in the vaccine group which were classified as asymptomatic based on the statistical analysis plan (SAP) but would meet the moderate case definition, and one centrally-confirmed SAP-classified asymptomatic case in the placebo group which would meet the mild case definition, with onset after 14 days post-vaccination. These cases were not included in the primary or secondary efficacy analyses, which are based on SAP-defined cases, but are not expected to significantly change the efficacy results. To remove possibly symptomatic COVID-19 cases from the analysis of asymptomatic infection, the Sponsor conducted a post hoc analysis including only participants without COVID-19 symptoms since screening.

As specified in the SAP, the secondary endpoint of efficacy against all SARS-CoV-2 infection with onset from Day 29 (including asymptomatic infection) will only be tested when at least 15,000 participants with Day 71 serology are available, and the secondary endpoint of efficacy against asymptomatic or undetected infection with onset from Day 29 will only be tested when all participants have at least 6 months of follow-up.

From Day 1 through Day 29, the data show only modest, non-statistically significant vaccine efficacy against asymptomatic SARS-CoV-2 infection. Analysis of the Day 29 and after timepoint shown below is based on an interim analysis of Day 71 serology results from 2,892 participants. These individuals represent 28.8% of the 10,045 participants who had completed the Day 71 visit by the data cutoff date of January 22 (serology results cutoff February 8). The percentage of available serology results are not evenly distributed across study sites (range: 16.9% of study participants in Chile to 68.4% of participants in South Africa). Although these results may suggest potential efficacy against asymptomatic infection after Day 29, this observation should be interpreted with caution as follow-up time is limited, and only a small percentage of participants had available N-serology data to contribute to this endpoint. This analysis was also done at an interim time point not pre-specified by the SAP.

Table 20. Vaccine Efficacy Against Asymptomatic SARS-CoV-2 Infections, Full Analysis Set

	Day 1-Day 29			After Day 29[e]		
	Ad26.COV2.S No. of Cases (Person-yrs)	**Placebo No. of Cases (Person-yrs)**	**VE% (95% CI)**	**Ad26.COV2.S No. of Cases (Person-yrs)**	**Placebo No. of Cases (Person-yrs)**	**VE% (95% CI)**
FAS seronegative at baseline	N=19739	N=19809		N=19301	N=19162	
+PCR and/or serology[b]	159 (1561.3)	182 (1564.1)	12.5% (-8.9, 29.7)	22 (3099.7)	54 (3064.2)	59.7% (32.8; 76.6)
+PCR and/or serology without previous symptoms[b,d]	87 (1556.2)	109 (1559.3)	20.0% (-7.0, 40.4)	10 (3098.0)	38 (3061.5)	74.0% (46.8; 88.4)
Serology risk set[a]	N=14084	N=14019		N=1346	N=1304	
Seroconverted[c]	153 (1114.3)	175 (1108.2)	13.1% (-8.6, 30.5)	18 (312.2)	50 (298.8)	65.5% (39.9; 81.1)

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	Day 1-Day 29			After Day 29[e]		
	Ad26.COV2.S No. of Cases (Person-yrs)	Placebo No. of Cases (Person-yrs)	VE% (95% CI)	Ad26.COV2.S No. of Cases (Person-yrs)	Placebo No. of Cases (Person-yrs)	VE% (95% CI)
Seroconverted without previous symptoms[c,d]	84 (1109.4)	108 (1103.7)	22.6% (-3.9, 42.5)	10 (310.9)	37 (296.6)	74.2% (47.1; 88.6)

[a] Serology risk set: Participants with a non-S protein serology result available on Day 29 or Day 71
[b] A participant will be considered to have experienced asymptomatic or undetected COVID-19 if the participant does not fulfil the criteria for suspected COVID-19 based on signs and symptoms as detected by the algorithm described in the SAP; 1) no symptoms on the day before, at or after the PCR positive test and 2) has a SARS-CoV-2 positive RT-PCR/molecular test result or develops a positive serology (non-S protein) test
[c] A participant will be considered serologically converted if the participant develops a positive serology (non-S protein) test without a SARS-CoV-2 positive RT-PCR before the positive serology test irrespective of whether previous symptoms occurred
d A participant is considered without previous symptoms if no COVID-19 symptoms occurred before the positive PCR or serology test at any point in time during the study
[e] N (for at risk set and serology risk set) for >Day 29 analysis based on Per Protocol Set
Source: Sponsor tables TEFSUM02B, TEFSUM02C, CSR addendum submitted February 12, 2021

Exploratory Efficacy Analyses

Additional vaccine efficacy analyses were conducted and described below.

Effect on All-Cause Mortality

As of the cutoff date for the primary analysis, 19 deaths were reported in the study. Of these 19 deaths, 6 were related to COVID-19, all in the placebo group. There is suggestion of a positive effect on all-cause mortality; however, the confidence interval is wide, with a lower bound below 0 after 28 days post-vaccination.

Table 21. Effect on All-Cause Mortality, Full Analysis Set

	Ad26.COV2.S N=21895 No. of Cases (Person-yrs)	Placebo N=21888 No. of Cases (Person-yrs)	VE% (95% CI)
At least 1 day after vaccination[a]	3 (3544.8)	16 (3542.2)	81.3% (34.6, 96.5)
At least 14 days after vaccination	3 (3544.8)	15 (3541.9)	80.0% (29.4, 96.3)
At least 28 days after vaccination	2 (3544.3)	8 (3540.7)	75% (-25.2, 97.4)

[a] Cases in the later timepoints are included in the earlier timepoint
Source: GEFACM01B1, GEFACM01B28, GEFACM01B14

An update on deaths reported from the time period of January 22 to February 5 included an additional 6 deaths. Of these 6 deaths, 2 occurred in the vaccine group and 4 occurred in the placebo group. One of the cases in the placebo group and none in the vaccine group was related to COVID-19.

Sequencing Data from Centrally Confirmed COVID-19 Cases

During the conduct of Study 3001 (September 21, 2020 through the data cutoff date of January 22, 2021), new SARS-CoV-2 variants emerged in geographical regions where the study took place. In a subgroup analysis of vaccine efficacy against moderate to severe/critical COVID-19 in the United States, South Africa, and Brazil, there was lower efficacy observed in South Africa compared to the United States. Vaccine efficacy against severe/critical COVID-19 was comparably high across the three countries, although there was a wide confidence interval around the point estimates for the United States and Brazil.

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Table 22. Vaccine Efficacy of First Occurrence of Moderate to Severe/Critical and Severe/Critical COVID-19 Including Non-centrally Confirmed Cases With Onset at Least 14 or at Least 28 Days After Vaccination, by Country of Participation, Per-Protocol Set, Study 3001

	Onset at Least 14 Days			Onset at Least 28 Days		
Country Subgroup	Ad26.COV2.S Cases (N) Person-yrs	Placebo Cases (N) Person-yrs	VE%[a] 95% CI	Ad26.COV2.S Cases (N) Person-yrs	Placebo Cases (N) Person-yrs	VE%[a] (95% CI)
United States						
Moderate to severe/critical	51 (9119) 1414.0	196 (9086) 1391.3	74.4% (65.0, 81.6)	32 (8958) 1403.4	112 (8835) 1375.6	72.0% (58.2, 81.7)
Severe/critical	4 (9119) 1417.2	18 (9086) 1404.8	78.0% (33.1, 94.6)	1 (8958) 1405.2	7 (8835) 1382.2	85.9% (-9.4, 99.7)
South Africa						
Moderate to severe/critical	43 (2473) 377.6	90 (2496) 379.2	52.0% (30.3, 67.4)	23 (2449) 376.1	64 (2463) 376.9	64.0% (41.2, 78.7)
Severe/critical	8 (2473) 380.2	30 (2496) 382.9	73.1% (40.0, 89.4)	4 (2449) 377.0	22 (2463) 379.0	81.7% (46.2, 95.4)
Brazil						
Moderate to severe/critical	39 (3370) 555.7	114 (3355) 548.8	66.2% (51.0, 77.1)	24 (3354) 554.8	74 (3312) 546.1	68.1% (48.8, 80.7)
Severe/critical	2 (3370) 558.9	11 (3355) 556.8	81.9% (17.0, 98.1)	1 (3354) 556.2	8 (3312) 549.8	87.6% (7.8, 99.7)

Source: Sponsor tables GEFPE09A, GEFPE09C, GEFBO05NC_A, GEFBO05NC_C
N=Total number of participants at risk per category

Strain sequencing of COVID-19 cases in Study 3001 to inform the vaccine efficacy analysis by region is ongoing. As of February 12, 2021, 71.7% of centrally confirmed primary analysis cases have been sequenced. In the United States, 73.5% of cases have been sequenced, of which 96.4% were identified as the SARS-CoV-2 Wuhan-H1 variant D614G. In South Africa, 66.9% of cases have been sequenced, of which 94.5% were identified as 20H/501Y.V2 variant (B.1.351). In Brazil, 69.3% of cases have been sequenced, of which 69.4% were identified as variant of the P.2 lineage and 30.6% were identified as the Wuhan-H1 variant D614G. As of February 12, 2021, there were no sequenced cases from the B1.1.7 or P.1 lineages. Because strain sequencing of all COVID-19 cases in the study is incomplete at the time of this analysis, and due to selection bias involved in prioritizing the cases to be sequenced first (moderate to severe/critical cases, cases with onset at least 14 days after vaccination, samples with viral load >200 copies/mL), vaccine efficacy against specific SARS-CoV-2 variants cannot be evaluated at this time.

Efficacy Summary

The data from the primary efficacy analysis, with a cutoff date of January 22, 2021, and median follow-up for efficacy of 2 months post-vaccination, met the prespecified success criteria established in the study protocol. Efficacy of the vaccine to prevent protocol-defined moderate to severe/critical COVID-19 occurring at least 14 days after vaccination was 66.9% (95% CI 59.0; 73.4), and 66.1% (95% CI 55.0; 74.8) for moderate to severe/critical COVID-19 occurring at least 28 days after vaccination, in participants without prior evidence of SARS-CoV-2 infection. Results for the secondary endpoint of vaccine efficacy against protocol-defined

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symptomatic COVID-19 of any severity (mild, moderate, or severe/critical) were similar to those of the primary endpoint of vaccine efficacy against moderate to severe/critical disease. For prevention of centrally confirmed, adjudicated severe/critical disease, vaccine efficacy (95% CI) was 76.7% (54.6, 89.1) with onset at least 14 days after vaccination and 85.4% (54.2, 96.9) with onset at least 28 days after vaccination. In a post hoc analysis of all COVID-19 related hospitalizations starting 14 days after vaccination, including non-centrally confirmed cases, there were 2 cases in the vaccine group (with no cases after 28 days) compared with 29 cases in the placebo group (with 16 cases after 28 days). The evaluation of vaccine efficacy against asymptomatic disease and its interpretation are limited at this time, since the measurements were performed in a small subset of participants.

Efficacy estimates across demographic subgroups in supportive analyses of primary and secondary endpoints were generally consistent with the efficacy estimates in the overall study population, but the small numbers of participants and cases in certain subgroups (e.g., certain racial subgroups, individual comorbid conditions) limit the interpretability of subgroup-specific efficacy results. Neither age nor presence of comorbidities alone impacted the efficacy estimates for the primary endpoints of moderate to severe/critical COVID-19, with the exception of a lower efficacy estimate for COVID-19 with onset at least 28 days post-vaccination in participants with comorbidities compared to those without comorbidities (Table 10 and Table 13).

The efficacy estimate for moderate to severe/critical COVID-19 with onset at least 28 days post-vaccination was lower for the subgroup of participants ≥60 years of age with comorbidities than for younger participants and participants ≥60 years of age without comorbidities (Table 13). Confidence intervals for efficacy estimates across subgroups generally overlapped, and efficacy estimates in participants ≥60 years of age with comorbidities increased as the number of cases included in the analysis increased (i.e., with inclusion of non-centrally confirmed cases and cases starting at 14 days post-vaccination), indicating that lower efficacy estimates in this subgroup potentially reflect imprecision associated with smaller numbers of cases. Efficacy estimates against centrally confirmed severe/critical COVID-19 were reduced in participants ≥60 years of age as compared to younger participants, but there was no meaningful reduction when cases not yet centrally confirmed were included in the analysis (Table 16). The two hospitalizations in vaccine recipients due to COVID-19 with onset at least 14 days post-vaccination occurred in participants ≥60 years of age with comorbidities (as compared to 11 hospitalizations in placebo recipients ≥60 years of age with comorbidities). No vaccine recipients were hospitalized due to COVID-19 with onset at least 28 days post-vaccination.

To explore the possible impact of circulation of variant strains on vaccine efficacy, a subgroup analysis of vaccine efficacy against moderate to severe/critical and severe/critical COVID-19 was done for the United States, South Africa, and Brazil. There was a lower efficacy against moderate to severe/critical disease endpoints observed in South Africa [52.0% (95% CI 30.3, 67.4) and 64.0% (95% CI 41.2, 78.7) starting 14 days and 28 days after vaccination, respectively] compared to the United States (74.4% (65.0, 81.6) and 72.0% (58.2, 81.7) starting 14 days and 28 days after vaccination, respectively), but vaccine efficacy against severe/critical COVID-19 at the two timepoints were similarly high in all 3 countries. Strain sequencing of COVID-19 cases in the study to inform the vaccine efficacy analysis by region is ongoing. As of February 12, 2021, 71.7% of central laboratory confirmed primary analysis cases have been sequenced. In the U.S., 96.4% of the sequenced cases were identified as the SARS-CoV-2 Wuhan-H1 variant D614G. In South Africa, 94.5% of the sequenced cases were identified as 20H/501Y.V2 variant (B.1.351). In Brazil, 69.4% were identified as variant of the P.2 lineage and

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30.6% were identified as the Wuhan-H1 variant D614G. As of February 12, 2021, there were no cases identified from B.1.1.7 or P1 lineages.

5.2.6 Safety

The safety analyses presented in this review are derived from safety data available through the cutoff date of January 22, 2021.

The protocol specified safety monitoring for the following:

- Solicited local and systemic reactions during the 7 days following vaccination in the safety subset (N=6,736)
- Unsolicited AEs during the 28 days following vaccination in the safety subset
- MAAEs during the 6 months following vaccination in the FAS (N=43,783)
- SAEs and AEs leading to study discontinuation for the duration of the study in the FAS

Overall, the proportions of participants with MAAEs, SAEs, and deaths were balanced between the vaccine and placebo groups. Rates of unsolicited AEs were also balanced across treatment groups; however, a greater percentage of participants in the vaccine group had unsolicited AEs considered to be related to the study product. As compared to the placebo group, a greater percentage of participants in the vaccine group experienced local and systemic solicited ARs. Rates of ARs were lower in participants ≥60 years of age compared to participants 18 to 59 years of age. The table below summarizes rates of AEs by treatment group and age group.

Table 23. Participants Reporting at Least One Adverse Event, Among All Participants and by Age Group

Adverse Event Type	Ad26.COV2.S n/N (%)	Placebo n/N (%)
Full analysis set	**N=21895**	**N=21888**
Medically attended adverse event	304/21895 (1.4)	408/21888 (1.9)
18-59 years of age	207/14564 (1.4)	272/14547 (1.9)
≥60 years of age	97/7331 (1.3)	136/7341 (1.9)
Related[b] medically attended adverse events	22/21895 (0.1)	22/21888 (0.1)
18-59 years of age	15/14564 (0.1)	18/14547 (0.1)
≥60 years of age	7/7331 (0.1)	4/7341 (0.1)
Serious adverse event	83/21895 (0.4)	96/21888 (0.4)
18-59 years of age	45/14564 (0.3)	56/14547 (0.4)
≥60 years of age	38/7331 (0.5)	40/7341 (0.5)
Related[b] serious adverse event	7/21895 (<0.1)	2/21888 (<0.1)[c]
18-59 years of age	4/14564 (<0.1)	1/14547 (<0.1)
≥60 years of age	3/7331 (<0.1)	1/7341 (<0.1)
Deaths	3/21895 (<0.1)	16/21888 (0.1)
18-59 years	1/14564 (<0.1)	7/14547 (<0.1)
≥60 years	2/7331 (<0.1)	9/7341 (0.1)
Related[b] deaths	0	0
AE leading to study discontinuation	0	0
Safety subset	**N=3356**	**N=3380**
Solicited local adverse reaction	1685/3356 (50.2)	657 /3380 (19.4)
18-59 years of age	1218/2036 (59.8)	413/2049 (20.2)
≥60 years of age	467/1320 (35.4)	244/1331 (18.3)
Grade 3 solicited local adverse reaction[a]	23/3356 (0.7)	6/3380 (0.2)
18-59 years of age	18/2036 (0.9)	4/2049 (0.2)
≥60 years of age	5/1320 (0.4)	2/1331 (0.2)

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Adverse Event Type	Ad26.COV2.S n/N (%)	Placebo n/N (%)
Solicited systemic adverse reaction	1850/3356 (55.1)	1185/3380 (35.1)
18-59 years of age	1252/2036 (61.5)	745/2049 (36.4)
≥60 years of age	598/1320 (45.3)	440/1331 (33.1)
Grade 3 solicited systemic adverse reaction[a]	61/3356 (1.8)	21/3380 (0.6)
18-59 years of age	47/2036 (2.3)	12/2049 (0.6)
≥60 years of age	14/1320 (1.1)	9/1331 (0.7)
Unsolicited adverse event up to 28 days after vaccination	440/3356 (13.1)	407/3380 (12.0)
18-59 years of age	285/2036 (14.0)	275/2049 (13.4)
≥60 years of age	155/1320 (11.7)	132/1331 (9.9)
Grade 3 unsolicited adverse event	16/3356 (0.5)	16/3380 (0.5)
18-59 years of age	10/2036 (0.5)	10/2049 (0.5)
≥60 years of age	6/1320 (0.5)	6/1331 (0.5)
Grade 4 unsolicited adverse event	3/3356 (0.1)	2/3380 (0.1)
18-59 years of age	2/2036 (0.1)	2/2049 (0.1)
≥60 years of age	1/1320 (0.1)	0/1331 (0.0)
Related[b] unsolicited adverse events	242/3356 (7.2)	154/3380 (4.6)
18-59 years of age	163/2036 (8.0)	96/2049 (4.7)
≥60 years of age	79/1320 (6.0)	58 /1331 (4.4)

Source: Sponsor tables TSFAE04, TSFAE05, TSFAESOLLOC27, TSFAESOLSYS27, TSFAESOL02, TSFAEUNSOL01 & TSFAEUNSOL12.
n = number of participants with specified event; N = number of exposed participants who submitted any data for the event, percentages are based on n/N.
[a]There were no reports of Grade 4 solicited adverse reactions
[b] Related as assessed by investigator
[c] 1 participant reported 2 SAEs

The following issues were identified during the safety review:

1. Several reports of solicited reactions and non-serious, unsolicited adverse events were omitted from the analyses due to incorrectly coded start dates. However, the omissions did not have a major impact on the estimated event rates (0% to 0.3% of the safety subset of the respective treatment group) and thus did not impact the safety conclusions.

2. Discrepancies were identified between the number of solicited reactions reported by participants in source documents and the number of events reported by the investigator and included in the datasets upon which the safety analyses were based. In response to an FDA information request, the Sponsor conducted queries of potential missing clinical event data for 210 subjects, of which 40% of the queried events were determined to not meet reporting criteria (e.g., participants who did not experience any solicited symptom during the planned 7-day evaluation period or those who experienced an event with toxicity <grade 1). Other than 44 open queries, the remaining queries resulted in corrected reporting of previously missing clinical event data to the relevant datasets that will be included in final safety analyses with the submission of the licensure application. However, based on FDA evaluation of the impacted data, and the fact that these participants represent a small proportion of the safety subset, the corrected solicited ARs are expected to have a minor impact on the rates submitted by the Sponsor in its EUA request.

Solicited Adverse Reactions

Solicited local and systemic ARs with onset within 7 days after vaccination were assessed across groups and are presented in the tables below stratified by age (18 to 59 years; ≥60 years) for participants in the safety subset (N=6,736). Solicited ARs were recorded daily by

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study participants using eDiaries and included the assessment of local injection site reactions (pain, erythema and swelling) and systemic reactions (fatigue, headache, myalgia, nausea and fever).

Local Adverse Reactions

Solicited local ARs were reported at higher rates in vaccine recipients than placebo recipients. The proportions of participants reporting any local AR were 50.2% and 19.4% in vaccine and placebo groups, respectively. The proportions reporting at least one grade 3 local AR were 0.7% and 0.2% in vaccine and placebo groups, respectively. There were no reports of grade 4 local reactions in either group.

The most frequently reported local AR was injection site pain, reported by 48.6% of vaccine recipients and 16.7% of placebo recipients. Grade 3 pain was reported in 0.3% of vaccine recipients and <0.1% of placebo recipients. Erythema (vaccine versus placebo: 7.3% versus 3.9%) and swelling (5.3% versus 1.6%) were reported less frequently.

All local ARs were reported more frequently among younger (18-59 years) than older (≥60 years) participants. Among participants in the vaccine group, injection site pain was reported in 58.6% of 18-59-year-olds and 33.3% of ≥60-year-olds. Erythema and swelling were similarly reported at higher rates among younger than older participants in the vaccine group (Table 24).

Among participants in the vaccine group, the overall rate of local ARs was similar between those who were seronegative for SARS-CoV-2 at baseline (n=3,202) and those who were seropositive at baseline (n=154): 50.0% versus 53.9%. Rates for local ARs by baseline serostatus were as follows (seronegative vs. seropositive): injection site pain 48.4% vs. 53.2%; swelling 5.2% vs. 6.5%; erythema 7.4% vs. 4.5%.

The table below provides rates of local ARs by treatment group and age group.

Table 24. Frequency of Solicited Local Adverse Reactions Within 7 Days Following Vaccination, Safety Subset[a], Study 3001

Adverse Reaction	18-59 Years Ad26.COV2.S N=2036 n (%)	18-59 years Placebo N=2049 n (%)	≥60 Years Ad26.COV2.S N=1320 n (%)	≥60 Years Placebo N=1331 n (%)
Any Local	1218 (59.8%)	413 (20.2%)	467 (35.4%)	244 (18.3%)
Grade 3	18 (0.9%)	4 (0.2%)	5 (0.4%)	2 (0.2%)
Pain[b]	1193 (58.6%)	357 (17.4%)	439 (33.3%)	207 (15.6%)
Grade 3	8 (0.4%)	0	3 (0.2%)	2 (0.2%)
Erythema[c]	184 (9.0%)	89 (4.3%)	61 (4.6%)	42 (3.2%)
Grade 3	6 (0.3%)	2 (0.1%)	1 (0.1%)	0
Swelling[b]	142 (7.0%)	32 (1.6%)	36 (2.7%)	21 (1.6%)
Grade 3	5 (0.2%)	2 (0.1%)	2 (0.2%)	0

Source: Sponsor Table TSFAESOLLOC27
[a] Safety subset: Subset of Full-Analysis Set for analysis of solicited and unsolicited AEs
n = number of participants with specified reaction
N = number of exposed participants who submitted any data for the event, percentages are based on n/N.
[b] Pain- Grade 3: any use of Rx pain reliever/prevents daily activity;
[c] Erythema and Swelling/Induration- Grade 3: >100mm;
Note: No grade 4 solicited local adverse reactions were reported.

The median time to onset of local ARs was within 2 days of vaccination, and the median duration was 2 days for erythema and pain and 3 days for swelling. Pain was reported to last greater than 7 days in 2.3% of participants in the vaccine group and 2.1% of participants in the

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placebo group. Among participants in the vaccine group, erythema and swelling had a duration >7 days in 0.8% and 0.5% of participants, respectively.

The table below provides time to onset and duration of local ARs by treatment group.

Table 25. Time (Days) to Onset and Duration of Solicited Local Adverse Events, Safety Subset[a], Study 3001

Adverse Reaction	Ad26.COV2.S N=3356	Placebo N=3380
Pain, n (%)	1632 (48.6%)	564 (16.7%)
Median time to onset (min, max)	2.0 (1, 8)	2.0 (1, 8)
Median duration (min, max)	2.0 (1, 67)	2.0 (1, 67)
>7 days duration	38 (2.3%)	14 (2.1%)
Erythema, n (%)	245 (7.3%)	131 (3.9%)
Median time to onset (min, max)	2.0 (1, 7)	1.0 (1, 8)
Median duration (min, max)	2.0 (1, 9)	2.0 (1, 19)
>7 days duration	13 (0.8%)	4 (0.6%)
Swelling, n (%)	178 (5.3%)	53 (1.6%)
Median time to onset (min, max)	2.0 (1, 8)	1.0 (1, 8)
Median duration (min, max)	3.0 (1, 14)	1.0 (1, 19)
>7 days duration	9 (0.5%)	2 (0.3%)

Source: Sponsor Table TSFAESOLLOC25
[a] Safety subset: Subset of Full-Analysis Set for analysis of solicited and unsolicited AEs
n = number of participants with specified reaction
N = number of exposed participants who submitted any data for the event, percentages are based on n/N.

Systemic Adverse Reactions

Solicited systemic ARs were reported at higher rates in vaccine than placebo recipients. The proportions of participants reporting any systemic ARs were 55.1% in the vaccine group and 35.1% in the placebo group. The proportions reporting at least one grade 3 systemic AR were 1.8% in the vaccine group and 0.6% in the placebo group. There were no reports of grade 4 systemic reactions in either group.

The most frequently reported systemic ARs were headache (vaccine versus placebo: 38.9% versus 23.7%) and fatigue (38.2% versus 21.5%). Rates of other systemic ARs in the vaccine versus placebo groups were as follows: myalgia (33.2% versus 12.7%); nausea (14.2% versus 9.7%); and fever (9.0% versus 0.6%).

Grade 3 systemic ARs were reported infrequently. The most frequently reported grade 3 systemic ARs were fatigue and myalgia, reported in 1.0% vs 0.3% and 1.0% vs. 0.2% of vaccine recipients and placebo recipients, respectively. Grade 3 fever (102.1-104°F) was reported in 0.2% of vaccine recipients and no placebo recipients.

Among participants in the vaccine group, all systemic ARs were reported more frequently among younger (18-59 years) than older (≥60 years) participants, although nausea was reported at more similar rates: 15.5% in participants 18-59 years and 12.3% in participants ≥60 years. Among vaccine group participants, rates of other systemic ARs by age group were as follows (18-59 and ≥60 years): headache (44.4% and 30.4); fatigue (43.8% and 29.7%); myalgia (39.1% and 24.0%); fever (12.8% and 3.1%).

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A higher percentage of participants in the vaccine group used antipyretics/analgesics in the 7 days following vaccination compared to participants the placebo group; 19.9% versus 5.7%. This was primarily driven by participants 18-59 years old. Among participants in the vaccine group, 26.4% of those 18-59 years used antipyretics/analgesics compared to 9.8% of those ≥60 years old.

The overall rate of systemic ARs was similar in vaccine recipients who were seronegative for SARS-CoV-2 at baseline (n=3,202) and those who were seropositive at baseline (n=154): 55.4% versus 50.0%. Rates for systemic ARs by baseline serostatus were as follows (seronegative vs. seropositive): headache 38.9% vs. 38.3%; fatigue 38.3% vs. 37.0%; myalgia 33.2% vs. 32.5%; nausea 14.3% vs. 12.3%; fever 9.1% vs. 6.5%.

The table below provides rates of systemic ARs by treatment group and age group.

Table 26. Frequency of Solicited Systemic Adverse Reactions Within 7 Days Following Vaccination, Safety Subset[a], Study 3001

Adverse Reaction	Ad26.COV2.S 18-59 Years N=2036 n/N (%)	Placebo 18-59 Years N=2049 n/N (%)	Ad26.COV2.S ≥60 Years N=1320 n/N (%)	Placebo ≥60 Years N=1331 n/N (%)
Any Systemic	1252 (61.5%)	745 (36.4%)	598 (45.3%)	440 (33.1%)
Grade 3	47 (2.3%)	12 (0.6%)	14 (1.1%)	9 (0.7%)
Fatigue[b]	891 (43.8%)	451 (22.0%)	392 (29.7%)	277 (20.8%)
Grade 3	25 (1.2%)	4 (0.2%)	10 (0.8%)	5 (0.4%)
Headache[b]	905 (44.4%)	508 (24.8%)	401 (30.4%)	294 (22.1%)
Grade 3	18 (0.9%)	5 (0.2%)	5 (0.4%)	4 (0.3%)
Myalgia[b]	796 (39.1%)	248 (12.1%)	317 (24.0%)	182 (13.7%)
Grade 3	29 (1.4%)	1 (<0.1%)	3 (0.2%)	5 (0.4%)
Nausea[c]	315 (15.5%)	183 (8.9%)	162 (12.3%)	144 (10.8%)
Grade 3	3 (0.1%)	3 (0.1%)	3 (0.2%)	3 (0.2%)
Fever[d]	261 (12.8%)	14 (0.7%)	41 (3.1%)	6 (0.5%)
Grade 3	7 (0.3%)	0	1 (0.1%)	0
Antipyretic/Analgesic Use	538 (26.4%)	123 (6.0%)	130 (9.8%)	68 (5.1%)

Source: Sponsor table TSFAESOLSYS27
n = number of participants with specified reaction
N = number of exposed participants who submitted any data for the event, percentages are based on n/N.
[a] Safety subset: Subset of Full-Analysis Set for analysis of solicited and unsolicited AEs
[b] Fatigue, Headache, Myalgia – Grade 3: incapacitating; prevents daily activity; use of Rx pain reliever. Grade 4: Requires E.R. visit or hospitalization
[c] Nausea –Grade 3: incapacitating; prevents daily activity. Grade 4: Requires E.R. visit or hospitalization
[d] Fever - Grade 3: ≥39.0 to ≤40.0°C or ≥102.1 to ≤104.0° F; Grade 4: >40.0°C or >104.0°F
Note: No grade 4 solicited local adverse reactions were reported.

Among participants in the vaccine group, the median time to onset of all solicited systemic ARs was within 2 days of vaccination. Median durations of systemic reactions in vaccine group participants were as follows: 2 days for fatigue, headache, and myalgia and 1 day for nausea and fever. Systemic reactions with a duration longer than 7 days were reported in vaccinated participants for all systemic ARs with the exception of fever. Percentages of vaccine group participants reporting systemic ARs with duration longer than 7 days were as follows: fatigue 1.6%, myalgia 1.1%, headache 0.7%, nausea 0.3%.

The table below provides time to onset and duration of systemic ARs by treatment group.

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Table 27. Time (Days) to Onset and Duration of Solicited Adverse Events, Safety Subset[a], Study 3001

Adverse Reaction	Ad26.COV2.S N=3356	Placebo N=3380
Fatigue, n (%)	1283 (38.2%)	728 (21.5%)
Median time to onset (min, max)	2.0 (1, 8)	2.0 (1, 8)
Median duration (min, max)	2.0 (1, 113)	2.0 (1, 110)
>7 days duration	29 (1.6%)	25 (2.1%)
Headache, n (%)	1306 (38.9%)	802 (23.7%)
Median time to onset (min, max)	2.0 (1, 8)	2.0 (1, 8)
Median duration (min, max)	2.0 (1, 68)	1.0 (1, 62)
>7 days duration	13 (0.7%)	8 (0.7%)
Myalgia, n (%)	1113 (33.2%)	430 (12.7%)
Median time to onset (min, max)	2.0 (1, 8)	2.0 (1, 8)
Median duration (min, max)	2.0 (1, 32)	2.0 (1, 44)
>7 days duration	20 (1.1%)	15 (1.3%)
Nausea, n (%)	477 (14.2%)	327 (9.7%)
Median time to onset (min, max)	2.0 (1, 8)	3.0 (1, 8)
Median duration (min, max)	1.0 (1, 15)	1.0 (1, 8)
>7 days duration	5 (0.3%)	4 (0.3%)
Fever, n (%)	302 (9.0%)	20 (0.6%)
Median time to onset (min, max)	2.0 (1, 8)	2.0 (1, 5)
Median duration (min, max)	1.0 (1, 7)	1.0 (1, 3)
>7 days duration	0	0

Source: Sponsor Table TSFAESOLSYS25
[a] Safety subset: Subset of Full-Analysis Set for analysis of solicited and unsolicited AEs
n = number of participants with specified reaction
N = number of exposed participants who submitted any data for the event, percentages are based on n/N.

Unsolicited AEs

Through the January 22, 2021 data cutoff, 54.6% of participants in the FAS (N=43,783) had at least 2 months of follow-up. The median duration of follow-up post-vaccination for all participants was 58 days. In the safety subset (N=6,736), 99.9% of participants completed the study through Day 28. The following unsolicited AEs were specified in the protocol:

- Unsolicited AEs during the 28 days following vaccination in the safety subset
- MAAEs during the 6 months following vaccination in the FAS
- SAEs for the duration of the study in the FAS
- AEs leading to discontinuation from study participation in the FAS

Additional unsolicited AEs collected from the spontaneous reports were also analyzed in the FAS. Determination of severity for all unsolicited AE were made by investigator assessment based on definitions of severity as grades 1 through 4 (mild to potentially life threatening). Causal relationship to study vaccine was determined by study investigator and classified as "related" or "not related."

AEs associated with molecularly confirmed SARS-CoV-2 infection were not included in the analysis of AEs.

Unsolicited Adverse Events

The table below shows rates of unsolicited AEs in the safety subset that occurred within 28 days of vaccination and at rates of ≥1% in the vaccine group. The proportions of participants with

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unsolicited AE were 13.1% and 12.0% in the vaccine and placebo groups, respectively. Overall, rates of unsolicited adverse events, including events grade 3 or higher, were similar between the treatment groups.

Table 28. Unsolicited Adverse Events Occurring in ≥1% of Vaccine Group Participants Within 28 Days Following Vaccination, by MedDRA Primary System Organ Class and Preferred Term, Safety Subset[a], Study 3001

System Organ Class Preferred Term	Ad26.COV2.S N=3356 Any Grade n (%)	Ad26.COV2.S N=3356 ≥Grade 3 n (%)	Placebo N=3380 Any Grade n (%)	Placebo N=3380 ≥Grade 3 n (%)
General disorders and administration site	211 (6.3%)	5 (0.1%)	134 (4.0%)	2 (0.1%)
Chills	67 (2.0%)	1 (<0.1%)	19 (0.6%)	0
Fatigue	64 (1.9%)	1 (<0.1%)	77 (2.3%)	1 (<0.1%)
Vaccination site pain	42 (1.3%)	1 (<0.1%)	22 (0.7%)	0
Musculoskeletal and connective tissue disorders	103 (3.1%)	3 (0.1%)	89 (2.6%)	4 (0.1%)
Myalgia	49 (1.5%)	0	58 (1.7%)	2 (0.1%)
Arthralgia	35 (1.0%)	1 (<0.1%)	24 (0.7%)	2 (0.1%)
Nervous system disorders	98 (2.9%)	3 (0.1%)	108 (3.2%)	5 (0.1%)
Headache	72 (2.1%)	1 (<0.1%)	82 (2.4%)	1 (<0.1%)
Respiratory, thoracic and mediastinal disorders	93 (2.8%)	3 (0.1%)	88 (2.6%)	4 (0.1%)
Nasal congestion	40 (1.2%)	1 (<0.1%)	38 (1.1%)	2 (0.1%)
Cough	33 (1.0%)	1 (<0.1%)	33 (1.0%)	0
Gastrointestinal disorders	87 (2.6%)	2 (0.1%)	90 (2.7%)	2 (0.1%)
Diarrhea	33 (1.0%)	2 (0.1%)	35 (1.0%)	0
Infections and infestations	57 (1.7%)	3 (0.1%)	87 (2.6%)	6 (0.2%)

Source: Sponsor Tables TSFAEUNSOL02_D & TSFAEUNSOL03_D
[a] safety subset: Subset of Full-Analysis Set for analysis of solicited and unsolicited AEs
n = # of participants with specified reaction
N = number of exposed participants who submitted any data for the event, percentages are based on n/N.

Unsolicited AEs considered related by the investigator to study vaccination were reported by 7.2% of vaccine recipients and 4.6% of placebo recipients. The proportions of participants who reported grade 3 or higher unsolicited AEs were 0.6% following vaccine (19 participants) and 0.5% following placebo (18 participants).

Unsolicited Adverse Events of Clinical Interest

FDA conducted both broad and narrow Standardized MedDRA Queries (SMQs) using FDA-developed software to evaluate unsolicited adverse events of clinical interest by searching preferred terms (PTs) that could together represent various conditions, including but not limited to allergic, neurologic, inflammatory, vascular, and autoimmune disorders. Narrow searches were done to identify cases highly likely to be the condition of interest whereas broad searches were done to identify all possible cases. Ten SMQs (broad and narrow combined) were conducted on AEs reported through the data cutoff date (requiring 2 months median follow-up following vaccination) and included events that occurred in the FAS (N=43,783). AEs in the FAS were collected through protocol specified collection methods as well as spontaneous reporting by study participants.

SMQs and associated PTs for which adverse events were reported at higher rates in vaccine recipients compared to placebo recipients are discussed below. For the additional SMQs, rates were comparable between vaccine and placebo recipients.

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The SMQ for "embolic and thrombotic events" in the FAS demonstrated a slight numerical imbalance; data through the cutoff date includes reports of such events among 0.06% of vaccine recipients (15 events in 14 participants) compared to 0.05% of placebo recipients (10 events in 10 participants). By PT, deep vein thrombosis (including PTs for "deep vein thrombosis," "venous thrombosis limb" and "embolism venous") was reported in 6 vaccine recipients (5 events within 28 days of vaccination) and 2 placebo recipients (2 events within 28 days of vaccination). Pulmonary embolism was reported in 4 vaccine recipients (2 events within 28 days of vaccination) and 1 placebo recipient (1 event within 28 days of vaccination). Cerebrovascular events (including PTs "cerebral infarction", "transverse sinus thrombosis", "hemiparesis", "cerebrovascular accident", "carotid artery occlusion" and "ischemic stroke") were reported in 3 vaccine recipients (4 events, 3 events within 28 days of vaccination) and 3 placebo recipients (3 events within 28 days of vaccination). Myocardial infarction was reported in 1 vaccine recipient (1 event within 28 days of vaccination) and 3 placebo recipients (2 events within 28 days of vaccination). One placebo recipient reported thrombosed hemorrhoids within 28 days of vaccination. Table 29 summarizes thromboembolic events in both vaccine and placebo recipients including investigator assessment of grade, seriousness and causality.

Table 29. Thromboembolic Events in Vaccine and Placebo Recipients, Full Analysis Set, Study 3001

Investigational Product	Adverse Event (PT)	Age/Sex	Day of Onset	Resolution Status	Grade/SAE[a]	Related[a]
Ad26.COV2.S	Deep vein thrombosis	90/M	13	Resolving	2/N	No
Ad26.COV2.S	Deep vein thrombosis	42/M	19	Unresolved	2/N	No
Ad26.COV2.S	Deep vein thrombosis	63/M	22	Resolved	4/Y	No
Ad26.COV2.S	Venous thrombosis limb	63/M	23	Resolved	2/N	No
Ad26.COV2.S	Deep vein thrombosis	52/M	27	Resolving	2/N	Yes
Ad26.COV2.S	Embolism venous	72/M	36	Unresolved	2/Y	No
Ad26.COV2.S	Pulmonary embolism	30/F	3	Resolved	4/Y	No
Ad26.COV2.S	Pulmonary embolism	68/M	7[c]	Unresolved	2/N	No
Ad26.COV2.S	Pulmonary embolism	54/M	45	Resolved	3/Y	No
Ad26.COV2.S	Pulmonary embolism	66/M	57	Unresolved	3/Y	No
Ad26.COV2.S	Transverse sinus thrombosis	25/M	21	Resolved	4/Y	No
Ad26.COV2.S	Cerebral infarction[b]	82/M	23	Resolving	4/Y	No
Ad26.COV2.S	Hemiparesis	49/F	28	Unresolved	1/Y	No
Ad26.COV2.S	Ischemic stroke[b]	82/M	41	Resolving	4/Y	No
Ad26.COV2.S	Myocardial infarction	70/M	12	Resolved	3/Y	No
Placebo	Deep vein thrombosis	57/M	3	Unresolved	2/N	No
Placebo	Deep vein thrombosis	44/M	6	Resolving	4/Y	Yes

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Investigational Product	Adverse Event (PT)	Age/Sex	Day of Onset	Resolution Status	Grade/SAE[a]	Related[a]
Placebo	Pulmonary embolism	53/M	29	Resolving	4/Y	No
Placebo	Carotid artery occlusion	58/F	9	Resolving	4/Y	No
Placebo	Hemiparesis	45/M	9	Resolving	2/N	No
Placebo	Cerebrovascular accident	71/F	22	Unresolved	3/Y	No
Placebo	Acute myocardial infarction	78/M	3	Resolved	3/Y	No
Placebo	Acute myocardial infarction	52/F	4	Resolved with sequelae	4/Y	No
Placebo	Acute myocardial infarction	61/M	62	Fatal	4/Y	No
Placebo	Hemorrhoids thrombosed	42/F	24	Resolved	1/N	No

[a] Classification of events as SAEs and relatedness determined by study investigators
[b] Events occurred in the same study participant
[c] This event was initially reported with day of onset of 20 days. Day updated based on Sponsor clarification obtained on 2/17/21.

Additional details are provided for selected events among vaccine recipients for which a contributory effect of the vaccine could not be excluded based on FDA assessment of the clinical information provided:

- A 25-year-old male with no past medical history and no concurrent medications experienced a transverse sinus thrombosis on Day 21 following vaccination. On Day 9 the participant experienced symptoms of fever, myalgia, headache, fatigue, abdominal pain, congestion and rhinorrhea. He tested negative for SARs-CoV-2 during this acute illness. Aside from headache, his symptoms improved. On Day 19 he experienced a tonic colonic seizure. A CT scan without contrast demonstrated a cerebral hemorrhage. On Day 21, a transverse sinus thrombosis was reported on a venogram. The participant underwent a thrombectomy as well as stent placement for stenosed right sigmoid sinus on Day 22. On Day 23 repeat venogram showed the presence of a new clot in the transverse sinus. A second thrombectomy with venoplasty was performed. Treating clinicians reported observing rapid thrombus formation during the two thrombectomy procedures that was consistent with a clinically hypercoagulable state. In their assessment, the transverse sinus thrombosis most likely occurred days before the participant's clinical presentation with a seizure; the seizure was reported to be a consequence of a secondary bleed caused by elevated venous pressure from the venous flow obstruction. Workup for hematologic and infectious causes of the thrombosis did not reveal an etiology. This event was initially thought to be related to the study product by the investigator and prompted a study pause. After thorough investigation and expert consultation no clear cause of the event was identified; however possible contributing factors, such as preceding infection and an anatomical anomaly, were suggested. The investigator's brochure and informed consent form were updated accordingly, and the study pause was lifted. The investigator and Sponsor's final assessment of this event was that it was not related to the study product.

- A 30-year-old female with hypothyroidism, obesity (body mass index: 36.5 kg/m^2), headaches, anxiety and depression and use of multiple medications including medroxyprogesterone, experienced a pulmonary embolism on Day 3 following vaccination. The participant was hospitalized following a syncopal episode and CT scan of the chest demonstrated an occlusive thrombus in a pulmonary artery. Treating clinicians attributed the

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pulmonary embolism to hypercoagulability due to medroxyprogesterone acetate birth control. The event was not considered related to the study product by the investigator or the Sponsor. The last date of medroxyprogesterone acetate is not recorded.

- A 52-year-old male with obesity (body mass index: 32.4 kg/m^2) experienced a deep vein thrombosis (DVT) on Day 27 following vaccination. The participant experienced calf pain following physical activity on Day 13. An ultrasound on Day 27 demonstrated a DVT in a vein of the left calf. The event was considered non-serious by the investigator and related to the study product. The Sponsor considered the event not related to the study product.

- A 63-year-old male with type 2 diabetes, hypertension and osteoarthritis experienced a DVT on Day 23 following vaccination. The event was considered non-serious and not related to the study product by the investigator.

- A 49-year-old female with no past medical history and medication use including medroxyprogesterone experienced hemiparesis on Day 28 following vaccination. The event was considered serious by the investigator. No laboratory or imaging results were reported. The event was unresolved and ongoing on Day 51. The event was not considered related to the study product by the investigator or the Sponsor.

Assessment of the cases above is confounded by the presence of risk factors in the individual participants. Nevertheless, given the numerical imbalance between vaccine and placebo recipients and temporal relationship, vaccine cannot be excluded as a contributing factor. As such, data at this time are insufficient to determine if there a causal relationship between the vaccine and thromboembolic events. FDA will recommend surveillance for further evaluation of thromboembolic events with deployment of the vaccine into larger populations.

The SMQ for “convulsions” in the FAS demonstrated a numerical imbalance, with single events in 4 vaccine recipients and 1 event in a placebo recipient. All of the convulsion events reported by the vaccine recipients occurred within 28 days of vaccination. Two events in the vaccine groups were considered serious. Of the two serious events, one event was discussed above and occurred secondary to a cerebral hemorrhage in a participant with a transverse sinus thrombosis. The other serious event and one of the non-serious events occurred in participants with a history of seizures. FDA’s assessment is that these events are unlikely related to the study vaccine.

The SMQ for “hearing and vestibular disorders” included the PT “tinnitus” for which was a numerical imbalance was observed across treatment groups. Tinnitus was reported in 6 vaccine recipients (6 events) compared to no placebo recipients. Events of tinnitus are summarized in the table below.

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Table 30. Tinnitus in Vaccine Recipients, Full Analysis Set, Study 3001

Investigational Product	Age/Sex	Day of Onset	Resolution Status	Grade/ SAE[a]	Possible Risk Factor(s)	Related[a]
Ad26.COV2.S	58/M	1	Resolving	1/N	Hypertension	No
Ad26.COV2.S	63/F	1	Resolved	1/N	Hypothyroidism	Yes
Ad26.COV2.S	25/F	2	Resolved	1/N	Allergic rhinitis, medication use	Yes
Ad26.COV2.S	51/M	12	Unresolved	1/N	Hypertension, hypothyroidism, medication use	No
Ad26.COV2.S	54/M	17	Resolving	1/N	Allergic rhinitis	No
Ad26.COV2.S	65/F	22	Resolving	2/N	History of tinnitus	No

[a] Classification of events as SAEs and relatedness determined by study investigators

An additional event of tinnitus was reported in the clinical development of Ad26.COV2.S. The event, reported in Study 1002, occurred in 21-year-old male with no reported past medical history and no concomitant medications who experienced sudden hearing loss on Day 34 post-vaccination with Ad26.COV2.S. The hearing loss was associated with tinnitus and blocked ear sensation. Testing revealed sensorineural hearing loss. Workup for etiology including laboratory tests and imaging did not reveal an etiology. Hearing improved and the event was resolved by Day 69. The event was not considered related to the study product by the investigator or the Sponsor.

Assessment of these cases is confounded by the presence of risk factors in the individual participants. As such, data at this time are insufficient to determine if there a causal relationship between the vaccine and tinnitus.

The SMQ for “angioedema” in the FAS demonstrated a numerical imbalance, with events reported among 0.2% of vaccine recipients (44 events in 44 participants) compared to 0.12% of placebo recipients (28 events in 27 participants). By PT, “urticaria” was reported in 8 vaccine recipients compared to 3 placebo recipients. Within 7 days of vaccination, 5 events occurred in the vaccine group and 1 event occurred in the placebo group, all of which were grade 1 or 2. Based on temporal association and biologic plausibility, FDA’s assessment is that the events of urticaria are possibly related to study vaccine.

The PT “wheezing” was reported in 12 vaccine recipients (0.05%) and 7 placebo recipients (0.03%). However, there was no meaningful imbalance in events within 7 days of vaccination, with 4 events occurring each group; one event in the placebo group was grade 3 and all others were grade 1 or 2.

The SMQ for “arthritis” in the FAS demonstrated a numerical imbalance, with events reported among 0.5% of vaccine recipients (110 events in 109 participants) compared to 0.36% of placebo recipients (83 events in 78 participants). By PT, “arthralgia” was reported in 91 vaccine recipients (92 events) compared to 62 placebo recipients (67 events). In vaccine recipients, 56 of these events (60.8%) occurred within 7 days following vaccination compared to 24 events (35.8%) in placebo recipients. FDA’s assessment is that these events likely represent vaccine reactogenicity.

The SMQ for “peripheral neuropathy” in the FAS demonstrated a numerical imbalance, with events reported among 0.21% of vaccine recipients (47 events in 45 participants) compared to 0.16% of placebo recipients (36 events in 35 participants). By PT, “muscular weakness” was reported by 31 vaccine recipients compared to 18 placebo recipients. In vaccine recipients, 18

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of these events (58.1%) occurred within 7 days following vaccination compared to 6 events (33.3%) in placebo recipients. FDA's assessment is that these events likely represent vaccine reactogenicity.

Immediate Adverse Events

Immediate unsolicited reactions occurring within 30 minutes of vaccination were infrequent and occurred in 0.2% of participants in both the vaccine and placebo groups. There were no reports of anaphylaxis immediately following vaccination.

Serious Adverse Events

Deaths

As of January 22, 2021, 19 deaths were reported (3 vaccine, 16 placebo). Two deaths in the vaccine group were secondary to respiratory infections not due to COVID-19. A 61-year-old participant died of pneumonia on Day 24 following onset of symptoms on Day 13. A 42-year-old participant with HIV died on Day 59 following diagnosis of a lung abscess on Day 33. A 66-year-old participant died of unknown causes after waking up with shortness of breath on Day 45. The placebo recipients died of pneumonia (n=2), suicide (n=1), accidental overdose (n=1), myocardial infarction (n=1), malaise (n=1), unknown cause (n=3) and confirmed COVID-19 (n=6). An update on deaths reported from the time period of January 22 to February 5 included an additional 6 deaths. Of these 6 deaths, 2 occurred in the vaccine group and 4, including 1 due to COVID-19, occurred in the placebo group. None were related to the study product.

Non-fatal Serious Adverse Events

The proportions of participants who had at least one SAE reported through January 22, 2021 were 0.4% in the vaccine group and 0.4% in the placebo group. The most commonly reported SAE was appendicitis occurring in 6 vaccine recipients and 5 placebo recipients. There were no significant numerical imbalances in SAEs by preferred term.

Seven SAEs occurring in 7 vaccine recipients and 3 SAEs occurring in 2 placebo recipients were assessed by the investigator as related to study vaccination (Table 31). Of the 7 SAEs in the vaccine group, the Sponsor assessed 3 as related/likely related, 2 as possibly related, 2 as unrelated to the vaccine.

Table 31. SAEs Considered Related by Investigator, Full Analysis Set, Study 3001

Investigational Product	SAE (PT)	Age/Sex	Day of Onset	Resolution Status	Grade	Related (Sponsor Assessment)
Ad26.COV2.S	Radiculitis brachial	30/M	1	Unresolved	3	Yes (Reassessed as injection site pain)
Ad26.COV2.S	Post-vaccination syndrome	35/M	2	Resolved	3	Yes (Reassessed as reactogenicity)
Ad26.COV2.S	Facial paralysis	62/M	3	Resolving	2	No
Ad26.COV2.S	Vaccination site hypersensitivity	42/M	3	Resolved	3	Likely
Ad26.COV2.S	Facial paralysis	43/M	16	Resolving	2	No
Ad26.COV2.S	Guillain-Barre Syndrome	60/F	16	Unresolved	4	Possibly
Ad26.COV2.S	Pericarditis	68/M	17	Resolved	4	Possibly
Placebo	Deep vein thrombosis	44/M	6	Resolving	4	Indeterminate

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Investigational Product	SAE (PT)	Age/Sex	Day of Onset	Resolution Status	Grade	Related (Sponsor Assessment)
Placebo	Epstein-Barr infection[a]	69/M	14	Resolved	3	No
Placebo	Atrial flutter[a]	69/M	21	Resolving	3	No

[a] Events occurred the same study participant

In FDA's opinion following review of narratives, the following 3 SAEs in the vaccine group are considered likely related to the study vaccine:

- A 42-year-old male with no personal or family history of allergic reactions experienced diffuse urticaria beginning on Day 3 following vaccination accompanied with systemic symptoms of fatigue, myalgia and arthralgia. Over the following two days the urticaria progressed, and the participant experienced angioedema of the lips as well as the sensation of itchy and tight throat, but no hypoxia or respiratory distress. The event did not meet Brighton Criteria for anaphylaxis. FDA's assessment is that this event was likely a hypersensitivity reaction to the study vaccine.

- A 30-year-old male was reported to have "brachial neuritis following vaccination" (PT: "radiculitis brachial") with pain at the site of vaccine administration on Day 1 which persisted and worsened over several days and was unresponsive to non-prescription analgesics. Evaluation included electroconductive studies, which revealed intact nerves with no denervation of the evaluated muscles, and MRI of the cervical spine, which did not reveal an etiology of the participant's symptoms. FDA's assessment of this event is that the pain at injection site is likely related to vaccination, however the diagnosis of brachial neuritis is unlikely given the findings on electroconductive studies.

- A 35-year-old male experienced generalized malaise, weakness, myalgia, shortness of breath, headache, sensation of numbness and tingling in upper extremities, chest pain and fever beginning on Day 2 following vaccination. The participant was hospitalized for exacerbated generalized weakness. Abnormal vital signs included fever (39.4°C), blood pressure (129/103 mmHg), heart rate (112bpm) and respiratory rate (19 breaths per minute). There was no hypoxia. On exam he complained of diffuse tenderness in the extremities. No abnormalities were noted on neurologic exam which included normal reflexes. Abnormal laboratory findings included a mild elevation of creatine kinase attributed to mild myositis. Laboratory testing was negative for COVID-19, influenza and RSV. Symptoms resolved by Day 4. FDA's assessment of this event is that it is likely systemic reactogenicity related to the study vaccine.

For the SAE of pericarditis, as no alternative etiology was determined, FDA's assessment is that the possibility that the vaccine contributed to the event cannot be excluded. Review of Janssen's safety database including all Ad26-based vaccines did not reveal any additional reports of pericarditis.

Reports of facial paralysis (Bell's Palsy) were overall balanced between vaccine and placebo recipients (2 vaccine, 2 placebo). In addition to the 2 SAEs of facial paralysis presented in Table 31 above, a third event in a 54-year-old vaccine recipient occurred on Day 19, described as facial swelling and "droopiness" with no facial asymmetry and intact cranial nerves II-XII. This event was not considered related by the investigator. In FDA's assessment, description of this event is not consistent with facial paralysis. Two events of facial paralysis were reported in placebo recipients on Days 2 and 29.

Obtained via FOIA by Judicial Watch, Inc.

There were single reports of Guillain-Barre Syndrome (GBS) in a 60-year-old vaccine recipient and a 75-year-old placebo recipient occurring on Days 16 and 10, respectively. The event in the vaccine group was preceded by symptoms of chills, nausea, diarrhea and myalgia. In FDA's assessment the events of facial paralysis and GBS are unlikely related to study vaccine but a causal relationship cannot be definitively excluded.

Subgroup Analyses

With the exception of more frequent, generally mild to moderate reactogenicity in participants 18-59 years of age, there were no specific safety concerns identified in subgroup analyses by age, race, ethnicity, medical comorbidities, or prior SARS-CoV-2 infection. Occurrence of solicited, unsolicited, and serious adverse events in these subgroups were generally consistent with the overall study population.

Pregnancies

Study participants of childbearing potential were screened for pregnancy prior to vaccination. Participants were excluded if they were pregnant or planned to become pregnant within 3 months of vaccine administration. The study is collecting outcomes for all reported pregnancies in study participants.

Eight pregnancies were reported through January 22, 2021 (4 vaccine, 4 placebo). In 7 participants (3 vaccine, 4 placebo) vaccination was within 30 days after last menstrual period (LMP) and in 1 vaccine recipient vaccination was prior to LMP. Unsolicited AEs related to pregnancy include spontaneous abortion (1 vaccine, 0 placebo), incomplete abortion (0 vaccine, 1 placebo), elective abortion (0 vaccine, 2 placebo) and ectopic pregnancy (1 vaccine, 0 placebo). Among participants in the vaccine group, two pregnancies are ongoing with outcomes unknown at this time.

A combined developmental and perinatal/postnatal reproductive toxicity study of Ad26.COV2.S in rabbits was submitted to FDA on January 19, 2021. FDA review of this study concluded that Ad26.COV.S given prior to mating and during gestation periods at dose of $1x10^{11}$ vp (2 times the human dose) did not have any adverse effects on female reproduction, fetal/embryonal development, or postnatal development.

Safety Summary

The information provided by the Sponsor was adequate for review and to make conclusions about the safety of the Ad26.COV2.S vaccine in the context of the proposed indication and population for intended use under EUA. The number of participants in the Phase 3 safety population (N=43,783; 21,895 vaccine, 21,888 placebo) meets the expectations for efficacy in FDA's guidance for industry Development and Licensure of Vaccines to Prevent COVID-19 (June 2020). A subset of participants (N=6,736) was followed for solicited reactions within 7 days following vaccination and unsolicited reactions within 28 days following vaccination. The demographic and baseline characteristics of the all-enrolled population and the safety subset were similar with respect to age and sex but had imbalances with respect to race, baseline comorbidities, SARS-CoV-2 serostatus and geographic distribution.

Local site reactions and systemic solicited events among vaccine recipients were frequent and mostly mild to moderate. The most common solicited adverse reactions were injection site pain (48.6%), headache (38.9%), fatigue (38.2%) and myalgia (33.2%); 0.7% and 1.8% of local and

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systemic solicited adverse reactions, respectively, were reported as grade 3. Overall, solicited reactions were reported more commonly in younger participants.

There were no meaningful imbalances in unsolicited adverse events in 28 days following vaccination between vaccine and placebo recipients in the safety subset. Among all adverse events collected through the data cutoff of January 22, 2021, a numerical imbalance was seen in urticaria events reported in the vaccine group (n=5) compared to placebo group (n=1) within 7 days of vaccination which is possibly related to the vaccine. Numerical imbalances were reported between vaccine and placebo recipients for thromboembolic events (15 versus 10) and tinnitus (6 versus 0). Based on currently available information, a contributory effect of the vaccine could not be excluded, although the imbalance was small (representing a difference of 0.06% of vaccine recipients vs. 0.05% of placebo recipients), and many of the participants had predisposing conditions. FDA will recommend surveillance for further evaluation of thromboembolic events with deployment of the vaccine into larger populations. There were no other notable patterns or numerical imbalances between treatment groups for specific categories of adverse events that would suggest a causal relationship to Ad26.COV2.S.

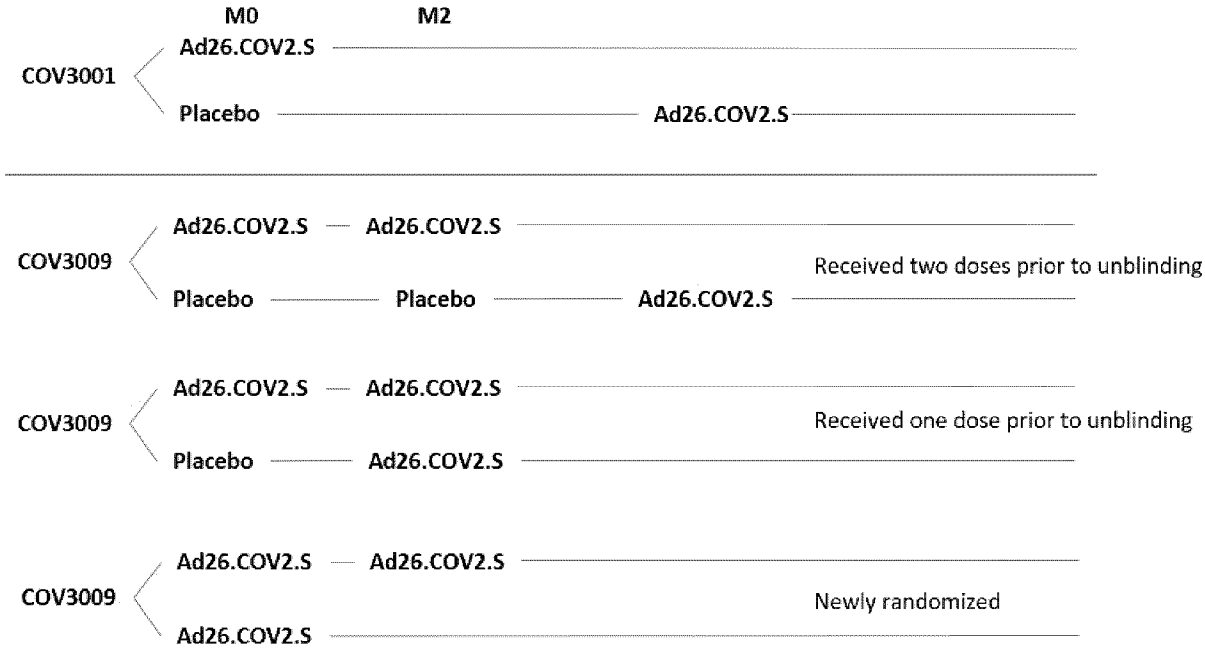
As of February 5, 2021, a total of 25 deaths were reported in the study (5 vaccine, 20 placebo). These deaths represent events and rates that occur in the general population of individuals in these age groups and include 7 deaths in the placebo group due to COVID-19 infection. Non-fatal serious adverse events, excluding those due to COVID-19, were infrequent and balanced between treatment groups with respect to rates and types of events (0.4% in both groups). A serious event of a hypersensitivity reaction, not classified as anaphylaxis, beginning 2 days following vaccination was likely related to receipt of the vaccine.

6. Sponsor's Plans for Continuing Blinded, Placebo-Controlled Follow-Up

In the event that the Ad26.COV2.S vaccine receives FDA authorization for emergency use, the Sponsor proposes to submit a protocol amendment to Study 3001 that would allow all participants who received placebo to receive the vaccine (Figure 2). This would effectively result in unblinding of participants and investigators. However, participants who crossover from placebo will be encouraged to remain in the study up to 2 years after vaccination so that they may be followed for efficacy/effectiveness, safety, and immunogenicity. The Sponsor anticipates that open-label crossover vaccination would also be offered to placebo recipients in the ongoing Phase 1 and 2 studies. Janssen also proposes offering a single dose of Ad26.COV2.S to enrolled participants who initially received two doses of placebo in study COV3009. Because the study is expected to still be enrolling, participants who received a first dose of placebo will receive a dose of Ad26.COV2.S as their second dose and participants yet to be enrolled will be randomized to either a single-dose or a two-dose schedule of Ad26.COV2.S. Crossover vaccination would be made available to U.S. participants as soon as operationally feasible following the issuance of an EUA. Study investigators will be encouraged to consider current local public health guidance for determining the scheduling priority of participants.

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Figure 2. Sponsor's Proposed Crossover Design Following Issuance of an EUA



7. Pharmacovigilance Activities

Janssen submitted a Pharmacovigilance Plan (PVP) to monitor safety concerns that could be associated with the Janssen COVID-19 Vaccine. The Sponsor identified vaccine-associated enhanced disease (including vaccine-associated enhanced respiratory disease), anaphylactic reactions (including anaphylaxis), and thromboembolic events as Important Potential Risks.

Important Missing Information includes: use during pregnancy and lactation, use in immunocompromised patients, use in patients with autoimmune or inflammatory disorders, use in frail patients with comorbidities (e.g., chronic obstructive pulmonary disease, diabetes, chronic neurological disease, and cardiovascular disorders), interaction with other vaccines, long-term safety, and use in pediatrics.

The Sponsor will conduct both passive and active surveillance activities for continued vaccine safety monitoring. Passive surveillance activities will include submitting spontaneous reports of the following events to the Vaccine Adverse Event Reporting System (VAERS) within 15 days:

- Serious adverse events (regardless of attribution to vaccination)
- Multisystem inflammatory syndrome
- COVID-19 disease resulting in hospitalization or death

The Sponsor will submit monthly safety reports containing a review of safety information received during the reporting interval, as well as cumulative data. Each periodic safety report is required to contain descriptive information which includes:

- A narrative summary and analysis of adverse events submitted during the reporting interval, including interval and cumulative counts by age groups, special populations (e.g., pregnant women), and adverse events of special interest
- A narrative summary and analysis of vaccine administration errors whether or not associated with an adverse event, that were identified since the last reporting interval

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- Safety concerns newly identified in the interval
- Actions taken since the last report because of adverse experiences (e.g., changes made to fact sheets given to vaccination providers, changes made to studies, or studies initiated)

The Sponsor plans to conduct long-term follow-up of participants in the ongoing clinical trials. The Sponsor has also submitted protocols for the post-authorization studies listed below. FDA is reviewing the protocols and will provide feedback.

Pregnancy study: multi-country, observational, prospective cohort study of pregnant women vaccinated with Ad26.COV2.S to assess obstetric, neonatal, and infant outcomes

Active surveillance study of safety: retrospective, observational, propensity-scored matched cohort study using health insurance claims and electronic health records to assess the risk of prespecified adverse events of special interest following vaccination with Ad26.COV2.S

Active surveillance study of effectiveness: retrospective, observational propensity-scored matched cohort study using health insurance claims and electronic health records to estimate the effectiveness of Ad26.COV2.S to prevent medically attended COVID-19 in individuals vaccinated according to national immunization recommendations

Reporting to VAERS and Janssen

Providers administering the Ad26.COV2.S vaccine must report to VAERS (as required by the National Childhood Vaccine Injury Act) and to the extent feasible, report to Janssen, the following information associated with the vaccine of which they become aware:

- Vaccine administration errors whether or not associated with an adverse event
- Serious adverse events (regardless of attribution to vaccination)
- Multisystem inflammatory syndrome
- COVID-19 disease resulting in hospitalization or death

Additional VAERS Reporting

An additional source of VAERS reports will be through a program administered by the CDC known as V-safe. V-safe is a smartphone-based opt-in program that uses text messaging and web surveys to help COVID-19 vaccine recipients monitor for and report side effects. The system also will provide telephone follow-up to anyone who reports medically important adverse events. Responses indicating missed work, inability to do normal daily activities, or receipt of care from a doctor or other healthcare professional will trigger the VAERS Call Center to reach out to the participant and collect information for a VAERS report, if appropriate.

8. Benefit/Risk Assessment in the Context of Proposed Indication and Use Under EUA

8.1 Known Benefits

The known benefits among recipients of the proposed vaccine relative to placebo are:

- Reduction in the risk of confirmed COVID-19 occurring at least 14 days after vaccination
- Reduction in the risk of confirmed severe COVID-19 (including reduction in the risk of COVID-19 requiring medical intervention) occurring at least 14 days after vaccination

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The vaccination regimen was effective in preventing PCR-confirmed COVID-19 occurring at least 14 days after receipt of the vaccine. The vaccine was effective in preventing COVID-19 using a less restrictive definition of the disease and for more severe disease, including COVID-19 requiring medical intervention, considering all cases starting 14 days after vaccination. Efficacy findings were also generally consistent across evaluable subgroups, including by age, race, ethnicity, and risk for severe COVID-19. Although VE estimates appeared to be lower in the subgroup of participants 60 years of age and older with comorbidities, an increase in VE estimates and narrowing of the CI was observed with inclusion of more cases (i.e., starting at 14 days post-vaccination and cases not yet centrally confirmed), indicating that the results seen potentially reflect imprecision associated with smaller numbers of cases. Additionally, case splits for COVID-19 requiring medical attention among participants 60 years of age and older with comorbidities further support benefit of the vaccine in this subgroup. Although a lower efficacy overall was observed in South Africa, where there was a predominance of B.1.3.5 lineage during the time period of this study, vaccine efficacy against severe/critical COVID-19 was similarly high across the United States, South Africa, and Brazil.

The vaccine is administered as a single dose, which provides operational benefits to mass vaccination campaigns.

8.2 Unknown Benefits/Data Gaps

Duration of protection

As the analyses have a limited length of follow-up, it is not possible to assess sustained efficacy over a period longer than 2 months.

Effectiveness in certain populations at higher risk of severe COVID-19

Although the proportion of participants at high risk of severe COVID-19 is adequate for the overall evaluation of safety in the available follow-up period, the subsets of certain groups such as immunocompromised individuals (e.g., those with HIV/AIDS) are too small to evaluate efficacy outcomes.

Effectiveness in individuals previously infected with SARS-CoV-2

Limited data suggest that individuals with prior SARS-CoV-2 infection can be at risk of COVID-19 (i.e., re-infection) and may benefit from vaccination. Regarding the benefit of the Ad26.COV2.S for individuals with prior infection with SARS-CoV2, there were limited cases of COVID-19 among study participants with positive SARS-COV-2 infection status at baseline. The study was not designed to assess the benefit in individuals with prior SARS-CoV-2 infection.

Effectiveness in pediatric populations

No efficacy data are available from participants ages 17 years and younger.

Future vaccine effectiveness as influenced by characteristics of the pandemic, changes in the virus, and/or potential effects of co-infections

The study enrollment and follow-up occurred during the period of September 21, 2020 to January 22, 2021, in sites across the United States, South Africa, and 6 countries in Latin America, which was a setting of high disease incidence with several regionally circulating SARS-CoV-2 variants. The evolution of the pandemic characteristics, including potential changes in the virus infectivity, antigenically significant mutations to the S protein, and/or the

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effect of co-infections may potentially limit the generalizability of the efficacy conclusions over time. Continued evaluation of vaccine effectiveness following issuance of an EUA and/or licensure will be critical to address these uncertainties.

Vaccine effectiveness against asymptomatic infection

Available Day 71 N-serology data from a small subset of participants in the study, with infrequent evaluations of serological and virological measurements, are limited to assess the effect of the vaccine in preventing asymptomatic infection. There is uncertainty about the interpretation of these data and definitive conclusions cannot be drawn at this time.

Additional evaluations will be needed to assess the effect of the vaccine in preventing asymptomatic infection, including data from clinical trials and from the vaccine's use post-authorization and including additional data to support the sensitivity of serologic and virologic surveillance methods.

Vaccine effectiveness against long-term effects of COVID-19 disease

COVID-19 disease may have long-term effects on certain organs, and at present it is not possible to assess whether the vaccine will have an impact on specific long-term sequelae of COVID-19 disease in individuals who are infected despite vaccination. Demonstrated high efficacy against symptomatic COVID-19 should translate to overall prevention of COVID-19-related sequelae in vaccinated populations, though it is possible that asymptomatic infections may not be prevented as effectively as symptomatic infections and may be associated with sequelae that are either late-onset or undetected at the time of infection (e.g., myocarditis). Additional evaluations will be needed to assess the effect of the vaccine in preventing long-term effects of COVID-19, including data from clinical trials and from the vaccine's use post-authorization.

Vaccine effectiveness against mortality

A larger number of individuals at high risk of COVID-19 and higher attack rates would be needed to confirm efficacy of the vaccine against mortality. However, non-COVID vaccines (e.g., influenza) that are efficacious against disease have also been shown to prevent disease-associated death.[8-11] Benefits in preventing death should be evaluated in large observational studies following authorization.

Vaccine effectiveness against transmission of SARS-CoV-2

Data are limited to assess the effect of the vaccine against transmission of SARS-CoV-2 from individuals who are infected despite vaccination. Demonstrated high efficacy against symptomatic COVID-19 may translate to overall prevention of transmission in populations with high enough vaccine uptake, though it is possible that if efficacy against asymptomatic infection were lower than efficacy against symptomatic infection, asymptomatic cases in combination with reduced mask-wearing and social distancing could result in significant continued transmission. Additional evaluations including data from clinical trials and from vaccine use post-authorization will be needed to assess the effect of the vaccine in preventing virus shedding and transmission, in particular in individuals with asymptomatic infection.

8.3 Known Risks

The vaccine elicited increased local and systemic adverse reactions as compared to those in the placebo arm, usually lasting 1 to 2 days. The most common solicited adverse reactions were

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injection site pain (48.6%), headache (38.9%), fatigue (38.2%) and myalgia (33.2%). Adverse reactions characterized as reactogenicity were generally mild to moderate; 0.7% and 1.8% of local and systemic solicited adverse reactions, respectively, were reported as grade 3. Overall, solicited reactions were reported more commonly in younger participants. Among all adverse events collected through the data cutoff of January 22, 2021, a numerical imbalance was seen in urticaria events reported in the vaccine group (n=5) compared to placebo group (n=1) within 7 days of vaccination with is possible related to vaccination. Numerical imbalances were also observed between vaccine and placebo recipients for thromboembolic events (15 versus 10) and tinnitus (6 versus 0), with many of the participants experiencing these events having predisposing risk factors. Data at this time are insufficient to determine a causal relationship between these events and the vaccine.

Serious adverse events, while uncommon (0.4% in both treatment groups), represented medical events that occur in the general population at similar frequency as observed in the study. Of the 7 SAEs that occurred in the vaccine group, FDA considered 3 as related: hypersensitivity reaction, not classified as anaphylaxis (n=1), severe and persistent injection site pain (n=1), and severe systemic reactogenicity (n=1). For the serious adverse events of pericarditis, facial paralysis and GBS, data are insufficient to determine a causal relationship to vaccination.

No specific safety concerns were identified in subgroup analyses by age, race, ethnicity, medical comorbidities, or prior SARS-CoV-2 infection.

8.4 Unknown Risks/Data Gaps

Safety in certain subpopulations

There are currently insufficient data to make conclusions about the safety of the vaccine in subpopulations such as children less than 18 years of age, pregnant and lactating individuals and their infants, and immunocompromised individuals.

FDA review of a combined developmental and perinatal/postnatal reproductive toxicity study of Ad26.COV2.S in female rabbits concluded that Ad26.COV2.S given prior to mating and during gestation periods at dose of $1x10^{11}$ vp (2 times human dose) did not have any effects on female reproduction, fetal/embryonal development, or postnatal development.

Adverse reactions that are very uncommon or that require longer follow-up to be detected

Following authorization of the vaccine, use in large numbers of individuals may reveal additional, potentially less frequent and/or more serious adverse events not detected in the trial population of approximately 20,000 vaccine recipients over the period of follow-up at this time. Active and passive safety surveillance will continue during the post-authorization period to detect new safety signals.

Vaccine-enhanced disease

Available data do not indicate a risk of vaccine-enhanced disease, and conversely suggest effectiveness against severe disease within the available follow-up period. However, risk of vaccine-enhanced disease over time, potentially associated with waning immunity, remains unknown and needs to be evaluated further in ongoing clinical trials and in observational studies that could be conducted following authorization and/or licensure.

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10. Appendix A. Other Clinical Studies Ad26.COV2.S

10.1 Study 1001

Design: Study 1001 is an ongoing, randomized, double-blind, placebo-controlled, first-in-human Phase 1/2a study, conducted in Belgium and the United States in healthy adults ages 18 to 55 years and in adults ≥65 years in good health with and without stable underlying conditions. Participants are randomized to placebo or Ad26.COV2.S administered at either of two dose levels (5×10^{10} vp or 1×10^{11} vp) and either as a single dose or as 2 doses 56 days apart. The total study population will include 1,045 adults. By the cutoff date of January 11, 2021, the median follow-up time for participants in the 18 to 55 and ≥65 age groups were 166 and 144 days, respectively.

Objectives/Endpoints Relevant to the EUA: The primary objective is to assess the safety and reactogenicity of Ad26.COV2.S at 2 dose levels. In addition, immunogenicity of the Ad26.COV2.S regimens is being assessed. Humoral immunogenicity is assessed via SARS-CoV-2 neutralizing antibody response as measured by a wild type SARS-CoV-2 neutralization assay (wtVNA). Spike protein binding antibody responses after one vaccination are measured by S-ELISA. Cellular immunogenicity is measured by S-specific CD4+ and CD8+ T-cell responses. All participants are followed for solicited adverse reactions through 7 days post each vaccination. Unsolicited AEs are collected through 28 days after each vaccination. All SAEs and medically attended adverse events are collected through the end of the study.

Results: A single dose of Ad26.COV2.S at the 5×10^{10} vp dose level (the dose level selected for the Phase 3 studies) elicited a SARS-CoV-2 neutralizing antibody (wtVNA) and SARS-CoV-2 Spike binding antibody response that was detected by Day 15 and is increased by the Day 57 timepoint. Ad26.COV2.S was able to elicit cellular responses in participants consistent with a Th-1 phenotype. Ad26.COV2.S, given as a single dose was found to have an acceptable safety and reactogenicity profile in adults ≥18 years of age and did not raise safety concerns in any of the assessed populations.

10.2 Study 1002

Design: Study 1002 is a randomized, double-blind, placebo-controlled Phase 1, non-US IND study being conducted in Japan. The study population is comprised of healthy adults ages 20 to 55 years and ≥65 years in good health with or without stable underlying conditions. The primary objective is to assess the safety and reactogenicity of Ad26.COV2.S at two dose levels, 5×10^{10} vp and 1×10^{11} vp, administered IM with a 56-day interval. The immunogenicity of the Ad26.COV2.S regimens is also being assessed.

Results: In an interim analysis (data cutoff October 3, 2020), a single dose of Ad26.COV2.S elicited SARS-CoV-2 neutralizing antibody responses in participants 20-55 years of age by Day 29 post-vaccination, consistent with results of Study 1001. Both dose levels had acceptable tolerability and no safety concerns have been identified.

10.3 Study 2001

Design: Study 2001 is a randomized, double-blind, placebo-controlled Phase 2a study being conducted in Germany, Spain, and the Netherlands in healthy adults ≥18 to ≤55 years of age and adults in good or stable health ≥65 years of age. The study will also include a cohort of adolescents ≥12 to ≤17 years of age (not yet enrolled). Adults receive placebo or Ad26.COV2.S

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at one of four dose levels: 1×10^{11} vp, 5×10^{10} vp, $2.5x10^{10}$ vp, and $1.25x10^{10}$. A target of approximately 550 adult participants will be enrolled, with approximately one third ≥65 years of age.

Objectives/Endpoints Relevant to the EUA: The study will evaluate the safety, reactogenicity, and humoral immune response of Ad26.COV2.S in 1- and 2-dose vaccination regimens followed by antigen presentation after 4 months (2-dose regimen) or 6 months (1-dose regimen).

Results: Ad26.COV2.S elicited SARS-CoV-2 neutralizing antibody responses by Day 29 post-vaccination, consistent to those of the Phase 1/2a Study 1001. No safety concerns have been identified in any of the assessed populations.

10.4 Study 3009

Design: Study 3009 is a multicenter, randomized, double-blind, placebo-controlled, Phase 3, pivotal efficacy and safety study in adults ≥18 years of age being conducted in 10 countries. Participants living in, or going to, locations with high risk for acquisition of SARS-CoV-2 infection are randomized 1:1 to receive Ad26.COV2.S 5×10^{10} vp or placebo as 2-dose regimen with a 56-day interval. The objectives and endpoints are similar to those of Study 3001.

Results: Enrollment is ongoing. No safety concerns had been identified based on blinded reports of SAEs and deaths with a cutoff date of February 5, 2021.

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11. Appendix B. Case Definitions for Mild COVID-19 and FDA Harmonized COVID-19

11.1 Case Definition for Mild COVID-19

- A SARS-CoV-2 positive RT-PCR or molecular test result from any available respiratory tract sample (e.g., nasal swab sample, sputum sample, throat swab sample, saliva sample) or other sample;

AND at any time during the course of observation:

- One of the following symptoms: fever (≥38.0°C or ≥100.4°F), sore throat, malaise (loss of appetite, generally unwell, fatigue, physical weakness), headache, muscle pain (myalgia), gastrointestinal symptoms, cough, chest congestion, runny nose, wheezing, skin rash, eye irritation or discharge, chills, new or changing olfactory or taste disorders, red or bruised looking feet or toes, or shaking chills or rigors.

A case was considered mild when it met the above case definition but not the moderate to severe/critical definition.

11.2 FDA Harmonized Case Definition for COVID-19

- A SARS-CoV-2 positive RT-PCR or molecular test result from any available respiratory tract sample (e.g., nasal swab sample, sputum sample, throat swab sample, saliva sample) or other sample;

AND

- Any COVID-19 symptom: fever or chills, cough, shortness of breath or difficulty breathing, fatigue, muscle or body aches, headache, new loss of taste or smell, sore throat, congestion or runny nose, nausea or vomiting, diarrhea.

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THE CORONAVIRUSES

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ABSTRACT

Coronaviruses of human origin have emerged as probable important etiologic agents of acute upper respiratory tract illnesses in adults; their role in the etiology of respiratory illnesses of childhood is less certain. The first coronavirus of human origin, B814, was described in 1965 and since that time only 34 additional strains have been recovered. Ten of these were originally recovered in human embryonic tracheal organ cultures only, and the remainder in monolayer cell cultures. All of the latter group were antigenically related to a prototype strain designated 229E. As a result of the fastidious growth requirements of these agents, most of the knowledge concerning the clinical syndromes associated with them has come from challenge studies in volunteers and seroepidemiologic investigations. Coronaviruses have been shown to be associated with a substantial number of adult respiratory illnesses especially during certain periods when rhinovirus infections are infrequent. Progress in propagating coronaviruses and in detecting coronavirus infections has been achieved recently : viruses similar to 229E were successfully recovered in human embryonic intestine cell cultures from patients with upper respiratory tract illnesses; 3OC strains (B814, LP and EVS) were recovered in L132 cell cultures from infectious nasal washings; OC43 (and OC38) viruses which were originally recovered in OC and later adapted to grow in suckling mice were not only shown to directly hemagglutinate various erythrocytes but were also adapted to grow in MK cell cultures; OC43 virus was also found to induce hemadsorption of rat and mouse erythrocytes in certain cell cultures; and a coronavirus strain was detected by immune electron microscopy. Coronaviruses are also associated with certain diseases in animals.

* * *

In recent years, it has become apparent that the coronaviruses, a group of agents sharing a distinctive morphologic appearance and other properties such as an RNA core, and a lipid envelope (Table I) are capable of infecting and causing illnesses in humans and many different animals including mice, pigs, rats, calves, chickens and turkeys. These illnesses embrace a broad spectrum of syndromes ranging from respiratory illnesses in man, chickens, and rats, to epidemic diarrhea of pigs, calves, and turkeys. This presentation will attempt to assess the importance of these agents with special emphasis on coronaviruses of humans.

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Table I

Basic properties of coronaviruses

Size	80-200 nm.
Morphology (by negative staining)	Round or elliptical, moderately pleomorphic, relatively widely spaced club-or pear-shaped projections which are narrow at base and approximately 10 nm at outer edge and approximately 20 nm in length, distributed uniformly on the circumference.
Nucleic Acid	RNA (insusceptible to DNA inhibitors)
Sensitivity to Lipid Solvents	Ether and chloroform labile
Sensitivity to Acid (pH approx. 3.0)	Strains from humans-acid labile. Strains from animals - some acid resistant or relatively acid resistant, some acid labile.
Buoyant Density	1.18-1.24 g/cm^3 in sucrose, or potassium tartrate. 1.23-1.24 g/cm^3 in cesium chloride (IBV)
Morphogenesis	Budding into cytoplasmic vesicles.

References : 1, 3, 13, 21,26, 37, 47, 67.

CORONAVIRUSES OF HUMANS

It is difficult to estimate the importance of coronaviruses in humans by the conventional method of determining the isolation patterns of these agents in epidemiologic settings, since coronaviruses are extremely fastidious agents. Since 1965, when the first human coronavirus was described, only 31 additional isolates have been reported from man (Table II). A history of the recovery of these 32 strains will serve to demonstrate the fastidious nature of these organisms.

In 1965, Tyrrell and Bynoe described the cultivation of a novel type of common cold virus, designated B814, which was derived from a nasal swab and washing obtained 5 years previously from a boy with a common cold-like illness (68). The agent could not be propagated in cell cultures but was able to induce a common cold-like illness in volunteers. Repeated attempts to cultivate the agent from infectious nasal washings were unsuccessful. However, it was found that washings retained infectivity following filtration through a 590 nm membrane but not following ether treatment. Since it was felt that the failure to cultivate this agent was a result of the use of the highly modified dedifferentiated cells used in cell culture systems, the nasal washings were inoculated into human embryo tracheal (HET) organ cultures, a system incidentally known at the time to be able to support the growth of respiratory viral agents including the rhinoviruses (33). It was found that B814 organ culture (OC) harvests regularly induced colds in volunteers indicating that the agent had multiplied in this system.

From these initial studies, Tyrrell and Bynoe concluded that the B814 agent was virtually unrelated to any other known virus that had been recovered from the upper respiratory tract of humans, and since it was ether labile, suggested it might be a myxovirus.

As so often happens in medical research, Hamre and Procknow (1966) in the United States were independently struggling at about the same time to characterize a fastidious respiratory tract agent which they had recovered from 5 medical students, 4 of whom had a mild upper respiratory illness.

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Table II

Summary of coronavirus isolation and adaptation attempts in various systems and some of the major antigenic relationships among the human coronaviruses

Reference	HUMAN CORONAVIRUS STRAIN	RESULTS OF INITIAL ISOLATION ATTEMPTS IN INDICATED SYSTEM*			RESULTS OF ADAPTATION OR FURTHER ISOLATION ATTEMPTS IN INDICATED SYSTEM			MAJOR ANTIGENIC RELATIONSHIPS TO OTHER HUMAN CORONAVIRUSES
		O.C.**	T.C.**	S.M. **	O.C.	T.C.	S.M.	
61, 41, 8, 12, 9	B814	+	-	-	+	+§	N.T.	Distinct
27, 51, 9	229E	N.T.	+	N.T.	+	+	N.T.	Distinct
	241G, 243B, 276D, 299G	N.T.	+	N.T.	N.T.	+	N.T	Similar to 229E
49, 14, 48, 51, 9 19, 41	OC38 (664)	+	-	N.T.	+	+	+	Distinct
	OC43 (690)	+	-	N.T.	+	+	+	Identical to OC38++
	OC44 (691)	+	-	N.T.	+	-	-	Related to OC38 and 43
	OC1 (501), OC37 (663) OC48 (703)	+	-	N.T.	+	-	-	Not Definite
39	489, 511, 515	-	+	N.T.	-	+	-	Similar to 229E
	844	N.T.	+	N.T.	±	+	-	Similar to 229E
	840, 862, 865, 868, 879	N.T.	+	N.T.	N.T.	+	N.T.	Similar to 229E
8, 69, 12, 9	LP	+	-	N.T.	+	+§	N.T.	Related to 229E
	EVS	+	-	N.T.	+	+§	N.T.	Not determined
56	Linder	N.T.	+	N.T.	N.T.	+	N.T.	Similar to 229E
25	220, 227, 297, 0661, 0744, 0765, 0312	N.T.	+	N.T.	N.T.	+	N.T.	Similar to 229E
40	692	+	-	-	+.	-	-	Not related to OC43 & 229E by

* + = Growth in indicated system; - = no growth in indicated system; N.T. = not tested.
** O.C. = Human embryonic tracheal organ culture; T.C. = monolayer cell culture; S.M. = Suckling Mouse
++ OC38 and OC43 demonstrate consistent oneway serologic relationship with certain MHV strains
§ Recovered from nasal washings of volunteers inoculated with this agent.

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These agents were recovered initially in a second blind passage in human kidney cells, producing a cytopathic effect. The prototype strain, designated 229E, was found to be ether labile, not inhibited by either 5-fluorodeoxyurine or 5-iododeoxyuridine (5-IUDR), measured approximately 89 nm by membrane filtration, and was apparently unrelated serologically to myxoviruses of humans. In addition, all 5 students had serologic evidence of infection with this agent. Electron microscopic studies of OC harvests of the B814 and 229E viruses reported by Almeida and Tyrrell (1967), revealed that these agents were indistinguishable morphologically from the avian infectious bronchitis virus (IBV), a well-known animal agent. They were pleomorphic, round or elliptical, with an average diameter of 80 to 120 nm, and possessed a distinct layer of projections about 20 nm long with a narrow stalk and a head roughly 10 nm wide. The characteristic appearance of the coronaviruses is shown in Figure 1.

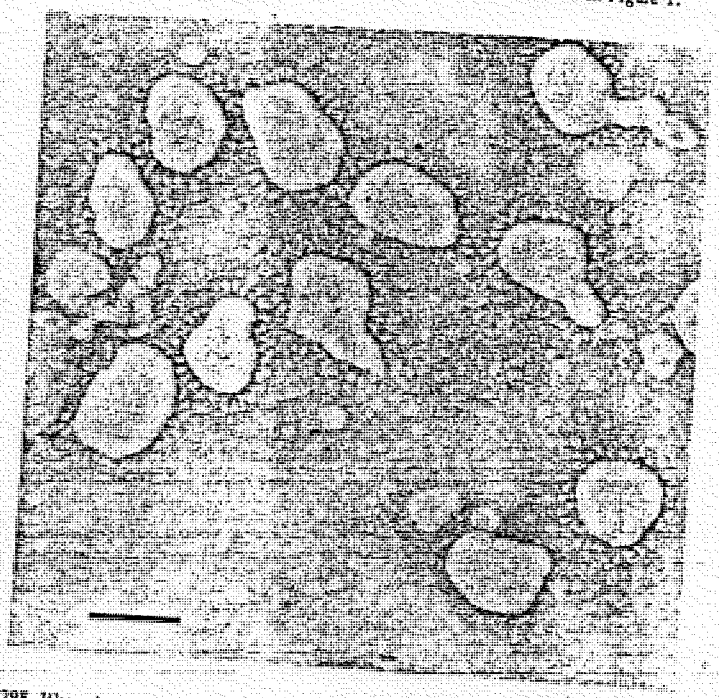


Fig. 1. 229E-like virus particles seen by electron microscopy in HEI-MAI77 cell culture harvests. These cultures had been inoculated with nasal-nasopharyngeal washings from a patient enrolled in the NIH 'common cold' study. Negative stain with 3% PTA. The bar = 100 nm. (From: A. Z. Kapikian: Diagnostic Procedures for Viral and Rickettsial Infections. Fourth Edition 1969, p. 931-946. Editors: E. H. Lennette and N. J. Schmidt. New York, N. Y.: American Public Health Association.)

As a result of the successful OC studies by Tyrrell and Bynoe, McIntosh et al. (1967) began to utilize the OC technique to study speciments which failed to yield agents in standard cell cultures.

Six agents which resemble IBV in morphology were recovered from 23 specimens obtained from adults with upper respiratory tract illnesses. All attempts to propagate the agents were unsuccessful; however, acute and convalescent sera of 2 patients were tested for neutralizing antibody by incubation with the homologous isolate followed by inoculation into organ cultures and examination of OC harvests for the presence or absence of 'IBV-like' particles by electron microscopy. Both patients demonstrated serologic evidence of infection by this technique. In related studies, it was found that mouse hepatitis virus (MHV) shared a similar morphologic appearance by negative staining (3).

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It was at about this time that an ad hoc international committee proposed the name coronavirus to include the avian IBV group, the MHV group, and the human IBV-like virus groups (19). This name was chosen since it was felt that the distinctive surface projections seen in negatively stained preparations of these agents were reminiscent of the solar corona.

We later described the isolation of 9 IBV-like agents - coronaviruses - from nasal-nasopharyngeal washings obtained from adults with upper respiratory infections, using a semicontinuous human embryonic intestine (HET-MA177) cell culture system (39).

Previous inoculation of the speciments into roller tube cell cultures of primary rhesus monkey kidney (MK), primary human embryonic kidney (HEK), Hep_2, roller tube cell cultures of human diploid cell strain (HDCS) WI_{26} or WI_{38} were negative for cytopathic effect. These agents were found to be chloroform-sensitive, acid labile, not inhibited by 5-IUDR, to have the typical coronavirus morphology, and to be neutralized by a hyperimmune 229E guinea pig antiserum. It is noteworthy that cell culture harvests of 4 of the isolates were passaged three times into HETOC and virus particles could not be visualized in the OC harvests indicating that the HEI tissue culture system was more sensitive than OC for the detection of these 4 strains. It should be noted, however, that the 6 strains recovered by Mclntosh et al. could not be adopted to grow in HEI cell cultures. It would appear, therefore, to be necessary to employ both HEI cell cultures, and organ cultures for the recovery of certain coronaviruses.

Two additional coronavirus strains LP and EVS were propagated in L132 cells (8). These agents had previously been propagated in OC only (69). The LP strain was found later to be similar but not identical to strain 229E (9). Eight additional 229E-like strains were recovered in cell cultures from adults with upper respiratory illness, 7 by Hamre and Beem, and one by Oshiro, Schieble and Lennette (25, 56).

We recently described the recovery of a strain designated 692, from an adult with an upper respiratory tract illness in HETOC but used immune electron microscopy for its detection (41). I will briefly summarize this study since I feel it is an important additional technique for the detection of these fastidious agents. We have recently reviewed the rationale for using this technique (38).

We adapted the technique of immune electron microscopy (2, 36) to the study of HETOC harvests derived from washings from adults with upper respiratory tract illnesses (41). A diluted nasal-nasopharyngeal washing from an NIH employee enrolled in our 'common cold study' was inoculated into roller tube cell cultures of primary rhesus MK, primary HEK, Hep_2, HEI-MA177, and WI_{38}. Neither cytopathic effect (CPE) nor hemadsorption (in MK cell cultures) was observed. Thus, the diluted washing was carried through three passages in HETOC and harvests from various days of the third OC passage were pooled and inoculated into the roller tube cell cultures previously mentioned except for Hep_2. As before, neither CPE nor hemadsorption was observed. Thus, the pooled harvests of the third OC passage were examined for the presence of virus particles by immune electron microscopy utilizing the patient's convalescent serum as the source of specific antibody in the hope that virus particles, if present, would appear in the form of aggregates and thus enable the visualization of a low titered coronavirus suspension which might not have been detectable without reaction with the specific antibody in the convalescent serum.

In this technique 0.1 ml of the OC harvest was incubated for one hour at room temperature with 0.1 ml of a 1 : 20 dilution of the patient's convalescent serum, and also with 0.1 ml of phosphate buf-

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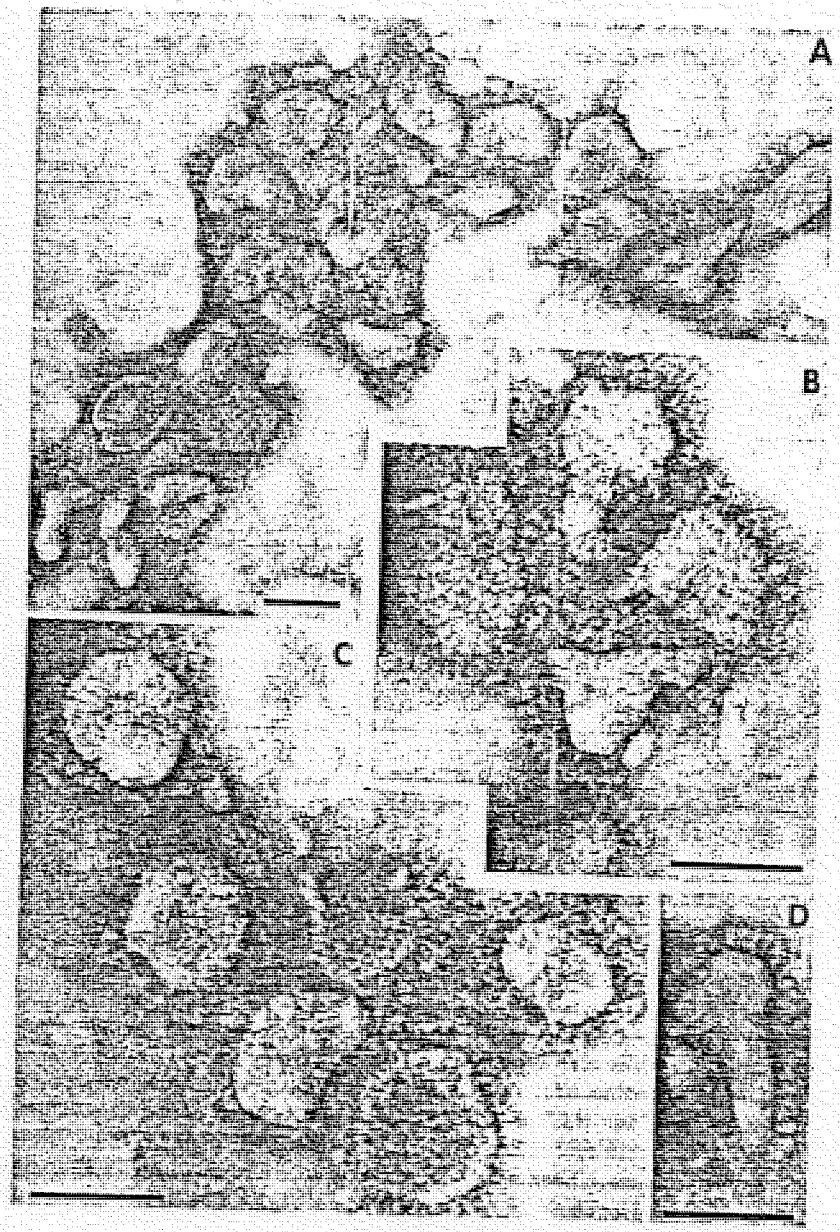


Fig. 2 A, B, C. A large and 2 small aggregates of coronavirus strain 692 observed using the technique of immune electron microscopy. The particles which appeared to be heavily coated with antibody were not randomly distributed but were present almost exclusively in aggregates.

Fig. 2 D. A single particle of coronavirus strain 692 observed on the same grid as the particles above. It appeared to be covered with little, if any, antibody. The bar in each figure equals 100 nm.

From A. Z. Kapikian, H. D. James, Jr, S. J. Kelly and A. L. Vaughn : Infection and Immunity 7 : 111-116 (1973).

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fered saline (PBS). An 0.8 ml amount of PBS was then added to each tube and the mixture centrifuged at 17,000 rpm for 90 min in a Sorvall RC2 centrifuge with an SS34 fixed angle rotor. The supernatant fluid was discarded, the pellet or residue resuspended with a few drops of distilled water, stained with 3% phosphotungstic acid and placed on a 400 mesh formvar carbon-coated grid; the excess fluid was withdrawn with filter paper. The grid was examined at a magnification of approximately 44,000 with a Siemens Elmiskop 1A electron microscope.

Reaction of the OC harvest with the patient's convalescent serum resulted in the appearance of aggregates of coronavirus-like particles heavily coated with antibody as seen in Figure 2. The particles were present almost exclusively as groups which stood out clearly from the surrounding matter. A single particle was observed which appeared to be covered with little, if any, antibody. Examination of the OC harvest-PBS mixture did not reveal any coronavirus particles. We carried out additional studies to determine if strain 692 was related to strains 229E and OC43, the only known distinct coronaviruses of humans which we have been able to propagate in cell cultures. In serological tests by immune electron microscopy in which the presence or absence of aggregation was used as the measure of serological reactivity, aggregates were observed following incubation of strain 692 with the homologous convalescent serum, but not with specific animal antisera to the other two coronaviruses, indicating that by this test system, strain 692 was not related serologically to strains OC43 and 229E. Thus, the technique of immune electron microscopy not only enabled the detection of strain 692 but also enabled the demonstration of its serologic distinctness.

This completes the review of the history of the isolation of the 32 coronavirus strains of humans reported since 1965 when the first strain, B814, was described. It is noteworthy that 10 were originally recovered in OC only, whereas 22 which were originally recovered in cell cultures are all similar, if not identical, to a prototype strain designated 229E (see Table I).

Attempts to adapt these fastidious agents to other 'in vitro' and 'in vivo' systems have met with limited success (Table I). Strains B814, LP and EVS were found to induce a cytopathic effect in L132 cells, a continuous human embryo lung cell line (8, 12). The OC38 and OC43 viruses were successfully adapted to the suckling mouse causing an encephalitis following inoculation (48); this enabled the development of a complement fixation (CF) and later an hemagglutination-inhibition (HI) test for these agents (44, 48). In addition, they induced infection without illness in weanling mice (48). These same agents were found to induce a cytopathic effect in MK cell cultures and later found to hemadsorb certain erythrocytes (14, 40). The other five NIH OC strains were uniformly negative in inducing cytopathic effect in cell cultures (14, 41). Thus, five of the 10 OC agents have been able to be successfully adopted to cell cultures or to an 'in vivo' system.

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ANTIGENIC RELATIONSHIPS AMONG THE CORONAVIRUSES

The absence of a cell culture or an animal system for many of the OC strains (OC16, 37, 44, 48, and B632) limits studies of antigenic relationships among coronaviruses of humans. However, using available systems such an investigation was carried out by McIntosh et al. (1969) and Bradburne (1970). Table III shows the results of complement-fixation tests of several coronaviruses with animal sera prepared against OC38, OC43, IBV-42 and 4 strains of MHV in studies by McIntosh et al. (1969). 229E, MHV strain A59, and IBV-42 failed to react with heterologous sera whereas strains OC38 and OC43 not only reacted identically with each other's serum but also fixed complement with the MHV polyvalent mouse serum. In further testing, OC43 reacted with individual antisera against MHV strains A59, JHM, MHV-1 and MHV-S at a titer 2 to 4-fold lower than that of the homologous reaction whereas none of these MHV strains fixed complement with strain OC43 mouse serum. Studies by Bradburne (1970) revealed a greater number of cross-reactions among the coronavirus strains by complement-fixation tests. Neutralization tests by McIntosh et al. (1969) confirmed that strains OC38 and OC43 were indistinguishable and revealed no significant cross-relationships among the MHV, 229E, IBV-42, and OC38 strains. Neutralization tests reported by Bradburne (1970) (a) confirmed the distinctness of IBV (strain Beaudette, or 42), (b) demonstrated that the B814 virus was not related to IBV, (Beaudette strain), MHV, 229E, LP and OC43 viruses, (c) showed the relative distinctness of OC43 virus and (d) demonstrated that LP and 229E viruses although not identical were quite similar to one another but relatively distinct from the other coronaviruses included in the neutralization studies. High titer OC43 mouse ascitic fluid was found to neutralize 229E virus but at

Table III

Coronavirus antigenic relationships studied by complement-fixation (CF) with hyperimmune animal sera. From K. McIntosh et al.: J. Immunol. 102: 1109-1118 (1969) (51)

Virus strain	Source of CF antigen	Units used in test	Reciprocal of antibody titer in animal serum prepared against designated virus*			
			OC38 (mouse)	OC43 (mouse)	MHV polyvalent (mouse)+	IBV-42 (hamster ascites)‡
OC38	Suckling mouse brain	4-8	160	320	40	<10
OC43	Suckling mouse brain	4-8	160	320	80	<10
MHV (A-59)	Mouse liver tissue culture**	4	<10	<10	≥160	<10
229E	WI38 tissue culture	8§	<10	<10	< 10	<10
IBV-42	Allantoic fluid	4	<10	<10	< 10	160

* Control CF antigens did not fix complement with these sera at a 1:10 dilution.

\+ Serum prepared by Dr. J. Parker against MHV strains A-59, JHM, MHV-1 and MHV-S.

‡ See text.

** Tissue culture line NCTC-1469 (42).

§ Measured with a convalescent human serum.

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a 32-fold lower titer than the homologous titer. It is noteworthy that the OC38-43 viruses have also been shown to be indistinguishable by HI and hemadsorption-neutralization tests (40, 44); in addition, with the HI technique, the lack of relatedness of OC38-43 viruses with hyperimmune serum to other coronaviruses has been demonstrated (9) as well as the relatedness of the OC38-43 viruses to certain MHV strains (9, 44). It thus appears that three relatively distinct coronavirus serotypes of humans can be classified - B814, 229E, and OC38 or OC43 (Table I). It should be noted however that in studies of paired sera from humans following natural or experimental infections, heterologous CF or HI responses occur quite commonly. Data on such neutralizing antibody responses is scanty. Bradburne and Somerset (1972) have shown that a significant increase in HI antibody to the OC43 virus occurred in 14 of 70 volunteers who developed illness following challenge with coronaviruses other than OC38 or OC43, whereas 6 of 13 challenged with the latter agents developed the homologous response. In addition, 10 of 63 volunteers who became ill following administration of coronaviruses other than 229E or LP, demonstrated significant CF antibody rises to the 229E antigen, and 18 of 83 who became ill following administration of various human coronaviruses developed CF antibody increases to MHV_3 virus. Certain heterologous CF antibody responses following natural infections are described later. It is obvious from these studies that antibody responses found in seroepidemiologic surveys to specific coronavirus antigens may represent either infections with an identical or closely related agent or infection with a more distantly related one.

CLINICAL MANIFESTATIONS OF CORONAVIRUS INFECTIONS IN HUMANS

This would be a good place to address ourselves to the question of the importance of coronaviruses as disease producing agents in man. Obviously the usual type of study which relies heavily on virus isolation techniques in order to establish an etiologic relationship is not possible since,as mentioned previously, only 32 human coronavirus isolates have been reported. Therefore, we must rely on seroepidemiologic studies using as antigens those coronaviruses which have been grown successfully 'in vitro' or 'in vivo'. In these serological surveys, we are restricted to the study of two agents, 229E and OC43, since these are the only two distinct coronaviruses which have been consistently grown in suitable 'in vitro' or 'in vivo' systems. As a result a CF, neutralization, and HI test is available for OC43 virus, and a CF and neutralization test for the 229E virus. The B814 agent has not been able to be grown in our laboratory and seroepidemiologic studies with this agent have not been reported.

Before we describe seroepidemiologic studies we must consider how we know that these agents are capable of producing disease, since seroepidemiologic surveys will not yield this information conclusively. In a study reported by Bradburne, Bynoe and Tyrrell (1967), the B814 and 229E viruses were ad-

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ministered by the nasal route to 26 and 75 volunteers as shown in Table IV; 50 and 45%, respectively, of inoculated volunteers developed illnesses resembling the common cold. The incubation period ranged from 2 to 5 days with a mean of just over 3 days. The duration of illness ranged from 2 to 18 days with a mean of 7 and 6 days for 229E and B814 viruses, respectively. The number of disposable paper tissues used daily ranged from 8 to 120 with a mean of about 20. Symptoms included malaise in slightly less than one half, headache in 85 and 53%, chills in 31 and 18%, sore throat in 54 and 79%, and cough in 31 and 44%

Table IV

Clinical features of colds produced by inoculating four viruses.
From A.F.Bradburne, M.L.Evnoe and D.A.J.Tyrrell : Brit.Med.J. 3 : 767-769 (1967) (10)

	Avian-Infectious-Bronchitis-like		Rhinoviruses	
	229-E	B814*	Type 2 (HGP or PK)	DC*
No. of volunteers inoculated	26	75	213	251
No. getting colds	13(50%)	34(45%)	78(37%)	77(31%)
Incubation period (days)				
Mean	3.3	3.2	2.1	2.1
Range	2-4	2-5	1-5	1-4
Duration (days)				
Mean	7	6	9	10
Range	3-18	2-17	3-19	2-26
Maximum No. of handkerchiefs used daily				
Mean	25	21	14	18
Range	8-105	8-120	3-38	3-60
Malaise (%)	46	47	28	25
Headache (%)	85	53	56	56
Chill (%)	31	18	28	15
Pyrexia (%)	23	21	14	18
Mucopurulent nasal discharge (%)	0	62	83	80
Sore throat (%)	54	79	87	73
Cough (%)	31	44	68	56
No. of volunteers with colds of indicated severity				
Mild	10(77%)	24(71%)	63(80%)	36(47%)
Moderate	2(15%)	7(20%)	12(15%)	28(36%)
Severe	1(8%)	3(9%)	4(5%)	13(17%)

*Virus was administered only as nasal washings.

The statistical probability of some of the features of the colds due to 229-E virus in relation to colds due to other cold viruses are shown below.

(1) t-test on incubation periods	229-E:	B814	0.3 > P > 0.25
	229-E:	Rhino type 2	0.005 > P > 0.001
	229-E:	DC	0.05 > P > 0.025
	DC :	Rhino type 2	0.498 > P > 0.495
(2) t-test on duration of colds	229-E:	B814	0.15 > P > 0.10
	229-E:	Rhino type 2	0.10 > P > 0.05
	229-E:	DC	0.20 > P > 0.15
	B814 :	Rhino type 2	0.10 > P > 0.05
	B814 :	DC	0.01 > P > 0.005
	DC :	Rhino type 2	0.95 > P > 0.90

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for the 229E and B814 viruses, respectively. It is noteworthy that about 1/5th of the volunteers with 229E-induced illness developed fevers which ranged from 99.2 to 100.4 degrees F. orally. It is of interest that the mean incubation period of the coronavirus colds were significantly longer by about one day, the duration of illness somewhat shorter, and the mean of the maximal number of paper tissues used daily greater than that observed in the common colds induced by rhinoviruses 2 and DC. Malaise appeared to be somewhat more common and cough less common in rhinovirus colds. The signs and symptoms observed following challenge with 229E and B814 viruses were similar to those observed in our later studies of 9 individuals from whom a 229E-like agent was recovered under natural conditions (39). In these 9, all had coryza, 8 nasal congestion, 7 sneezing and 5 sore throat. Less common symptoms were headache, cough, muscular or general aches, chills and feverishness. In addition, in the studies by Bradburne and Somerset (1972), characteristic common colds were induced in volunteers with strains LP, EVS and NIH OC strains 16, 37, 38, 43, 44 and 48. From the volunteer challenge studies it is obvious that coronaviruses have the capacity to induce a common cold-like illness in adults. Seroepidemiological studies using antigens for OC38 or OC43, and 229E have yielded valuable but limited information on the relative importance of these agents in man. These studies are summarized in Table V and are discussed below.

SEROEPIDEMIOLOGICAL STUDIES OF CORONAVIRUSES IN HUMANS

The first seroepidemiologic survey involving a coronavirus in humans was actually carried out in 1963 by Hartley et al. (1964), before the existence of the group was known, when in attempting to establish the specificity of a CF test for MHV, it was found that 65 (12%) of 544 paired sera obtained from marine recruits reporting for various reasons to the dispensary during January to March of 3 years had four-fold or greater rises in CF antibody to the MHV-A59 virus (Table V, study A). The authors suggested as a likely explanation for the antibody rises, that infection had occurred with an as yet undescribed virus of humans generically related to the mouse hepatitis viruses. This was borne out some years later when the antigenic relationship between MHV and certain human coronaviruses was described.

Hamre and Beem (1972) reported a surveillance study of acute respiratory disease among medical students embracing 6 consecutive seasons between 1961 and 1968 which included 937 student years of observation (Table V, study B).

Paired sera surrounding illnesses and routine specimens collected at 6 week intervals were included in the serologic tests for 229E virus. A total of 133 students developed CF antibody rises to 229E virus for an infection rate of about 15 per 100 student years. An antibody increase from <4 to 4 was tabulated as a seroresponse in this study. This may account in part for the high infection rate. It is noteworthy that only 66 of the 133 students with CF evidence of infection had neutralizing antibody responses. In the six seasons of surveillance there were three high seasons in which there was an infection rate of 15 to 35 per 100 student years, and three low seasons of 1 to 5 per 100 student years. In addition, 12 strains of 229E virus were recovered in this study. It was noteworthy that in each of the six academic years of

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Table V

Incidence of coronavirus infections in various populations as determined by serologic tests

Study designation	Reference(s)	Study group	Major illness*	Location of study	Duration of study	No. of illnesses	No. under surveillance	No. with antibody increases** to indicated agent	
								229E	OC43***
A	28	Military recruits	Unspecified	Camp Lejeune, North Carolina, USA	Jan.-March during 3 years	--	544	N.T.	65 (12%)
B	25	Medical students	URI	Chicago, Illinois, USA	1961-1967+	--	937 s.y.#	133 (15%)	N.T.#
C	63	Hospital employees	URI	Chicago, Illinois, USA	1967-1968	88	--	7 (8%)	N.T.
D	29	Insurance Co. employees	URI	Charlottesville, Virginia, USA	1963-1966 ++	592	--	10 (1.7%)	16 (2.4%)
					1968-1970 ++	620	--	51 (7%)	48 (7%)
							683 p.y.#		
							693 p.y.		
E	45	5-19 yr. old church home residents	URI	Atlanta, Georgia, USA	1960-1967	1328	--	N.T.	44 (3.3%)
F	30	Military group	URI	South Cerney, Gloucestershire, England	1966-1967	91	--	0	0
G	17 55	Family study	URI	Tecumseh, Michigan	1966-1967	--	758 p.y.	58 (8%)	N.T.
					1965-1969	--	910 p.y.	N.T.	156 (17%)
H	15	Outpatient infants and children	RI	Sao Paulo, Brazil	July 1969	36	--	4 (11%)	N.T.
I	7	Adults	P or ARTI	Krakow, Poland	--	59		0	N.T.
J	52	Hospitalized infants and children	LRTI+	Children's Hospital, District of Columbia, USA	1965-1966	567	--	--	20 (3.5%)
	37				1966-1967				
	37				1962-1965	892	--	1	N.T.
	37				1966-1967	222	--	0	N.T.
K	37	Infants and children	LRTI	WHO collaborative study+++	1964-1965	261	--	0	N.T.
L	19,52	NIH employees	URI	Bethesda, Maryland, USA	1962-1964	256	--	5 (2%)	4 (1.6%)
	37,52				1965-1967	317	--	24 (7%)	23 (7%)
	V2				1965-1970	541	--	32 (6%)	31 (6%)
M	37	College students	URI	College Park, Maryland, USA	1960-1961	110	--	12 (11%)	7 (6%)

* URI = upper respiratory tract illness; RI = respiratory tract illness; P = pneumonia; ARTI = acute respiratory tract infection; LRTI = lower respiratory tract illness.

** Antibody increases for 229E virus determined by CF test; antibody increases for OC43 virus (or group) determined by CF test in studies A, J, L, and M, by HI test in study D & E, and by HI and CF tests in study G. Percentages below 4 rounded to nearest 0.1, otherwise rounded to nearest whole number.

*** OC43 or OC43 group (OC43 A/or OC38 A/or MHV A-59);

\+ academic years;

\# s.y. = student years; p.y. = person years; N.T. = not tested.

++ No sera available 1967, and only 11 pairs studied from winter and spring of both 1966 and 1968.

+++ Sera from: Cairo, Egypt; Hong Kong; New Delhi, India; Jamaica; Singapore; and Trinidad

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surveillance, virus isolation and CF seroconversions occurred almost exclusively during the winter and spring months. This pattern is repeated in other studies as well, as will be shown below.

In a study embracing one year, July 1, 1967 to June 30, 1968, by Schaaf, Boswell and Mufson (1971), among female hospital workers who were hospitalized in the infirmary with upper respiratory illnesses, paired sera were tested against a battery of agents including coronavirus strain 229E (Table V, study C).

Paired sera were obtained from 88 individuals and 7 or 8% demonstrated serological evidence of 229E virus infection. In this study a viral agent was detected in 27% of the 213 patients studied. It is noteworthy that the antibody increases to 229E virus were detected from October through January. No coronaviruses were recovered in cell cultures and 42 which were negative in such cultures were passaged in OC but without success for detecting coronaviruses.

In a study of respiratory illnesses during an eight year period between 1963 and 1970, Hendley, Fishburne and Gwaltney (1972) tabulated 4,259 respiratory illnesses in an average study population of 433 individuals (Table V, study D).

Paired sera surrounding illnesses were available for testing from 592 of these illnesses for strain 229E and 620 for strain OC43. No sera were available for 1967 and only 11 pairs were studied from the winter and spring of both 1966 and 1968. Serological evidence of 229E virus infection as determined by the CF test was demonstrated in ten (2%) of the 592 illness episodes. It was noteworthy that nine of these seroresponses occurred in the winter and spring when 229E virus was associated with 3% of the respiratory illnesses whereas in the summer and fall it was associated with only 0.4% of the respiratory illnesses. One percent of the asymptomatic controls during both periods also had serologic evidence of 229E virus infection. Testing for OC43 virus by the HI technique revealed that in 2% of the 620 illnesses a serologic response to OC43 virus could be demonstrated. It was noteworthy, that in 5% of the winter and spring colds a serologic response to OC43 virus was found whereas such responses did not occur in the summer and fall. Only one of 579 control individuals demonstrated serologic evidence of OC43 virus infection. In summary, 229E and OC43 virus infections were associated with 4% of all respiratory illnesses and 8% of winter and spring respiratory illnesses. It is of interest that attempts to recover coronaviruses from secretions from the nose and throat from ten individuals who seroconverted to 229E were made but without success.

In this study, in addition to studying the association of coronavirus infections with respiratory illnesses, these authors determined the coronavirus infection rates per person year (Table V, study D). A 12-month period in which specimens were collected from an individual was designated as a person year and a 4-fold or greater increase in antibody regardless of the interval between samples was considered as serologic evidence of infection. With such criteria, 206 employees were observed for 683 person years for 229E virus infection and, in this group, 51 antibody increases in 46 individuals were found, for a rate of 7.5 infections per one hundred person years. Ten of these were reinfections with 229E or a related virus.

In a similar analysis, 211 employees were observed for 693 person years for evidence of OC43 virus infections and 48 were found in 43 individuals for an infection rate of 7 per one hundred person years. Eighteen of the 48 were reinfections. Thus, for 229E and OC43 viruses combined, the total rate of infection was 14.5 per one hundred person years.

Kaye, Marsh and Dowdle (1971) conducted a longitudinal survey of respiratory illnesses in a church sponsored children's home from 1960 to 1968 (Table V, study E). The population consisted of healthy children 5 to 19 years of age admitted for socio-economic reasons.

Children with respiratory illnesses were examined and throat swab specimens were collected for virus and bacteria; acute and convalescent blood specimens were collected two to three weeks apart. Control sera were also collected at different intervals. Among 1,328 respiratory illnesses studied over the 7 year period, 44 (3%) were found to be associated with OC43 virus as determined by the CF and/or

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HI tests. Inapparent infections as measured in paired control sera were also found. It was noteworthy that the major presenting symptoms of the ill children were sore throat, cough and coryza, with pharyngitis, coryza, fever and cervical adenitis as the predominating signs. A seasonal distribution was again quite striking as three distinct outbreaks occurred during the winter and spring quarters of 1960-1961, 1964-1965, and 1966-1967, when sixty-seven of the total 93 seroconversions, and 37 of the 44 among ill individuals, occurred. As in other studies, reinfections were frequent.

Higgins and colleagues (1970) studied virologically all respiratory illnesses reported to medical officers between September 1966 and December 1967 on a Royal Air Force station of 350 men, and no evidence of coronavirus infection was found even though specimens which failed to yield a viral agent following inoculation into cell cultures or newborn mice were inoculated into OC (Table V, study F). Ninety-two paired sera were tested for CF antibody increases to 229E and OC43 viruses and none was found.

In a recent report Monto and Lim (1974) studied the incidence of OC43 virus infection among families with respiratory illnesses in Tecumseh, Michigan (Table V, study G). CF and HI tests were performed on all sera collected from November 1965 to June 1969 from members of 269 families.

During the four years studied, which included 910 person years of surveillance, 156 paired sera showed a rise in antibody titer by HI and/or CF tests for a rate of 17.1 infections per one hundred person years among individuals 5 years to greater than 40 years of age. It was noteworthy that peaks of infection were found in the winter and spring of 1966, 1968 and 1969 with infections occurring sporadically at other times. It was also noteworthy that age did not appear to be important in determining the antibody response as a high annual infection rate was found in all age groups. The outbreak in late 1968 and early 1969 was studied more intensively and included blood specimens collected on filter paper discs from the 0-4 year age group.

In 72 person years of observation in this youngest age group, 21 or 29.2% had evidence of infection with this agent; this was the highest rate observed, although the infection rates were comparable in all age groups. Familial aggregation of infections was frequent with as many as 4 infections occurring in a single family. The Tecumseh study also revealed that reinfection with OC43 virus was quite common as 81.5% of the infections studied by the neutralization technique occurred despite the presence of neutralizing antibody.

Cavallaro and Monto (1970) had previously reported a sharp outbreak of 229E virus infection in the winter-spring of 1967 when 54 (34%) of 159 sets of sera tested had CF or neutralizing antibody increases to 229E virus but over a 2 year period embracing 1966-1967, 58 229E virus infections occurred in 758 patient years of observation for a total of 7.7%. In this study, also, a change in CF antibody from <4 to 4 was considered to be significant.

229E virus infection has also been described in Brazil by Candeias, de S. Carvalho and Antonacio (1972). They found a low prevalence (3.2%) of CF antibody in children and a higher prevalence (26.2%) in adults (Table V, study H).

They also studied paired sera from 36 children with respiratory illnesses from 1 to 3 years of age and found that 4 (11%) of the 36 developed serologic evidence of infection. It is noteworthy that the 4 children exhibiting a serologic response to 229E virus had severe bronchitis and that these illnesses occurred in July 1969 during the winter season.

In addition, it is of interest that Zakstelskaya et al. (1972) have reported the presence of both CF and HI antibody in sera from children, adolescents, and adults in the USSR. Also, Borysiewicz et al. (1973) in Poland reported that CF antibody to 229E virus was not detected in paired sera from 59 patients with

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a clinical diagnosis of pneumonia or acute respiratory tract illnesses who were hospitalized in a District Military Hospital (Table V, study I).

Our laboratory has also studied the role of coronaviruses in respiratory tract illness by predominantly serological methods. Before describing these studies, I would like to show Figure 3 which is from a study by McIntosh et al. (1970). This Figure shows the number and percentage of antibody rises to the various coronavirus antigen used in tests with paired sera from children and adults. The largest percentage of dual responses involved OC38 and OC43 viruses in children. As noted earlier, these agents were found to be identical by reciprocal neutralization and CF tests. A moderate sharing of response also occurred between MHV and OC38 and/or OC43 whereas few or no dual responses were found with 229E and MHV, and 229E and OC38 and/or OC43. On account of the frequent sharing of antibody responses between OC38, OC43 and MHV and their already described antigenic relationships, these agents are grouped together in considering serologic responses in the following studies.

We attempted to determine the role, if any, of coronavirus infections in lower respiratory tract disease in infants and children and found that infections with coronaviruses 229E and the OC43 group were not significantly associated with pediatric lower respiratory tract disease. Only one of 892 paired sera obtained from October 1962 through August 1965 from infants and children admitted to Children's Hospital in the District of Columbia for predominantly lower respiratory tract disease demonstrated serological evidence of infection (39) (Table V, study J). In a similar study of 222 infants and children admitted to Children's Hospital from December 1966 through April 1967, none developed

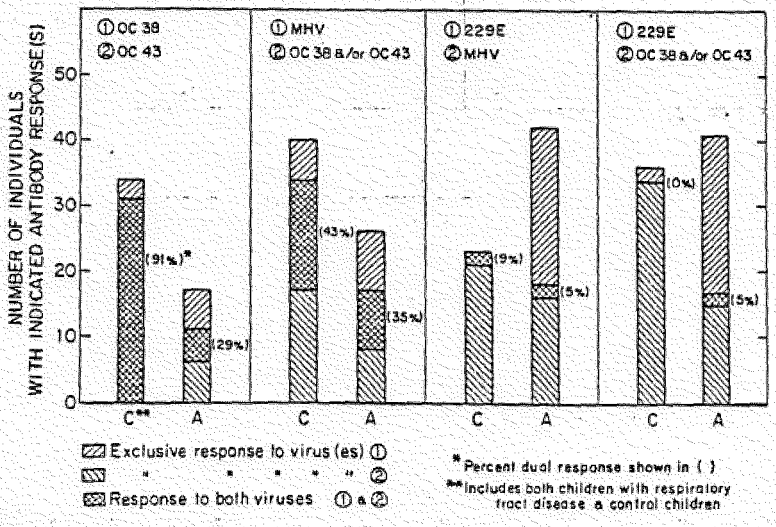


Fig. 3. Single and dual antibody responses to various coronavirus strains in children (C) or adults (A).
From K. McIntosh, A.Z. Kapikian, H.C. Turner, J.W. Hartley, R.H. Parrott and R.M. Chanock: Amer. J. Epid. 91: 585-592 (1970).

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an antibody increase to 229E virus (39) (Table V, study J). In addition, none of the 261 paired sera obtained from June 1964 through June 1965 from infants and young children with predominantly lower respiratory tract illnesses in Jamaica, Trinidad, Hong Kong, Cairo, Singapore, and New Delhi demonstrated evidence of 229E virus infection (39) (Table V, study K). Paired sera obtained from October 1965 through August 1966, and October 1966 through April 1967 from infants and children with lower respiratory tract disease at Children's Hospital, were studied for antibody increases to the OC43 group of agents by McIntosh et al. and it was found that in only 20 or 3.5% of 565 such illnesses was a serologic response found (52) (Table V, study J). However, this result was not considered significant since 8.2% of control infants who were not matched with respect to their length of hospital stay also developed serological evidence of infection with these agents. The negative correlation with lower respiratory tract disease was statistically significant and was particularly striking in children over one year of age.

In a study of upper respiratory infections among NIH employees which began in 1962 and was suspended in 1964, it was found that 5 (2%) of 256 patients had evidence of 229E virus infection and a similar percentage of individuals had infections with the OC43 virus group (39, 52) (Table V, study L). This study was reinstituted in September 1965 and continues to the present. The results of the 1965 to 1967 portion of this study have already been reported (39) (Table V, study L). I would like to present a 5 year summary of this study from 1965 to 1970 (42).

Nasal-nasopharyngeal wash specimens for virus isolation were obtained on or before the 4th day of illness and were inoculated into numerous cell cultures. Specimens which did not yield a cytopathic effect were passage into HETOC three times and the harvest passaged back into cell cultures. If the specimens were negative, the OC harvest was examined by electron microscopy and more recently by immune electron microscopy using the patient's convalescent serum as the source of specific antibody as previously outlined. Some of these studies are still in progress. Acute and convalescent sera were obtained on most patients. A total of 566 illnesses have been studied over this 5 year period. Rhinoviruses were recovered from 27% of these illnesses; thus, as shown by many investigators this group of agents was the major known etiologic agent of acute adult upper respiratory infection (24, 35, 66). It is noteworthy that the coronaviruses were the second most important group of agents associated with the upper respiratory infections; in serologic (CF) studies of 541 paired sera, 229E virus was associated with 32 (6%) and the OC43 virus group with 31 (6%) of the illnesses (Table V, study L). It is of interest that using the OC, HEI cell culture, and immune electron microscopy procedures, we have been able to recover 22 strains of coronaviruses from this 5 year period. In addition, approximately one half of the CF increases found in this study were to the coronavirus antigens. It is noteworthy that rhinovirus infections decreased significantly during the winter periods of the study and that, in general, coronavirus infections when present appeared to be most prevalent during the winter-early spring periods.

In another seroepidemiologic survey we studied the role of these agents in upper respiratory illnesses in college students (37).

In 1964, we described a pilot study of acute respiratory illnesses in college students in which only 2 viruses (parainfluenza types 1 and 4) were recovered from 210 ill students and in addition in an intensive serologic survey utilizing 21 CF antigens, serologic evidence of infection could be demonstrated in only 30 (25%) of 122 students from whom sera were available (43). Influenza B virus accounted for over one half of these infections. The incidence of infections by rhinoviruses was not determined since methods for their study were not available and when such methods became known the throat swab specimens were no longer available. We studied the paired acute and convalescent sera of these indivi-

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duals for evidence of infection with the OC43 virus group and with 229E virus. Paired sera from 110 of the 122 students who were previously studied by serology were available for testing by the CF technique and it was found that 19 (17%) had evidence of coronavirus infection, 12 with 229E and 7 with OC38 (Table V, study L). It was noteworthy that 17 of the 19 coronavirus infections occurred in the December, January, February and March period.

The epidemiologic studies summarized in this section are all limited by the paucity of isolation data. However, certain conclusions can be drawn from them. Most importantly, it appears that coronaviruses are important etiologic agents of upper respiratory tract illnesses in adults. In spite of the fact that only 2 strains can be tested for in serologic surveys, an appreciable percentage of illnesses are associated with these agents or related agents. If antigens were available for even one of the other known strains, the rate of detectable infection with coronaviruses would undoubtedly be even greater. It also appears that reinfection with these agents or related agents is quite common thereby raising the possibility that vaccines if they are found to be necessary, and if administered parenterally, may not be beneficial in coronavirus infections. In addition, it appears that these agents are important in upper respiratory infections of infants and children but are not major etiologic agents of lower respiratory tract disease in this age group, although some recent reports indicate that they may be responsible for a small proportion of such illnesses (15) and may be implicated in exacerbations of wheezing among asthmatic children (50).

CORONAVIRUSES OF ANIMALS

Coronaviruses are now known to cause diseases in a variety of animals, including chickens, mice, pigs, rats, calves, and turkeys. These agents cause a broad spectrum of clinical syndromes. Table VI summarizes the known diseases associated with the animal coronaviruses. Additional information on IBV is presented elsewhere in this volume by Cunningham. A detailed comparative review of coronaviruses has recently been made by McIntosh (1974).

CONCLUDING REMARKS

It thus appears that members of the coronavirus group are rather widely distributed in nature infecting humans and a variety of animals including chickens, pigs, mice, rats, calves and turkeys. The list of animals found to be infected by coronaviruses will undoubtedly increase as research efforts are intensified. In addition, coronaviruses also demonstrate a tropism for a variety of organ systems such as the brain, salivary glands, upper and lower respiratory tracts, kidneys, genital tract and small and large intestine. At the present time, it appears that the coronaviruses are capable of causing more serious disease in animals than in man; however, intensive efforts should be made to determine whether these fastidious agents are responsible for more serious disease in humans also.

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Table VI

Coronaviruses of animals

Reference	Species Type	Animal Host	Serotypes or Possible Serotypes	Diseases Associated with These Agents
21, 20, 5, 32, 31, 70	Infectious Bronchitis Virus(IBV)	Chicken	Massachusetts Connecticut Iowa 97 Iowa 609 Gray Holte JMK SE17 Clarke 333 Delaware 2868 Delaware 2897 and others	Acute, highly contagious respiratory disease characterized by respiratory distress, tracheal rales, coughing, and in young chicks a nasal discharge also. Marked decrease in egg production and egg quality. Ovarian damage may occur. Mortality rate in very young chicks may reach 25%; in chickens > 6 wks. of age mortality negligible. World-wide distribution. Inactivated and live attenuated virus vaccines available. Nephrosis and uremia recently reported.
22, 18, 3, 58, 42	Mouse Hepatitis Virus (MHV)	Mouse	JHM MHV-1 MHV (Pr) EHF-120 H747 MHV-3 A59 MHV-S others	Hepatitis, encephalitis. Subclinical, endemic infections common.
6, 65	Transmissible gastroenteritis virus (TGEV)	Pig	One type	Highly contagious, enteric disease with vomiting, severe diarrhea, dehydration, high mortality rate in piglets under 2 wks. of age; mortality rate approaches 100% in newborn pigs. One of the major causes of illness and death in piglets. Adult pigs become infected also, and develop a generally milder disease. Occurs predominantly in winter. Live attenuated vaccine available
16, 61, 59, 23, 54	Hemagglutinating encephalomyelitis (HEV) (Vomiting and wasting disease virus)	Pig	All similar	Encephalomyelitis in piglets Vomiting and wasting disease in piglets. High morbidity and mortality rates in newborn pigs. Piglets < 2 wks. of age most susceptible to disease.
57	Rat Coronavirus (RCV)	Rat	One strain described	Respiratory distress from pneumonitis in rats < 48 hrs. of age. High morbidity and mortality rates in this group. Rats 7 and 14 days of age develop respiratory disease but recover. Rats > 21 days of age show no outward sign of respiratory disease.
53,69	Neonatal calf diarrhea virus	Calf	One strain described	Diarrhea in calves; may cause mortality in neonatal calf.
4	Sialodacryoadenitis virus (SDAV)	Rat	One strain described	Acute disease of submaxillary and harderian glands; low mortality.
49	Transmissible enteritis virus	Turkey	One strain described	Outbreaks of enteritis in flocks; may be associated with high mortality rate. Associated with some cases of bluecomb disease.

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General Discussion

Dr S. R. MOSTOW : I should like to add one epidemiological observation. While studying children in a closed population we found two outbreaks of respiratory disease for which we could find no isolates. Retrospectively serological studies revealed that these two sharp one-week outbreaks occurring after Easter vacation were due to coronaviruses. Clinically these children had mild upper respiratory infection.

Dr J. B. McFERRAN : Referring to your statement on coronavirus in turkeys and whether it causes bluecomb, an orbivirus has also been implicated in the etiology of bluecomb. We have isolated coronavirus from turkeys in Northern Ireland which had respiratory disease but did not have bluecomb.

Dr A. Z. KAPIKIAN : And the orbivirus has been recovered from the stools of turkeys with enteritis ? If I may ask a question, have you classified it as an orbivirus rather than a reovirus on the basis of its morphology, or have you been able to grow it in tissue culture and therefore determine its acid sensitivity ?

Dr J. B. McFERRAN : This work was done in America by different groups of workers. On morphology and stability it is probable that it is an orbivirus.

Dr A. Z. KAPIKIAN : It has been grown in tissue culture, the orbivirus-like agent. I see, thank you.

Dr J. DESMYTER : In our laboratory Dr Bradburne has confirmed the presence of coronavirus in a few sera of hepatitis patients. We feel that, at least in some cases, this is true coronavirions and not only corona-like structures, but of course the relationship with hepatitis may be coincidental. I wonder what the most recent information is on direct visualization of coronavirus in the serum of cases of acute respiratory illness.

Dr A. Z. KAPIKIAN : There really is not very much information about this. However, in examining serum and stool filtrate mixtures by electron microscopy, we find objects that bear a resemblance to the coronaviruses but their significance must be determined by the technique of immune electron microscopy in which specific antiserum is added to the particle containing preparation to determine if the particle in question is aggregated by, or if not aggregated is very heavily coated with, the specific antibody.

Dr R. H. WALDMAN : If one were a cynic, which I would not want to be, one could say from your slide on serology and epidemiology that it appeared that coronavirus protects against disease rather than causes disease. The incidence of seroconversion was higher in your group that did not have illness than in the group that did have illness.

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Dr A. Z. KAPIKIAN : It was a significant difference at a high level. However, these controls were not matched according to duration of hospital stay and one very possible explanation for the negative correlation is that some of these children when they went home may have developed very mild respiratory illnesses associated with coronaviruses and therefore demonstrated serologic evidence of coronavirus infection when paired sera were tested. If one took temperatures on these children daily and were able to thus really monitor the occurrence of illnesses as was done in the Junior Village studies of Dr J. A. Bell and colleagues, some of the mild illnesses might have been detected. All we could say from the data is that coronaviruses were not major etiology agents of lower respiratory tract disease; this study was not designed to determine the role of coronaviruses in upper respiratory infections of children.

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From: Gruber, Marion [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=019CD2669C7048F7A116D72B7682DE44-GRUBER]
Sent: 1/14/2021 2:49:24 PM
To: El Sahly, Hana M. [Hana.ElSahly@bcm.edu]; Hayes, Kathleen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb93ef79b3474f7099917a7d1ed56be9-Kathleen.Ha]; Atreya, Prabhakara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f96e446284da421a91a4479bb6e553c1-AtreyaP]
Subject: RE: RESPONSE NEEDED –February NVAC Meeting-Written Updates and RSVP
Attachments: VRBPAC-12.10.20-Meeting-Summary-Minutes.pdf; VRBPAC-12.17.20-Meeting-Summary-Minutes.pdf

Dear Hana,
I wrote the summaries from the Dec 10 and 17 meetings, see attached.
Marion

From: El Sahly, Hana M. <Hana.ElSahly@bcm.edu>
Sent: Thursday, January 14, 2021 1:57 PM
To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Hayes, Kathleen <Kathleen.Hayes@fda.hhs.gov>; Atreya, Prabhakara <Prabhakara.Atreya@fda.hhs.gov>
Subject: FW: RESPONSE NEEDED –February NVAC Meeting-Written Updates and RSVP

Group,

We did have the flu vaccine meeting since Sep2019, but importantly the EUA COVID-19 meetings took place. I was recused from those.
Do you want to prepare a brief written summary for those? I can do it, as everything is in public domain but I do not want to break any rules.
Let me know who should prepare this summary.
Thanks.

From: "Chavez, Ilka (HHS/OASH)" <ilka.chavez@hhs.gov>
Date: Thursday, January 14, 2021 at 11:02 AM
To: "'El Omeiri, Nathalie (PAHO)'" <elomeirin@paho.org>, Rebecca Coyle <coyler@Immregistries.org>, Kristen Ehresmann <kristen.ehresmann@state.mn.us>, "John M. Douglas" <jmdouglas@tchd.org>, "'Nordin, Jim (AHIP)'" <james.d.nordin@healthpartners.com>, Jeane-Venable Goode <jrgoode@vcu.edu>, James Blumenstock <jblumenstock@astho.org>, "El Sahly, Hana M." <Hana.ElSahly@bcm.edu>, "gina.charos@canada.ca" <gina.charos@canada.ca>, "channan@immunizationmanagers.org" <channan@immunizationmanagers.org>, "cregal@ahip.org" <cregal@ahip.org>
Cc: "Aikin, Ann (OS/OASH)" <Ann.Aikin@hhs.gov>, "cshell@explorepsa.com" <cshell@explorepsa.com>, Erika Noyes PSA <ENoyes@explorepsa.com>
Subject: RESPONSE NEEDED –February NVAC Meeting-Written Updates and RSVP

*****CAUTION:*** This email is not from a BCM Source. Only click links or open attachments you know are safe.**

Good Afternoon,

Happy New Year! I hope this email finds you well and safe. The next NVAC meeting will be on **February 4-5, 2021** from **1:00-5:30 PM Eastern Time.** This meeting will be held virtually. The agenda and meeting logistics will be provided in a calendar appointment.

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If you are not able to attend, please email your alternate by **Friday, January 22, 2021.** I am also asking that you provide a written update of your organization's immunization-related activities since the last NVAC meeting in September, 2020 by **Monday, January 25, 2021.** Please reply to Ann Aikin and I.

Thank you for your time and attention to this matter.

Respectfully,

Ilka Chavez, MPA
Senior Public Health Advisor
Vaccine Division

Email: Ilka.Chavez@hhs.gov
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OASH | Office of Infectious Disease and HIV/AIDS Policy

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Food and Drug Administration
Center for Biologics Evaluation and Research

SUMMARY MINUTES
162nd VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE

December 10, 2020

Committee Members
Hana El Sahly, M.D., Chair +
Archana Chatterjee, M.D., Ph.D.
CAPT. Amanda Cohn, M.D.
Hayley Gans, M.D.
Holly Janes, Ph.D. +
Michael Kurilla, M.D., Ph.D.
Myron Levine, M.D., D.T.P.H., F.A.A.P. +
H. Cody Meissner, M.D.
Paul Offit, M.D.
Steven Pergam, M.D., M.P.H.
Andrea Shane, M.D., M.P.H., M.Sc. +
Paul Spearman, M.D. +
Geeta K. Swamy, M.D. +

Industry Representatives
Paula Annunziato, M.D.
Gregg Sylvester, M.D., M.P.H. <+

Consumer Representative
Sheldon Toubman, J.D. *

Designated Federal Officer's (DFO)
Prabhakara Atreya, Ph.D.
Kathleen Hayes, M.P.H.

Committee Management Specialist(s)
Monique Hill, M.H.A.

* Consumer Representative
+ Not in attendance
< Alternate Industry representative

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David Kim, M.D., M.A.
Eric Rubin, M.D., Ph.D.
James Hildreth, Sr., Ph.D., M.D.
Jeannette Lee, Ph.D.
Juan Gea-Banacloche, M.D.
Mark Sawyer, M.D., F.A.A.P.
Melinda Wharton, M.D., M.P.H.
Ofer Levy, M.D., Ph.D.
Pamela McInnes, D.D.S., M.Sc.
Patrick Moore, M.D., M.P.H.
Ralph Tripp, Ph.D.
Stanley Perlman, M.D., Ph.D.

Speakers and Guest Speakers
Anita Patel, Pharm.D., M.S.
Aron Hall, D.V.M., M.S.P.H., Dipl. A.C.V.P.M.
Doran Fink, M.D., Ph.D. - FDA
Kathrin Jansen, Ph.D. - Sponsor
Nancy Messonnier, M.D.
Steven Goodman, M.D., Ph.D.
Susan Wollersheim, M.D.- FDA
William C. Gruber, M.D. - Sponsor

FDA Participants
Marion Gruber, M.D.
Philip Krause, M.D.
Peter W. Marks, M.D., Ph.D.
CDR. Valerie Marshall, M.P.H., P.M.P.
Celia M. Witten, Ph.D., M.D.
Jerry Weir, Ph.D.

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These summary minutes for the December 10, 2020 Meeting of the Vaccines and Related Biological Products Advisory Committee were approved on January 6, 2021.

I certify that I participated in the December 10, 2020 Meeting of the Vaccines and Related Biological Products Advisory Committee and that these minutes accurately reflect what transpired.

_____/s/_____
Prabhakara Atreya, Ph.D.
Designated Federal Officer

_____/s/_____
Arnold Monto, M.D.
Acting Chair

On December 10, 2020 at 9:00 a.m. Eastern Standard Time (EST), the 162nd Meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) met in open session to discuss EUA of the Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 in individuals 16 years of age and older.

Dr. Arnold Monto, the Acting Chair, called the meeting to order. The DFO made administrative remarks, conducted roll call and invited the committee members to introduce themselves, and read the Conflict of Interest (COI) statement into the public record. It was stated that one conflict of interest waiver was issued under 18 U.S. Code 208 in connection with the meeting and the waiver was posted on the FDA website for public disclosure.

Dr. Doran Fink of FDA provided an introductory presentation titled “Emergency Use Authorization Overview and Considerations for COVID-19 Vaccines.” This was followed by a presentation by Dr. Aron Hall from the Centers for Disease Control and Prevention (CDC) entitled, "Epidemiology of COVID-19 in the United States.” Following Dr. Hall’s presentation, the Committee was released for a 10-minute break. Following the break was a vaccine safety and effectiveness overview presentation by Dr. Nancy Messonnier from the CDC titled “COVID-19 vaccine post-authorization safety and effectiveness monitoring.” Once her presentation concluded, Dr. Anita Patel, also with CDC, presented “Distribution Overview.” Dr. Steven Goodman with Stanford University School of Medicine then presented “Considerations for placebo-controlled trial design if an unlicensed vaccine becomes available.”

After a 45-minute lunch break, the Open Public Hearing (OPH) session was held for 60 minutes during which 21 public pre-registered speakers made presentations and oral comments. The names of OPH speakers and their oral remarks may be obtained from the transcript posted on the website. Following the OPH session, the presentations resumed starting with the Sponsor’s (Pfizer Inc.) presentation by Moderator, Kathrin Jansen, Ph.D., and then by William Gruber, M.D. titled “BNT162b2 Vaccine Candidate Against COVID-19.” Dr. Susan Wollersheim with FDA then presented “FDA Review of Efficacy and Safety of Pfizer-BioNTech COVID-19 Vaccine Emergency Use Authorization Request.”

After the presentations concluded and a 10-minute break, the Committee then proceeded with

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discussions and recommendations portion of the meeting. There were two discussion items presented to the Committee, with no vote:

1) Pfizer has proposed a plan for continuation of blinded, placebo-controlled follow-up in ongoing trials if the vaccine were made available under EUA. Please discuss Pfizer's plan, including how loss of blinded, placebo-controlled follow-up in ongoing trials should be addressed.

2) Please discuss any gaps in plans described today and in the briefing documents for further evaluation of vaccine safety and effectiveness in populations who receive the Pfizer-BioNTech Vaccine under an EUA.

The committee discussed potential implications of loss of blinded, placebo-controlled follow-up in ongoing trials including how this may impact availability of safety data to support a biologics license application. Some pointed out the importance of long-term safety data for the Pfizer-BioNTech COVID-19 Vaccine as it is made using a technology not used in previously licensed vaccines. In response to the question whether the ongoing Phase 3 study would still be sufficiently powered if eligible placebo recipients would be vaccinated, Pfizer asserted that even with an anticipated loss of placebo-controlled follow-up of 20%, the study would maintain adequate statistical power and would be positioned to accrue additional data on vaccine efficacy, including efficacy against severe disease, as well as safety, although unblinding of the study would reduce interpretability of results. It was pointed out that non-random loss of placebo recipients from the study, as would be expected when unblinded placebo recipients would receive vaccination based on Advisory Committee on Immunization Practices (ACIP) recommendations, would further reduce interpretability of results. There was also discussion of a blinded trial design proposed by Dean Follmann, Ph.D. of NIH in which duration of efficacy would be compared in clinical trial participants originally vaccinated with the vaccine to those later administered the vaccine as part of a planned blinded cross-over. Pfizer stated that this design was considered but would present logistical challenges including the need for reconsenting subjects and additional study visits.

The lack of data on how the vaccine impacts asymptomatic infection and viral shedding was also pointed out and that this should be addressed prior to study unblinding. Other committee members were concerned about limited data available in certain subpopulations such as HIV-infected individuals, individuals with prior exposure to SARS-CoV-2 and certain demographic groups.

The committee inquired about information regarding anaphylactoid reactions occurring in 2 individuals vaccinated with the Pfizer/BioNTech vaccine in the UK. Pfizer briefly summarized the available information, i.e., the two cases of anaphylactoid reactions were in individuals with a strong past history of allergic reactions both of whom carried an epinephrine auto injector. These individuals developed symptoms of anaphylactoid reaction shortly after receiving the vaccine. Both recovered after appropriate treatment. FDA referred to its analysis of safety data derived from the ongoing pivotal trial that excluded subjects with allergic reactions to previous vaccine administrations but did not exclude subjects with non-vaccine related allergies. A slight numerical imbalance of adverse events potentially representing allergic reactions, with more

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participants reporting hypersensitivity-related adverse events in the vaccine group compared with the placebo group (137 vs. 111). None of these were considered to be serious, and none of these events occurred in the immediate post-vaccination period. FDA noted that the fact sheet and prescribing information for Pfizer-BioNTech COVID-19 vaccine will include information under the contraindications section that the vaccine should not be administered to individuals with known history of a severe allergic reaction to any component of the vaccine. Under the warning section, there will be a statement that appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 Vaccine.

In reference to the voting question, and prior to the committee members casting their votes committee members asked FDA's perspective on use of the vaccine in pregnancy. FDA explained that data from the preclinical developmental and reproductive toxicity study for this product are expected soon. Even though there are insufficient data to inform vaccine-associated risks in pregnancy, there are also no data warranting a contraindication. Some committee members expressed concerns about including adolescents 16 and 17 years of age in the indication for the vaccine because of the limited amount of safety and efficacy data available in this population. Other committee members encouraged authorization of the vaccine under EUA in adolescents because this would support initiating pediatric clinical trials and because benefits would be expected to outweigh any theoretical risks in this population. Inclusion of vaccines against COVID-19 in the pediatric vaccination schedule will ultimately likely be needed to increase the uptake of the vaccine and to reach herd immunity. Pfizer is planning studies in pediatric subjects using an age-stratified step-down approach. Some committee members raised concerns about the small number of severe COVID-19 cases and limited conclusions about the prevention of severe disease based on the study endpoints. FDA pointed out that vaccine development has a long history and that FDA is not aware of an example of any vaccine that is effective against mild disease that is not also effective against severe disease and that even though limited, data for Pfizer-BioNTech COVID-19 Vaccine suggest efficacy against severe disease.

Following the discussion topics, the Committee then went into the voting portion of the meeting. One voting question was put forward to the Committee:

1) Based on the totality of scientific evidence available, do the benefits of the Pfizer-BioNTech COVID-19 Vaccine outweigh its risks for use in individuals 16 years of age and older?".

The results of the vote were as follows: Yes = 17, No = 4, Abstain = 1. Thus, the committee voted in favor of a determination that based on the totality of scientific evidence available, the benefits of the Pfizer-BioNTech COVID-19 Vaccine outweigh its risks for use in individuals 16 years of age and older.

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Following the vote, the meeting was then adjourned on December 10, 2020 at 5:35 PM EST.

Additional information and details may be obtained from the transcript and the recording of the webcast of the meeting that may be viewed at:
https://www.youtube.com/watch?v=owveMJBTc2I&feature=youtu.be

Obtained via FOIA by Judicial Watch, Inc.

Food and Drug Administration
Center for Biologics Evaluation and Research

SUMMARY MINUTES
163rd VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE

December 17, 2020

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Hayley Gans, M.D.
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Doran Fink, M.D., Ph.D.-FDA
Jacqueline Miller, M.D., F.A.A.P – Sponsor
Rachel Zang, M.D.-FDA
Steven Goodman, M.D., Ph.D.
Tal Zaks, M.D. – Sponsor

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Celia M. Witten, Ph.D., M.D.CDR. Valerie Marshall, M.P.H., P.M.P.
Jerry Weir, Ph.D.

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These summary minutes for the December 17, 2020 Meeting of the Vaccines and Related Biological Products Advisory Committee were approved on January 6, 2021.

I certify that I participated in the December 17, 2020 Meeting of the Vaccines and Related Biological Products Advisory Committee and that these minutes accurately reflect what transpired.

_____/s/_____
Prabhakara Atreya, Ph.D.
Designated Federal Officer

_____/s/_____
Arnold Monto, M.D.
Acting Chair

On December 17, 2020 at 9:00 a.m. Eastern Standard Time (EST), the 163rd Meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) met in open session to discuss emergency use authorization (EUA) of the Moderna COVID-19 Vaccine for the prevention of COVID-19 in individuals 18 years of age and older.

Dr. Arnold Monto, the Acting Chair, called the meeting to order. The DFO made administrative remarks, conducted roll call and invited the committee members to introduce themselves, and read the Conflict of Interest (COI) statement into the public record. It was stated that one conflict of interest waiver was issued under 18 U.S. Code 208 in connection with the meeting and the waiver was posted on the FDA website for public disclosure.

Dr. Doran Fink of FDA provided an introductory presentation titled "Emergency Use Authorization; Overview and Considerations for COVID-19 Vaccines." This was followed by a presentation by Dr. Steven Goodman with Stanford University School of Medicine titled "Considerations for placebo-controlled trial design if an unlicensed vaccine becomes available." The sponsors then gave their presentation " Emergency Use Authorization (EUA) Application for mRNA-1273" provided by Dr. Tal Zaks, Dr. Jacqueline Miller, Melissa Moore, and Dr. David Martin from ModernaTx, Inc. and by Dr. Lindsey Robert Baden with Brigham and Women's Hospital.

After the Sponsors presentations concluded and a 10-minute break, the Committee conducted a 60-minute Open Public Hearing (OPH) session in which 18 public pre-registered speakers made presentations and oral comments. The names of OPH speakers and their oral remarks may be obtained from the transcript posted on the website. Following the OPH session, the Committee held a 30 additional Q &A session for the Sponsor presenters and were then released for lunch.

Following a 30-minute lunch break, the Committee heard from Dr. Rachel Zhang with FDA who presented "FDA Review of Efficacy and Safety of Moderna COVID-19 Vaccine Emergency Use Authorization Request." After Dr. Zhang's presentation, the Committee proceeded with the discussion and voting portion of the meeting. There was one discussion item presented to the Committee, with no vote:

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In considering Moderna's plans for unblinding and crossover of placebo recipients, please discuss the most critical data to further inform vaccine safety and effectiveness to support licensure that should be accrued in:

- Ongoing clinical trials with the Moderna COVID-19 vaccine
- Other studies (e.g., additional clinical trials or observational studies) with the Moderna COVID-19 vaccine

Regarding critical data to be obtained in ongoing trials with the Moderna COVID-19 vaccine, committee members discussed the importance of collecting blood specimens obtained from breakthrough cases to evaluate T- and B- cell immunity and to identify correlates of protection, and the importance of collecting respiratory specimens obtained from breakthrough cases to evaluate effect of the vaccine on shedding of infectious virus and to provide information about potential antigenic escape mutants. Members commented that efforts should be made to obtain data on long term safety of the vaccine, waning of immunity, the vaccine's impact on virus transmission, and asymptomatic infection. In addition, they suggested that ongoing studies should collect additional data on vaccine effectiveness in subjects at increased risk for COVID-19, pregnant women and pediatric populations.

Committee members were asked to discuss whether the ongoing Phase 3 trial should be continued using a blinded cross-over design or an open-label design as proposed by Moderna. Some members stressed the importance of using a blinded cross-over design in order to preserve data integrity and to allow an evaluation of waning of immunity and duration of protection. Other members opined that even though a blinded cross-over design would be ideal, it would present with logistical challenges, and that high drop-out rates can be anticipated because clinical trial participants would obtain a vaccine made available under EUA before a blinded cross-over could be implemented. Therefore, open-label unblinded vaccination of placebo recipients, even though not ideal, may be a more realistic option. However, to preserve blinded placebo-controlled follow-up for as long as is practical, some committee members opined that placebo recipients should be offered the vaccine as they become eligible for vaccination according to CDC prioritization groups.

The committee suggested for the following data to be obtained in additional studies (e.g., additional clinical trials or observational studies) with the Moderna COVID-19 vaccine: data on vaccine effectiveness in the elderly, immunogenicity data from dose ranging studies, in particular in immunocompromised subpopulations, effectiveness of the vaccine following one dose, and interchangeability of the two COVID-19 mRNA vaccines. Additional studies should be conducted to obtain data regarding duration of protection, to identify a correlate of protection, to further evaluate Bell's palsy as an adverse event as well as to evaluate other neurological and cardiac outcomes (both in terms of vaccine safety and effect of vaccination on prevention of these outcomes when related to COVID-19), co-administration with other vaccines, and vaccine safety and effectiveness in pregnant and pediatric subjects.

Following the discussion topic, the Committee was asked to take a vote on the following

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question:

1) Based on the totality of scientific evidence available, do the benefits of the Moderna COVID-19 Vaccine outweigh its risks for use in individuals 18 years of age and older?

The results of the vote were as follows: Yes = 20, No = 0, Abstain = 1. Thus, the committee voted in favor of a determination that based on the totality of scientific evidence available, the benefits of the Moderna COVID-19 Vaccine outweigh its risks for use in individuals 18 years of age and older.

Following the vote, the meeting was then adjourned on December 17, 2020 at 5:00 PM EST.

Additional information and details may be obtained from the transcript and the recording of the webcast of the meeting that may be viewed at:
https://www.youtube.com/watch?v=l4psAfbUtC0&feature=youtu.be

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Sent: 5/13/2021 4:19:57 PM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Schuchat, Anne (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=848b7544f27d4a2a9554a80e78d002fc-HHS-acs1-cd]
CC: Gruber, Marion [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=019cd2669c7048f7a116d72b7682de44-gruber]; Walinsky, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97a2ad6b3c4549a78542fce1a086f7ea-Sarah.Walin]
Subject: RE: [EXTERNAL] RE: Quick Q - vaccine coadministration

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Best Regards,
Peter

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Sent: Thursday, May 13, 2021 4:00 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: FW: [EXTERNAL] RE: Quick Q - vaccine coadministration

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Lorrie

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To: Nordlund, Kristen (CDC) <hok4@cdc.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Coffin, Nicole (CDC) <ndc3@cdc.gov>
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Subject: RE: Quick Q - vaccine coadministration

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Thanks much!

Lorrie

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Director

Office of Communication, Outreach and Development
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration
Tel: 240-402-8119
lorrie.mcneill@fda.hhs.gov



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To: Cohn, Amanda C (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4cbff30d34c4611a2e973fcb192de37-HHS-anc0-cd]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
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To: Marks, Peter (FDA/CBER) <Peter.Marks@fda.hhs.gov>; Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>
Cc: Gruber, Marion (FDA/CBER) <Marion.Gruber@fda.hhs.gov>; Walinsky, Sarah (FDA/CDER) <Sarah.Walinsky@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: Quick Q - vaccine coadministration

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To: Marks, Peter <Peter.Marks@fda.hhs.gov>
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lorrie.mcneill@fda.hhs.gov





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Sent: 5/13/2021 4:33:53 PM
To: Schuchat, Anne (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=848b7544f27d4a2a9554a80e78d002fc-HHS-acs1-cd]; Cohn, Amanda C (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4cbff30d34c4611a2e973fcb192de37-HHS-anc0-cd]
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Subject: RE: [EXTERNAL] RE: Quick Q - vaccine coadministration

Dear Anne,

Thanks so much. Will give Amanda a call.

Best Regards,
Peter

From: Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>
Sent: Thursday, May 13, 2021 4:24 PM
To: Cohn, Amanda C (CDC) <anc0@cdc.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Walinsky, Sarah <Sarah.Walinsky@fda.hhs.gov>
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<Sarah.Walinsky@fda.hhs.gov>
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To: Cohn, Amanda C (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4cbff30d34c4611a2e973fcb192de37-HHS-anc0-cd]; Schuchat, Anne (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=848b7544f27d4a2a9554a80e78d002fc-HHS-acs1-cd]
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Subject: RE: [EXTERNAL] RE: Quick Q - vaccine coadministration

Dear Amanda,

Can I give you a call about 6 PM with Marion? If so, what number? Thanks.

Best Regards,
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Sure, we are happy to. I am available late afternoon/early evening but am giving a talk from 7:30-9.

I have another issue to discuss as well, reports of myocarditis in adolescents. I am putting together an email, but this may come to the surface this weekend.

Thanks,
Amanda

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Thursday, May 13, 2021 4:16 PM
To: Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>; Cohn, Amanda (CDC/DDID/NCIRD/OD) <anc0@cdc.gov>
Cc: Gruber, Marion (FDA/CBER) <Marion.Gruber@fda.hhs.gov>; Walinsky, Sarah (FDA/CDER) <Sarah.Walinsky@fda.hhs.gov>
Subject: FW: [EXTERNAL] RE: Quick Q - vaccine coadministration

Dear Anne and Amanda,

Could we have a discussion here? We could have missed something at ACIP, but we have the following concerns:

1) We would recommend consideration be given to stating that the coadministration of live attenuated virus vaccines with COVID-19 vaccines should be avoided, if possible.

Obtained via FOIA by Judicial Watch, Inc.

2) At the very least, there should be some mention that coadministration could possibly reduce the efficacy of either or both of the co-administered vaccines.

Thanks. If you think we are totally off base, just tell us so.

Best Regards,
Peter

From: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>
Sent: Thursday, May 13, 2021 4:00 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: FW: [EXTERNAL] RE: Quick Q - vaccine coadministration

Hi Peter –

Here's the latest version.

Lorrie

From: Woodworth, Kate (CDC/DDNID/NCBDDD/DBDID) <vnt0@cdc.gov>
Sent: Thursday, May 13, 2021 3:54 PM
To: Nordlund, Kristen (CDC) <hok4@cdc.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Coffin, Nicole (CDC) <ndc3@cdc.gov>
Cc: Mbaeyi, Sarah A (CDC) <vif6@cdc.gov>
Subject: [EXTERNAL] RE: Quick Q - vaccine coadministration

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Here is the latest version if helpful!

Coadministration with other vaccines
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If multiple vaccines are administered at a single visit, administer each injection in a different injection site. For adolescents and adults, the deltoid muscle can be used for more than one intramuscular injection.

Obtained via FOIA by Judicial Watch, Inc.

Best practices for multiple injections include:

- Label each syringe with name and dosage (amount) of the vaccine, lot number, the initials of the preparer, and the exact beyond-use time, if applicable.
- Separate injection sites by 1 inch or more, if possible.
- **Administer COVID-19 and vaccines that may be more likely to cause a local reaction (e.g., tetanus-toxoid-containing and adjuvanted vaccines) in different limbs, if possible.**

From: Nordlund, Kristen (CDC/DDID/NCIRD/OD) <hok4@cdc.gov>
Sent: Thursday, May 13, 2021 3:49 PM
To: McNeill, Lorrie (FDA/CBER) <Lorrie.McNeill@fda.hhs.gov>; Coffin, Nicole (CDC/DDID/NCEZID/DHQP) <ndc3@cdc.gov>
Cc: Woodworth, Kate (CDC/DDNID/NCBDDD/DBDID) <vnt0@cdc.gov>; Mbaeyi, Sarah (CDC/DDID/NCIRD/OD) <vif6@cdc.gov>
Subject: RE: Quick Q - vaccine coadministration

Hi Lorrie,

We plan to updated the clinical guidance tomorrow after 1pm. Attached is the edited version of the guidance that we put up during ACIP, but I've not seen the exact language. I've cced Drs. Woodworth and Mbaeyi who are working on this in case they can share the latest version.

Thanks,
Kristen

From: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>
Sent: Thursday, May 13, 2021 3:43 PM
To: Nordlund, Kristen (CDC/DDID/NCIRD/OD) <hok4@cdc.gov>; Coffin, Nicole (CDC/DDID/NCEZID/DHQP) <ndc3@cdc.gov>
Subject: Quick Q - vaccine coadministration

Hi all – Dr. Marks and Dr. Woodcock participated in a stakeholder call this afternoon to discuss the authorization of the Pfizer vaccine for 12 through 15 year olds, and a question was asked about coadministration of COVID vaccine with other vaccines (meaning childhood vaccines). One of the participants said CDC was recommending that there no longer needed to be a waiting period between vaccination with COVID and other vaccines. I'm not sure he/she was completely correct. We know the issue was discussed at ACIP yesterday (I was unable to watch), but am not sure any recommendations have come out yet. Can you all let me know if there's an update?

Thanks much!

Lorrie

Lorrie H. McNeill
Director

Office of Communication, Outreach and Development
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration
Tel: 240-402-8119
lorrie.mcneill@fda.hhs.gov



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From: Marks, Peter [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DFBB2B5BD38445CB9C9ADCA3F72DF53A-MARKSP]
Sent: 5/14/2021 1:29:20 PM
To: Gruber, Marion [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=019cd2669c7048f7a116d72b7682de44-gruber]; Cohn, Amanda C (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4cbff30d34c4611a2e973fcb192de37-HHS-anc0-cd]
CC: Mbaeyi, Sarah A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=da4de16472154335afbbd91258c63d83-HHS-vif6-cd]
Subject: RE: [EXTERNAL] FW: Coadministration of COVID-19 Vaccines with Other Vaccines During Pregnancy

Dear Amanda and Sarah,

I can live with this as well.

Please let me know if you want to connect about the adverse event issue later today. Seems like work is still ongoing, but let me know. Thanks.

Best Regards,
Peter

From: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Sent: Friday, May 14, 2021 1:11 PM
To: Cohn, Amanda C (CDC) <anc0@cdc.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Mbaeyi, Sarah A (CDC) <vif6@cdc.gov>
Subject: RE: [EXTERNAL] FW: Coadministration of COVID-19 Vaccines with Other Vaccines During Pregnancy

I am fine with this language.
Marion

From: Cohn, Amanda (CDC/DDID/NCIRD/OD) <anc0@cdc.gov>
Sent: Friday, May 14, 2021 1:08 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Cc: Mbaeyi, Sarah A (CDC) <vif6@cdc.gov>
Subject: [EXTERNAL] FW: Coadministration of COVID-19 Vaccines with Other Vaccines During Pregnancy

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Peter and Marion- Here is the updated language, let us know if you have any additional input! It's going live this afternoon.

Thanks,
Amanda

Coadministration with other vaccines

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Best practices for multiple injections include:

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- **Administer the COVID-19 vaccines and vaccines that may be more likely to cause a local reaction (e.g., tetanus-toxoid-containing and adjuvanted vaccines) in different limbs, if possible.**

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From: Cohn, Amanda (CDC/DDID/NCIRD/OD) [anc0@cdc.gov]
Sent: 5/14/2021 1:46:04 PM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Gruber, Marion [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=019cd2669c7048f7a116d72b7682de44-gruber]
CC: Mbaeyi, Sarah A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=da4de16472154335afbbd91258c63d83-HHS-vif6-cd]
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We have a meeting with Rochelle at 3:30 about if we should (b) (5)
(b) (5)

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To: Gruber, Marion (FDA/CBER) <Marion.Gruber@fda.hhs.gov>; Cohn, Amanda (CDC/DDID/NCIRD/OD) <anc0@cdc.gov>
Cc: Mbaeyi, Sarah (CDC/DDID/NCIRD/OD) <vif6@cdc.gov>
Subject: RE: [EXTERNAL] FW: Coadministration of COVID-19 Vaccines with Other Vaccines During Pregnancy

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Please let me know if you want to connect about the adverse event issue later today. Seems like work is still ongoing, but let me know. Thanks.

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To: Cohn, Amanda C (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4cbff30d34c4611a2e973fcb192de37-HHS-anc0-cd]; Gruber, Marion [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=019cd2669c7048f7a116d72b7682de44-gruber]
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Subject: RE: [EXTERNAL] FW: Coadministration of COVID-19 Vaccines with Other Vaccines During Pregnancy

Dear Amanda,

Understood and agreed. Even if we do proceed, we might want to do so in an orderly manner at the beginning of next week, especially given all of the uncertainties around this possible signal.

Look forward to hearing one way or the other later. Thanks.

Best Regards,
Peter

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Sent: Friday, May 14, 2021 1:46 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>
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To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Anderson, Steven [Steven.Anderson@fda.hhs.gov]; Forshee, Richard [Richard.Forshee@fda.hhs.gov]; Gruber, Marion [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=019cd2669c7048f7a116d72b7682de44-gruber]; Krause, Philip [Philip.Krause@fda.hhs.gov]; Nair, Narayan [Narayan.Nair@fda.hhs.gov]; Shimabukuro, Tom (CDC) [ayv6@cdc.gov]; Messonnier, Nancy E (CDC) [nar5@cdc.gov]
CC: Clark, Thomas A (CDC) [tnc4@cdc.gov]; Farizo, Karen [Karen.Farizo@fda.hhs.gov]; Fox, Kimberley (CDC) [kaf6@cdc.gov]; Wharton, Melinda (CDC) [mew2@cdc.gov]; DeStefano, Frank (CDC) [fxd1@cdc.gov]

Subject: Coordination on adverse events
Attachments: Capecchi JSTH 2018.pdf
Location: https://fda.zoomgov.com/(b) (6)

Start: 4/12/2021 9:30:00 AM
End: 4/12/2021 10:00:00 AM
Show Time As: Busy

Required Attendees: Marks, Peter; Anderson, Steven; Richard Forshee (Richard.Forshee@fda.hhs.gov); Gruber, Marion (Marion.Gruber@fda.hhs.gov); Philip Krause (Philip.Krause@fda.hhs.gov); Nair, Narayan; Shimabukuro, Tom (CDC); Messonnier, Nancy E (CDC)
Optional Attendees: Clark, Thomas A. (CDC/DDID/NCIRD/DVD); Farizo, Karen; Fox, Kimberley (CDC/DDID/NCIRD/DBD); Wharton, Melinda (CDC/DDID/NCIRD/ISD); Destefano, Frank (CDC/DDID/NCEZID/DHQP)

Sorry for the second last minute change – this should be the last one. We will start at 9:30 due to an EMA meeting. Thanks!

Hi there,

Peter.Marks@fda.hhs.gov is inviting you to a scheduled ZoomGov meeting.

Join Zoom Meeting

Phone one-tap: US: +16692545252,(b) (6) or +16468287666,,(b) (6)

Meeting URL: https://fda.zoomgov.com/(b) (6)

Obtained via FOIA by Judicial Watch, Inc.

Meeting ID: (b) (6)
Passcode

Join by Telephone

For higher quality, dial a number based on your current location.

Dial:

US: +1 669 254 5252 or +1 646 828 7666 or +1 551 285 1373 or +1 669 216 1590 or 833 568 8864 (Toll Free)

Meeting ID: (b) (6)

Passcode

International numbers

Join from an H.323/SIP room system

H.323:

Meeting ID: (b) (6)

Passcode:

SIP:

Passcode: (b) (6)

Check for updates

Journal of Thrombosis and Haemostasis, **16**: 1918–1931 Obtained via FOIA by Judicial Watch, Inc. DOI: 10.1111/jth.14210

REVIEW ARTICLE

Cerebral venous sinus thrombosis

M. CAPECCHI, M. ABBATTISTA and I. MARTINELLI

A. Bianchi Bonomi Hemophilia and Thrombosis Center, Fondazione IRCCS Ca' Granda - Ospedale Maggiore Policlinico, Milan, Italy

To cite this article: Capecchi M, Abbattista M, Martinelli I. Cerebral venous sinus thrombosis. *J Thromb Haemost* 2018; **16**: 1918–31.

Summary. The cerebral venous system is an unusual site of thrombosis, with a particularly high incidence in young adults. This incidence has increased in past decades because of the improvement of neuroradiological techniques. Risk factors for cerebral venous sinus thrombosis overlap with those of other venous thromboembolism sites; however, some are specific for this particular anatomical district. Prognosis is favorable in most cases if diagnosis is made rapidly and treatment is promptly initiated, even if acute complications or chronic invalidity still occur in a quarter of patients. The mainstay of treatment is anticoagulation, which is necessary in order to block clot propagation and obtain recanalization. Intracranial bleeding does not contraindicate anticoagulation. Endovascular procedures are reserved for patients with a particularly severe presentation or rapidly declining neurological symptoms despite appropriate anticoagulation, although data from clinical trials are lacking. Specifically, this review addresses the epidemiology, clinical presentation and course, risk factors, and treatment of cerebral venous sinus thrombosis, with a special focus on the pediatric population.

Keywords: anticoagulants; cerebral hemorrhage; intracranial thrombosis; low-molecular-weight heparin; sinus thrombosis; venous thromboembolism.

Anatomy

The cerebral venous system can be divided into two major compartments considering the anatomic and functional characteristics of the blood vessels: the cerebral veins and the dural venous sinuses (Fig. 1). Considering the topographic distribution, a superficial and a deep system can be distinguished. The superficial system drains blood from the cerebral cortex mainly into the superior sagittal sinus, which in turn drains into the transverse sinuses. The deep system drains blood from the deep white matter and the basal ganglia to the inferior sagittal sinus, that continues into the straight sinus and then into the transverse sinuses. From the transverse and the straight sinuses blood flows out of the sigmoid sinuses, passing through the sinus confluence (torcular Herophili), and finally into the internal jugular veins. Many anastomoses exist between the cerebral veins from the fetal period onwards. The dural venous sinuses are delimited by the superficial (periosteal) and the deep (meningeal) layer of the dura mater and their walls are composed of only the dura mater layer lined with endothelium, hence lacking the tunica media. Additionally, these sinuses lack valves. Dural venous sinuses drain blood from the cerebral veins and the cerebrospinal fluid from the subarachnoid space, via the arachnoid Pacchionian granulations, which are present particularly in the superior sagittal sinus. The classic anatomy varies considerably among individuals and the knowledge of such variations is essential for a correct interpretation of radiological images. The most frequent anatomic variants are: asymmetries of transverse sinuses, observed in nearly 50% of patients; hypo-/aplasia of all or part of the transverse sinuses, observed in nearly 20% of patients; and less frequently hypo-/aplasia of the frontal part of the superior sagittal sinus [1].

Pathophysiology

The formation of a thrombus in the cerebral venous circulation leads to an increase in the hydrostatic pressure in the veins and capillaries upstream of the occlusion. However, because of the anastomotic circuit of the cerebral venous system, the increased venous pressure is usually compensated to some extent. If the increase in the venous pressure overcomes the compensation capacity the following can occur: blood–brain barrier disruption, extravasation of fluids into the cerebral parenchyma and consequent localized edema. Furthermore, if the venous pressure exceeds the arterial pressure, a reduction of

Correspondence: Ida Martinelli, A.Bianchi Bonomi Hemophilia and Thrombosis Center, Fondazione IRCCS Ca' Granda - Ospedale Maggiore Policlinico, Via Pace 9, 20122 Milan, Italy
Tel.: +39 02 5503 5468
E-mail: ida.martinelli@policlinico.mi.it

Received: 29 March 2018
Manuscript handled by: F. R. Rosendaal
Final decision: F. R. Rosendaal, 5 June 2018

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FDA-CBER-2021-5762-00144

Obtained via FOIA by Judicial Watch, Inc.

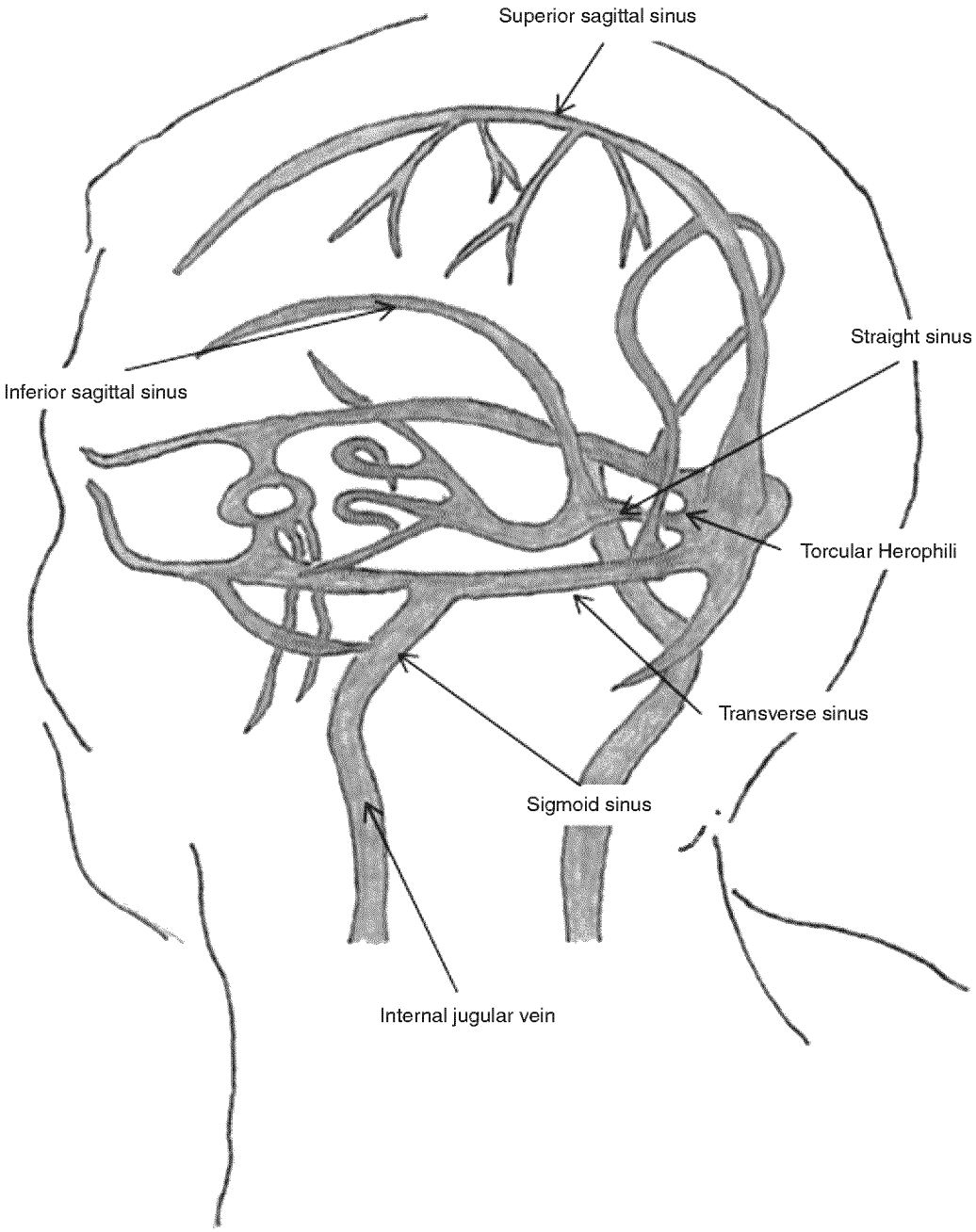


Fig. 1. Anatomy of the cerebral venous system.

arterial flow and consequent arterial ischemia can occur and, if not adequately treated, it may progress to hemorrhagic infarction [2]. A peculiar characteristic that distinguishes vasogenic (due to venous occlusion) from cytotoxic (due to arterial occlusion) edema, is that in the former the perfusion pressure is not usually reduced and therefore irreversible brain tissue damage is unlikely. Indeed, in venous stroke a resolution of thrombi and a favorable prognosis are more likely than in arterial stroke. The peculiarity of venous occlusion is the reduction of cerebrospinal fluid reabsorption, by reducing cerebrospinal fluid access to the arachnoidal Pacchionian granulations, leading to intracranial hypertension [3]. This scenario is more frequent with superior sagittal sinus occlusion (where arachnoidal Pacchionian granulations are present), but can also occur in the occlusion of other sinuses.

Epidemiology

Cerebral venous sinus thrombosis (CVST) is a rare manifestation of thrombosis with an incidence that varies

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between studies. In adults, the annual incidence of CVST is two to five cases per million individuals [3,4], but it is likely to be underestimated because of the lack of well-designed epidemiological studies. Two recent studies in the Netherlands and southern Australia found a higher incidence than previously reported of 13.2 and 15.7 annual cases per million, respectively [5,6]. The high prevalence of infection-related CVST can result in even higher figures in others countries (18% in Pakistan), but the exact incidence among different ethnic groups is pending investigation [7–9]. At variance with arterial stroke that is more prevalent in the elderly, CVST typically affects young adults with a mean age of 35 years and is more common in women than in men (2.2:1) because of sex-specific risk factors [10]. The superior sagittal and the transverses are the most frequently involved sinuses (60% of patients), followed by the internal jugular and cortical veins (20%). In almost two-thirds of patients CVST involves more than one sinus.

Epidemiology in children and neonates

The annual incidence of CVST in the pediatric population is approximately seven cases per million and is higher in neonates than in children [11–14]. The sex ratio seems balanced because of the absence of sex-specific risk factors [12]. Similarly to adults, the superficial sinuses are the most frequently involved (particularly the superior sagittal and the transverse sinuses) and the transverse sinuses are more frequently involved in children older than 2 years of age (60% vs. 39%) [11,15].

Clinical presentation

Because symptoms of CVST are variable and aspecific, diagnosis is often delayed to a median period of 7 days from the onset of clinical manifestations [16]. The International Study on Cerebral Venous and Dural Sinus Thrombosis (ISCVT), which included 624 patients, described the following as the most common presenting symptoms: headache (88.8%), seizures (39.3%), paresis (37.2%), papilledema (28.3%) and mental status changes (22%) [16].

Headache is usually the first symptom at onset of CVST. In only 10% of cases does the headache have a thunderclap outbreak, mimicking a subarachnoid hemorrhage [17]. Because of its aspecific nature, physicians must have a high suspicion of CVST when dealing with a new onset and progressively increasing intensity of headache, which is the only presenting symptom in about 32% of patients [17]. The location of the headache is not informative as it does not correlate with the thrombosis site. The absence of headache is typical of elderly patients, especially men [18], and in those with cortical vein thrombosis who have normal cerebrospinal fluid homeostasis. The pathophysiologic mechanism of headache in CVST is the increase in intracranial pressure due to reduced cerebrospinal fluid reabsorption. For this reason, the intensity of the headache typically increases when patients lie down and after the Valsalva maneuver. For reasons not yet fully understood, headache is more common in patients with CVST than in those with arterial stroke (25% of cases) [19].

Seizures are focal in one quarter of patients, in another quarter they begin as focal and then generalize and in the remaining half, seizures are generalized *ab initio*[20]. Seizures are more frequent in patients with CVST than in those with arterial stroke (2–9%) [20], perhaps as a consequence of the accumulation of catabolic products due to venous stasis.

Focal neurological deficits such as paresis, dysarthria and aphasia are due to localized damage in the cerebral cortex, secondary to a venous infarction. Focal deficits are more frequent in patients with thrombosis of the superficial system with involvement of the parasagittal cortex, where the motor and sensory areas are located.

Papilledema is the consequence of intracranial hypertension and can cause diplopia and visual loss. Patients with thrombosis of the cavernous sinuses may also develop proptosis, orbital pain, chemosis and ophthalmoplegia secondary to a palsy of the oculomotor (III), trochlear (IV) and abducens (VI) cranial nerves.

Mental status changes such as amnesia, mutism, confusion or delirium are seen in patients with thrombosis of the deep system, particularly those with large venous infarctions or bilateral edema of the basal ganglia and thalami. The most severe cases can have a rapid neurological deterioration, leading to coma and death.

Clinical presentation in children and neonates

In children, symptoms at onset are even more aspecific than in adults and are frequently attributable to more common diseases such as infections or dehydration, making the suspicion and diagnosis of CVST particularly difficult. In general, symptoms in children are the same as in adults, but generalized neurological deficits are more common and seizures are more frequent in neonates [11].

Diagnosis

When CVST is suspected in adults the first-line imaging technique is unenhanced computed tomography (CT) scan; this allows for the ruling out of brain tumors, abscesses or arterial stroke. In the acute phase, CVST is seen in unenhanced CT scans as a hyperdense signal in the vessel lumen, that becomes iso- and then hypodense after the first week. Depending on the location of CVST, two specific radiological signs are described: the 'dense triangle sign' when thrombosis is located in the superior sagittal sinus, and the 'dense cord sign' when located in a cortical or deep vein [3] (Fig. 2A). However, such signs

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are rarely described (considering that the unenhanced CT scan has a low sensitivity), resulting positive in only 30% of patients with CVST [21]. The addition of contrast agent increases the sensitivity to 99% for sinus thrombosis and 88% for vein thrombosis, figures similar to those obtained with magnetic resonance imaging (MRI) [22,23]. In the presence of the contrast agent, a specific radiological sign is the 'empty delta sign', a filling defect in the middle of the venous lumen with a peripheral enhancement (Fig. 2B). Advantages of CT scanning are the availability in emergency and the ability to show the presence of local complications associated with CVST, such as subarachnoid or intraparenchymal hemorrhage or cerebral edema. Disadvantages are the exposure to ionizing radiation and the need for contrast agent to increase the accuracy. Currently, MRI is the reference standard imaging technique for diagnosis of CVST, despite the fact that exact sensitivity and specificity are not known because of the lack of proper comparative studies with catheter angiography. Catheter angiography was the historical reference standard technique, which today, due to its invasiveness, is reserved for patients with an inconclusive CT scan and MRI or for candidates undergoing endovascular procedures [24,25]. Maximum accuracy is obtained with the combination of classic MRI sequences, which are able to show the thrombus, together with venography, which can show reduction or absence of flow and therefore distinguish hypoplastic sinuses, partial sinus occlusion, thrombosis of cortical cerebral veins, or filling defects due to hyperplastic arachnoid granulations (Fig. 3) [26]. The advantages of MRI are the absence of both radiation exposure and intravenous contrast agent, and the ability to establish the age of the clot. Finally, when D-dimer is high it increases the likelihood of deep vein thrombosis of the lower limbs or pulmonary embolism; it has been investigated in several studies as a predictive factor for CVST, but has consistently shown a low sensitivity and specificity [27]. Despite this, the ESO guidelines suggest measuring D-dimer before neuroimaging in patients with suspected CVST, except in those with isolated headache and in the case of prolonged duration of symptoms (i.e. > 1 week). The quality of evidence is low and the strength of recommendation is weak [28].

Diagnosis in children and neonates

In children, imaging techniques for diagnosis are the same as in adults, whereas in neonates the first choice is the transfontanellar doppler ultrasound, which has the advantage of being extensively available and non-invasive, albeit strongly operator dependent. In the case of inconclusive results and a persistent clinical suspicion of CVST, enhanced CT scan and MRI must be performed.

Prognosis

For a long time CVST has been considered a life-threatening condition, but the case fatality rate has decreased proportionally over time, from more than 50% to 5–10% [29]. Increased clinical awareness, the advancement of neuroimaging techniques and the improvement in therapeutic management have enabled earlier diagnosis and identification of less severe cases, ensuring a better prognosis. However, data on clinical outcome stem from

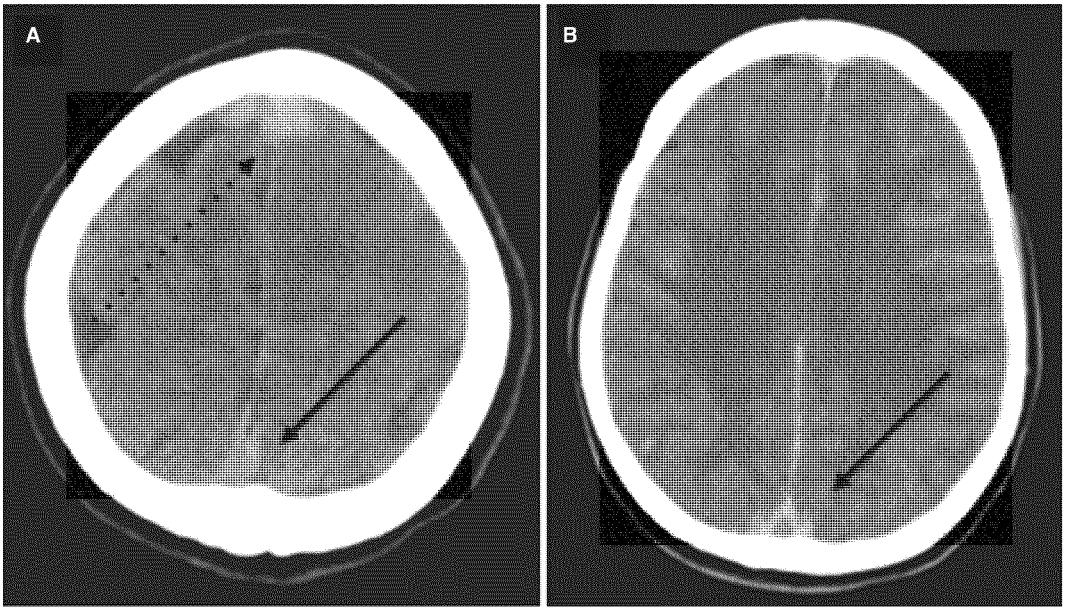


Fig. 2. Superior sagittal sinus thrombosis on computed tomography (CT) scan. (A) Unenhanced CT scan showing the dense triangle sign (arrow) and a peri-thrombotic frontal hemorrhagic suffusion (dashed arrow). (B) Enhanced CT scan showing the empty delta sign (arrow) of the superior sagittal sinus.

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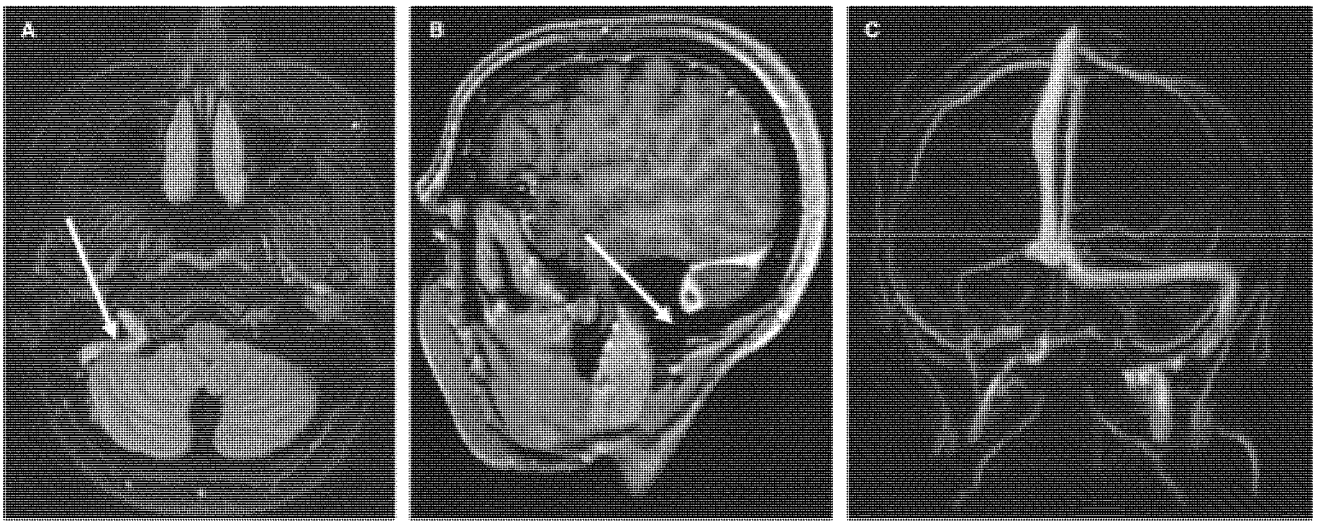


Fig. 3. Cerebral sinus vein thrombosis on magnetic resonance imaging (MRI) sequences. (A) Fluid attenuated inversion recovery axial sequence showing absence of flow-void in the right sigmoid sinus (arrow). (B) Sagittal contrast enhanced T1-weighted sequence showing a partial occlusion of the right sigmoid sinus (arrow). (C) Three-dimensional reconstruction of the cerebral venous system showing the absence of flow in the right transverse and sigmoid sinuses and right internal jugular vein.

studies with small sample sizes, which suffer from methodological heterogeneity and are usually referred for follow-up visits for up to only 12 months. The clinical course of the acute phase is unpredictable and in approximately 5% of patients intracranial hemorrhage followed by herniation, seizures, pulmonary embolism or severe comorbidity can be fatal [16,30,31]. A minority of patients with CVST (15–20%), have different degrees of permanent disability or die [16,32]. A meta-analysis reported an overall mortality of 9.4% (122 deaths among 1303 patients), although the causes of death during follow-up were mainly related to concomitant diseases (e.g. cancer) rather than to CVST itself [30,33]. The majority of patients who recover completely achieve relative independence, usually expressed as between 0 and 2 on the modified Rankin Scale (mRS), although mild residual symptoms, such as headache, motor deficits, linguistic difficulties, and impaired vision or cognition, often remain [16,34–36]. Only 5–10% of patients who survive the acute phase remain moderately or severely dependent (mRS 3 or 4) [16,34]; however, this proportion increases up to 34% in those with massive CVST [37].

Recanalization

To date, few studies with small sample sizes have investigated the recanalization rate of CVST. Differences in the definition of recanalization and time of evaluation across studies make it difficult to pool data and to provide homogenous results. With these limitations, the rate of recanalization (complete or partial) is around 85%, ranging between 73% and 93% [30,38]. Almost 50% of cases achieve a complete recanalization after a median time of 6 months. Recanalization occurs mainly in the first months after CVST and is a dynamic process continuing for up to 12 months, whereas recanalization after 1 year is rare [30,38,39]. A late recanalization has been described in patients with CVST, occurring during hormonal treatment [39]. Controversial and limited data are available regarding the influence of the degree of recanalization on functional outcome [40,41]. One study reported a greater chance of good functional outcome associated with complete recanalization [38], whereas others did not confirm this finding [39,42]. A recent large study including 508 patients showed a high recanalization rate at 3 months after CVST (81%) and an independent association between recanalization and a favorable neurological outcome [43].

Recurrence rate

Data on recurrent venous thrombosis derive mainly from studies with small sample sizes and retrospective design, underpowered to detect potential risk factors for recurrence. The overall incidence of recurrent venous thrombosis within the first year after a first episode of CVST is estimated at around 4 per 100 patient-years (p-y) [44]; that of recurrent CVST is 0.5% to 2.2% p-y and that of recurrent deep vein thrombosis of the lower limbs and/or pulmonary embolism is 1.1% to 5.0% p-y [16,44–47]. Notably, male sex is associated with a 7-fold increased risk of recurrence [44,46]. Cohort studies on long-term evaluation of the risk of recurrent thrombosis after anticoagulant therapy discontinuation showed higher figures in the first period (5.0% p-y, 2.6% p-y and 1.7% p-y in the first, third and tenth year after discontinuation,

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respectively) for an overall risk of 2 to 3.5 per 100 p-y [46,47].

Prognosis in children and neonates

The mortality rate varies from 5% to 10% and increases up to 25% in newborns [48]. Few studies have investigated the clinical outcome of neonates and children who survive the acute phase of CVST and no data on their subsequent neurodevelopment are available. The longest observational period was described in a large prospective study that included 104 neonates followed for a median period of 2.5 years (range 6 months to 15 years) [49]. Prognosis in children seems worse than in adults, with 20–70% of patients presenting residual neurological deficits [13,49,50]. In a series of 42 neonates, one died and only 21% of those who completed 2 years of follow-up recovered completely [51]. A European cohort study reported a recanalization rate of 69% (46% complete and 42% partial) between 3 and 6 months after CVST [52], and another recent study found a rate of 85% at 3 months in neonates compared with 56% in children [53]. Despite the limited data, complete recanalization seems to occur earlier in children than in adults, particularly in neonates [53].

The recurrence rate of thrombosis varies between 0% and 20% [15,48–50], with the highest figures in children older than 2 years [11,52]; this is mainly due to underlying systemic diseases (e.g. systemic lupus erythematosus and Behçet disease) [54]. The avoidance of anticoagulant therapy, the lack of recanalization and the presence of the G20210A prothrombin gene mutation have all been associated with an increased risk of recurrence of 11.2-, 4.1- and 4.3-fold, respectively [38,52].

Table 1 Risk factors for cerebral vs. sinus thrombosis

Permanent risk factors	Transient risk factors
Inherited thrombophilia	Sex related
Prothrombin G20210A mutation	Oral contraceptive
Factor V Leiden	Pregnancy
Antithrombin deficiency	Puerperium
Protein C deficiency	Infections
Protein S deficiency	Head and neck infections (e.g. mastoiditis, sinusitis, otitis, osteomyelitis, abscess and meningitis)
Malignancy	Malignancy
Advanced-stage cancer	Cerebral and non-cerebral solid cancer
Systemic diseases	Mechanical
Antiphospholipid syndrome	Head trauma, neurosurgical procedures, lumbar puncture, jugular vein catheterization
Autoimmune diseases (systemic lupus erythematosus, Behçet disease and vasculitis)	Other
Inflammatory bowel diseases	L-asparaginase treatment
Nephrotic syndrome	Severe dehydration
Hematological diseases	Severe anemia
Paroxysmal nocturnal hemoglobinuria	Obesity
Sickle cell disease	Maternal (specific for neonates)
β-thalassemia, myeloproliferative neoplasms	Maternal infections
	Obstetrical trauma
	Obstetrical complications (gestational diabetes, preeclampsia/eclampsia and premature rupture of membranes)

Risk factors

Like any thrombosis, CVST has a multifactorial etiology (Table 1). In 85% of patients at least one risk factor is identified and 50% of events are triggered by the interaction of more risk factors. A small proportion of cases remains idiopathic (i.e. no direct cause or risk factor can be identified) [16,55].

Sex related

CVST is more common in women of reproductive age than in men, as a result of the use of oral contraceptives or hormone replacement therapy, pregnancy and the puerperium [56]. Oral contraceptive use is by far the most common risk factor, reported in more than 80% of women in various series and associated with a pooled estimate of approximately 6-fold increased risk of CVST [57]. A recent case–control study showed that overweight and obesity in women using oral contraceptives further increased the risk of CVST up to 30-fold in a dose-dependent manner [58]. An increase in risk also occurs with the multiplicative interaction between oral contraceptive use and the presence of thrombophilia abnormalities [59,60]. Pregnancy or the puerperium are responsible for 5–20% of CVST, with an incidence of 12 cases per 100 000 deliveries [4,56,61].

Thrombophilia abnormalities

Inherited thrombophilia abnormalities, that is, the common gain-of-function mutations in factor (F) V and FII (FV Leiden and prothrombin G20210A polymorphism) and the rare lack-of-function deficiencies in antithrombin, protein C and protein S, are well-established risk factors for venous thromboembolism, including CVST. Heterozygous FV Leiden or prothrombin polymorphism are reported in 6–24% of patients with CVST, with the latter being more prevalent in several case series [16,62,63]. A recent meta-analysis that included 23 cohort and 33 case–control studies reported a solid risk estimate of CVST for

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prothrombin polymorphism (OR, 6.05; 95% CI, 4.12–8.90) and FV Leiden (2.89; 95% CI, 2.10–3.97), and a strong estimate for protein C (OR, 8.35; 95% CI, 2.61–26.67) and protein S (OR, 6.45; 95% CI, 1.89–22.03) deficiency [62]. With regard to the severe acquired thrombophilia due to the presence of antiphospholipid antibodies, data on the association with CVST are lacking and only case reports or small case series are available [30,63–65]. A study of 163 patients with CVST and 163 with deep vein thrombosis showed a stronger association of anticardiolipin antibodies with the former rather than the latter (17% vs. 4%) [65]. Data are scanty for other thrombophilia markers such as high FVIII and hyperhomocysteinemia. Only one case–control study investigated the association between high FVIII and CVST, showing higher levels in patients than controls [66]. Hyperhomocysteinemia is associated with a 3-fold increased risk of CVST [62,64]; however, the homozygous MTHFR C677T polymorphism, a genetic determinant of homocysteine levels, does not independently increase the risk of CVST [64,67].

Cancer

Approximately 7% of patients with CVST have a concomitant solid (cerebral or non-cerebral) or hematological cancer [16,47]. In a recent case–control study, among 594 patients with CVST the prevalence of cancer was 8.9%, for a nearly 5-fold increased risk (OR, 4.86; 95% CI, 3.46–6.81) [33]. Moreover, CVST can be a complication of chemotherapy with L-asparaginase. Out of 706 treated patients, 22 (3.1%) developed CVST, 20 of whom during treatment with L-asparaginase [68]. Although the incidence rate of CVST in patients with myeloproliferative neoplasms (MPN) is around 1%, approximately 4% of patients with CVST have an overt myeloproliferative neoplasm [69–71]. Hence, such diseases must be suspected and appropriately searched for in patients with CVST.

Systemic diseases and infections

CVST occurs in 0.5–7.5% of patients with chronic inflammatory bowel diseases, as a complication of the hypercoagulable state due to mucosal inflammation that leads to upregulation of tissue factor, high platelet count and impaired fibrinolysis [72,73]. Additional systemic conditions are vasculitis, especially Behçet disease, with an incidence rate for CVST of 3 per 1000 p-y [74], whereas few data are available on systemic lupus erythematosus and nephrotic syndrome [75]. A local infection becomes a strong risk factor for CVST through endothelial injury and activation of procoagulant pathways. The most common are otitis, mastoiditis, sinusitis, meningitis, skin or dental infections. However, in the antibiotic era the prevalence of infection-related CVST has dropped to 8–12%, although it remains higher in less developed countries [9,16,47].

Other risk factors

Additional mechanical risk factors for CVST include neurosurgery, internal jugular catheterization and lumbar puncture [3,4]. Regarding genetic causes, several loci on chromosome 6 (within the human histocompatibility complex) and chromosome 9 (close to the ABO gene) have been involved in the development of CVST [76], although these associations remain to be confirmed in large genome-wide association studies [77]. The association of CVST with other candidate genes, such as plasminogen activator inhibitor-1 4G/5G polymorphism [78] and protein Z G79A polymorphism [79], remains controversial. Janus Kinase-2 (JAK2) V617F somatic mutation, a primary molecular marker of Philadelphia-negative MPN, is also present in a small percentage (0–6.2%) of CVST without an overt MPN and it could be linked to an increased risk of cerebral thrombosis [80,81].

Risk factors in children and neonates

As in adults, CVST in children and neonates has a multifactorial etiology. Compared with adults, children develop idiopathic events less frequently and have a partially different set of risk factors due to anatomical and rheological characteristics of the cerebral circulation. The hemostatic system in children is in a dynamic state, with quantitative and qualitative differences in coagulation factors compared with adults. In neonates the hemostatic system is accelerated as a result of decreased levels of the natural anticoagulant proteins (antithrombin, protein C and protein S) that rise up to physiological adult levels at approximately 6 months after birth [82,83]. Despite this, neonates have a good hemostatic balance that can be altered by concomitant comorbidities such as systemic or local infections, dehydration, chronic renal failure and brain tumors [84,85]. In neonates there are also obstetrical predisposing conditions, including premature rupture of membranes, infections, gestational diabetes, hypertension and hypoxic ischemic injury [86]. Specifically, the compression of the skull bones during delivery can result in damage of the dural venous sinuses and this, together with typical neonatal dehydration, can increase the risk of CVST development [24,87]. Additionally, the usual supine position assumed by neonates has a major influence on intracranial venous outflow, contributing to local venous stasis. This happens particularly in the thrombosis of the superior sagittal sinus (OR, 2.5; 95% CI, 1.07–5.67) [84]. In children and adolescents, head and neck infections (otitis media, mastoiditis and sinusitis) are the most common risk factors for CVST [11,13,85,88]. Other risk factors observed in more than 50% of cases include underlying chronic diseases such as nephrotic syndrome (which confers an acquired prothrombotic state due to urinary loss of anticoagulant proteins) [89], liver diseases [11], systemic lupus erythematosus [90], malignancy

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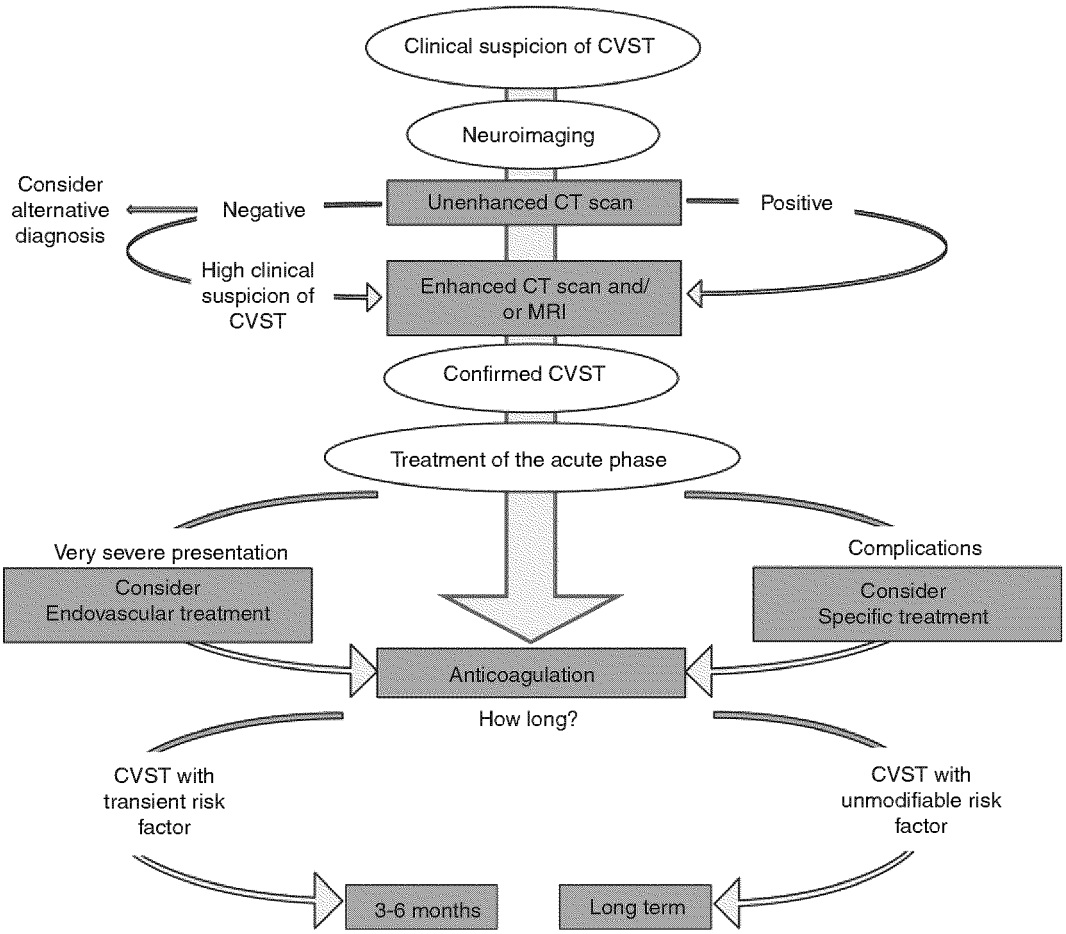


Fig. 4. Diagnostic and therapeutic algorithm in cerebral venous sinus thrombosis.

[15,91], head trauma or neurosurgery [48,49]. CVST has also been reported in children with iron deficiency anemia and to a lesser extent with hemolytic anemia, β-thalassemia and sickle cell disease[15]. Inherited thrombophilia has been poorly investigated in pediatric CVST and reported in 20% to 62% of cases [11,12,15,48]. The association of CVST with FV Leiden and prothrombin G20210A polymorphism appears weaker in children than in adults [12,15,92]. The combination of acquired thrombophilia and underlying conditions provides a major contribution to the pathogenesis of pediatric CVST [12,89].

Treatment of the acute phase

Anticoagulant treatment

The use of heparin was first described in 1942 by a British gynecologist who successfully treated a puerpera with CVST [93]. The initial indication of anticoagulation in patients with CVST comes from two small randomized controlled trials performed in the 1990s that compared heparin with placebo. The first included 20 patients and was prematurely stopped because of safety concerns due to 3/10 intracranial hemorrhages in the placebo group compared to 0/10 in the unfractionated heparin (UFH) arm [94]. The second study included 59 patients and showed a better outcome in the low-molecular-weight heparin (LMWH) arm (death or dependence rate 13% vs. 21%) [95]. A subsequent meta-analysis of the two trials showed a 13% reduction in the risk of death or dependency in patients treated with heparin [96]. None of the 18 patients with intracranial hemorrhage included in the two studies cited above and treated with heparin had worsened bleeding [94,95].An observational study including 102 CVST patients with hemorrhagic venous infarction or subarachnoid hemorrhage treated with LMWH or UFH showed a deterioration in clinical course only in 11% of patients, without a difference between the two treatment group [97]. Based on these data, current guidelines state that intracranial hemorrhage does not represent a contraindication to anticoagulant therapy in the acute phase of CVST [28]. Our personal opinion is to use subtherapeutic doses (i.e. 50–75% of the full dose) of LMWH in the case of vast intracranial hemorrhage. No consensus exists on the superiority of one type of heparin over the other. The first indirect comparison between LMWH and UFH in patients with CVST was made in the framework of the ISCVT study and showed a lower

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Table 2 Ongoing clinical trials in patients with cerebral venous sinus thrombosis.

Title	NCT number	Study type and design	Interventions	Primary outcome	Estimated completion date	Age of patients enrolled
A Clinical Trial Comparing Efficacy and Safety of Dabigatran Etexilate With Warfarin in Patients With Cerebral Venous and Dural Sinus Thrombosis (RE-SPECT CVT)	NCT02913326	Interventional randomized (phase 3)	Dabigatran etexilate vs. warfarin for 6 months	Composite rate of major bleeding and venous thromboembolism	June 2018	18–78 years
The Efficacy and Safety of Dabigatran Etexilate for the Treatment of Cerebral Venous Thrombosis	NCT03217448	Interventional randomized (phase 3)	Dabigatran etexilate vs. warfarin for 6 months	Incidence of recanalyzed veins after 6 months	January 2019	18–80 years
Comparison of the Efficacy of Rivroxaban to Coumadin (Warfarin) in Cerebral Venous Thrombosis	NCT03191305	Non-randomized, parallel assignment	Rivaroxaban vs. warfarin	Recurrent CVT or any hemorrhage	September 2018	13–50 years
Study of Rivaroxaban for CeREbral Venous Thrombosis (SECRET)	NCT03178864	Prospective randomized controlled (phase 2)	Rivaroxaban vs. standard of care	Composite rate of all-cause mortality, symptomatic intracranial bleeding, major extracranial bleeding	June 2020	≥18 years
Thrombolysis or Anticoagulation for Cerebral Venous Thrombosis (TO-ACT)	NCT01204333	Interventional randomized (phase 3)	Endovascular local thrombolysis vs. heparin	Favorable clinical outcome (mRS 0-1) at 12 months	Completed	≥18 years
Thrombin Generation and Thrombus Degradation in Cerebral Venous Thrombosis: Clinical and Radiological Correlations	NCT02013635	Observational prospective case-only	Non-interventional	Evolution of thrombin generation parameters and D-dimer levels from baseline and correlation with clinical presentation	Completed	≥16 years
The Role of Factor XIII Activation Peptide and D-dimer Values for the Diagnosis of Cerebral Venous Thrombosis (CVT)	NCT00924859	Observational prospective case-only	Non-interventional	To assess the overall accuracy of D-dimer and FXIII-AP (activation peptide) using a newly developed ELISA test, to exclude CVT in patients with clinical suspicion of CVT	Completed	18–85 years

incidence of disability at 6 months in the LMWH group, without differences in overall survival [98]. Subsequently, two randomized controlled trials compared LMWH and UFH. The first showed a significantly lower mortality rate in the LMWH group (0% vs. 18.8%) [99], whereas the second showed no differences between the two groups in mortality (3.8% vs. 5.6%) and in new symptomatic intracranial hemorrhage (none in both groups) [100]. UFH, with its shorter half-life and easier reversibility, can be preferred in unstable patients or in those requiring invasive procedures.

Thrombolysis and endovascular treatment

No randomized clinical trials have assessed the role of systemic thrombolysis in CVST. The most recent systematic review on this issue included only case reports and case series for a total of 26 patients [101]. Urokinase was the most frequently administered thrombolytic agent (73.1%), whereas streptokinase and recombinant tissue plasminogen activator (rt-PA) were used in 7.7% of cases each. Extracranial hemorrhage occurred in five patients (19.2%) and intracranial in three (11.5%), with two deaths. Partial or complete recanalization occurred in 16 patients (61.5%). Only case reports and small case series are available in the literature on endovascular treatment of CVST with local thrombolysis (urokinase, streptokinase or rt-PA) and mechanical thrombectomy. This treatment should be reserved for patients with a very severe presentation or rapidly declining neurological symptoms despite appropriate anticoagulant therapy, after exclusion of other causes of deterioration. Endovascular treatment is associated with a high risk of intracranial hemorrhage (7.6%) and mortality (9.2%), half of which are due to new onset or worsening of pre-existing intracranial hemorrhage [102]. These estimates are likely to be underestimated because of the publication bias in favor of successful case reports. The randomized controlled trial TO-ACT (NCT01204333) comparing local thrombolysis and heparin treatment has been prematurely interrupted after the inclusion of 67 patients because of no difference in primary outcome (mRS 0–1 at 12 months) [103].

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Hence, currently available data raise concerns about safety of thrombolysis and endovascular treatment in patients with CVST.

Treatment of complications

The most severe patients present complications in the acute phase that require specific management. In the case of seizures, antiepileptic drugs are indicated to prevent recurrences, although the optimal duration of this therapy and its use as primary prophylaxis are not well established. In the case of hydrocephalus associated with neurological deterioration, shunting procedures to drain excess cerebrospinal fluid are required after temporary withdrawal of anticoagulation. Intracranial hypertension does not usually require treatment, but in symptomatic cases shunting procedures or serial lumbar puncture are required to promptly reduce intracranial pressure in case of papilledema and reduced visual acuity. Acetazolamide can also be administered to reduce cerebrospinal fluid production [28]. Rarely, patients with CVST present transtentorial herniation in the acute phase and need decompressive surgery, a lifesaving procedure. A prospective evaluation of the outcome of patients with CVST undergoing decompressive surgery is ongoing (DECOMPRESS-2 registry) and the interim analysis on 22 patients showed a 6-month mortality rate of 23.8% in patients treated vs. 100% in those not treated [104]. The role of steroids in reducing vasogenic edema is controversial; their use is not suggested in acute CVST, particularly in patients without parenchymal lesions, whereas it is recommended in CVST with an associated inflammatory disease (e.g. Behçet's disease) [28].

Treatment of the chronic phase

The optimal duration of anticoagulant therapy for secondary prevention of CVST should be decided for the single patient, evaluating the risk–benefit ratio. The absolute risk of recurrent thrombosis is low and long-term anticoagulation is reserved for patients with persistent and unmodifiable risk factors (e.g. severe thrombophilia, or solid or hematological neoplasms) and those with recurrent CVST. Whether also patients with unprovoked CVST should continue anticoagulation is not known (Fig. 4). AHA/ASA guidelines recommend that patients with CVST secondary to a transient risk factor receive anticoagulant therapy with a vitamin K antagonist (VKAs) for 3–6 months, maintaining an INR range between 2 and 3, whereas those with unprovoked CVST receive therapy for 6–12 months [24]. An exception is CVST during pregnancy, which requires therapeutic doses of LMWH possibly adjusted for bodyweight to ensure efficacy until delivery [28] because of the teratogenic effect of VKAs. AHA/ASA guidelines recommend antiplatelet therapy after a period of anticoagulation in patients with CVST without a recognized thrombophilia, although in the absence of controlled trials or observational studies this indication sounds arbitrary [105]. In line with studies conducted in patients with venous thromboembolism, we might accept the recommendation for patients with unprovoked events. Randomized clinical trials are required and the ongoing EXCOA-CVT study comparing a short (3–6 months) with a long (12 months) duration of oral anticoagulant therapy in patients with CVST will provide new insights into this crucial issue [106]. Recanalization of CVST can be considered among the criteria, potentially helping the decision on the optimal duration of anticoagulant therapy. Repeat imaging (CT or MRI) is recommended at 3–6 months from the index event or in the case of persistent or recurrent symptoms suggestive of CVST during anticoagulation therapy [24]. In the case of complete recanalization further neuroimaging is not required, whereas in the case of partial recanalization we suggest considering the possibility of prolonging anticoagulation until a reassessment at 12 months from the event. Another emerging issue in the treatment of CVST is the role of direct oral anticoagulants (DOACs), which showed a similar efficacy and a better safety profile compared with VKAs in patients with proximal deep vein thrombosis of the lower limbs or pulmonary embolism. All phase III clinical trials on the use of DOACs excluded patients with CVST and we thus have no certainties on their appropriateness for these patients, although three case series including respectively two, six and seven patients treated with rivaroxaban, confirmed its safety [107–109]. Clinical trials comparing efficacy and safety of dabigatran etexilate or rivaroxaban with warfarin or standard of care are ongoing (Table 2).

Secondary prevention

Concerning antithrombotic prophylaxis in high-risk situations after a first episode of CVST, it has been proposed to follow suggestions reported in guidelines on extracranial venous thrombosis. Concerning pregnancy, prophylactic doses of LMWH for women who discontinued oral anticoagulation are recommended [24].

Treatment in children and neonates

In children, the correction of concomitant conditions such as dehydration or infections is of crucial importance, even more so than in adults. When CVST is secondary to otitis media complicated by mastoiditis, antibiotic treatment with cephalosporins is indicated. Antibiotics are also used in patients with infection-related jugular vein thrombosis (Lemierre's syndrome), in particular against anaerobic microorganisms such as *Fusobacterium necrophorum*. In the absence of randomized controlled trials on anticoagulant treatment in children with CVST, current guidelines recommend doses of therapeutic heparin independently of concomitant intracranial hemorrhage and endovascular

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treatment for patients with rapidly deteriorating neurological functions despite adequate anticoagulation, similarly to adults [110]. For neonates there is no consensus on the management of the acute phase, and both anticoagulation or a conservative approach should be considered, treating concomitant illnesses. A promising alternative to the parenteral heparin or VKAs that require laboratory monitoring (very uncomfortable in the pediatric population) are DOACs, at present under investigation in any phase trials [111]. The optimal duration of anticoagulant treatment is not well established; however, 6 weeks to 3 months are recommended for neonates, and 3 to 6 months for children [112].

Thrombolysis should be used only in highly selected patients because of the risk of bleeding, which is particularly high in neonates due to their immature hemostatic system. Moreover, the naturally low levels of plasminogen in neonates may decrease the efficacy of chemical thrombolysis and some authors suggest infusion of plasminogen through fresh frozen plasma before the procedure [110].

Conclusions

Despite its low incidence rate, CVST represents one of the leading causes of stroke in young adults. A prompt diagnosis is necessary to avoid acute complications and long-term disabilities. The mainstay of therapy is anticoagulation, even if the optimal duration of treatment is currently under investigation. DOACs represent a fascinating option for treatment of CVST, taking into consideration their safety profile and the lack of laboratory monitoring. Clinical trials with DOACs are currently ongoing in adults and children and their results will help in decision making.

Addendum

M. Capecchi and M. Abbattista reviewed the literature and wrote the paper. I. Martinelli established the structure of the manuscript and reviewed the final version. All authors approved the final manuscript.

Acknowledgements

We thank C. M. Lensing for drawing Figure 1 and A. Paolucci for the images in Figures 2 and 3.

Disclosure of Conflict of Interests

The authors state that they have no conflict of interest.

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Subject: Agenda attached :: Coordination of COVID-19 Vaccine Safety Surveillance Efforts - USG mtg
Attachments: Agenda - COVID-19 Vaccine Safety Surveillance Efforts 5-17-21 (final).pdf
Location: WebEx (shown below)

Start: 5/17/2021 12:30:00 PM
End: 5/17/2021 1:00:00 PM
Show Time As: Tentative

Recurrence: Weekly
every 2 week(s) on Monday from 12:30 PM to 1:00 PM

Required Attendees: Kessler, David A (OS); Marks, Peter; Anderson, Steven; Hepburn, Matt (OS); Johnson, Robert (OS); Disbrow, Gary (OS); Runstrom, Mark (OS); Clark, Matthew (OS); Gorman, Richard (OS); Hamilton, Holli (OS); Horwith, Gary (OS); Mcqueen, Anthony (OS); 'Ake, Julie (mail.mil)'; Faison, Tremel (OS); Martin, Stacey (CDC); Wharton, Melinda (CDC); Cohn, Amanda C (CDC); Wasley, Annemarie (CDC); Shimabukuro, Tom (CDC); Clark, Thomas A (CDC); Franklin, Joseph; Witten, Celia (CBER); Cho, David S (CBER); Gruber, Marion; Maloney, Diane; Forshee, Richard; Nair, Narayan; Krause, Philip; Fink, Doran; Farizo, Karen; Roberts, Jeff; Izurieta, Hector; McNeill, Lorrie; Frantz-Bohn, Susan; Kelman, Jeffrey A (CMS); Chu, Steve (CMS); 'Choy, Michael'; 'Harjivan, Chandresh (US SCA)'; 'alvaro.rossi@bcg.com'; Brooks,

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Kiahana (CMS); Malluwa-Wadu, Prabath P (CMS); Jason, Marybeth (CMS); Tierney, Julia; Walinsky, Sarah; Schuchat, Anne (CDC)

Optional Attendees: Wong, Hui-Lee; Despres, Sarah (OS); Inglesby, Thomas (OS); Yogurtcu, Osman; Huang, Yin

This meeting will be used to discuss the efforts of FDA, CDC, and other government agencies to follow the safety of COVID-19 vaccines that are deployed for use.

All mtgs run from 12:30pm-1:00pm EST.
Monday, 4/5/21
Monday, 4/19/21
Monday, 5/3/21
Monday, 5/17/21

Please refer to your principals within your organizations, prior to forwarding this calendar invitation.

With questions, please contact below, or send email to the FDA Covid-19 Vaccine Pharmacovigilance Coordination Team at Covid19VaccinePV@fda.hhs.gov.

Thank you.

On behalf of Peter Marks, MD, PhD, Director, FDA Center for Biologics Evaluation and Research

Leslie Haynes, RD
Program Manager (PDUFA Oversight)
Immediate Office of the Director
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration

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Coordination of COVID-19 Vaccine Safety Surveillance Efforts Meeting

Monday, May 17, 2021

12:30 – 1:00 PM EST

Dial-in Number: 1-877-465-7975

Meeting number (access code): (b) (6)

Meeting password: (b) (6)

Meeting Topic	Presenter
Surveillance strategy for FDA for the Pfizer adolescent vaccine	FDA
Johnson & Johnson (Janssen) COVID-19 vaccine Adverse Events	CDC
Other Topics	All

Next Mtg: June 7, 2021

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Coordination of COVID-19 Vaccine Safety Surveillance Efforts Meeting

Monday, May 17, 2021

12:30 – 1:00 PM EST

Dial-in Number: 1-877-465-7975

Meeting number (access code): (b) (6)

Meeting password: (b) (6)

Meeting Topic	Presenter
Surveillance strategy for FDA for the Pfizer adolescent vaccine	FDA
Johnson & Johnson (Janssen) COVID-19 vaccine Adverse Events	CDC
Other Topics	All

Next Mtg: June 7, 2021

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CC: Clark, Thomas A (CDC) [tnc4@cdc.gov]; Farizo, Karen [Karen.Farizo@fda.hhs.gov]; Fox, Kimberley (CDC) [kaf6@cdc.gov]; Wharton, Melinda (CDC) [mew2@cdc.gov]

Subject: Coordination on adverse events
Attachments: Capecchi JSTH 2018.pdf
Location: https://fda.zoomgov.com(b) (6)

Start: 4/12/2021 9:30:00 AM
End: 4/12/2021 10:00:00 AM
Show Time As: Busy

Required Attendees: Marks, Peter; Anderson, Steven; Richard Forshee (Richard.Forshee@fda.hhs.gov); Gruber, Marion (Marion.Gruber@fda.hhs.gov); Philip Krause (Philip.Krause@fda.hhs.gov); Nair, Narayan; Shimabukuro, Tom (CDC); Messonnier, Nancy E (CDC)
Optional Attendees: Clark, Thomas A. (CDC/DDID/NCIRD/DVD); Farizo, Karen; Fox, Kimberley (CDC/DDID/NCIRD/DBD); Wharton, Melinda (CDC/DDID/NCIRD/ISD)

Sorry for the second last minute change – this should be the last one. We will start at 9:30 due to an EMA meeting. Thanks!

The linked im...

Hi there,

Peter.Marks@fda.hhs.gov is inviting you to a scheduled ZoomGov meeting.

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Journal of Thrombosis and Haemostasis, **16**: 1918–1931 Obtained via FOIA by Judicial Watch, Inc. DOI: 10.1111/jth.14210

REVIEW ARTICLE

Cerebral venous sinus thrombosis

M. CAPECCHI, M. ABBATTISTA and I. MARTINELLI

A. Bianchi Bonomi Hemophilia and Thrombosis Center, Fondazione IRCCS Ca' Granda - Ospedale Maggiore Policlinico, Milan, Italy

To cite this article: Capecchi M, Abbattista M, Martinelli I. Cerebral venous sinus thrombosis. *J Thromb Haemost* 2018; **16**: 1918–31.

Summary. The cerebral venous system is an unusual site of thrombosis, with a particularly high incidence in young adults. This incidence has increased in past decades because of the improvement of neuroradiological techniques. Risk factors for cerebral venous sinus thrombosis overlap with those of other venous thromboembolism sites; however, some are specific for this particular anatomical district. Prognosis is favorable in most cases if diagnosis is made rapidly and treatment is promptly initiated, even if acute complications or chronic invalidity still occur in a quarter of patients. The mainstay of treatment is anticoagulation, which is necessary in order to block clot propagation and obtain recanalization. Intracranial bleeding does not contraindicate anticoagulation. Endovascular procedures are reserved for patients with a particularly severe presentation or rapidly declining neurological symptoms despite appropriate anticoagulation, although data from clinical trials are lacking. Specifically, this review addresses the epidemiology, clinical presentation and course, risk factors, and treatment of cerebral venous sinus thrombosis, with a special focus on the pediatric population.

Keywords: anticoagulants; cerebral hemorrhage; intracranial thrombosis; low-molecular-weight heparin; sinus thrombosis; venous thromboembolism.

Anatomy

The cerebral venous system can be divided into two major compartments considering the anatomic and functional characteristics of the blood vessels: the cerebral veins and the dural venous sinuses (Fig. 1). Considering the topographic distribution, a superficial and a deep system can be distinguished. The superficial system drains blood from the cerebral cortex mainly into the superior sagittal sinus, which in turn drains into the transverse sinuses. The deep system drains blood from the deep white matter and the basal ganglia to the inferior sagittal sinus, that continues into the straight sinus and then into the transverse sinuses. From the transverse and the straight sinuses blood flows out of the sigmoid sinuses, passing through the sinus confluence (torcular Herophili), and finally into the internal jugular veins. Many anastomoses exist between the cerebral veins from the fetal period onwards. The dural venous sinuses are delimited by the superficial (periosteal) and the deep (meningeal) layer of the dura mater and their walls are composed of only the dura mater layer lined with endothelium, hence lacking the tunica media. Additionally, these sinuses lack valves. Dural venous sinuses drain blood from the cerebral veins and the cerebrospinal fluid from the subarachnoid space, via the arachnoid Pacchionian granulations, which are present particularly in the superior sagittal sinus. The classic anatomy varies considerably among individuals and the knowledge of such variations is essential for a correct interpretation of radiological images. The most frequent anatomic variants are: asymmetries of transverse sinuses, observed in nearly 50% of patients; hypo-/aplasia of all or part of the transverse sinuses, observed in nearly 20% of patients; and less frequently hypo-/aplasia of the frontal part of the superior sagittal sinus [1].

Pathophysiology

The formation of a thrombus in the cerebral venous circulation leads to an increase in the hydrostatic pressure in the veins and capillaries upstream of the occlusion. However, because of the anastomotic circuit of the cerebral venous system, the increased venous pressure is usually compensated to some extent. If the increase in the venous pressure overcomes the compensation capacity the following can occur: blood–brain barrier disruption, extravasation of fluids into the cerebral parenchyma and consequent localized edema. Furthermore, if the venous pressure exceeds the arterial pressure, a reduction of

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Received: 29 March 2018
Manuscript handled by: F. R. Rosendaal
Final decision: F. R. Rosendaal, 5 June 2018

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FDA-CBER-2021-5762-00167

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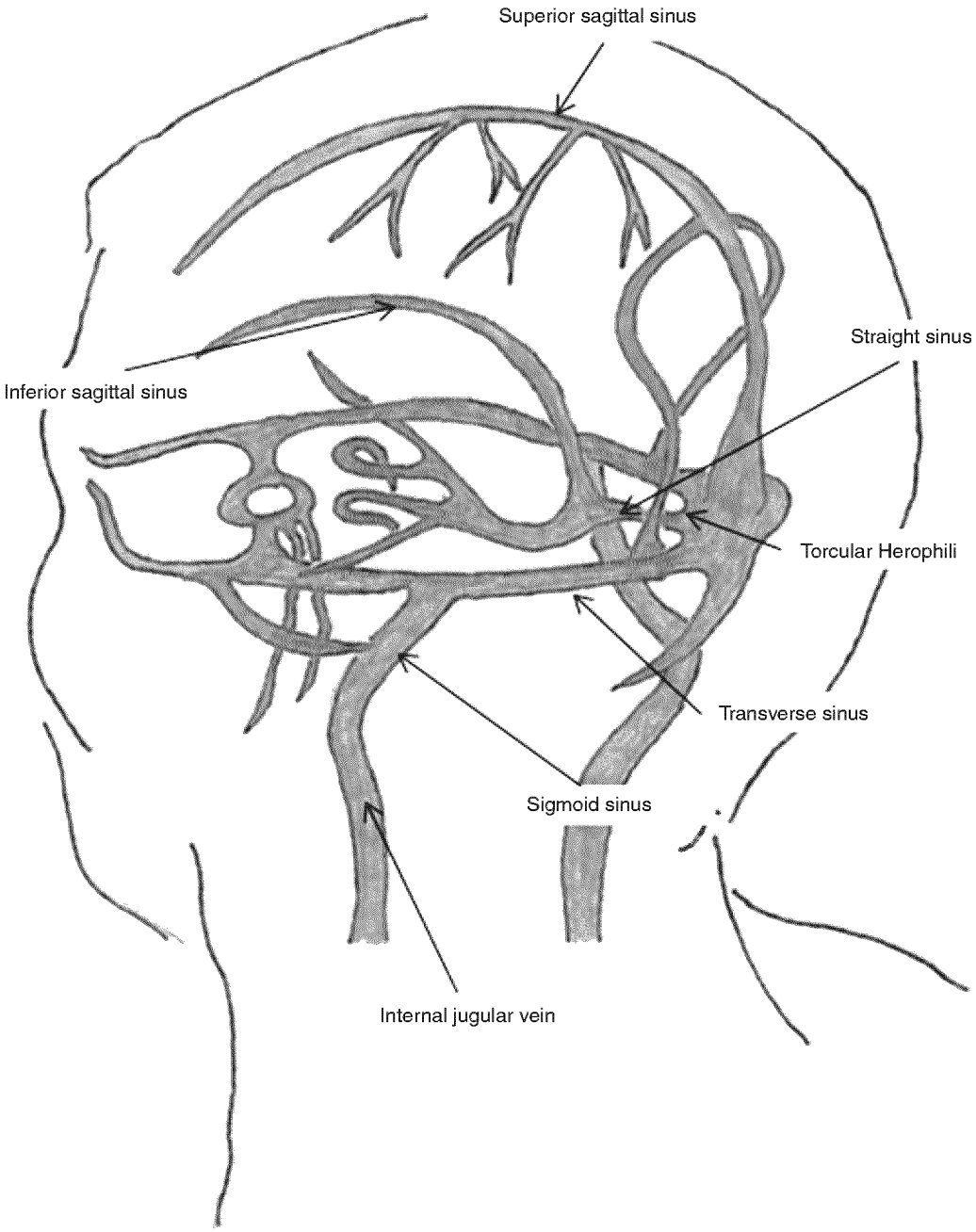


Fig. 1. Anatomy of the cerebral venous system.

arterial flow and consequent arterial ischemia can occur and, if not adequately treated, it may progress to hemorrhagic infarction [2]. A peculiar characteristic that distinguishes vasogenic (due to venous occlusion) from cytotoxic (due to arterial occlusion) edema, is that in the former the perfusion pressure is not usually reduced and therefore irreversible brain tissue damage is unlikely. Indeed, in venous stroke a resolution of thrombi and a favorable prognosis are more likely than in arterial stroke. The peculiarity of venous occlusion is the reduction of cerebrospinal fluid reabsorption, by reducing cerebrospinal fluid access to the arachnoidal Pacchionian granulations, leading to intracranial hypertension [3]. This scenario is more frequent with superior sagittal sinus occlusion (where arachnoidal Pacchionian granulations are present), but can also occur in the occlusion of other sinuses.

Epidemiology

Cerebral venous sinus thrombosis (CVST) is a rare manifestation of thrombosis with an incidence that varies

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between studies. In adults, the annual incidence of CVST is two to five cases per million individuals [3,4], but it is likely to be underestimated because of the lack of well-designed epidemiological studies. Two recent studies in the Netherlands and southern Australia found a higher incidence than previously reported of 13.2 and 15.7 annual cases per million, respectively [5,6]. The high prevalence of infection-related CVST can result in even higher figures in others countries (18% in Pakistan), but the exact incidence among different ethnic groups is pending investigation [7–9]. At variance with arterial stroke that is more prevalent in the elderly, CVST typically affects young adults with a mean age of 35 years and is more common in women than in men (2.2:1) because of sex-specific risk factors [10]. The superior sagittal and the transverses are the most frequently involved sinuses (60% of patients), followed by the internal jugular and cortical veins (20%). In almost two-thirds of patients CVST involves more than one sinus.

Epidemiology in children and neonates

The annual incidence of CVST in the pediatric population is approximately seven cases per million and is higher in neonates than in children [11–14]. The sex ratio seems balanced because of the absence of sex-specific risk factors [12]. Similarly to adults, the superficial sinuses are the most frequently involved (particularly the superior sagittal and the transverse sinuses) and the transverse sinuses are more frequently involved in children older than 2 years of age (60% vs. 39%) [11,15].

Clinical presentation

Because symptoms of CVST are variable and aspecific, diagnosis is often delayed to a median period of 7 days from the onset of clinical manifestations [16]. The International Study on Cerebral Venous and Dural Sinus Thrombosis (ISCVT), which included 624 patients, described the following as the most common presenting symptoms: headache (88.8%), seizures (39.3%), paresis (37.2%), papilledema (28.3%) and mental status changes (22%) [16].

Headache is usually the first symptom at onset of CVST. In only 10% of cases does the headache have a thunderclap outbreak, mimicking a subarachnoid hemorrhage [17]. Because of its aspecific nature, physicians must have a high suspicion of CVST when dealing with a new onset and progressively increasing intensity of headache, which is the only presenting symptom in about 32% of patients [17]. The location of the headache is not informative as it does not correlate with the thrombosis site. The absence of headache is typical of elderly patients, especially men [18], and in those with cortical vein thrombosis who have normal cerebrospinal fluid homeostasis. The pathophysiologic mechanism of headache in CVST is the increase in intracranial pressure due to reduced cerebrospinal fluid reabsorption. For this reason, the intensity of the headache typically increases when patients lie down and after the Valsalva maneuver. For reasons not yet fully understood, headache is more common in patients with CVST than in those with arterial stroke (25% of cases) [19].

Seizures are focal in one quarter of patients, in another quarter they begin as focal and then generalize and in the remaining half, seizures are generalized *ab initio*[20]. Seizures are more frequent in patients with CVST than in those with arterial stroke (2–9%) [20], perhaps as a consequence of the accumulation of catabolic products due to venous stasis.

Focal neurological deficits such as paresis, dysarthria and aphasia are due to localized damage in the cerebral cortex, secondary to a venous infarction. Focal deficits are more frequent in patients with thrombosis of the superficial system with involvement of the parasagittal cortex, where the motor and sensory areas are located.

Papilledema is the consequence of intracranial hypertension and can cause diplopia and visual loss. Patients with thrombosis of the cavernous sinuses may also develop proptosis, orbital pain, chemosis and ophthalmoplegia secondary to a palsy of the oculomotor (III), trochlear (IV) and abducens (VI) cranial nerves.

Mental status changes such as amnesia, mutism, confusion or delirium are seen in patients with thrombosis of the deep system, particularly those with large venous infarctions or bilateral edema of the basal ganglia and thalami. The most severe cases can have a rapid neurological deterioration, leading to coma and death.

Clinical presentation in children and neonates

In children, symptoms at onset are even more aspecific than in adults and are frequently attributable to more common diseases such as infections or dehydration, making the suspicion and diagnosis of CVST particularly difficult. In general, symptoms in children are the same as in adults, but generalized neurological deficits are more common and seizures are more frequent in neonates [11].

Diagnosis

When CVST is suspected in adults the first-line imaging technique is unenhanced computed tomography (CT) scan; this allows for the ruling out of brain tumors, abscesses or arterial stroke. In the acute phase, CVST is seen in unenhanced CT scans as a hyperdense signal in the vessel lumen, that becomes iso- and then hypodense after the first week. Depending on the location of CVST, two specific radiological signs are described: the 'dense triangle sign' when thrombosis is located in the superior sagittal sinus, and the 'dense cord sign' when located in a cortical or deep vein [3] (Fig. 2A). However, such signs

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are rarely described (considering that the unenhanced CT scan has a low sensitivity), resulting positive in only 30% of patients with CVST [21]. The addition of contrast agent increases the sensitivity to 99% for sinus thrombosis and 88% for vein thrombosis, figures similar to those obtained with magnetic resonance imaging (MRI) [22,23]. In the presence of the contrast agent, a specific radiological sign is the 'empty delta sign', a filling defect in the middle of the venous lumen with a peripheral enhancement (Fig. 2B). Advantages of CT scanning are the availability in emergency and the ability to show the presence of local complications associated with CVST, such as subarachnoid or intraparenchymal hemorrhage or cerebral edema. Disadvantages are the exposure to ionizing radiation and the need for contrast agent to increase the accuracy. Currently, MRI is the reference standard imaging technique for diagnosis of CVST, despite the fact that exact sensitivity and specificity are not known because of the lack of proper comparative studies with catheter angiography. Catheter angiography was the historical reference standard technique, which today, due to its invasiveness, is reserved for patients with an inconclusive CT scan and MRI or for candidates undergoing endovascular procedures [24,25]. Maximum accuracy is obtained with the combination of classic MRI sequences, which are able to show the thrombus, together with venography, which can show reduction or absence of flow and therefore distinguish hypoplastic sinuses, partial sinus occlusion, thrombosis of cortical cerebral veins, or filling defects due to hyperplastic arachnoid granulations (Fig. 3) [26]. The advantages of MRI are the absence of both radiation exposure and intravenous contrast agent, and the ability to establish the age of the clot. Finally, when D-dimer is high it increases the likelihood of deep vein thrombosis of the lower limbs or pulmonary embolism; it has been investigated in several studies as a predictive factor for CVST, but has consistently shown a low sensitivity and specificity [27]. Despite this, the ESO guidelines suggest measuring D-dimer before neuroimaging in patients with suspected CVST, except in those with isolated headache and in the case of prolonged duration of symptoms (i.e. > 1 week). The quality of evidence is low and the strength of recommendation is weak [28].

Diagnosis in children and neonates

In children, imaging techniques for diagnosis are the same as in adults, whereas in neonates the first choice is the transfontanellar doppler ultrasound, which has the advantage of being extensively available and non-invasive, albeit strongly operator dependent. In the case of inconclusive results and a persistent clinical suspicion of CVST, enhanced CT scan and MRI must be performed.

Prognosis

For a long time CVST has been considered a life-threatening condition, but the case fatality rate has decreased proportionally over time, from more than 50% to 5–10% [29]. Increased clinical awareness, the advancement of neuroimaging techniques and the improvement in therapeutic management have enabled earlier diagnosis and identification of less severe cases, ensuring a better prognosis. However, data on clinical outcome stem from

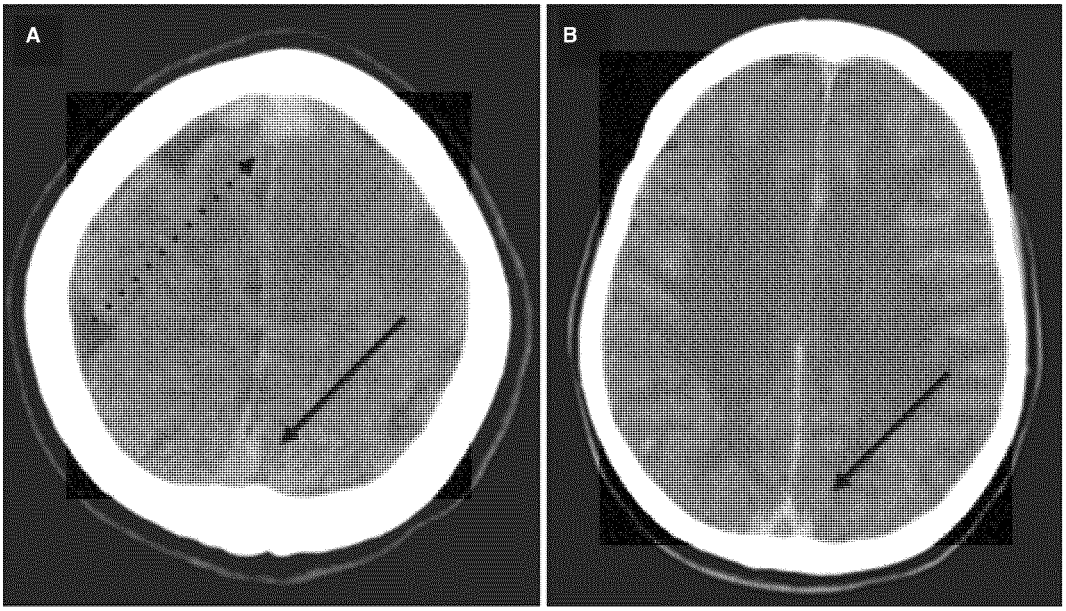


Fig. 2. Superior sagittal sinus thrombosis on computed tomography (CT) scan. (A) Unenhanced CT scan showing the dense triangle sign (arrow) and a peri-thrombotic frontal hemorrhagic suffusion (dashed arrow). (B) Enhanced CT scan showing the empty delta sign (arrow) of the superior sagittal sinus.

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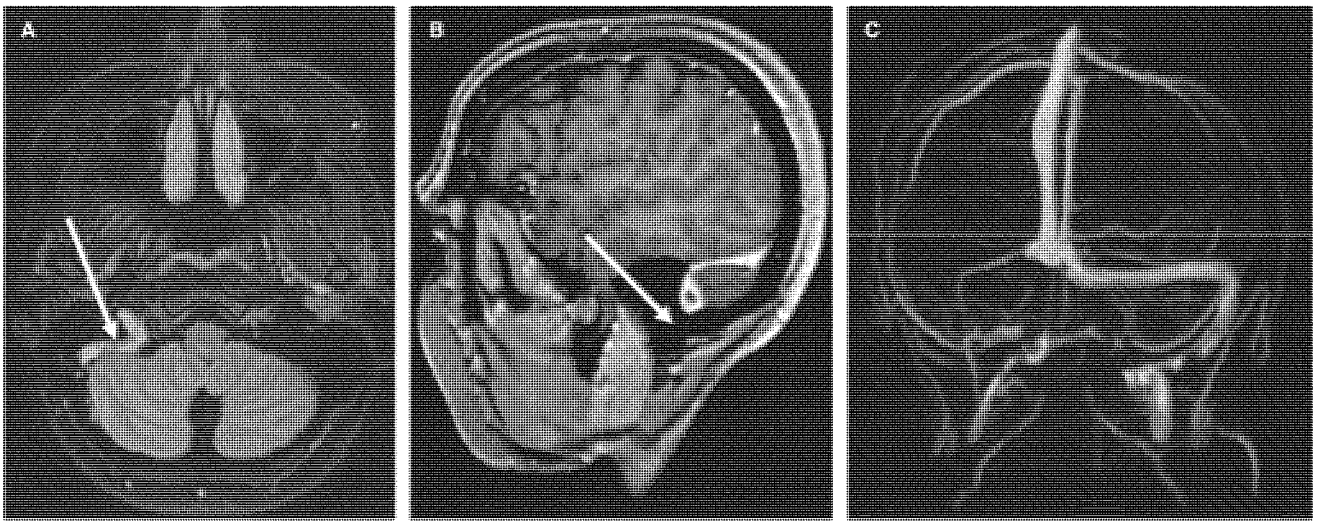


Fig. 3. Cerebral sinus vein thrombosis on magnetic resonance imaging (MRI) sequences. (A) Fluid attenuated inversion recovery axial sequence showing absence of flow-void in the right sigmoid sinus (arrow). (B) Sagittal contrast enhanced T1-weighted sequence showing a partial occlusion of the right sigmoid sinus (arrow). (C) Three-dimensional reconstruction of the cerebral venous system showing the absence of flow in the right transverse and sigmoid sinuses and right internal jugular vein.

studies with small sample sizes, which suffer from methodological heterogeneity and are usually referred for follow-up visits for up to only 12 months. The clinical course of the acute phase is unpredictable and in approximately 5% of patients intracranial hemorrhage followed by herniation, seizures, pulmonary embolism or severe comorbidity can be fatal [16,30,31]. A minority of patients with CVST (15–20%), have different degrees of permanent disability or die [16,32]. A meta-analysis reported an overall mortality of 9.4% (122 deaths among 1303 patients), although the causes of death during follow-up were mainly related to concomitant diseases (e.g. cancer) rather than to CVST itself [30,33]. The majority of patients who recover completely achieve relative independence, usually expressed as between 0 and 2 on the modified Rankin Scale (mRS), although mild residual symptoms, such as headache, motor deficits, linguistic difficulties, and impaired vision or cognition, often remain [16,34–36]. Only 5–10% of patients who survive the acute phase remain moderately or severely dependent (mRS 3 or 4) [16,34]; however, this proportion increases up to 34% in those with massive CVST [37].

Recanalization

To date, few studies with small sample sizes have investigated the recanalization rate of CVST. Differences in the definition of recanalization and time of evaluation across studies make it difficult to pool data and to provide homogenous results. With these limitations, the rate of recanalization (complete or partial) is around 85%, ranging between 73% and 93% [30,38]. Almost 50% of cases achieve a complete recanalization after a median time of 6 months. Recanalization occurs mainly in the first months after CVST and is a dynamic process continuing for up to 12 months, whereas recanalization after 1 year is rare [30,38,39]. A late recanalization has been described in patients with CVST, occurring during hormonal treatment [39]. Controversial and limited data are available regarding the influence of the degree of recanalization on functional outcome [40,41]. One study reported a greater chance of good functional outcome associated with complete recanalization [38], whereas others did not confirm this finding [39,42]. A recent large study including 508 patients showed a high recanalization rate at 3 months after CVST (81%) and an independent association between recanalization and a favorable neurological outcome [43].

Recurrence rate

Data on recurrent venous thrombosis derive mainly from studies with small sample sizes and retrospective design, underpowered to detect potential risk factors for recurrence. The overall incidence of recurrent venous thrombosis within the first year after a first episode of CVST is estimated at around 4 per 100 patient-years (p-y) [44]; that of recurrent CVST is 0.5% to 2.2% p-y and that of recurrent deep vein thrombosis of the lower limbs and/or pulmonary embolism is 1.1% to 5.0% p-y [16,44–47]. Notably, male sex is associated with a 7-fold increased risk of recurrence [44,46]. Cohort studies on long-term evaluation of the risk of recurrent thrombosis after anticoagulant therapy discontinuation showed higher figures in the first period (5.0% p-y, 2.6% p-y and 1.7% p-y in the first, third and tenth year after discontinuation,

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respectively) for an overall risk of 2 to 3.5 per 100 p-y [46,47].

Prognosis in children and neonates

The mortality rate varies from 5% to 10% and increases up to 25% in newborns [48]. Few studies have investigated the clinical outcome of neonates and children who survive the acute phase of CVST and no data on their subsequent neurodevelopment are available. The longest observational period was described in a large prospective study that included 104 neonates followed for a median period of 2.5 years (range 6 months to 15 years) [49]. Prognosis in children seems worse than in adults, with 20–70% of patients presenting residual neurological deficits [13,49,50]. In a series of 42 neonates, one died and only 21% of those who completed 2 years of follow-up recovered completely [51]. A European cohort study reported a recanalization rate of 69% (46% complete and 42% partial) between 3 and 6 months after CVST [52], and another recent study found a rate of 85% at 3 months in neonates compared with 56% in children [53]. Despite the limited data, complete recanalization seems to occur earlier in children than in adults, particularly in neonates [53].

The recurrence rate of thrombosis varies between 0% and 20% [15,48–50], with the highest figures in children older than 2 years [11,52]; this is mainly due to underlying systemic diseases (e.g. systemic lupus erythematosus and Behçet disease) [54]. The avoidance of anticoagulant therapy, the lack of recanalization and the presence of the G20210A prothrombin gene mutation have all been associated with an increased risk of recurrence of 11.2-, 4.1- and 4.3-fold, respectively [38,52].

Table 1 Risk factors for cerebral vs. sinus thrombosis

Permanent risk factors	Transient risk factors
Inherited thrombophilia	Sex related
Prothrombin G20210A mutation	Oral contraceptive
Factor V Leiden	Pregnancy
Antithrombin deficiency	Puerperium
Protein C deficiency	Infections
Protein S deficiency	Head and neck infections (e.g. mastoiditis, sinusitis, otitis, osteomyelitis, abscess and meningitis)
Malignancy	Malignancy
Advanced-stage cancer	Cerebral and non-cerebral solid cancer
Systemic diseases	Mechanical
Antiphospholipid syndrome	Head trauma, neurosurgical procedures, lumbar puncture, jugular vein catheterization
Autoimmune diseases (systemic lupus erythematosus, Behçet disease and vasculitis)	Other
Inflammatory bowel diseases	L-asparaginase treatment
Nephrotic syndrome	Severe dehydration
Hematological diseases	Severe anemia
Paroxysmal nocturnal hemoglobinuria	Obesity
Sickle cell disease	Maternal (specific for neonates)
β-thalassemia, myeloproliferative neoplasms	Maternal infections
	Obstetrical trauma
	Obstetrical complications (gestational diabetes, preeclampsia/eclampsia and premature rupture of membranes)

Risk factors

Like any thrombosis, CVST has a multifactorial etiology (Table 1). In 85% of patients at least one risk factor is identified and 50% of events are triggered by the interaction of more risk factors. A small proportion of cases remains idiopathic (i.e. no direct cause or risk factor can be identified) [16,55].

Sex related

CVST is more common in women of reproductive age than in men, as a result of the use of oral contraceptives or hormone replacement therapy, pregnancy and the puerperium [56]. Oral contraceptive use is by far the most common risk factor, reported in more than 80% of women in various series and associated with a pooled estimate of approximately 6-fold increased risk of CVST [57]. A recent case–control study showed that overweight and obesity in women using oral contraceptives further increased the risk of CVST up to 30-fold in a dose-dependent manner [58]. An increase in risk also occurs with the multiplicative interaction between oral contraceptive use and the presence of thrombophilia abnormalities [59,60]. Pregnancy or the puerperium are responsible for 5–20% of CVST, with an incidence of 12 cases per 100 000 deliveries [4,56,61].

Thrombophilia abnormalities

Inherited thrombophilia abnormalities, that is, the common gain-of-function mutations in factor (F) V and FII (FV Leiden and prothrombin G20210A polymorphism) and the rare lack-of-function deficiencies in antithrombin, protein C and protein S, are well-established risk factors for venous thromboembolism, including CVST. Heterozygous FV Leiden or prothrombin polymorphism are reported in 6–24% of patients with CVST, with the latter being more prevalent in several case series [16,62,63]. A recent meta-analysis that included 23 cohort and 33 case–control studies reported a solid risk estimate of CVST for

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prothrombin polymorphism (OR, 6.05; 95% CI, 4.12–8.90) and FV Leiden (2.89; 95% CI, 2.10–3.97), and a strong estimate for protein C (OR, 8.35; 95% CI, 2.61–26.67) and protein S (OR, 6.45; 95% CI, 1.89–22.03) deficiency [62]. With regard to the severe acquired thrombophilia due to the presence of antiphospholipid antibodies, data on the association with CVST are lacking and only case reports or small case series are available [30,63–65]. A study of 163 patients with CVST and 163 with deep vein thrombosis showed a stronger association of anticardiolipin antibodies with the former rather than the latter (17% vs. 4%) [65]. Data are scanty for other thrombophilia markers such as high FVIII and hyperhomocysteinemia. Only one case–control study investigated the association between high FVIII and CVST, showing higher levels in patients than controls [66]. Hyperhomocysteinemia is associated with a 3-fold increased risk of CVST [62,64]; however, the homozygous MTHFR C677T polymorphism, a genetic determinant of homocysteine levels, does not independently increase the risk of CVST [64,67].

Cancer

Approximately 7% of patients with CVST have a concomitant solid (cerebral or non-cerebral) or hematological cancer [16,47]. In a recent case–control study, among 594 patients with CVST the prevalence of cancer was 8.9%, for a nearly 5-fold increased risk (OR, 4.86; 95% CI, 3.46–6.81) [33]. Moreover, CVST can be a complication of chemotherapy with L-asparaginase. Out of 706 treated patients, 22 (3.1%) developed CVST, 20 of whom during treatment with L-asparaginase [68]. Although the incidence rate of CVST in patients with myeloproliferative neoplasms (MPN) is around 1%, approximately 4% of patients with CVST have an overt myeloproliferative neoplasm [69–71]. Hence, such diseases must be suspected and appropriately searched for in patients with CVST.

Systemic diseases and infections

CVST occurs in 0.5–7.5% of patients with chronic inflammatory bowel diseases, as a complication of the hypercoagulable state due to mucosal inflammation that leads to upregulation of tissue factor, high platelet count and impaired fibrinolysis [72,73]. Additional systemic conditions are vasculitis, especially Behçet disease, with an incidence rate for CVST of 3 per 1000 p-y [74], whereas few data are available on systemic lupus erythematosus and nephrotic syndrome [75]. A local infection becomes a strong risk factor for CVST through endothelial injury and activation of procoagulant pathways. The most common are otitis, mastoiditis, sinusitis, meningitis, skin or dental infections. However, in the antibiotic era the prevalence of infection-related CVST has dropped to 8–12%, although it remains higher in less developed countries [9,16,47].

Other risk factors

Additional mechanical risk factors for CVST include neurosurgery, internal jugular catheterization and lumbar puncture [3,4]. Regarding genetic causes, several loci on chromosome 6 (within the human histocompatibility complex) and chromosome 9 (close to the ABO gene) have been involved in the development of CVST [76], although these associations remain to be confirmed in large genome-wide association studies [77]. The association of CVST with other candidate genes, such as plasminogen activator inhibitor-1 4G/5G polymorphism [78] and protein Z G79A polymorphism [79], remains controversial. Janus Kinase-2 (JAK2) V617F somatic mutation, a primary molecular marker of Philadelphia-negative MPN, is also present in a small percentage (0–6.2%) of CVST without an overt MPN and it could be linked to an increased risk of cerebral thrombosis [80,81].

Risk factors in children and neonates

As in adults, CVST in children and neonates has a multifactorial etiology. Compared with adults, children develop idiopathic events less frequently and have a partially different set of risk factors due to anatomical and rheological characteristics of the cerebral circulation. The hemostatic system in children is in a dynamic state, with quantitative and qualitative differences in coagulation factors compared with adults. In neonates the hemostatic system is accelerated as a result of decreased levels of the natural anticoagulant proteins (antithrombin, protein C and protein S) that rise up to physiological adult levels at approximately 6 months after birth [82,83]. Despite this, neonates have a good hemostatic balance that can be altered by concomitant comorbidities such as systemic or local infections, dehydration, chronic renal failure and brain tumors [84,85]. In neonates there are also obstetrical predisposing conditions, including premature rupture of membranes, infections, gestational diabetes, hypertension and hypoxic ischemic injury [86]. Specifically, the compression of the skull bones during delivery can result in damage of the dural venous sinuses and this, together with typical neonatal dehydration, can increase the risk of CVST development [24,87]. Additionally, the usual supine position assumed by neonates has a major influence on intracranial venous outflow, contributing to local venous stasis. This happens particularly in the thrombosis of the superior sagittal sinus (OR, 2.5; 95% CI, 1.07–5.67) [84]. In children and adolescents, head and neck infections (otitis media, mastoiditis and sinusitis) are the most common risk factors for CVST [11,13,85,88]. Other risk factors observed in more than 50% of cases include underlying chronic diseases such as nephrotic syndrome (which confers an acquired prothrombotic state due to urinary loss of anticoagulant proteins) [89], liver diseases [11], systemic lupus erythematosus [90], malignancy

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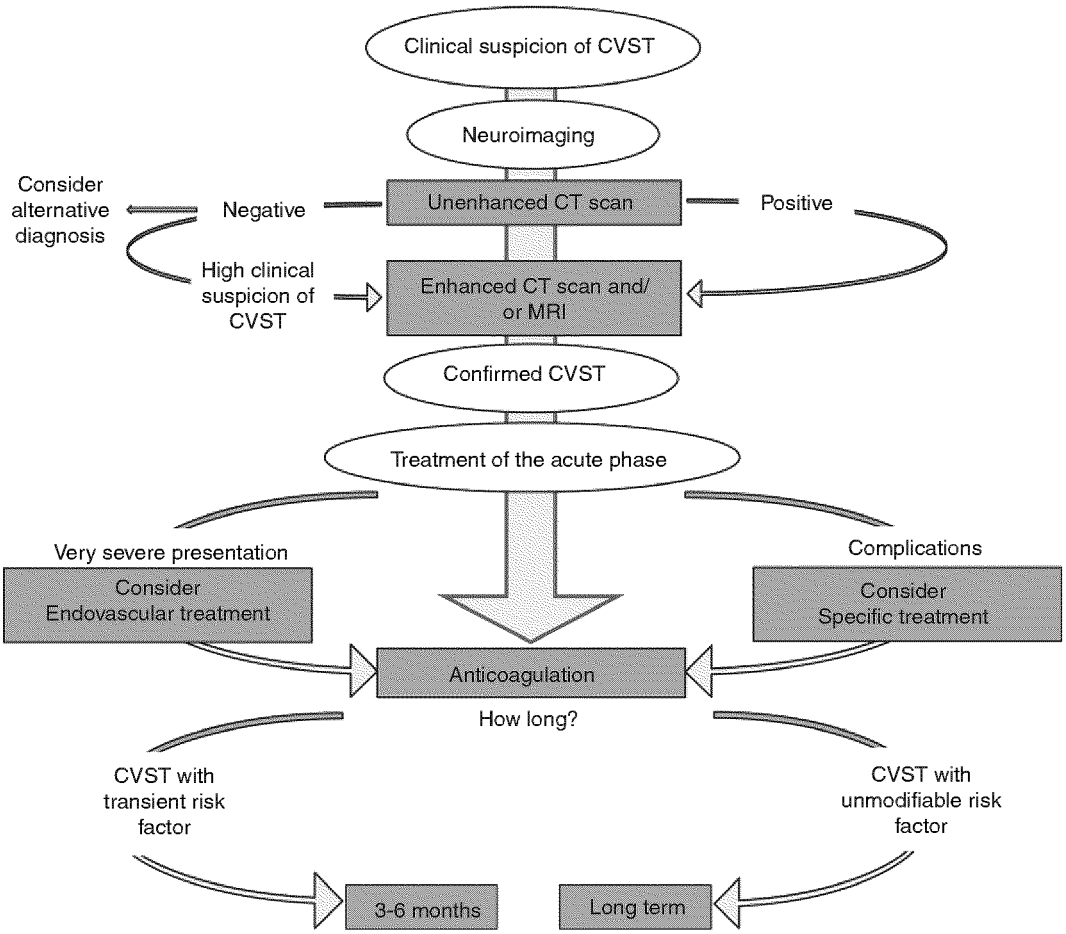


Fig. 4. Diagnostic and therapeutic algorithm in cerebral venous sinus thrombosis.

[15,91], head trauma or neurosurgery [48,49]. CVST has also been reported in children with iron deficiency anemia and to a lesser extent with hemolytic anemia, β-thalassemia and sickle cell disease[15]. Inherited thrombophilia has been poorly investigated in pediatric CVST and reported in 20% to 62% of cases [11,12,15,48]. The association of CVST with FV Leiden and prothrombin G20210A polymorphism appears weaker in children than in adults [12,15,92]. The combination of acquired thrombophilia and underlying conditions provides a major contribution to the pathogenesis of pediatric CVST [12,89].

Treatment of the acute phase

Anticoagulant treatment

The use of heparin was first described in 1942 by a British gynecologist who successfully treated a puerpera with CVST [93]. The initial indication of anticoagulation in patients with CVST comes from two small randomized controlled trials performed in the 1990s that compared heparin with placebo. The first included 20 patients and was prematurely stopped because of safety concerns due to 3/10 intracranial hemorrhages in the placebo group compared to 0/10 in the unfractionated heparin (UFH) arm [94]. The second study included 59 patients and showed a better outcome in the low-molecular-weight heparin (LMWH) arm (death or dependence rate 13% vs. 21%) [95]. A subsequent meta-analysis of the two trials showed a 13% reduction in the risk of death or dependency in patients treated with heparin [96]. None of the 18 patients with intracranial hemorrhage included in the two studies cited above and treated with heparin had worsened bleeding [94,95].An observational study including 102 CVST patients with hemorrhagic venous infarction or subarachnoid hemorrhage treated with LMWH or UFH showed a deterioration in clinical course only in 11% of patients, without a difference between the two treatment group [97]. Based on these data, current guidelines state that intracranial hemorrhage does not represent a contraindication to anticoagulant therapy in the acute phase of CVST [28]. Our personal opinion is to use subtherapeutic doses (i.e. 50–75% of the full dose) of LMWH in the case of vast intracranial hemorrhage. No consensus exists on the superiority of one type of heparin over the other. The first indirect comparison between LMWH and UFH in patients with CVST was made in the framework of the ISCVT study and showed a lower

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Table 2 Ongoing clinical trials in patients with cerebral venous sinus thrombosis.

Title	NCT number	Study type and design	Interventions	Primary outcome	Estimated completion date	Age of patients enrolled
A Clinical Trial Comparing Efficacy and Safety of Dabigatran Etexilate With Warfarin in Patients With Cerebral Venous and Dural Sinus Thrombosis (RE-SPECT CVT)	NCT02913326	Interventional randomized (phase 3)	Dabigatran etexilate vs. warfarin for 6 months	Composite rate of major bleeding and venous thromboembolism	June 2018	18–78 years
The Efficacy and Safety of Dabigatran Etexilate for the Treatment of Cerebral Venous Thrombosis	NCT03217448	Interventional randomized (phase 3)	Dabigatran etexilate vs. warfarin for 6 months	Incidence of recanalyzed veins after 6 months	January 2019	18–80 years
Comparison of the Efficacy of Rivroxaban to Coumadin (Warfarin) in Cerebral Venous Thrombosis	NCT03191305	Non-randomized, parallel assignment	Rivaroxaban vs. warfarin	Recurrent CVT or any hemorrhage	September 2018	13–50 years
Study of Rivaroxaban for CeREbral Venous Thrombosis (SECRET)	NCT03178864	Prospective randomized controlled (phase 2)	Rivaroxaban vs. standard of care	Composite rate of all-cause mortality, symptomatic intracranial bleeding, major extracranial bleeding	June 2020	≥18 years
Thrombolysis or Anticoagulation for Cerebral Venous Thrombosis (TO-ACT)	NCT01204333	Interventional randomized (phase 3)	Endovascular local thrombolysis vs. heparin	Favorable clinical outcome (mRS 0-1) at 12 months	Completed	≥18 years
Thrombin Generation and Thrombus Degradation in Cerebral Venous Thrombosis: Clinical and Radiological Correlations	NCT02013635	Observational prospective case-only	Non-interventional	Evolution of thrombin generation parameters and D-dimer levels from baseline and correlation with clinical presentation	Completed	≥16 years
The Role of Factor XIII Activation Peptide and D-dimer Values for the Diagnosis of Cerebral Venous Thrombosis (CVT)	NCT00924859	Observational prospective case-only	Non-interventional	To assess the overall accuracy of D-dimer and FXIII-AP (activation peptide) using a newly developed ELISA test, to exclude CVT in patients with clinical suspicion of CVT	Completed	18–85 years

incidence of disability at 6 months in the LMWH group, without differences in overall survival [98]. Subsequently, two randomized controlled trials compared LMWH and UFH. The first showed a significantly lower mortality rate in the LMWH group (0% vs. 18.8%) [99], whereas the second showed no differences between the two groups in mortality (3.8% vs. 5.6%) and in new symptomatic intracranial hemorrhage (none in both groups) [100]. UFH, with its shorter half-life and easier reversibility, can be preferred in unstable patients or in those requiring invasive procedures.

Thrombolysis and endovascular treatment

No randomized clinical trials have assessed the role of systemic thrombolysis in CVST. The most recent systematic review on this issue included only case reports and case series for a total of 26 patients [101]. Urokinase was the most frequently administered thrombolytic agent (73.1%), whereas streptokinase and recombinant tissue plasminogen activator (rt-PA) were used in 7.7% of cases each. Extracranial hemorrhage occurred in five patients (19.2%) and intracranial in three (11.5%), with two deaths. Partial or complete recanalization occurred in 16 patients (61.5%). Only case reports and small case series are available in the literature on endovascular treatment of CVST with local thrombolysis (urokinase, streptokinase or rt-PA) and mechanical thrombectomy. This treatment should be reserved for patients with a very severe presentation or rapidly declining neurological symptoms despite appropriate anticoagulant therapy, after exclusion of other causes of deterioration. Endovascular treatment is associated with a high risk of intracranial hemorrhage (7.6%) and mortality (9.2%), half of which are due to new onset or worsening of pre-existing intracranial hemorrhage [102]. These estimates are likely to be underestimated because of the publication bias in favor of successful case reports. The randomized controlled trial TO-ACT (NCT01204333) comparing local thrombolysis and heparin treatment has been prematurely interrupted after the inclusion of 67 patients because of no difference in primary outcome (mRS 0–1 at 12 months) [103].

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Hence, currently available data raise concerns about safety of thrombolysis and endovascular treatment in patients with CVST.

Treatment of complications

The most severe patients present complications in the acute phase that require specific management. In the case of seizures, antiepileptic drugs are indicated to prevent recurrences, although the optimal duration of this therapy and its use as primary prophylaxis are not well established. In the case of hydrocephalus associated with neurological deterioration, shunting procedures to drain excess cerebrospinal fluid are required after temporary withdrawal of anticoagulation. Intracranial hypertension does not usually require treatment, but in symptomatic cases shunting procedures or serial lumbar puncture are required to promptly reduce intracranial pressure in case of papilledema and reduced visual acuity. Acetazolamide can also be administered to reduce cerebrospinal fluid production [28]. Rarely, patients with CVST present transtentorial herniation in the acute phase and need decompressive surgery, a lifesaving procedure. A prospective evaluation of the outcome of patients with CVST undergoing decompressive surgery is ongoing (DECOMPRESS-2 registry) and the interim analysis on 22 patients showed a 6-month mortality rate of 23.8% in patients treated vs. 100% in those not treated [104]. The role of steroids in reducing vasogenic edema is controversial; their use is not suggested in acute CVST, particularly in patients without parenchymal lesions, whereas it is recommended in CVST with an associated inflammatory disease (e.g. Behçet's disease) [28].

Treatment of the chronic phase

The optimal duration of anticoagulant therapy for secondary prevention of CVST should be decided for the single patient, evaluating the risk–benefit ratio. The absolute risk of recurrent thrombosis is low and long-term anticoagulation is reserved for patients with persistent and unmodifiable risk factors (e.g. severe thrombophilia, or solid or hematological neoplasms) and those with recurrent CVST. Whether also patients with unprovoked CVST should continue anticoagulation is not known (Fig. 4). AHA/ASA guidelines recommend that patients with CVST secondary to a transient risk factor receive anticoagulant therapy with a vitamin K antagonist (VKAs) for 3–6 months, maintaining an INR range between 2 and 3, whereas those with unprovoked CVST receive therapy for 6–12 months [24]. An exception is CVST during pregnancy, which requires therapeutic doses of LMWH possibly adjusted for bodyweight to ensure efficacy until delivery [28] because of the teratogenic effect of VKAs. AHA/ASA guidelines recommend antiplatelet therapy after a period of anticoagulation in patients with CVST without a recognized thrombophilia, although in the absence of controlled trials or observational studies this indication sounds arbitrary [105]. In line with studies conducted in patients with venous thromboembolism, we might accept the recommendation for patients with unprovoked events. Randomized clinical trials are required and the ongoing EXCOA-CVT study comparing a short (3–6 months) with a long (12 months) duration of oral anticoagulant therapy in patients with CVST will provide new insights into this crucial issue [106]. Recanalization of CVST can be considered among the criteria, potentially helping the decision on the optimal duration of anticoagulant therapy. Repeat imaging (CT or MRI) is recommended at 3–6 months from the index event or in the case of persistent or recurrent symptoms suggestive of CVST during anticoagulation therapy [24]. In the case of complete recanalization further neuroimaging is not required, whereas in the case of partial recanalization we suggest considering the possibility of prolonging anticoagulation until a reassessment at 12 months from the event. Another emerging issue in the treatment of CVST is the role of direct oral anticoagulants (DOACs), which showed a similar efficacy and a better safety profile compared with VKAs in patients with proximal deep vein thrombosis of the lower limbs or pulmonary embolism. All phase III clinical trials on the use of DOACs excluded patients with CVST and we thus have no certainties on their appropriateness for these patients, although three case series including respectively two, six and seven patients treated with rivaroxaban, confirmed its safety [107–109]. Clinical trials comparing efficacy and safety of dabigatran etexilate or rivaroxaban with warfarin or standard of care are ongoing (Table 2).

Secondary prevention

Concerning antithrombotic prophylaxis in high-risk situations after a first episode of CVST, it has been proposed to follow suggestions reported in guidelines on extracranial venous thrombosis. Concerning pregnancy, prophylactic doses of LMWH for women who discontinued oral anticoagulation are recommended [24].

Treatment in children and neonates

In children, the correction of concomitant conditions such as dehydration or infections is of crucial importance, even more so than in adults. When CVST is secondary to otitis media complicated by mastoiditis, antibiotic treatment with cephalosporins is indicated. Antibiotics are also used in patients with infection-related jugular vein thrombosis (Lemierre's syndrome), in particular against anaerobic microorganisms such as *Fusobacterium necrophorum*. In the absence of randomized controlled trials on anticoagulant treatment in children with CVST, current guidelines recommend doses of therapeutic heparin independently of concomitant intracranial hemorrhage and endovascular

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treatment for patients with rapidly deteriorating neurological functions despite adequate anticoagulation, similarly to adults [110]. For neonates there is no consensus on the management of the acute phase, and both anticoagulation or a conservative approach should be considered, treating concomitant illnesses. A promising alternative to the parenteral heparin or VKAs that require laboratory monitoring (very uncomfortable in the pediatric population) are DOACs, at present under investigation in any phase trials [111]. The optimal duration of anticoagulant treatment is not well established; however, 6 weeks to 3 months are recommended for neonates, and 3 to 6 months for children [112].

Thrombolysis should be used only in highly selected patients because of the risk of bleeding, which is particularly high in neonates due to their immature hemostatic system. Moreover, the naturally low levels of plasminogen in neonates may decrease the efficacy of chemical thrombolysis and some authors suggest infusion of plasminogen through fresh frozen plasma before the procedure [110].

Conclusions

Despite its low incidence rate, CVST represents one of the leading causes of stroke in young adults. A prompt diagnosis is necessary to avoid acute complications and long-term disabilities. The mainstay of therapy is anticoagulation, even if the optimal duration of treatment is currently under investigation. DOACs represent a fascinating option for treatment of CVST, taking into consideration their safety profile and the lack of laboratory monitoring. Clinical trials with DOACs are currently ongoing in adults and children and their results will help in decision making.

Addendum

M. Capecchi and M. Abbattista reviewed the literature and wrote the paper. I. Martinelli established the structure of the manuscript and reviewed the final version. All authors approved the final manuscript.

Acknowledgements

We thank C. M. Lensing for drawing Figure 1 and A. Paolucci for the images in Figures 2 and 3.

Disclosure of Conflict of Interests

The authors state that they have no conflict of interest.

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CC: Patel, Anita (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c06ec0295ce4ea4985d72c66e086749-HHS-bop1-cd]; Despres, Sarah (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e5f3d3f26584babb7b48c3cac8bba82-HHS-Sarah.D]; Inglesby, Thomas (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=242b7111806943f190b993fa62a67dd6-HHS-Thomas.]; Yogurtcu, Osman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df5df596d31f40f6a900b215feeb743d-Osman.Yogur]; Huang, Yin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3f6f5a5a8dc64e76b1ec512b0619aa52-HuangYin1]

Subject: Agenda attached :: Coordination of COVID-19 Vaccine Safety Surveillance Efforts - USG mtg
Attachments: Agenda - COVID-19 Vaccine Safety Surveillance Efforts 5-3-21 (final).pdf
Location: WebEx (shown below)

Start: 5/3/2021 12:30:00 PM
End: 5/3/2021 1:00:00 PM
Show Time As: Tentative

Recurrence: Weekly
every 2 week(s) on Monday from 12:30 PM to 1:00 PM

Required Attendees: Kessler, David A (OS); Marks, Peter; Anderson, Steven; Hepburn, Matt (OS); Johnson, Robert (OS); Disbrow, Gary (OS); Runstrom, Mark (OS); Clark, Matthew (OS); Gorman, Richard (OS); Hamilton, Holli (OS); Horwith, Gary (OS); Mcqueen, Anthony (OS); 'Ake, Julie (mail.mil)'; Faison, Tremel (OS); Martin, Stacey (CDC); Wharton, Melinda (CDC); Cohn, Amanda C (CDC); Wasley, Annemarie (CDC); Shimabukuro, Tom (CDC); Clark, Thomas A (CDC); Franklin, Joseph; Witten, Celia (CBER); Cho, David S (CBER); Gruber, Marion; Maloney, Diane; Forshee, Richard; Nair, Narayan; Krause, Philip; Fink, Doran; Farizo, Karen; Roberts, Jeff; Izurieta, Hector; McNeill, Lorrie; Frantz-Bohn, Susan; Kelman, Jeffrey A (CMS); Chu, Steve (CMS); 'Choy, Michael'; 'Harjivan, Chandresh (US SCA)'; 'alvaro.rossi@bcg.com'; Brooks,

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Kiahana (CMS); Malluwa-Wadu, Prabath P (CMS); Jason, Marybeth (CMS); Tierney, Julia; Walinsky, Sarah; Schuchat, Anne (CDC)

Optional Attendees: Patel, Anita (CDC); Despres, Sarah (OS); Inglesby, Thomas (OS); Yogurtcu, Osman; Huang, Yin

This meeting will be used to discuss the efforts of FDA, CDC, and other government agencies to follow the safety of COVID-19 vaccines that are deployed for use.

All mtgs run from 12:30pm-1:00pm EST.
Monday, 4/5/21
Monday, 4/19/21
Monday, 5/3/21
Monday, 5/17/21

Please refer to your principals within your organizations, prior to forwarding this calendar invitation.

With questions, please contact below, or send email to the FDA Covid-19 Vaccine Pharmacovigilance Coordination Team at Covid19VaccinePV@fda.hhs.gov.

Thank you.

On behalf of Peter Marks, MD, PhD, Director, FDA Center for Biologics Evaluation and Research

Leslie Haynes, RD
Program Manager (PDUFA Oversight)
Immediate Office of the Director
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration

10903 New Hampshire Avenue
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Coordination of COVID-19 Vaccine Safety Surveillance Efforts Meeting
Monday, May 3, 2021
12:30 – 1:00 PM EST

Dial-in Number: 1-877-465-7975
Meeting number (access code): (b) (6)
Meeting password: (b) (6)

Meeting Topic	Presenter
Johnson & Johnson (Janssen) COVID-19 vaccine Adverse Events	CDC
Vaccine administration by product and age	CDC
Other Topics	All

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Coordination of COVID-19 Vaccine Safety Surveillance Efforts Meeting

Monday, May 3, 2021

12:30 – 1:00 PM EST

Dial-in Number: 1-877-465-7975

Meeting number (access code): (b) (6)

Meeting password: (b) (6)

Meeting Topic	Presenter
Johnson & Johnson (Janssen) COVID-19 vaccine Adverse Events	CDC
Vaccine administration by product and age	CDC
Other Topics	All

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From: Messonnier, Nancy (CDC/DDID/NCIRD/OD) [nar5@cdc.gov]
Sent: 4/11/2021 5:05:15 PM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Anderson, Steven [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c0c242feba45fa954f4f9b05eb3557-AndersonSt]; Forshee, Richard [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc6a16c85d124b81893beb85a6929867-Forshee]; Gruber, Marion [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=019cd2669c7048f7a116d72b7682de44-gruber]; Krause, Philip [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00c6330fea0042fdb5571c3fdef792ed-krause]; Nair, Narayan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=debe49605be845e5a44d59cf099b8cb8-Narayan.Nai]
CC: Shimabukuro, Tom (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8313741a075c4f3d8d8351e106d1ffbc-HHS-ayv6-cd]; Fox, Kimberley (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=27601b74a37849b9be431991aba66055-HHS-kaf6-cd]; Cohn, Amanda C (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4cbff30d34c4611a2e973fcb192de37-HHS-anc0-cd]; Clark, Thomas A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7654dd7010c34f819e1e2eb29bcc86d1-HHS-tnc4-cd]
Subject: [EXTERNAL] RE: Coordination on adverse events

Importance: High

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Peter – this time is really not good for us. Can we find an alternative time – I could met at 8 or at 9?

-----Original Appointment-----
From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Sunday, April 11, 2021 2:53 PM
To: Marks, Peter; Anderson, Steven (FDA/CBER); Forshee, Richard (FDA/CBER); Gruber, Marion (FDA/CBER); Krause, Philip (FDA/CBER); Nair, Narayan (FDA/CBER); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Messonnier, Nancy (CDC/DDID/NCIRD/OD)
Subject: Coordination on adverse events
When: Monday, April 12, 2021 8:30 AM-9:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: https://fda.zoomgov.com/(b) (6)

The linked im...

Hi there,

Peter.Marks@fda.hhs.gov is inviting you to a scheduled ZoomGov meeting.

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Sent: 4/11/2021 7:32:33 PM
To: Messonnier, Nancy E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3db273e5a524ff690738a633d2c15de-HHS-nar5-cd]; Anderson, Steven [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c0c242feba45fa954f4f9b05eb3557-AndersonSt]; Forshee, Richard [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc6a16c85d124b81893beb85a6929867-Forshee]; Gruber, Marion [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=019cd2669c7048f7a116d72b7682de44-gruber]; Krause, Philip [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00c6330fea0042fdb5571c3fdef792ed-krause]; Nair, Narayan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=debe49605be845e5a44d59cf099b8cb8-Narayan.Nai]
CC: Shimabukuro, Tom (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8313741a075c4f3d8d8351e106d1ffbc-HHS-ayv6-cd]; Fox, Kimberley (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=27601b74a37849b9be431991aba66055-HHS-kaf6-cd]; Cohn, Amanda C (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4cbff30d34c4611a2e973fcb192de37-HHS-anc0-cd]; Clark, Thomas A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7654dd7010c34f819e1e2eb29bcc86d1-HHS-tnc4-cd]
Subject: RE: [EXTERNAL] RE: Coordination on adverse events

Dear Nancy,

I can make 9:10 AM work for half an hour then, so will send an update. It probably will just take us 20 minutes to coordinate. I have a pretty clear shopping list of things organized on our side. Thanks.

Best Regards,
Peter

From: Messonnier, Nancy (CDC/DDID/NCIRD/OD) <nar5@cdc.gov>
Sent: Sunday, April 11, 2021 5:05 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Anderson, Steven <Steven.Anderson@fda.hhs.gov>; Forshee, Richard <Richard.Forshee@fda.hhs.gov>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Krause, Philip <Philip.Krause@fda.hhs.gov>; Nair, Narayan <Narayan.Nair@fda.hhs.gov>
Cc: Shimabukuro, Tom (CDC) <ayv6@cdc.gov>; Fox, Kimberley (CDC) <kaf6@cdc.gov>; Cohn, Amanda C (CDC) <anc0@cdc.gov>; Clark, Thomas A (CDC) <tnc4@cdc.gov>
Subject: [EXTERNAL] RE: Coordination on adverse events
Importance: High

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.

Peter – this time is really not good for us. Can we find an alternative time – I could met at 8 or at 9?

-----Original Appointment-----
From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Sunday, April 11, 2021 2:53 PM
To: Marks, Peter; Anderson, Steven (FDA/CBER); Forshee, Richard (FDA/CBER); Gruber, Marion (FDA/CBER); Krause, Philip (FDA/CBER); Nair, Narayan (FDA/CBER); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Messonnier, Nancy

Obtained via FOIA by Judicial Watch, Inc.

(CDC/DDID/NCIRD/OD)
Subject: Coordination on adverse events
When: Monday, April 12, 2021 8:30 AM-9:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: https://fda.zoomgov.com(b) (6)

Hi there,

Peter.Marks@fda.hhs.gov is inviting you to a scheduled ZoomGov meeting.

Join Zoom Meeting

Phone one-tap: US: +16692545252,(b) (6) # or +16468287666,,(b) (6)
Meeting URL: https://fda.zoomgov.com/(b) (6)
Meeting ID: (b) (6)
Passcode (b) (6)

Join by Telephone

For higher quality, dial a number based on your current location.
Dial:
US: +1 669 254 5252 or +1 646 828 7666 or +1 551 285 1373 or +1 669 216 1590 or 833 568 8864 (Toll Free)

Meeting ID: (b) (6)
Passcode (b) (6)

International numbers

Join from an H.323/SIP room system

H.323: (b) (6) (US West)
(US East)
Meeting ID: (b) (6)
Passcode: (b) (6)

Obtained via FOIA by Judicial Watch, Inc.

SIP: (b) (6)

Passcode (b) (6)

Obtained via FOIA by Judicial Watch, Inc.

From: Haynes, Leslie (CBER) [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02015880B0CE4A78953D370750FD4748-LESLIE.HAYN]
Sent: 4/15/2021 2:18:00 PM
To: Kessler, David A (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=efb6a7c634694533833de5d2f4beaee3-HHS-David.K]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Messonnier, Nancy E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3db273e5a524ff690738a633d2c15de-HHS-nar5-cd]; Anderson, Steven [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c0c242feba45fa954f4f9b05eb3557-AndersonSt]; Hepburn, Matt (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=68c7e72407d94642b6e0761db3088888-HHS-Matt.He]; Johnson, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c7eb3a419464ea2917f9d1e3f6e57a4-HHS-Robert.]; Disbrow, Gary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-HHS-Gary.Di]; Runstrom, Mark (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87730c0209a340f1b779812822b74f70-HHS-Mark.Ru]; Clark, Matthew (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7016989d4b7e476781fe395661cbead4-HHS-Matthew]; Gorman, Richard (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60cb802883ef4f29aa00909646b6ab97-HHS-Richard]; Hamilton, Holli (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d9dd10bd6974f7f82128d5f9b193722-HHS-Holli.H]; Horwith, Gary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d6472efbb7f4130b46287660c7db94a-HHS-Gary.Ho]; Mcqueen, Anthony (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e76ec4716deb491ea440f22bb0baffbd-HHS-Anthony]; 'Ake, Julie (mail.mil)' [julie.a.ake.mil@mail.mil]; Faison, Tremel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4945bc9afa3c4d34a274cb286e2f2a09-HHS-Tremel.]; Martin, Stacey (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=75d5b37f96474b98892a56a967a0f55b-HHS-zmt0-cd]; Wharton, Melinda (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=20ac94633baa479e8282a619f083bbfb-HHS-mew2-cd]; Cohn, Amanda C (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4cbff30d34c4611a2e973fcb192de37-HHS-anc0-cd]; Wasley, Annemarie (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85a0afa0eb31495c8122d407d74d04eb-HHS-acw5-cd]; Shimabukuro, Tom (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8313741a075c4f3d8d8351e106d1ffbc-HHS-ayv6-cd]; Clark, Thomas A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7654dd7010c34f819e1e2eb29bcc86d1-HHS-tnc4-cd]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Witten, Celia (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc08ebb3ac61486da9f1b4046757c5cf-Witten]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Gruber, Marion [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=019cd2669c7048f7a116d72b7682de44-gruber]; Maloney, Diane [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e59205500e944c9eacc4524ea18ed5bb-MaloneyD]; Forshee, Richard [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc6a16c85d124b81893beb85a6929867-Forshee]; Nair, Narayan

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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=debe49605be845e5a44d59cf099b8cb8-Narayan.Nai]; Krause, Philip [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00c6330fea0042fdb5571c3fdef792ed-krause]; Fink, Doran [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b3bfbf3e7bea40b1b726937796eba4e8-FinkDo]; Farizo, Karen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4e44a6d3b754a66ad321c00f9b1debd-Farizo]; Roberts, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f99ba866ca234f6d826007b9f1429e8e-RobertsJ]; Izurieta, Hector [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2dde96468af24b2d9ef03b853eeb3af9-Izurieta]; McNeill, Lorrie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77b0b352c9c24851bf0c7330f53e00d9-McNeill]; Frantz-Bohn, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c4a10821c774ffa9c5cf59bda6bcf75-frantz_bohn]; Kelman, Jeffrey A (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bcbadfaf1f347738e547528d0cd214e-HHS-Jeffrey]; Chu, Steve (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d3536db09984be3b195d2749a47c982-HHS-Steve.C]; 'Choy, Michael' [Choy.Michael@bcg.com]; 'Harjivan, Chandresh (US SCA)' [Harjivan.Chan@bcgfed.com]; 'alvaro.rossi@bcg.com' [alvaro.rossi@bcg.com]; Brooks, Kiahana (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3126cd972164be98303910ff693d811-HHS-Kiahana]; Malluwa-Wadu, Prabath P (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7bb1730cca864e569e8ac6dc3c84ab30-HHS-Prabath]; Jason, Marybeth (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f9af6b02fc67424181f8c9bb002b9c09-HHS-Marybet]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]

CC: Despres, Sarah (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e5f3d3f26584babb7b48c3cac8bba82-HHS-Sarah.D]; Inglesby, Thomas (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=242b7111806943f190b993fa62a67dd6-HHS-Thomas.]; Yogurtcu, Osman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df5df596d31f40f6a900b215feeb743d-Osman.Yogur]; Huang, Yin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3f6f5a5a8dc64e76b1ec512b0619aa52-HuangYin1]

Subject: AGENDA :: Coordination of COVID-19 Vaccine Safety Surveillance Efforts - USG mtg
Attachments: Agenda - COVID-19 Vaccine Safety Surveillance Efforts 4-19-21.pdf
Location: WebEx (shown below)

Start: 4/19/2021 12:30:00 PM
End: 4/19/2021 1:00:00 PM
Show Time As: Tentative

Recurrence: Weekly
every 2 week(s) on Monday from 12:30 PM to 1:00 PM

Required Attendees: Kessler, David A (OS); Marks, Peter; Messonnier, Nancy E (CDC); Anderson, Steven; Hepburn, Matt (OS); Johnson, Robert (OS); Disbrow, Gary (OS); Runstrom, Mark (OS); Clark, Matthew (OS); Gorman, Richard (OS); Hamilton, Holli (OS); Horwith, Gary (OS); Mcqueen, Anthony (OS); 'Ake, Julie (mail.mil)'; Faison, Tremel (OS); Martin, Stacey (CDC); Wharton, Melinda (CDC); Cohn, Amanda C (CDC); Wasley, Annemarie (CDC); Shimabukuro, Tom (CDC); Clark, Thomas A (CDC); Abernethy, Amy; Franklin, Joseph; Witten, Celia (CBER); Cho, David S (CBER); Gruber, Marion; Maloney, Diane; Forshee, Richard; Nair, Narayan; Krause, Philip; Fink, Doran; Farizo, Karen; Roberts, Jeff; Izurieta, Hector; McNeill, Lorrie; Frantz-Bohn, Susan; Kelman, Jeffrey A (CMS); Chu, Steve (CMS); 'Choy, Michael'; 'Harjivan, Chandresh (US SCA)'; 'alvaro.rossi@bcg.com'; Brooks, Kiahana (CMS); Malluwa-Wadu, Prabath P (CMS); Jason, Marybeth (CMS); Tierney, Julia

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Optional Attendees: Despres, Sarah (OS); Inglesby, Thomas (OS); Yogurtcu, Osman; Huang, Yin

This meeting will be used to discuss the efforts of FDA, CDC, and other government agencies to follow the safety of COVID-19 vaccines that are deployed for use.

All mtgs run from 12:30pm-1:00pm EST.
Monday, 4/5/21
Monday, 4/19/21
Monday, 5/3/21
Monday, 5/17/21

Please refer to your principals within your organizations, prior to forwarding this calendar invitation.

With questions, please contact below, or send email to the FDA Covid-19 Vaccine Pharmacovigilance Coordination Team at Covid19VaccinePV@fda.hhs.gov.

Thank you.

On behalf of Peter Marks, MD, PhD, Director, FDA Center for Biologics Evaluation and Research

Leslie Haynes, RD
Program Manager (PDUFA Oversight)
Immediate Office of the Director
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration

10903 New Hampshire Avenue
WO Bldg 71, Room 7222
Silver Spring, MD 20993-0002
Tel: 1-240-402-8074; Fax: 1-301-595-1310
Email: leslie.haynes@fda.hhs.gov



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Coordination of COVID-19 Vaccine Safety Surveillance Efforts Meeting
Monday, April 19, 2021
12:30 – 1:00 PM EST

Dial-in Number: 1-877-465-7975
Meeting number (access code): (b) (6)
Meeting password: (b) (6)

Meeting Topic	Presenter
Johnson & Johnson (Janssen) COVID-19 vaccine Adverse Events	CDC, FDA
Other Topics	All

Obtained via FOIA by Judicial Watch, Inc.

Coordination of COVID-19 Vaccine Safety Surveillance Efforts Meeting
Monday, April 19, 2021
12:30 – 1:00 PM EST

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Meeting Topic	Presenter
Johnson & Johnson (Janssen) COVID-19 vaccine Adverse Events	CDC, FDA
Other Topics	All

Obtained via FOIA by Judicial Watch, Inc.



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From: Aikin, Ann (OS/OASH) [Ann.Aikin@hhs.gov]
Sent: 6/10/2021 7:19:58 PM
To: Mills, Justin (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7aab23a7ddfe4b60bd65bb83778386b8-HHS-Justin.]; Lambert, Linda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0ffbd5d0ecbf476f827232a2e04f7c17-HHS-Linda.L]; Hrncir, David E CIV DHA IMMUNIZATION (USA) (b) (6); Marshall, Valerie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=42f1176fd7ed477f8ec7241d392eaf2c-MarshallV]; Rubin, Mary (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e1a248bd71c1423c9f7a6ca5ee64b9c2-HHS-MRubin-]; Mulach, Barbara L (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b3356e88e1cb4499bdaee41159778493-HHS-BMulach]; Knighton, Troy (VA) [troy.knighton@va.gov]; Hance, Mary Beth E (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bccd0abd73f44c5a1f78b2c5a005478-HHS-marybet]; Chukwuma, Uzo (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9729a0c717544e5391c0d1f502a92be7-HHS-Uzo.Chu]; Wharton, Melinda (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=20ac94633baa479e8282a619f083bbfb-HHS-mew2-cd]
CC: Kelman, Jeffrey A (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bcbadfaf1f347738e547528d0cd214e-HHS-Jeffrey]; Posner, Samuel F (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad9a360b86fc4d8fb4b8de8f8f57a7b8-HHS-shp5-cd]; Scott, Ardeana R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb6944733653452c84f227e0b3c0853c-HHS-ypq8-cd]; (b) (6); Gruber, Marion [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=019cd2669c7048f7a116d72b7682de44-gruber]; Pavani Ram [pram@usaid.gov]; Srinivas, Geetha B - APHIS [geetha.b.srinivas@usda.gov]; Chris Dumm [CDumm@explorepsa.com]; Caroline Shell PSA [CShell@explorepsa.com]; Erika Noyes PSA [ENoyes@explorepsa.com]
Subject: RE: June 2021 NVAC Meeting
Attachments: NVAC Feb 2021 Meeting Summary for Approval.docx; IES draft report May 24 2021 for NVAC review.docx

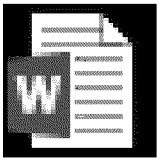
Good Day NVAC Members and Alternates,

In advance of our meeting, I wanted to let you know that we are placing files on the SharePoint site and should have more presentations up on Monday and Tuesday.

The Immunization Equity Subcommittee has finished their report, so I expect that the committee may want to vote on approving it. I am attaching it here so you can read it in advance, but Melody will also be presenting on it and giving a brief update at the meeting.



Likewise, for ease, I am also attaching the meeting minutes from our last meeting for review. Both documents are on the SharePoint site as well.



As a reminder, I provided some information for SharePoint below for those of you who have access to the site (not all of you do). Also, if you have not already submitted your written update, please do so by tomorrow at noon. Otherwise, Emily or I will reach out to you specifically for it.

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Best,

Ann

SharePoint URL
The NVAC SharePoint site URL is
https:(b) (6)
(b) (6)

Your email will be something like this:
AnnAikin@xcollhhsgov.onmicrosoft.com
Ann.Aikin@xcollhhsgov.onmicrosoft.com

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NVAC NATIONAL VACCINE ADVISORY COMMITTEE

February 4–5, 2021, Virtual Meeting Minutes

Committee Members in Attendance

Robert H. Hopkins Jr., M.D., MACP, FAAP; Chair
Debra Blog, M.D.
Melody Anne Butler, B.S.N., RN, CIC
Timothy Cooke, Ph.D.
John Dunn, M.D., M.P.H.
Kristen R. Ehresmann, RN, M.P.H.
David Fleming, M.D.
Leonard Friedland, M.D.
Daniel F. Hoft, M.D., Ph.D.
Molly Howell, M.P.H.
Mary Anne Jackson, M.D., FAAP, FPIDS, FIDSA
Melissa Martinez, M.D., FAAFP
Cody Meissner, M.D., FAAP
Robert Schecter, M.D.
Geeta Swamy, M.D.
Robert Swanson, M.P.H.

NVAC Ex Officio Members

Uzo Chukwuma, Indian Health Service (IHS)
Troy Knighton, M.Ed., Ed.S., LPC, Department of Veterans Affairs (VA)
Linda Lambert, Ph.D., Biomedical Advanced Research and Development Authority (BARDA)
LTC Valerie Marshall, M.P.H. (for Marion Gruber, Ph.D.), Food and Drug Administration (FDA)
Justin A. Mills, M.D., M.P.H., Agency for Healthcare Research and Quality (AHRQ)
Barbara Mulach, Ph.D., National Institutes of Health (NIH)
Kristin Pope (for Nancy Messonnier, M.D., CAPT), Centers for Disease Control and Prevention (CDC)
Mary Rubin, M.D., Division of Injury Compensation Programs, Health Resources and Services Administration (HRSA)
Margaret Ryan, M.D., Department of Defense (DoD)
Geetha Srinivas, D.V.M., M.S., U.S. Department of Agriculture (USDA)

NVAC Liaison Representatives

Kimberly Martin (for James S. Blumenstock), Association of State and Territorial Health Officials (ASTHO)
Rebecca Coyle, M.S.Ed., American Immunization Registry Association (AIRA)
John Douglas, M.D., National Association of County and City Health Officials (NACCHO)
Claire Hannan, Association of Immunization Managers (AIM)
Jean-Venable "Kelly" Goode, Pharm.D., BCPS, FAPhA, FCCP, American Pharmacists Association (APhA)
Christopher Regal, M.S., America's Health Insurance Plans (AHIP)

Designated Federal Officer

Ann Aikin, M.A., Communications Director, Office of Infectious Disease and HIV/AIDS Policy (OIDP), Department of Health and Human Services (HHS)

Obtained via FOIA by Judicial Watch, Inc.

Proceedings
Day One

Call to Order and Rules of Engagement—Ann Aikin, M.A., NVAC Designated Federal Officer, Communications Director, OIDP, HHS

Ms. Aikin called the meeting to order at 1 p.m. ET and welcomed the participants. She briefly outlined the agenda and described key parts of the Federal Advisory Committee Act, its conflict-of-interest rules, and standards of ethical conduct for NVAC members. Ms. Aikin thanked the OIDP staff for their support in organizing the meeting and called the roll.

Opening Remarks—RADM Felicia Collins, M.D., M.P.H., FAAP, U.S. Public Health Service, Acting Assistant Secretary for Health (ASH), HHS

RADM Collins said that as a pediatrician, she particularly appreciates the importance of NVAC's work to ensure that the entire immunization system remains strong. In her long career in public health, she has focused on vulnerable and underserved populations in the pursuit of optimal health for all. RADM Collins said she was honored to be the Acting ASH amidst a worldwide, unprecedented vaccine effort. She offered gratitude for those on the front lines and behind the scenes of the COVID-19 pandemic response.

The pandemic has affected millions, and people of color have been hit disproportionately hard. In her work as director of the HHS Office of Minority Health, RADM Collins daily considered what could be done to support COVID-19 vaccination and decrease disparities faced by vulnerable and underserved populations. She praised NVAC's December 2020 recommendations, which offered suggestions on how to enhance informed decision-making about vaccines, increase confidence in the COVID-19 vaccine, enhance vaccination of diverse populations, and apply the lessons learned from the rapid COVID-19 vaccine development process to increase availability of new vaccines to the American public. Thanks to the tireless efforts of experts across the immunization system, there is momentum around COVID-19 vaccination.

HHS and its partners are working toward the goal of providing 100 million COVID-19 vaccinations within the first 100 days of the new Biden administration, following the announcement of the [HYPERLINK "https://www.whitehouse.gov/wp-content/uploads/2021/01/National-Strategy-for-the-COVID-19-Response-and-Pandemic-Preparedness.pdf"]. The Strategy outlines ways to convert vaccines into vaccination, improving allocation, distribution, administration, tracking, and support to State, local, Tribal, and Territorial governments. The Strategy supports a large-scale, targeted, data-driven campaign to build trust and vaccine confidence, capitalizing on CDC's Vaccinate with Confidence framework and delivering culturally competent materials. The Strategy also calls for additional work to ensure that science-based information about vaccines and COVID-19 is communicated effectively and equitably, so everyone has accurate, up-to-date information on which to base decisions.

The Strategy outlines ways to focus on high-risk and hard-to-reach populations, recognizing that community-driven approaches are critical to making vaccine acceptable and equitable. NVAC has supported many of the components of the Strategy, and HHS will continue to rely on NVAC for its input, said RADM Collins.

RADM Collins called on NVAC members to spread the word that volunteers are still needed for vaccine clinical trials. More information is available at the[HYPERLINK

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"https://combatcovid.hhs.gov/"]. NIH's [HYPERLINK "https://covid19community.nih.gov/"] offers tools for encouraging diversity so that clinical trials adequately represent all of America, including people of various races and ethnicities and people with disabilities.

Finally, RADM Collins thanked two NVAC members who are completing their terms as of this meeting for providing their valuable time and expertise: Mary Anne Jackson, M.D., FAAP, FPIDS, FIDSA, and Melissa Martinez, M.D., FAAFP. She also welcomed Uzo Chukwuma, who took over as IHS's representative to NVAC.

Chair's Welcome—Robert H. Hopkins Jr., M.D., MACP, FAAP, NVAC Chair

Dr. Hopkins welcomed the participants to the virtual public meeting, which was accessible to the public by live webcast and telephone. He outlined the agenda for this meeting. NVAC members approved the minutes of the three previous meetings (September 23–24, October 16, and December 4, 2020) as written, unanimously.

Dr. Hopkins described the procedure for delivering public comments during the meeting. Written comments can be sent to NVAC for consideration by e-mail (nvac@hhs.gov). The agenda, minutes, and recordings of past meetings are available [HYPERLINK "https://www.hhs.gov/vaccines/nvac/meetings/index.html"]. NVAC is scheduled to meet next on June 16–17 and September 15–16, 2021. (See the appendix for a list of abbreviations used in this report.)

Fear of Needles and Vaccine Compliance

Barriers to Getting the COVID-19 Vaccine—Jeanine P. D. Guidry, Ph.D., Virginia Commonwealth University

Dr. Guidry outlined the rate of vaccine hesitancy globally and particularly among people of color in the United States, who have a disproportionately higher risk of infection with COVID-19 and face more severe consequences. Vaccine misinformation and disinformation have contributed to people's concerns, as has the rapid pace of development and approval of the vaccine. Dr. Guidry and colleagues surveyed people in July 2020 about what would affect their acceptance of a theoretical COVID-19 vaccine. They identified the following:

- More people and more people of color in particular, said they were less likely to accept a vaccine approved through emergency use authorization (EUA) than through the conventional approval process.
- Fear of needles was a significant predictor of refusal to accept vaccine.
- Other specific barriers to being vaccinated were concerns about side effects and a possible vaccine shortage.

Dr. Guidry called out the unnecessary use of "fear visuals," such as pictures of very large needles, which amplify people's fears. Messages involving fear visuals tend to grab attention and are often unrealistic. Online, fear visuals are often associated with misinformation. Dr. Guidry advised communicators to pay more attention to how the graphics they use can affect fears around needles and vaccination. Her research demonstrates that many of the barriers to COVID-19 vaccine uptake predate the arrival of the vaccine.

In addition to portraying vaccination in a more positive light, Dr. Guidry recommended that providers discuss potential side effects honestly and that communication plans lean on trusted

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messengers, including health care providers, community leaders, and social media influencers, to reach diverse populations and address barriers to vaccine uptake.

Fear of Needles: A Common Barrier to Vaccine Compliance—Jennifer McLenon, M.P.H., University of Michigan

Ms. McLenon said the fear of needles can range from being afraid yet able to tolerate needle procedures to more severe conditions (e.g., phobia) that can cause someone to avoid medical care. Fear of needles is more prevalent in children and decreases with age. It is more common among women, and prevalence varies by country. Research studies often target people who have a lot of health care procedures involving needles. Notably, fear of needles has been documented among as much as 41 percent of people with diabetes, and higher levels of fear are associated with lower levels of control of diabetes.

The percentage of adults who avoid the influenza vaccine because of fear of needles ranges from 6 percent in the general population to 27 percent of hospital employees. About 20 percent of adults have not received pneumococcal or tetanus vaccines because of their discomfort with needles. Alternatives to injections are in development and have the added benefit of requiring less training for administration. Techniques to reduce fear include pain reduction, especially in children; distraction; and hypnosis. Cognitive behavioral interventions (e.g., desensitization through gradually increasing exposure) are also effective and merit more research. Ms. McLenon concluded that, because needle fear and phobia are more prevalent among children and women, efforts should target those populations.

Overcoming Needle Dread—Amy Baxter, M.D., FAAP, FACEP, Augusta University

Dr. Baxter emphasized that 38 million people in the United States might not get the COVID-19 vaccine because of their fear of needles, and 64 million people might not get the second dose in the regimen because of a combination of fear of needles, side effects, and pain. She pointed to research suggesting that the fear of needles has increased in adults as a result of an increase in the number of vaccines administered when they were young children. Some parents choose to space out injections; children who got one or two vaccinations on the same day had lower levels of needle fear later on than those who got four or five vaccinations on the same day.

The pain of vaccination can be reduced by neuromodulation (through topical anesthetics, ice, or devices). In children, combining pain relief with interventions to address fear through distraction is effective. Dr. Baxter noted that Buzzy®, a mechanical stimulation device, is used by children and adults to block stimulus and distract, and it can block the vasovagal response that causes fainting. Other distraction techniques are easy to teach. Addressing pain, fear, and other factors that contribute to needle dread (including shame and fear of fainting) in adults and children can chip away at vaccine resistance, said Dr. Baxter. She proposed that a major pharmacy chain invest in training staff on techniques to minimize fear and creating a comfortable space. Addressing needle fear could restore faith in health care systems among some populations.

Treatment of High Levels of Needle Fear—C. Meghan McMurtry, Ph.D., C. Psych, University of Guelph

Dr. McMurtry pointed out that pain and fear exacerbate each other. When pain is not properly managed, an individual may experience anxiety and fear around the next procedure, which leads to avoidance. Phobias are a combination of fear, anxiety, and avoidance that is out of proportion to the danger posed. Needle phobia can cause increased blood pressure, increased heart rate, dizziness, shakiness, sweating, tunnel vision, nausea, and fainting.

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Dr. McMurtry and colleagues published companion evidence-based guidelines for those with low to moderate fear of needles and those who experience high needle fear or phobia. The latter recommends screening for fainting and related conditions (e.g., dizziness, nausea) as well as screening for needle fear, recognizing that the two can be distinct or overlap.

A substantial body of evidence supports exposure-based therapy for overcoming phobias. The process involves facing one's fears in a gradual, controlled manner. The guidelines put forth by Dr. McMurtry recommend that individuals—rather than their health care providers—generate their own list of steps toward overcoming their fear and organize the steps from least to most difficult. Working methodically through each step, an individual comes to belief that the worst possible outcome is unlikely or, if it does happen, survivable. Dr. McMurtry added that individuals often escape a fearful situation before it reaches a peak and therefore never experience any resolution of the fear, which perpetuates the instinct to avoid the feared situation.

Ideally, exposure-based therapy is conducted in person with a mental health care provider, but alternatives include using a computer program or self-directed imagery. For those who experience fainting and related conditions, exposure-based therapy combined with muscle contraction-and-release exercises is effective. Access to exposure-based therapy is limited by cost, lack of insurance coverage, lack of trained providers, and stigma. Dr. McMurtry seeks to develop self-guided materials, tailored by age groups, to expand access to the treatment.

Patient Story—Armand Davila

Mr. Davila described his own extreme fear of needles, particularly the fear of being invaded by a foreign object. He did not know when his fear emerged, but he recalled that as a young man, the fear meant he was unable to donate blood for a cousin who needed a life-saving transfusion. Later, he was diagnosed with diabetes but could not administer his own insulin on a reliable basis. His fear of needles motivated him to manage his diabetes primarily through lifestyle changes, but he still requires some injections, which necessitate a raft of coping mechanisms.

Mr. Davila acknowledged that he is embarrassed by his fear and the tactics he must employ to tolerate needle procedures, and he recognizes the fear as irrational. The body remembers the fear, he said, and it cannot be rationalized away. Mr. Davila said he will push down the fear and do his best to get the COVID-19 vaccine because not being vaccinated could affect the whole planet. His philosophy is to consider the needs of the greater good.

Mr. Davila urged NVAC and others to think about the messaging around science, medical cures, and even failures (e.g., the Tuskegee syphilis experiment). The messages must be more digestible for the general public and for marginalized populations in particular. Mr. Davila appreciated the opportunity to tell his story and hoped it would help guide treatment of people like him and marginalized groups who have issues with getting vaccinated.

Discussion

Dr. Hopkins asked the panelists whether any common themes around needle fears have emerged. Dr. Baxter noted that people with needle fear need mechanisms for controlling and managing the experience, but they have different concerns about what aspect of the experience is distressing. She suggested giving people lots of management options from which to choose. In keeping with Dr. Guidry's observation, Dr. Baxter noted that even materials about dealing with needle fear feature pictures of big needles.

Dr. Guidry stressed that recognizing that images of needles can trigger a fear can help. She also noted that the past year has resulted in tremendous uncertainty for so many, some of whom have

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lost loved ones, lost their livelihoods, and had their lives upended. Dr. Guidry urged empathy for people experiencing so much disruption.

Via chat, John Douglas, M.D., asked how providers could better communicate about vaccines. Mr. Davila echoed that the pictures of needles are unhelpful, and media outlets seem to use them without thinking. He suggested thinking more thoroughly about all the possible angles of a message and recognizing that without information, the brain fills the gaps with the worst possible scenario as a protective mechanism. Mr. Davila called for improving access to reliable information, perhaps through an online portal. The previous administration muffled science, and the lack of a cohesive message left room for doubt and fear to take hold, he stated.

Dr. Baxter said some research indicates that among Black people, the word "immunization" is far preferable to "vaccination," and images of needles in the media are conflated with needle injection. Underscoring the need for an individualized approach to needle fear, Dr. Baxter said that at the time of injection, some will need to control their fear by watching the process, while others will need to look away. The promise that the jet injector (which does not use a needle) will be faster helps some but not all those with needle fears. Mr. Davila said the length of the intervention—a few seconds for an influenza vaccine compared with a few minutes for a blood draw—makes a big difference to him.

Dr. Guidry added that COVID-19 vaccination campaigns will likely try to handle a lot of people in a very short time, which affects what providers can do. Those organizing mass vaccination events should consider what can be done to minimize trauma. Dr. Baxter said mass vaccination events are likely to be very frightening for people with needle fear, so having an option such as a pharmacy that promotes a comfort-based approach would be ideal for them. If one such site was adequately prepared to address people with fear of needles, other, larger sites would not have to alter their approach.

Dr. McMurtry pointed to practice guidelines from the World Health Organization (WHO) on stress responses to immunization. She noted that mass campaigns should consider privacy, recognizing that seeing something go wrong could evoke a response in someone waiting to be vaccinated. Long wait times also contribute to fearfulness.

Robert Swanson, M.P.H., asked why the intranasal influenza vaccine and other alternatives have not been more widely adapted. Dr. McMurtry said that for some, like Mr. Davila, non-needle-based delivery systems do not address fears of invasive foreign materials, for example. Dr. Baxter added that the first intranasal influenza vaccine was not very effective and was taken off the market. However, she said, people do use alternatives when available. She also pointed to research showing that some people who were concerned about the damage that vaccines can cause were willing to accept the oral polio vaccine, indicating that fears about injection of foreign bodies do not necessarily translate to oral and intranasal vaccines.

Reducing Vaccination Pain: Interventions and Guidelines

Interventions to Reduce Vaccination Pain in Adults—Vibhuti Shah, M.D., Mount Sinai Hospital

Dr. Shah provided the conclusions of two systematic reviews of pharmacological and simple psychological interventions to minimize injection pain for adults. Topical anesthetics such as lidocaine are effective and should be considered, but it can take 30–60 minutes for the anesthetic to take effect. Vapocoolant sprays prevent pain transmission but can cause minor pain for some. Oral analgesics are not effective.

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No studies addressed psychological interventions for vaccination injection pain, but research on other common needle procedures indicates that letting the individual know when the procedure will begin may reduce pain. Various methods of distraction work better in children than adults. Neither audio nor visual distractions had any impact on adults' pain, but breathing exercises were effective. The quality of evidence for all of the psychological interventions was low. Dr. Shah concluded that the literature on preventing or reducing injection pain among adults is limited. It might be helpful to allow individuals to choose the intervention they think might work.

Vaccination Pain: Clinical Practice Guideline and Outcomes—Anna Taddio, Ph.D., University of Toronto

Dr. Taddio pointed out that pain following vaccination is common and mostly ignored, but it is an iatrogenic harm that the field is obligated to address. Pain can diminish vaccine confidence, and the lack of attention to a patient's comfort can be a barrier; both factors can contribute to vaccine hesitancy. Addressing vaccine pain improves the quality of care. It might increase patient satisfaction and trust. Patients have a right to pain relief, Dr. Taddio emphasized. The combination of pain and fear may cause individuals to avoid getting health care, leading to poor outcomes.

An evidence-based clinical guideline for those with low to moderate fear of needles (mentioned earlier by Dr. McMurtry) addresses pain management through the "Five P's." The first four address procedures (e.g., give injections quickly), physical considerations (e.g., positioning), pharmacological interventions (e.g., topical anesthetic), psychological interventions (e.g., distraction). The fifth P, process, refers to educating providers, parents, patients, and consumers about the interventions available. The guideline offers other practice recommendations to minimize fear and anxiety, such as limiting fear-inducing stimuli and patient waiting time.

Dr. Taddio presented some of the educational materials used for providers and parents. The guidelines for addressing pain have been implemented in various health care settings. The most complicated set of materials describes the Comfort, Ask, Relax, Distract (CARD) System, which encourages individuals to select and apply the types of interventions that work for them.

Dr. Taddio emphasized that in a mass vaccination setting, discomfort and dissatisfaction can be addressed through some simple steps, such as offering more basic education (e.g., about the vaccine and the concept of community immunity), acknowledging and addressing pain, demonstrating care for vaccinees, and taking a patient-centered approach when setting up the clinical space. Providers and individuals should know what tools are available to minimize pain, and evaluation mechanisms should be implemented to assess the impact of such tools. Addressing pain more consistently across the life span could improve people's experiences and increase vaccine uptake. Dr. Taddio said taking steps to minimize vaccination pain and displaying more positive images of vaccination procedures could make a big difference.

Discussion

Robert Schecter, M.D., asked whether pain and anxiety affect the immune response and whether nonsteroidal anti-inflammatory drugs (NSAIDs) affect immunogenicity. Dr. Taddio said most providers recognize that NSAIDs do not work well for vaccine pain and are not recommended for preemptive use. However, because of concerns about the painful side effects of the COVID-19 vaccine, some providers may be reverting to preventive drugs. Dr. Shah said the effects of NSAIDs on immunogenicity vary and should be studied for each vaccine. There is little research about their effect on newer vaccines.

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Cody Meissner, M.D., FAAP, invited the panelists to comment on reports of shoulder injury related to vaccine administration (SIRVA) with the COVID-19 vaccine. Dr. Taddio said SIRVA can be avoided with proper injection technique, and individuals can assist by wearing clothing that allows the provider to access the upper arm easily. She said there have been few reports of SIRVA related to COVID-19 vaccine in Canada. Pharmacists have only recently been authorized to deliver vaccines in Canada, and some people vaccinated by pharmacists have reported SIRVA. Dr. Hopkins noted that advising individuals about what to wear is one of the steps systems can take to prevent vaccination problems.

Dr. Taddio asked whether the United States is considering eliminating the step of swabbing the injection site with alcohol, which is unnecessary, time-consuming, and has been abandoned by other countries. Providers in Canada are reluctant to change, but doing so could save time and money and decrease waste, she noted, and the smell of the alcohol might also increase anxiety. Dr. Taddio hoped the need for efficiency in mass vaccination would be the impetus for getting rid of alcohol swabbing in the United States and Canada.

Vaccine Confidence Subcommittee Update—John Dunn, M.D., M.P.H., and Cody Meissner, M.D., FAAP, Co-Chairs

In June 2019, the ASH charged the Subcommittee with creating a report on what affects vaccine confidence over a lifetime, what HHS can do to increase vaccine confidence, and how to foster confidence based on evidence. The Subcommittee will present a full report for review at the June 2021 NVAC meeting.

Dr. Dunn summarized some notable themes from recent presentations to the Subcommittee. While CDC and others have launched vaccine confidence efforts, misinformation and disinformation campaigns are broad, pervasive, and difficult to counter. A literature review offered insight on how vaccine hesitancy and confidence vary by type of vaccine and population. Rather than propose a single approach to improve overall vaccine confidence, the Subcommittee intends to recommend strategies, informed by evidence, that can be tailored as needed depending on the vaccine and the target population.

The report will define vaccine acceptance as receiving a vaccination. It will highlight the subtle distinction between vaccine confidence and hesitancy and explore these issues across the life span. The report is not intended to describe the state of vaccine acceptance or how to increase uptake but rather how confidence and hesitancy contribute to acceptance, recognizing that they might not be primary drivers of acceptance, delay, or low coverage. The Subcommittee acknowledges that attitudes about vaccination exist on a continuum that spans from rejection to acceptance, with a lot of overlap in the perceptions that affect individuals' decision-making. Dr. Dunn said it will be challenging for the Subcommittee's report to put forward recommendations that speak to these complexities while also being easy to read and to use. He welcomed input from NVAC members.

Discussion

Dr. Hopkins observed that WHO, HHS, and CDC are working to address vaccine confidence but many issues still require attention. He also noted that the Vaccine Confidence Subcommittee's work is closely tied with that of the Immunization Equity Subcommittee. Dr. Dunn said the topic is complex, nuanced, and challenging. At the very least, he added, the report will identify and categorize the issues, while calling out areas where more evidence is needed. Dr. Dunn also indicated that much of the Subcommittee's report should be broadly applicable to most vaccines.

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Dr. Douglas asked about the implications of links between vaccine misinformation and disinformation and other types of misinformation and disinformation. Dr. Dunn said one presenter laid out how easily misinformation and disinformation are spread through cross-promotion on social media with unrelated topics. Dr. Meissner added that according to several presenters, foreign actors, particularly from Russia and China, may deliberately spread disinformation to support an anti-vaccine movement.

Vaccine Confidence Consults—Neetu Abad, Ph.D., CDC

Dr. Abad said that although some populations are reliably fixed on one end of the vaccine acceptance/rejection spectrum, many people fall into the "movable middle," and efforts can focus on how to build confidence in vaccines among them. CDC's Vaccine Confidence Team aligns expertise in behavioral science, health communication, community engagement, and clinical care with its goal of promoting uptake of COVID-19 vaccine by conducting research and implementing activities in line with CDC's Vaccinate with Confidence framework. The framework rests on three pillars:

- **Build trust** by delivering clear, complete, accurate messages; taking visible steps to promote vaccination; and communicating transparently about processes for vaccine authorization and recommendations.
- **Empower health care providers** by increasing vaccine acceptance among providers and building their capacity for counseling patients about vaccination, engaging national professional associations to help disseminate good information.
- **Engage communities and individuals** in sustainable, equitable, inclusive ways to increase trust and build collaboration, acknowledging the role of peers and trusted messengers.

Dr. Abad outlined several Vaccine Confidence Team initiatives, including development of community partnerships, creation of communication toolkits, new data collection and assessment approaches, and efforts to provide targeted support on demand to States and jurisdictions. The team is developing a new rapid community assessment guide to assist State and local immunization program managers with better understanding community needs, such as which populations are disproportionately affected by COVID-19 vaccine and who is at risk for low uptake of COVID-19 vaccine. The guide will help users translate their findings into strategies for increasing vaccine confidence and uptake.

The Vaccine Confidence Team is also launching one-on-one consultations between vaccine experts and State and Territory immunization programs on how to address COVID-19 vaccine confidence. Through consultations, experts will diagnose barriers, provide guidance, share resources and tools, and link States and Territories to individuals and organizations with specialized expertise. Dr. Abad anticipated covering topics such as communicating effectively about COVID-19 vaccine, addressing misinformation, increasing health care providers' confidence in the vaccine and their capacity to counsel patients, and engaging community partners and trusted messengers. He noted that CDC welcomes experts to join the team of consultants. States and Territories are encouraged to contact CDC to talk about their needs.

Discussion

Dr. Meissner pointed out that it is difficult to assess vaccine hesitancy while the COVID-19 vaccine supply is inadequate, and Dr. Abad agreed. Dr. Abad said CDC surveys include questions about access to vaccine as a way to determine where individuals fall on the vaccine

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rejection/acceptance spectrum. CDC is considering using geomapping to identify whether hot spots are related to low access or hesitancy, on the basis of other data. Dr. Abad noted that triangulating data from multiple sources is important.

Experiences in the Field: Increasing Acceptance of COVID-19 Vaccination in Nursing Home Settings—Lee Fleisher, M.D., Centers for Medicare & Medicaid Services (CMS)

Dr. Fleisher reminded participants that nursing homes were on the leading edge of the COVID-19 pandemic. Declines in infections represented the effects of infection control interventions and the rollout of the vaccines. Vaccine uptake is critical to restoring normalcy in nursing homes and revising the current guidance that restricts visitors to nursing homes. Uptake varies, and CMS relies on data from pharmacies to assess the situation. Among residents, about 80 percent accepted the first vaccine dose. However, only about 38 percent of staff received the first dose, which is a cause for great concern, Dr. Fleisher noted.

CMS is engaged in a 3-month partnership to ensure that nursing home staff and residents have access to vaccine through specialty pharmacies. Once the partnership ends, nursing homes will have to seek vaccination through whatever mechanisms are available to the general community.

CMS hosts weekly virtual meetings with the long-term care community to provide information and respond to questions. Participants have expressed concerns about the safety of the vaccine given the rapid development. Nursing homes are often staffed by hourly workers, most of whom are people of color. In the weekly meetings, some indicated that they lacked personal protective equipment early in the pandemic and that they felt abandoned. As a result, now that they are prioritized for vaccination, some say they feel like guinea pigs. Others have raised questions that stem from misinformation about the vaccine. A number have asked whether the vaccine was studied in people who look like them. Another common question is how soon one can be vaccinated after COVID-19 infection.

Dr. Fleisher emphasized that many people are worried about becoming sick—either from the virus or the vaccine. Those who are concerned want to hear from people like them, not celebrities. In response, Dr. Fleisher said, his office has identified about 15 people who initially refused the vaccine but changed their minds. He hopes these "converters" will be help communicate about the vaccine. CMS has also engaged a group of behavioral psychologists on how to encourage people to teach each other about the benefits of COVID-19 vaccination.

Discussion

Dr. Hopkins noted that vaccine acceptance in nursing homes seems to be related to whether the local medical director advocates vaccination. Dr. Fleisher said some efforts have been made to communicate with medical directors, but their level of engagement and their influence vary widely across the country.

Dr. Douglas asked whether CMS is considering expanding the partnership to promote vaccination. Dr. Fleisher replied that CDC is working on numerous approaches, but it is up to the COVID-19 Task Force to determine whether to expand the partnership.

Molly Howell, M.P.H., suggested that CMS provide incentives and reimbursement to increase staff uptake. Dr. Fleisher responded by referring to CDC's visitation guidelines. Once more people are protected and rates of infection go down, the visitation guidelines will be revised accordingly.

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Exploring Incentives and Disincentives for COVID-19 Vaccination—Daniel Polsky, Ph.D., Johns Hopkins University

In the context of COVID-19, Dr. Polsky explained, young, healthy people have the least to gain from vaccination, because they are least susceptible to severe disease. Yet they are also the most likely to interact with others and spread the virus, so vaccinating them has the most "positive externality"—or benefit to others. Such a situation provides a natural justification for incentivizing individuals to get the vaccine.

One incentive, already endorsed by the Federal government, is subsidizing the cost of vaccine by ensuring that individuals pay no out-of-pocket costs. However, Dr. Polsky noted, it is not clear how long that subsidy will remain in place. Another approach is addressing nonmonetary costs—such as the time and effort involved in determining eligibility, ensuring access, and counseling individuals. Some have proposed paying people to get vaccinated, including partial payment at the time of vaccination and the rest when the community reaches an immunity threshold. Mandating vaccination is another mechanism, but it is difficult to implement.

Dr. Polsky said paying people to get vaccinated addresses one barrier but, from an economic perspective, the most effective use of resources is to invest only as much money as needed to reach a certain threshold. That raises questions about when to start offering a cash incentive. Furthermore, those who have already been vaccinated would not receive payment, creating tensions between fairness and efficiency.

Since the approval of the first COVID-19 vaccines in December 2020, the number of people who say they will get the vaccine as soon as it is available has increased. A number of people remain unsure, and that "wait-and-see" group should be the target of incentives, said Dr. Polsky. Black and Hispanic people are more likely than people of other races and ethnicities to remain uncertain, which underscores concerns about equity.

Reducing disincentives by tackling nonmonetary costs could be a more efficient and more equitable approach, Dr. Polsky stated. Those facing the greatest costs—such as barriers to access—are also the most likely to benefit from vaccination, and fixing systematic barriers could fix some of the ingrained inequities. However, Dr. Polsky added, the Patient Protection and Affordable Care Act reduced out-of-pocket costs for preventive services, but that did not result in increased uptake.

Discussion

Dr. Hopkins questioned whether paying people to get vaccinated poses a moral issue. Dr. Polsky noted that payment could have the unintended effect of signaling that something is wrong with the vaccine.

Dr. Meissner noted that mandates could also have the unintended effect of reducing uptake, because people dislike being told what to do. On the other hand, health insurers require smokers to pay higher premiums than nonsmokers, which could be a model for incentivizing vaccination. Dr. Polsky said vaccine mandates are difficult to impose, although they have been used in schools and some workplaces. He also noted that the Affordable Care Act prohibited insurers from basing premiums on preexisting conditions with the exception of tobacco use, so that model is worth observation.

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In response to Timothy Cooke, Ph.D., Dr. Polsky did not think that any jurisdiction in the world had implemented cash incentives for vaccination. Melody Anne Butler, B.S.N., RN, CIC, pointed out that Australia offers financial incentives to families who have their children vaccinated according to the approved schedule. She believed the United States could consider tax credits or insurance incentives. Ms. Butler asked how an incentive could be implemented without alienating those who cannot be vaccinated. Dr. Polsky said vaccine messaging has traditionally emphasized the benefits to others as well as the individual who is vaccinated, and the fact that such a message has not been at the forefront of perceptions about COVID-19 vaccine indicates that the campaign is already behind.

Dr. Polsky noted that the Federal investment in vaccine is time-limited. Eventually, the cost of vaccination will fall on insurance companies. He urged NVAC to think about incentives now, anticipating that the issue will become more prominent when the immediate crisis is past.

Public Comment

Virginia Bader, M.B.A., of Students Assist America said that the United States now has two authorized vaccines being administered and other viable candidates on the way. A number of governors are using trained students to help administer vaccines with supervision in their States. These are both positive steps, but they are not consistently applied across the country. The pandemic is revealing that a fragmented, patchwork approach to vaccination is creating inconsistent, inequitable, and unpredictable access to vaccines. Equally troubling, vaccine doses are going to waste because of a lack of planning and workforce. Ms. Bader said 11 associations and Students Assist America submitted to HHS a letter asking for a declaration under the Public Readiness and Emergency Preparedness Act to permit all students in the health professions who are trained to give intramuscular injections with supervision to do so. Students Assist America has access to more than 830,000 students who are already trained to give intramuscular injections or who can easily translate their method of injection to the deltoid muscle of the arm.

Students Assist America also has access to almost 150,000 additional students who stand ready to help with other, nonclinical aspects of the mass vaccination effort that are essential to an efficient roll-out. NVAC has discussed the need for consistent communication strategies about the importance and safety of COVID vaccines, and students can be essential to this effort, among others. The United States has implemented this approach for influenza vaccination efforts for decades and deployed students during the H1N1 influenza pandemic. The country needs a national, unified protocol for students to help during this unprecedented time. The nation is at war and needs to allow this group of students who are willing to volunteer to help their country, said Ms. Bader.

Wrap Up—Robert H. Hopkins Jr., M.D., MACP, FAAP, NVAC Chair

Dr. Hopkins thanked the participants and the OIDP staff and recessed the meeting at 5:26 p.m.

Day Two

Call to Order and Chair's Welcome—Robert H. Hopkins Jr., M.D., MACP, FAAP, NVAC Chair

The meeting resumed at 1:01 p.m. Dr. Hopkins summarized the proceedings of day one and gave an overview of the agenda for day two. He noted that as of Monday, February 8, more than 26

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million people in the United States had received a first COVID-19 vaccine dose and about 6 million had received a second dose.

COVID-19 Vaccine Safety Monitoring

CDC Advisory Committee on Immunization Practices (ACIP) COVID-19 Vaccine Safety Technical Subgroup (VaST)—Robert H. Hopkins Jr., M.D., MACP, FAAP

Dr. Hopkins, who co-chairs VaST, described the group's role in evaluating and interpreting COVID-19 vaccine data safety. In addition to NVAC and ACIP members, the group includes representatives and liaisons from various HHS agencies and other Federal departments. VaST considers active surveillance data from V-safe after-vaccination health checker, passive surveillance from the Vaccine Adverse Event Reporting System (VAERS) and VA's Adverse Drug Event Reporting System, and individual cases identified by CDC's Clinical Immunization Safety Assessment (CISA) project. As more data become available from larger databases, VaST will dig deeper into potential links between COVID-19 vaccine and adverse events.

VaST discussions have confirmed that well-established vaccine safety surveillance systems remain the cornerstone of COVID-19 vaccine safety monitoring in the United States, and novel approaches to surveillance have enriched understanding in the early phases of vaccine deployment.

Consistent with clinical trial data, local and systemic reactions are commonly reported following vaccination. Anaphylaxis following COVID-19 vaccination is being closely monitored; it is currently estimated to occur 2.8 to 5 times per million doses. In response, CDC has recommended screening for anaphylaxis risk, monitoring for symptoms after vaccination, and preparing for early recognition and management of anaphylaxis on site. Data from the United States and Europe suggest that reports of serious adverse events after vaccination are consistent with all-cause mortality rates, particularly in frail, elderly people.

COVID-19 Vaccine Safety Update—Tom Shimabukuro, M.D., M.P.H., M.B.A., CDC

Dr. Shimabukuro described surveillance systems that are capturing data on adverse events following immunization (AEFIs). V-safe is a smartphone app that links vaccinees to web-based surveys to monitor for adverse events for up to a year. It also helps identify women who were pregnant at the time of vaccination or became pregnant shortly after, some of whom have been enrolled in a pregnancy registry. Symptoms of vaccine reactogenicity are similar for Moderna and Pfizer vaccines. As observed during clinical trials, the second dose elicits substantially more reactions, which is a sign that the vaccine has induced a vigorous immune response.

VAERS is co-managed by CDC and FDA and rapidly detects potential safety signals and rare events. VAERS is best viewed as a mechanism for generating hypotheses for further investigation. Among the first 9,000 reports about COVID-19 vaccine, the median age of the individual vaccinated is 43 years, and 70 percent of events occurred among females, which might reflect the demographics of the U.S. health care workforce. About 45 serious events have been reported per one million doses, which is consistent with other adult vaccines. The types of events reported are consistent with those of clinical trial observations. FDA uses data mining techniques to identify disproportional adverse event reporting and has not yet detected adverse event–vaccine pairs reported at least twice as frequently as expected for a COVID-19 vaccine.

CISA's Project COVIDvax is a collaboration with seven medical research centers to address safety questions that are not otherwise addressed by guidelines. It has responded to 143 requests

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for consultation to date to evaluate complex medical issues and convened a working group to discuss cases of anaphylaxis, their mechanisms, and recommendations for management.

Dr. Shimabukuro described reports to VAERS of anaphylaxis following COVID-19 vaccination, noting that more than 80 percent of cases occurred in people with a history of allergies or allergic reactions. Most cases occurred after the first dose of the vaccine, which may be a function of timing, as relatively few people have had the second dose. Most incidents occurred within 25 minutes of vaccination, so CDC recommended a 30-minute observation period after vaccination for people with a history of allergies or allergic reactions. The rate of cases per million has decreased over time for the Pfizer vaccine (from 11 per million to 5 per million) and stayed relatively constant for the Moderna vaccine (at about 2.5 per million).

VAERS received 196 reports of deaths following vaccination, about one fifth in people under age 65 years and about two thirds among people living in long-term care facilities. Dr. Shimabukuro described the methodology for calculating the background mortality rate to put the reports in context and the processes for evaluating the potential cause of death. Most of the deaths among those living in long-term care facilities occurred in elderly people, one third of whom were in hospice care or had do-not-resuscitate or do-not-intubate orders. Data from a large database of 25,000 nursing home residents found that mortality rates were lower among those residents who were vaccinated.

Dr. Shimabukuro said analysis of all the available data suggests COVID-19 vaccination does not lead to excess deaths among long-term care residents. Similar evaluations are underway for deaths in people under age 65 who were not in long-term care. So far, most of those deaths have been attributed to cardiac issues, and one was related to COVID-19 infection. Dr. Shimabukuro concluded that the United States has implemented the most intense, comprehensive safety monitoring ever and the findings so far are consistent with clinical trial observations. Anaphylaxis is rare, and it does not appear that the vaccine is more harmful to older long-term care residents.

Rapid Cycle Analysis to Monitor the Safety of COVID-19 Vaccines in Near Real-Time within the Vaccine Safety Datalink (VSD)—Nicola Klein, M.D., Ph.D., Kaiser Permanente Vaccine Study Center

Dr. Klein said the VSD incorporates data from electronic health records (EHRs) of about 12.4 million people, and rapid cycle analysis of VSD information enhances the ability to detect rare AEFIs. She gave a detailed overview of a 3-year project to monitor the safety of COVID-19 vaccines in relation to predetermined outcomes. Investigators will compare the number of adverse events among vaccinees with the number of expected events in other groups of vaccinated and unvaccinated people. Various analytical approaches will be used to determine whether adverse events appear to be related to vaccination and will consider factors such as age, sex, race or ethnicity, geographic location, and prior COVID-19 infection.

Discussion

Dr. Jackson said people of color in her community have raised questions about the death of baseball legend Hank Aaron just weeks after he had received the COVID-19 vaccine. She asked for advice on better communicating about temporally related deaths. Dr. Hopkins agreed that messaging must take into account the concerns of the population targeted. Dr. Jackson said it is helpful to spell out the risks versus the benefits, reminding people that the virus is deadly, but more communication is needed.

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Dr. Martinez noted that four cases of Bell's palsy during the vaccine clinical trials were reported in the lay press. Dr. Klein said another four cases were identified after the vaccines were authorized for use in the public. Dr. Klein said the surveillance systems are monitoring for cases of Bell's palsy, and no alarming signals have arisen yet.

In response to Dr. Douglas, Dr. Shimabukuro detailed the procedure for analyzing deaths reported to VAERS, indicating that clinicians review medical charts, death certificates, autopsy reports, and automated data. They also rely on data mining to reveal unusual findings or patterns. He reiterated that there is no evidence of excess deaths that would raise concerns about the safety of the COVID-19 vaccine.

Dr. Meissner pointed out that among the general population, the rate of anaphylaxis is similar to that with influenza vaccine. He proposed eliminating the post-vaccination observation period for people whose history does not appear to increase the risk of anaphylaxis. Dr. Shimabukuro replied that the recommendations are based on VAERS reports, which are not sufficient to assess the impact of risk factors. He added that anaphylaxis can occur after any vaccination. Dr. Hopkins said he encourages recipients of any kind of vaccine to stay in the clinic afterward out of an abundance of caution.

Dr. Schecter wondered how often the VSD rapid cycle analysis would identify signals that could be expected to occur by chance. Dr. Klein said the threshold for detecting signals was set at a relatively stringent level.

Immunization Equity Subcommittee Update—Melody Anne Butler, B.S.N., RN, CIC, Co-Chair

Ms. Butler described the charge and membership of the Subcommittee, which recognizes that immunization equity is vital to the success of vaccination efforts, yet disparities, inequities, and inequality persist. The Subcommittee presented draft recommendations for NVAC input on the following topics:

> **Access:** Recommendations focus on expanding the capacity of pharmacists to deliver vaccines, highlighting best practices to improve vaccination rates in rural areas, and addressing barriers related to disability, language, and immigration status.
> **Affordability:** Recommendations propose creating a Vaccines for All program to provide routine vaccines at no cost, exploring other mechanisms to remove financial barriers, addressing current roadblocks, and studying the impact of financial coverage on vaccine uptake.
> **Knowledge and Awareness:** Recommendations advocate for improving vaccine education, communication, and health literacy among trainees and health care providers and working with professional and community organizations to expand education.
> **Attitudes, Beliefs, and Vaccine Acceptance:** Recommendations call for increased investment and research in 1) understanding vaccine attitudes and beliefs, 2) effective communication approaches for various audiences, and 3) evidence-based practice interventions.
> **Data Tracking and Reporting Infrastructure:** Recommendations call for funding to facilitate the use of immunization information systems (IIS) data for research and exploration of creating a national IIS identifier to enhance data sharing.

Discussion

FDA-CBER-2021-5762-00216

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Dr. Dunn appreciated that the Immunization Equity Subcommittee addressed a number of topics that were related to but beyond the scope of the Vaccine Confidence Subcommittee. He was pleased that the recommendations apply broadly and that they suggest the Federal government take a more assertive position. Ms. Butler said the Subcommittee members agreed that the piecemeal approach is not working, and it took a pandemic to illustrate why a strong immunization system is needed. Subcommittee members agreed that now is the right time to ask for these steps.

NVAC Liaison Updates

Vaccine and Related Biological Products Advisory Committee (VRBPAC)—Marion Gruber, Ph.D.

Dr. Gruber summarized VRBPAC's recent efforts on behalf of VRBPAC Chair Hana El Sahly, M.D., who recused herself from the NVAC meeting. At its October 2020 meeting, VRBPAC endorsed FDA's approach to evaluation of the safety and efficacy data for COVID-19 vaccines in development, expressing some concerns about the duration of follow-up monitoring of safety and efficacy. VRBPAC also discussed the underrepresentation of certain racial and ethnic groups in the studies underway and how to address pediatric populations. VRBPAC members debated how to preserve blinded follow-up of phase III trial participants and, if that is not possible, how the lack of blinding would affect the safety and efficacy data used to support vaccine approval.

At its December 10, 2020, meeting, VRBPAC discussed the data presented to FDA by Pfizer in support of its vaccine candidate. The overwhelming majority of members agreed that the benefits of the vaccine outweighed the risks, and FDA issued an EUA 24 hours later. VRBPAC again discussed the implications of the loss of blinding during follow-up, for which Pfizer had a plan. Members discussed how to get data on the impact of the vaccine on asymptomatic infection and viral shedding, potentially through studies to be conducted after EUA.

At the December 17, 2020, meeting, VRBPAC reviewed the data presented to FDA by Moderna in support of its vaccine candidate. It voted unanimously (with one abstention) in favor of the vaccine, and FDA issued an EUA. Members again raised questions about ongoing research design, expressing concerns that people would drop out of phase III trials and seek vaccination instead. VRBPAC proposed alternative designs and suggested that the company offer the vaccine to study participants who received a placebo (as they become eligible under CDC's guidelines for prioritization). Members also suggested other studies be conducted after EUA, such as dose-ranging studies in the elderly, how to help immunocompromised people, the effectiveness of a single dose (for two-dose regimens), and the potential for interchangeability of COVID-19 vaccines.

Advisory Commission on Childhood Vaccines (ACCV)—Mary Rubin, M.D.

At its December 3, 2020, meeting ACCV members received routine program updates from the HRSA Division of Injury Compensation Programs and the Department of Justice. An ACCV workgroup presented proposed language from the Vaccine Injury Compensation Program (VICP) statute of limitations to be added to vaccine information statements. Members voted three to one to approve adding the language, which describes the minimal timeframe for filing VICP claims. Invited stakeholders gave their input on the VICP's draft notice of proposed rulemaking, which proposes to amend the Vaccine Injury Table. ACCV received program updates from CDC, FDA, the National Institute of Allergy and Infectious Diseases, and OIDP. An ACCV member proposed that HHS initiate a study comparing health outcomes among vaccinated and unvaccinated populations, and CDC provided some background data on the issue. ACCV is seeking more input on the proposal in advance of its March 2020 meeting as it considers making a recommendation.

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AIM— Claire Hannan

AIM is helping members roll out their COVID-19 vaccination programs by providing opportunities to learn from each other through weekly updates, peer connections, meetups, and general membership calls. AIM is also offering webinars featuring vaccine manufacturers and vaccine hesitancy researchers, among others. It is participating with other COVID-19 efforts organized by the National Association Leadership Council on COVID-19 Vaccination, the Trust for America's Health, and the Ad Council, to name a few. AIM manages the Health Equity and Immunization Learning Hub for CDC's Racial and Ethnic Approaches to Community Health (REACH) project, which includes engaging specialists and subject matter experts to increase influenza vaccine uptake, and that effort will expand to include COVID-19 vaccine.

Through its partnership with the National Association of Community Health Centers, AIM wrote letters urging community health centers to use the influenza vaccine allotted to them and to prepare for COVID-19 vaccination. A collaboration among AIM, NACCHO, and the Johns Hopkins University Research Collaboration on increasing vaccine confidence will conduct focus groups to learn more about vaccine attitudes and beliefs and inform efforts to build trust. The information gathered will be shared with the Ad Council's initiative to increase confidence in the COVID-19 vaccine.

AIRA—Rebecca Coyle, M.S.Ed.

AIRA released two guidance documents on reporting priority populations and serologic testing. It is working on developing standards to record the information gathered. AIRA's measurement and improvement initiative was expanded to assess information needed for COVID-19 vaccines, and the organization created reports to show jurisdictions where they need to expand their reporting. In September, AIRA's cooperative agreement with CDC was extended to include the Immunization Integration Program, which brings together key stakeholders with expertise in IIS, public health, and EHRs. The goal is to work together to solve interoperability issues, beginning with the transport of information from the EHR to an IIS. Ms. Coyle said States have expressed a lot of interest in how AIRA can help them analyze and visualize their data.

APhA—Jean-Venable "Kelly" Goode, Pharm.D.

Dr. Goode said APhA continues to focus on providing training, education, information, and resources on vaccines, and COVID-19 vaccine in particular. It is partnering with ASTHO and CDC on immunization guidance for pharmacies and their staff. In early January 2020, an APhA survey indicated that most pharmacists plan to get the COVID-19 vaccine, and 50 percent had already received the first dose. Also, 98 percent said they were comfortable addressing patients' concerns, and 79 percent felt they were adequately staffed to administer the vaccine.

ASTHO—Kimberly Martin

ASTHO continues to support its members through situational awareness, technical assistance, information sharing, and resource development. It holds calls twice a week and publishes a daily newsletter with updated information from briefings. ASTHO regularly coordinates with Federal, State, and Territorial partners. It is developing materials to help increase vaccine confidence. The organization hopes to convene State health equity leaders, public health immunization program managers, and community stakeholders to identify best practices for increasing immunization uptake within diverse communities. ASTHO is working with HHS' Office of the National Coordinator for Health Information Technology, AIM, and AIRA to expand health information sharing to help public health agencies identify people who need a second vaccine dose and those at high risk who still need to be vaccinated.

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NACCHO—John Douglas, M.D.

NACCHO accepted nominations for its 2021 Model Practices Awards for excellence among local health departments, and one award this year focuses specifically on work around the COVID-19 pandemic. Winners will be announced at the organization's annual conference, to be held virtually from June 29 to July 1, 2021. NACCHO's Immunization Workgroup named new co-chairs and launched an initiative to increase vaccine confidence. NACCHO selected three local health departments to participate in intensive technical assistance to address vaccine hesitancy. On the advocacy front, NACHHO sent letters to Congress and the administration about several immunization and vaccine issues, including equitable access to COVID-19 vaccine. It is educating members about the vaccine through a host of webinars; two webinars addressed vaccine equity, and one discussed vaccine confidence.

Federal Agency Updates

BARDA—Linda Lambert, Ph.D.

BARDA continues to work closely with interagency partners to develop safe and effective vaccines for COVID-19, including advanced development and manufacturing of six vaccine candidates. BARDA's dedicated CoronaWatch portal on its website allows developers to request a meeting with BARDA and its partners. BARDA supported late-stage development of Merck's single-dose Ebola vaccine, which was approved by FDA in December 2019. Efforts are underway to gather data to support its use in pediatric populations and among people living with HIV. BARDA is supporting a phase I clinical study of Takeda's purified, inactivated, adjuvanted Zika vaccine.

DoD—Margaret Ryan, M.D.

DoD's COVID-19 vaccine implementation plan encompasses Active Duty, U.S. Coast Guard, Reserve, and National Guard personnel, in addition to retirees, beneficiaries, and others authorized to receive COVID-19 vaccine from DoD. This population of approximately 11.1 million people will be offered the COVID-19 vaccine in a phased approach that closely aligns with CDC recommendations. Vaccinations within DoD began December 14, 2020, and were rolled out in phases. If COVID-19 vaccines receive full licensure, DoD may consider making the COVID-19 vaccine a requirement, similar to influenza vaccine.

As of January 30, 2020, DoD has administered more than 500,000 COVID-19 vaccines at more than 300 immunization sites globally. The vast majority of immunization sites are well into phase 1B, which includes critical national capabilities, those preparing to deploy, and people who are 75 years of age or older. The Defense Health Agency engages with its beneficiary population through articles, videos, social media updates, graphic packages, communications tool kits, briefings, websites, town halls, community calls, and various social media platforms both inside and outside the military health system.

The vast majority of AEFIs reported have been expected side effects. DoD is monitoring VAERS reports and participating in CDC's VaST. The Defense Health Agency offers its own clinical call center for vaccine-related issues, which identifies some adverse events. Vaccine loss through reported temperature excursions or deviation from procedure has been exceedingly low to date: less than 0.03 percent. DoD eagerly anticipates additional COVID-19 vaccine candidates to be added to the portfolio to increase availability and access to vaccine worldwide.

FDA—Valerie Marshall, M.P.H.

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Ms. Marshall reiterated that FDA gave EUAs for the Pfizer and Moderna COVID-19 vaccines in December 2020. On February 26, 2020, VRBPAC will meet to discuss Janssen Biotech's request for approval of its vaccine candidate. FDA is working on multiple fronts to address the COVID-19 pandemic.

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HRSA—Mary Rubin, M.D.

Dr. Rubin said HRSA's Bureau of Primary Health Care awarded more than $2 billion to health centers for COVID-19 testing, contact tracing, vaccine development and distribution, and treatment. As of January 15, 2020, HRSA health centers had conducted more than 8 million tests and administered nearly 88,000 vaccines. The pandemic led to alarming declines in well-child visits and routine immunizations. In August 2020, HRSA urged health centers and health care providers to increase childhood immunization rates and improve access to immunization.

As of January 1, 2021, petitioners had filed 526 claims with the VICP, and $78 million was awarded to petitioners, including attorneys' fees and costs. As of January 11, 2021, HRSA had a backlog of 1,067 VICP claims alleging vaccine injury awaiting review. As of December 1, 2020, the Countermeasures Injury Compensation Program (CICP) determined that 39 claims were eligible for compensation totaling $6 million.

The HHS Secretary issued a Marburgvirus and Marburg disease declaration effective November 25, 2020, which provides liability immunity for the manufacture, testing, development, distribution, administration, and use of the covered countermeasures. The declaration permits individuals seriously injured by covered countermeasures to file a claim with the CICP.

IHS—Uzo Chukwuma

Ms. Chukwuma reported that IHS partners with various stakeholders to increase the vaccination rate among IHS populations. Data from the IHS influenza surveillance system for the 2020–2021 influenza season indicate more than 207,000 doses of influenza vaccine have been administered to date, with overall population coverage at 28.9 percent. Vaccination uptake was highest among the most vulnerable populations, specifically young children and elderly people.

During the COVID-19 pandemic, American Indian/Alaska Native early childhood immunization coverage has slightly decreased, but adolescent immunization coverage has remained stable. Specifically, immunization coverage among 2-year-olds slightly decreased from 64.7 percent after December 2019 to 60.6 percent at the end of March 2020. Immunization coverage rebounded to 63.6 percent by the end of September 2020. IHS has engaged in various initiatives to promote routine and catch-up immunizations during the COVID-19 pandemic, including hosting various webinars, sharing CDC and HHS communication and education materials, and disseminating provider resources and toolkits on childhood immunizations. IHS also promoted the HHS Catch Up to Get Ahead childhood immunization campaign's materials and toolkits, and it conducted a survey to assess childhood and adolescent immunization coverage before and during the campaign. Analysis of survey results is currently being performed.

IHS established a COVID Vaccine Task Force in September 2020 to finalize development of agency-wide planning for COVID-19 vaccine allocation, distribution, and administration within IHS, Tribal, and Urban Indian Health Facilities receiving vaccine from the IHS. IHS continues to work with CDC and other HHS agencies to track COVID-19 vaccine distribution and administration data.

Written updates only were provided by AHIP, AHRQ, CDC, the Public Health Agency of Canada, and VA.

Building Trust in and Access to a COVID-19 Vaccine Among People of Color and Tribal Nations: A Framework for Action—J. Nadine Gracia, M.D., M.S.C.E., Trust for America's Health

Obtained via FOIA by Judicial Watch, Inc.

Dr. Gracia outlined the framework being spearheaded by the Trust in partnership with the National Medical Association and UnidosUS. The framework emerged from a convening of 40 organizations to craft policies to ensure access to COVID-19 vaccines in communities at high risk of disease because of racism and inequities. The underlying principles of the framework wemphasize agency, transparency, relevancy, and accountability. Dr. Gracia summarized policy recommendations under each of the following six areas:

1. **Ensure scientific fidelity of vaccine development process** through diversity among trial participants and transparency of clinical trial data released.
2. **Equip and fund trusted community organizations**, acknowledging that these organizations often lack the resources needed to do the work.
3. **Communicate needed information through trusted messengers** at local, State, and national levels, with materials that are culturally and linguistically appropriate, and through mechanisms tailored to the community.
4. **Make it easy for people to be vaccinated** by placing vaccine sites in communities disproportionately affected by the disease and allowing flexibility in funding to address barriers such as transportation and fears of immigration enforcement.
5. **Ensure complete coverage of costs associated with the vaccine**, including administrative costs.
6. **Fund and require disaggregated data collection and reporting**, so that data are available to inform decision-making.

Critical actions to achieve these goals include overcoming the challenges to collecting disaggregated data by race and ethnicity. Fewer than half of States report these and other key demographic data that would help tailor resource targeting. The lack of data can exacerbate inequities. It is also necessary to ensure that people of color and Tribal nations have resources to address the pandemic and that public agencies at all levels are held accountable for equity.

Discussion

David Fleming, M.D., wondered how systems could be incentivized to ensure vaccine is available to all who need it. Dr. Hopkins said incentives might be helpful, as would filling the gaps that lead to inequities.

Dr. Douglas asked for more detail on the barriers to data disaggregation. Dr. Gracia said State and local health departments receive data from various sources, not all of which report race and ethnicity. Some health departments use archaic data systems, making it difficult to communicate data across systems. These problems reflect the broader issue of underfunding of public health. During the pandemic, some localities have required data collection, resulting in some improvement. Modernizing data collection methods and gathering more demographic information are important to address a number of outcomes, not just those related to public health emergencies, Dr. Gracia concluded.

A New National Strategy for Vaccination—David Kim, M.D., Division of Vaccines, OIDP, HHS

Dr. Kim explained that the new 5-year strategic plan builds on the 2010 National Vaccine Plan and its corresponding midcourse reviews as well as the 2016 National Adult Immunization Plan. Development was guided by an interagency working group informed by vaccine experts representing numerous perspectives as well as public input. The plan addresses vaccination across the life span. It was limited to 5 years in recognition of how rapidly the field is moving forward.

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OIDP released the National Strategy for Vaccination around the same time as it released new national strategic plans for HIV, sexually transmitted infections, and viral hepatitis.

Dr. Kim described the five overarching goals of the plan and summarized the objectives for each:

1. Foster innovation in vaccine development and related technologies.
2. Maintain the highest levels of vaccine safety.
3. Increase confidence in vaccines.
4. Increase access to vaccines.
5. Support global immunization efforts.

The strategy outlines 10 national indicators for assessing progress toward the goals and objectives, drawing on data routinely collected already. Five of the indicators focus on children (including one for adolescents), four address adults (including one for pregnant women and one for older people), and one—for influenza immunization—looks at all ages. Dr. Kim noted that OIDP is developing an implementation plan to advance the strategy.

Discussion

Dr. Cooke asked whether HHS had enough capacity to implement the strategy now that the National Vaccine Program Office has been folded into OIDP. Dr. Kim responded that the OIDP Division of Vaccines took on the work of the National Vaccine Program Office. He added that the strategy aligns with OIDP's approach to addressing infectious diseases.

Public Comment

Glen Hazlewood, M.D., Ph.D., of the Canadian Rheumatology Association noted that patients who have autoimmune diseases were excluded from the major clinical trials of COVID-19 vaccine. He asked when efficacy and safety data would be available for patients with autoimmune diseases. Specifically, he and his colleagues are interested in serious adverse events, autoimmune adverse events, and, in particular, the controlled data from the VaST analyses.

Theresa Wrangham, executive director of the National Vaccine Information Center, said her organization supports every individual's right to make voluntary, informed vaccine decisions, without sanction, and the public's access to vaccines, but it is against vaccine mandates that do not provide flexible exemptions. NVAC's discussion of incentives to promote vaccination raises many concerns. She voiced a concern about privacy and security associated with EHRs and IIS, which house sensitive medical information belonging to individuals, and think that written permission should be sought before their use. She also expressed concern for mandates and expressed the need for informed consent.

The National Vaccine Information Center also has concern about a lack of funding for high-quality research, and noted that this was echoed by Dr. Dan Salmon in his November 2019 remarks to NVAC. He also noted the importance of including those with safety concerns into stakeholder efforts and policy-making to address these concerns. Ms. Wrangham would like to see more NVAC activities include these voices, as well as those who opt out of one or more vaccines and to address the public's concerns to increase trust and decrease hesitancy. She asked NVAC to consider how vaccine hesitancy and uptake have been affected by informed consent.

Wrap Up and Adjournment—Robert H. Hopkins Jr., M.D., MACP, FAAP, NVAC Chair

Dr. Hopkins thanked the participants and the NVPO staff and adjourned the meeting at 4:11 p.m.

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APPENDIX: Abbreviations

ACCV	Advisory Commission on Childhood Vaccines
ACIP	Advisory Committee on Immunization Practices
AEFIs	adverse events following immunization
AHIP	America's Health Insurance Plans
AHRQ	Agency for Healthcare Research and Quality
AIM	Association of Immunization Managers
AIRA	American Immunization Registry Association
AMR	antimicrobial resistance
APhA	American Pharmacists Association
ASH	Assistant Secretary for Health
ASTHO	Association of State and Territorial Health Officials
BARDA	Biomedical Advanced Research and Development Authority
CDC	Centers for Disease Control and Prevention
CICP	Countermeasures Injury Compensation Program
CISA	Clinical Immunization Safety Assessment
CMS	Centers for Medicare & Medicaid Services
COVID-19	coronavirus disease (2019)
DoD	Department of Defense
EHR	electronic health record
EUA	emergency use authorization
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
HRSA	Health Resources and Services Administration
IHS	Indian Health Service
IIS	immunization information systems
NACCHO	National Association of County and City Health Officials
NIH	National Institutes of Health
NSAIDs	nonsteroidal anti-inflammatory drugs
NVAC	National Vaccine Advisory Committee
OIDP	Office of Infectious Disease and HIV/AIDS Policy
SIRVA	shoulder injury related to vaccine administration
USDA	U.S. Department of Agriculture
VA	U.S. Department of Veterans Affairs
VAERS	Vaccine Adverse Event Reporting System
VaST	Vaccine Safety Technical Subgroup
VICP	Vaccine Injury Compensation Program
VRBPAC	Vaccine and Related Biological Products Advisory Committee
VSD	Vaccine Safety Datalink
WHO	World Health Organization

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NVAC | NATIONAL VACCINE ADVISORY COMMITTEE

Advancing Immunization Equity: Recommendations from the National Vaccine Advisory Committee

Draft Report: Last Updated on May 24, 2021
Predecisional | DO NOT SHARE

DRAFT

INTRODUCTION

Immunization inequity contributes to negative health outcomes for both individuals and the population as a whole. Equitable immunization systems not only prevent potentially devastating vaccine-preventable illnesses, but also generate health more broadly by attracting people, including marginalized populations, into healthcare to improve other health inequalities. While longstanding inequities in vaccination persist, immunization equity is a requirement of an optimized vaccination system. The COVID-19 pandemic, for instance, has amplified the existence and impact of health disparities, inequities and inequalities in the United States.

People from marginalized and disadvantaged populations, as well as indigenous, institutionalized, homeless and incarcerated people have higher morbidity and mortality rates from COVID-19 than White people,[i] and these inequities not only impact individuals of those populations but also the overall health of the nation. The COVID-19 pandemic illustrates the importance of protecting everyone to stop the spread of disease, but widespread immunization inequity is a longstanding and persistent plague to immunization uptake for almost all recommended vaccines.

For example, recent data indicate the following:

- Black, Hispanic, and Asian adults have lower vaccination rates than Whites for all recommended adult vaccines.[ii] Inequities for childhood vaccines exist but are far less dramatic.

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- Rural adolescents are less likely to receive human papillomavirus (HPV) or meningococcal conjugate vaccines than those living in urban areas.[iii]
- Adults with health insurance have vaccination rates two to five times higher than people without health insurance for influenza, shingles, HPV, and other diseases.[iv]
- Black and Hispanic health care professionals (HCPs) have lower vaccination rates than White HCPs for influenza, hepatitis B, and tetanus, diphtheria, and pertussis (combined Tdap vaccine).[v]
- Beyond racial, ethnic, and geographic disparities, disparities also exist for other vulnerable populations, such as people with disabilities[vi] and those who are homeless.[vii]

The National Vaccine Advisory Committee (NVAC) believes these and other disparities are a result of underlying systemic barriers and biases that persist as a result of lack of access to immunization, unaffordability, and other system, policy and environmental barriers that result in differential receipt of vaccinations. Shortcomings in data reporting also influence immunization inequity. Current data allows for some understanding of disparities, but more robust data would drive a deeper awareness, a clearer understanding of the scope and complexity of the problem and an effective plan to address the issues. For example, current measurements of vaccine coverage do not disaggregate data for many meaningful sub-populations (e.g., distinct Asian-American sub-populations, institutionalized or incarcerated persons, or homeless people).

This report offers recommendations to address challenges to achieving equity in immunization and other system, policy and environmental barriers that result in differential receipt of vaccinations and refers specifically to vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) for use in the United States for routine preventive care. While the NVAC fully supports immunization equity, it has not previously developed a report devoted to best practices to promote equity and eliminate disparities in vaccination in the United States. Over the years, the NVAC has written a number of recommendations to improve immunization

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equity or reduce disparities in vaccination. Table 1 provides an overview of selected NVAC recommendations related to immunization equity, and this report builds on these recommendations as well as other efforts to decrease disparities in immunization rates.

The Vaccines for Children (VFC) program, for instance, has changed the landscape of childhood immunization, and the United States has made great strides toward immunization equity for children as a result. The program provides vaccines at no cost to eligible children through 18 years of age (approximately 50 percent of U.S. children). With the removal of cost barriers, childhood disparities in immunization have diminished markedly since 1994[viii] with some regional gaps in coverage and hesitancy[ix]. Additionally, with the passage of the Affordable Care Act (ACA), historic gains in the coverage of both children and adults has improved access to routinely recommended vaccinations for those covered by a non-grandfathered, private insurance plan and those covered by Medicare and Medicaid. These historic gains in coverage helped to close the gap in immunization inequity, but work is still needed to close the gap in immunization inequities.

Table 1. Select NVAC Guidance from Previous Reports Related to Immunization Equity

Guidance Summary	Report	Date
Recommendations 1 and 2 focused on the expansion of the VFC and improving vaccine administration reimbursement in VFC.	*Assuring Vaccination of Children and Adolescents without Financial Barriers*	Approved September 16, 2008
Opportunity Area 3 focused on eliminating financial and systems barriers for providers and consumers to facilitate access to routinely recommended vaccines.	*Evaluation of the 2010 National Vaccine Plan Mid-course Review*	Approved February, 2017
Acknowledged women, especially pregnant women, were underrepresented in vaccine research trials.	*Overcoming Barriers and Identifying Opportunities for Developing Maternal Immunizations*	Approved September 20, 2016
Recognized that disparities exist between public and private payers and found access issues with some groups more likely to be vaccinated than others. This report called for more diverse communications, including using new technologies. Recommendation 2.1 recommended "support vaccine administration as a routine standard of practice." Recommendation 3	*Reducing Patient and Provider Barriers to Maternal Immunizations*	Approved June 11, 2014

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Guidance Summary	Report	Date
recommended the ASH "focus efforts to improve financing for immunization services during pregnancy and postpartum.		
Documented several racial/ethnic, geographic and socioeconomic disparities. Focus area 4 centered on meeting the needs of rural providers.	*Strengthening the Effectiveness of National, State, and Local Efforts to Improve HPV Vaccination Coverage in the United States*	June 25, 2018

IMMUNIZATION EQUITY AND RELATED TERMS

Although the term *disparities* is often interpreted to mean racial or ethnic disparities, many dimensions of disparity exist in the United States, particularly in health. If a health outcome is seen to a greater or lesser extent between populations, there is disparity. Race or ethnicity,* sex, sexual identity, age, disability, socioeconomic status, and geographic location all influence the likelihood of achieving good health.[x] *Equity* is the absence of avoidable, unfair, or remediable differences among groups of people, whether those groups are defined socially, economically, demographically, geographically, or by other means of stratification. The goal of *health equity*, therefore, is that all people should have a fair opportunity to attain their full health potential,[xi,xii] including access to and receipt of vaccinations.

In terms of immunization, an effective system must be optimized so it is equitable and avoids differences in immunization coverage between groups by addressing policies, structures, governance, communication efforts and vaccination program implementation and evaluation. This optimization will be achieved by addressing systemic issues, vaccine access, and the *social determinants of health*—the underlying conditions in which people are born, grow, live, play, worship, work and age[xiii].

CHARGE

Health inequity is a complex problem that requires creative, responsive, collaborative, interprofessional approaches that must be sustained over time. The Assistant Secretary for

* Race and ethnicity are self-reported constructs.

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Health (ASH) charged the National Vaccine Advisory Committee (NVAC) on March 25, 2019, with developing a report with recommendations to build a foundation for an effective national strategy to end immunization inequities in the United States. To assist with this effort, the NVAC established the Immunization Equity Subcommittee to 1) deliver a set of system-wide recommendations for overcoming drivers of immunization disparities and reducing gaps in coverage that will provide the foundation for development of a collaborative immunization equity strategy and 2) review and summarize the complex and interrelated factors that contribute to vaccination disparities such as access, affordability, awareness, acceptance, and activation.

PROCESS

In response to this charge, the NVAC established the Immunization Equity Subcommittee, which was composed of NVAC members and several individuals not currently serving on the committee with relevant expertise. A number of additional experts presented their work to the subcommittee and the full committee to support the findings and recommendations in this report. The subcommittee worked together to reach consensus on all of the recommendations in this report in both group meetings and over email discussions and in final reviews of various parts of this report as well as the full report. Table 2 lists the experts who presented in support of this report.

Table 2. Invited speakers and panel presentations given during the NVAC meetings or Immunization Equity Subcommittee meetings

Topic	Date	Speaker(s)
Adult Disparities in Vaccination Coverage	8/20/2019	Megan C. Lindley
Vaccination Hesitancy, Confidence and Immunization Disparities	9/9/2019	Glen Nowak
Immunization Equity among Diverse Populations	9/9/2019	Paula M. Frew
Vaccine Equity Literature Review	9/18/2019	Melissa Martinez
Health Literacy and Immunization	9/18/2019	Melissa G. French
Collaboration for Vaccine Education and Research	10/8/2019	Barbara Pahud

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Topic	Date	Speaker(s)
Vaccine Financing	10/8/2019	Angela K. Shen
Disparities in Immunizations in Rural Health Areas	10/21/2019	Paul Moore
Pharmacists: Access to Vaccinations and Addressing Disparities	10/21/2019	Mitchel C. Rothholz
Vaccination Coverage among U.S. Children and Adolescents	11/5/2019	Tanja Y. Walker
Vaccines for Children Program and Disparities	11/5/2019	Cindy Weinbaum
Using an IIS for Identifying Populations At Risk	11/18/2019	Rebecca Coyle
IIS to Evaluate Health Equity	11/18/2019	Miriam Muscoplat
Seasonal Influenza on Latino Adults	12/16/2019	Elena Rios
Factors Leading to Ethnic Disparities in Access to Adult Vaccines	12/16/2019	Sonja S. Hutchins
Medicare vs Medicaid: Vaccines, State Flexibility, State Options, HEDIS Measures	1/14/2020	Jeffrey Kelman, Mary Beth Hance
Medicaid Vaccination Services for Pregnant Women	1/14/2020	Charleigh Granade
Immunization Disparities among American Indian/Alaska Native People	1/14/2020	Jillian Doss-Walker
Maternal Immunizations	1/27/2020	Laura E. Riley
Health Insurance Providers are Addressing the Social Determinants of Health	2/11/2020	Chris Regal
Vaccinate your Family: the Next Generation of Every Child by Two	2/11/2020	Amy Pisani
Immunization Equity Summary	3/10/2020	Alan Hinman

Several times over the course of writing the report the subcommittee presented progress to the full committee during public meetings. This report was also shared with the full committee once for comments during the development process and again, once finalized, before the vote to approve the report. The NVAC approved this report on June 16, 2021.

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ACCESS

Gaining access to vaccines can be complex and driven by multiple factors, such as financial or system barriers that impede a patients ability to get vaccinated and providers ability to give vaccinations. Geography also plays a notable role in access. In general, vaccination rates are

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higher in urban than rural areas[xiv,xv, xvi, xvii, xviii]. In rural areas, even insured patients may face barriers to access, because they may live a considerable distance away from their closest in-network healthcare provider. Likewise, certain populations—such as some undocumented immigrants, those experiencing homelessness, incarceration, or those housed in long-term care facilities or who are homebound—face substantial barriers to access and are considered particularly hard to reach through routine care.[xix] People who are vaccine-hesitant are also less likely than others to obtain routine vaccinations.

Vaccines may be available at physicians' offices, some local health departments, and pharmacies,[xx, xxi, xxii, xxiii, xxiv, xxv, xxvi] as well as through community dissemination mechanisms (e.g., schools, prisons, drive-through immunization clinics, mobile health units, community health centers, churches, shelters, and senior centers)[xxvii, xxviii]. Individual and community efforts have met with success and serve as examples. Nonetheless an evidence-based comprehensive and coordinated plan is needed.

The most common point of access for vaccinations is a primary care provider, yet approximately 20 percent of Americans (23 percent of Whites, 31 percent of Blacks, 47 percent of Hispanics) have no primary care provider, and younger adults are less likely than older adults to visit one. Some people are more likely to visit a medical subspecialist than a primary care provider and perceive the subspecialist as their provider of routine care. Few subspecialty providers stock vaccines. Even some specialties that are considered primary care providers, such as obstetrician-gynecologists,[xxix] do not always offer the full range of ACIP-recommended vaccines for their patients.

Even access to a primary care provider does not guarantee access to immunization. Among family physicians and internists, for example, only 27 percent stock all adult vaccines, in part because of the cost of stocking vaccines and the need for appropriate storage equipment.[xxx, xxxi] Although vaccinations are increasingly available at community-based pharmacies, some rural areas and low-income urban areas[xxxii] do not have access to pharmacies that provide vaccines.

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In 2013, the NVAC's *Updated Standards for Adult Immunization Practice* stated, "Every clinician, in all settings, has a fundamental responsibility in ensuring that all patients are up-to-date with respect to recommended immunizations."[xxxiii] The NVAC further recommended that all healthcare professionals should assess patients' vaccine needs, strongly recommend needed vaccines, and either provide the vaccines or refer patients to a provider who immunizes.

Recommendation 1.1: The Department of Health and Human Services (HHS) should work with state immunization programs, who are responsible for the VFC program, to increase collaboration with pharmacies by facilitating pharmacies' participation in VFC, especially in rural areas where pharmacists are among the few accessible immunization providers. An amendment to the Public Readiness and Emergency Preparedness Act (PREP Act) provided authority to pharmacists and certain pharmacy interns to order and administer vaccines to children ages three through 18 years, under several requirements during the current public health emergency. NVAC recommends this practice continues to allow for greater flexibility to immunize children when the medical home is not being utilized.

Recommendation 1.2: HHS should develop model legislative language about the provision of immunizations by pharmacists and provide it to states to make it easier for them to change or add in language to state pharmacist vaccination laws.

Recommendation 1.3: To address access to providers in rural areas, the ASH should work with public and private groups to highlight best practices and promising community approaches for improving vaccination rates. As part of this effort, the ASH should highlight evidence-based approaches to increase access by removing or decreasing financial concerns or transportation issues. The ASH and the HHS Office of the National Coordinator for Health Information Technology should work with the Centers for Disease Control and Prevention (CDC), public and private groups to develop an actionable guide to use immunization information systems (IIS) and geomapping to determine the extent of vaccine deserts (in rural

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and urban areas), track immunization rates in hard-to-reach populations, and assess efforts to overcome access barriers. The guide should be presented to NVAC for review and approval within the next two years before it is published and disseminated to immunization stakeholders.

The NVAC recommends the ASH work with medical, dental, and other provider groups to promote vaccines for all patients by all specialties, even among healthcare professionals who do not administer vaccines. The NVAC standards for immunization practice can be used to provide a rationale and a 4-step process for all healthcare professionals to ensure their patients are fully immunized.

Recommendation 1.4: To address access issues relative to disability, language, and immigration status, the ASH should work with public and private groups to develop guidance for providers on ways to reduce these barriers and evaluate the impact of these activities.

AFFORDABILITY

Access to vaccines is closely tied to affordability. Despite the availability of the VFC program and the vaccine coverage legislated by the Patient Protection and Affordable Care Act (ACA), disparities based on insurance status persist. Concerns have been raised about the VFC program, such as its administrative and logistical burdens for providers (e.g., regulations dictating that providers separate VFC vaccine from other vaccine stocks), missed opportunities for immunization due to delays in vaccine delivery, and delayed vaccine administration due to issues maintaining stored vaccine temperature. These concerns may prevent some healthcare providers from taking part in the VFC program, thus decreasing patients' access to an affordable immunization option.

Medicare does not cover all vaccines as a medical benefit.[xxxiv] Vaccines that are covered as a pharmacy benefit rather than a medical benefit, such as the shingles vaccine, are less likely to be stocked at provider clinics and more likely to require a copay, resulting in income-associated

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disparities in vaccination rates.[xxxv] In addition, Medicaid coverage of ACIP-recommended vaccines for adults varies by state, with mandatory coverage of ACIP-recommended vaccines for the Medicaid expansion population and children. In addition, states have flexibility to set Medicaid reimbursement rates. As a result, many adult Medicaid beneficiaries do not have access to all of the ACIP-recommended vaccines for adults.[xxxvi]

For providers, the costs of administering vaccines includes the financial burdens of vaccine purchase, storage, and vaccine insurance, as well as the time required for counseling patients and administering vaccine.[xxxvii, xxxviii] In addition, all vaccination providers must invest time and money in recordkeeping, maintaining reminder/recall systems, and IIS reporting. The costs of vaccines and related supplies are also increasing,[xxxix, xl] and providers must pay for them upfront and await reimbursement, which varies considerably by insurer. As such, the financial burden on providers can diminish patients' access.

Recommendation 2.1: A Vaccines for All program should be created and operated in parallel with the VFC program to provide vaccines at no cost to the recipient, so that all financial barriers to ACIP-recommended, routine vaccines are removed. Payment to healthcare professionals should include adequate reimbursement for administration and counseling. To address the cost to practices of stocking vaccines, the ASH, in collaboration with CMS, should work with vaccine suppliers, payers, and professional organizations to ensure that HCPs receive adequate compensation for vaccinating in their clinical settings. This program should also ensure that all Medicare and Medicaid beneficiairies have access to all ACIP-recommended vaccines at no additional cost to beneficiaries.

Recommendation 2.2*:* The ASH should convene a meeting and report findings from this meeting to explore the development of a system that removes all financial barriers to ACIP-recommended, routine vaccines for people of all ages.

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Recommendation 2.3: The CDC and CMS should convene a series of meetings with VFC providers and state program managers to listen to concerns regarding the delivery of vaccines and other program policy issues, and then develop a plan to address the findings.

Recommendation 2.4: The ASH should work with the CDC and other appropriate agencies to study how financial coverage of vaccines impacts vaccination rates and health outcomes and report these findings to the NVAC.

KNOWLEDGE AND AWARENESS

Provider recommendations are key to vaccine uptake.[xli, xlii] Given the rapid rate of new vaccine development and changes in vaccine recommendations, not all providers are knowledgeable about vaccines and vaccine recommendations across the lifespan.[xliii, xliv] Medical providers—including physicians, nurses, advanced practice providers, and pharmacists—vary in their training and may have knowledge gaps regarding vaccines and their importance. Moreover, as the pace of vaccine development has increased and the evidence about their use has expanded, the complexity of ACIP recommendations has increased as well, which further complicates the already nuanced process of shared decision-making between healthcare professionals and patients.

Young physicians are less likely to champion vaccines, partly because they lack personal experience with vaccine-preventable diseases and partly because they lack confidence in providing information about vaccine safety and risks.[xlv] There is no standardized vaccine curriculum in medical, nursing, or dental schools, and most involve only a few hours of learning on the topic. Immunizations might be covered in didactic sessions during primary care (family medicine, internal medicine and pediatric) residencies or in fellowships. Even infectious disease specialty education has no standardized curriculum about vaccines. The online curriculum created by the multidisciplinary Collaboration for Vaccine Education and Research was deemed to increase residents' confidence in discussing vaccines with parents and patients.[xlvi]

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Recommendation 3.1: The ASH should work with appropriate governmental and private agencies to ensure an emphasis on vaccine education, communication, and health literacy during training, particularly during postgraduate and in-service training with the goal of improving immunization equity. For example, the ASH should consider working with CDC to develop a model of interdisciplinary vaccine education, building on the foundation created by CDC's Epidemiology and Prevention of Vaccine-Preventable Diseases (a.k.a., the Pink Book),[xlvii] which is linked to free online continuing education opportunities. Currently, more training is needed on vaccines in general, as well as communication strategies for professionals working in immunization settings to discuss vaccination and make a strong recommendation for it. Additionally professionals need more training to recognize inequities and disparities and create solutions to resolve this issues.

Recommendation 3.2: The CDC should develop online training about best practices for providers already in the field, including addressing health literacy, addressing unconscious or perceived bias and instituting diversity training, and incorporating successful practice-level interventions (e.g., making strong vaccine recommendations and using motivational interviewing in practice).

Recommendation 3.3: The CDC should continue to work with professional associations and community and voluntary organizations to provide ongoing education about immunization to their members.

ATTITUDES, BELIEFS, AND VACCINE ACCEPTANCE

Attitudes about vaccines influence vaccine uptake. Mistrust of vaccines, government institutions, or health care systems may stem from personal or community experience or perceived or actual discrimination, particularly among underserved communities.[xlviii, xlix, l, li, lii, liii, liv, lv, lvi, lvii, lviii, lix] Acknowledging discrimination, recognizing bias, and working to deliver culturally sensitive care could help mitigate longstanding barriers to trust in health care and government institutions.

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A person's likelihood of obtaining some specific vaccines, such as the HPV vaccine, is influenced by race, ethnicity, geography, socioeconomic status, and other factors.[lx, lxi, lxii, lxiii, lxiv] Knowledge about vaccines (including of the benefits of certain vaccines for people with chronic conditions) plays a substantial role in vaccine uptake.[lxv, lxvi] Vaccine confidence, also can vary by person and vaccine. The NVAC has written about this issue previously, so this report will not focus on vaccine confidence except to say that this issue plays a significant role in vaccine disparities. For example, Black communities report high distrust of COVID-19 and flu vaccines, citing various reasons including enduring structural racism. [lxvii, lxviii, lxix, lxx, lxxi]

Recommendation 4.1: The ASH should fund the Office of Infectious Disease and HIV-AIDS Policy (OIDP) and the CDC to conduct focus groups, listening sessions and/or structured interviews with representatives of undervaccinated populations and the providers who serve these groups to better understand what type of messaging would be effective in reaching these populations and the messengers that serve as trusted voices in the specific communities we are trying to reach. In addition, the OIDP should gather information about how to best package information for providers to support their efforts in increasing immunization rates and provide this information to immunization stakeholders involved in vaccine communication.

Recommendation 4.2: The ASH should continue to support efforts to identify effective communication strategies that improve communication, education, and health literacy[lxxii, lxxiii, lxxiv] and should work with the CDC to incorporate these strategies into vaccine training, educational offerings and Vaccine Information Statements. HHS should continue to dissemiate health information that is accurate, accessible, and actionable. Trusted messengers in the community and social media influencers should be further engaged to help disseminate information. The CDC and other groups developing immunization information should continue to develop culturally and linguistically appropriate health information, including visual communication, and the ASH should actively encourage the expansion of these efforts in the

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community, espcially during outbreaks, using the Office of Minority Health's National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care (CLAS standards).

Recommendation 4.3: The ASH should invest in new, targeted communication strategies to promote tested messages about the benefits of vaccination and measure message effectiveness and improved reach in underserved groups for all routine vaccines. Communication strategies should recognize that correcting myths can have the unintended effect of reinforcing them.[lxxv] The communication efforts should be independently evaluated and findings distributed widely to relevant groups promoting vaccination.

Recommendation 4.4: The ASH should promote the use of interventions for which there is an evidence-base for improving equity including practice-level interventions,[lxxvi, lxxvii, lxxviii, lxxix, lxxx, lxxxi, lxxxii] such as the use of standing orders, reminder/recall systems, enhanced training, and information technology systems.

Recommendation 4.5: The ASH should identify funding to increase research and evaluation of evidence-based interventions that reduce disparities in immunization as well as ways to better counter vaccine hesitancy in marginalized populations. NVAC recognizes the work of the U.S. Preventive Health Services Task Force and the Community Preventive Services Task Force in providing reviews of evidence to form recommendations for practice and encourages future work to highlight effective interventions to improve equity in immunization across the lifespan.

DATA TRACKING AND REPORTING INFRASTRUCTURE

Robust, consistent, and timely data are needed to identify disparities; to dispel myths, misconceptions, and disinformation that may be barriers to immunization; and to monitor disparities over time to improve equity. Current measurements of vaccine coverage do not disaggregate data for many meaningful sub-populations (e.g., distinct Asian-American sub-

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populations, institutionalized/incarcerated, homeless). In addition, national surveys have lower response rates from racial and ethnic minority groups, so the data tend to lack precision. For example, vaccination rates for American Indian/Alaska Native adults are not often reported, Pacific Islanders sub-populations are often grouped into a broader category with all Asians, and many respondents report mixed race or ethnicity. Even within racial and ethnic groups, diversity in vaccination rates and monitoring exists.

In addition, geographic data are reported based on metropolitan service areas (MSAs) but are not cross-referenced with health professional shortage areas. Data are reported at the state level[lxxxiii] (and not always by county, ZIP code, or neighborhood) and are inconsistent across jurisdictions.[lxxxiv] Claims data and serologies have logistic limitations and are expensive sources for research.[lxxxv, lxxxvi]

Although the Community Preventive Service Task Force recommends the use of IIS (because of strong evidence that they improve vaccine coverage[lxxxvii]), IIS are not used universally across the life span.[lxxxviii] Currently, effective use of IIS requires substantial resources. As IIS evolve, it may be possible to gain more specific data on locations and populations with low vaccine rates. For example, cross-mapping IIS data with health professional shortage areas may yield useful data. Geomapping may be applied to IIS data. In addition to race and ethnicity, improved data on factors such as neighborhood location, languages spoken, income and occupation, payers, and sites of immunizations could help tailor interventions. Better collection of data through IIS will enable resources to be concentrated in areas of need and facilitate measurement of interventions. NVAC anticipates that COVID-19 vaccination efforts provide new tools for data reporting to track immunization for the purpose of ensuring equitable access and vaccination coverage.

Recommendation 5.1: The ASH should facilitate funding to allow use of IIS to be a source of deidentified data for research purposes. To assist with this recommendation, the ASH should work with CDC, state, territorial and tribal health officers, and state governments to remove

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barriers to interjurisdictional sharing of information from IIS and increase use of IIS for all patients.

Recommendation 5.2: The ASH should study the feasibility of creating a national IIS identifier to facilitate interjurisdictional sharing of information both to improve immunization coverage and to support research.

Recommendation 5.3: The CDC should collect data yearly on immunization rates for all ACIP-recommended, routine vaccines based on social determinants of health and by county to provide data to support planning of targeted interventions.

Recommendation 5.4: The ASH should work with CMS, the CDC, HRSA, and the National Coordinator for Health Information Technology (ONC) to create an improved decision support system in Electronic Health Records (EHRs) to automate vaccination updates and information and establish training and incentive programs to encourage providers and hospital systems to use EHR systems to seamlessly capture bidirectional flow of vaccination data between and among EHR systems and IIS.

Recommendation 5.5: The ASH should explore the feasibility of requiring IIS reporting for all immunization providers across the lifespan.

Recommendation 5.6: While we are still learning lessons from the COVID-19 pandemic, learnings from the systems that have been built to track COVID-19 vaccines should eventually be compiled and disseminated by the CDC, state and local health departments, and other relevant groups.

CONCLUSION

The NVAC fully supports efforts at HHS to improve equity in immunization to improve the health of all Americans and save lives, and believes underlying systemic barriers and biases in the

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immunization system should be removed to create a truly optimal, health-for-all system. The report provides a number of recommendations to address known challenges to achieving equity in immunization and contributing to health equity overall.

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From: Hicks, Lauri (CDC/DDID/NCEZID/DHQP) [auq3@cdc.gov]
Sent: 7/21/2021 1:33:36 PM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Gruber, Marion [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=019cd2669c7048f7a116d72b7682de44-gruber]
CC: Cohn, Amanda C (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4cbff30d34c4611a2e973fcb192de37-HHS-anc0-cd]
Subject: [EXTERNAL] Slides for the ACIP meeting tomorrow
Attachments: 07 COVID Oliver July 2021_CLEAN.pptx; 05 COVID Mbaeyi July 2021 (3).pptx

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,
I wanted to share these two slide sets for the ACIP meeting tomorrow. There are other slide sets, but these are the ones that summarize the discussion and how it will be presented to ACIP. Interested to know if there is anything in these that concern you! Please let us know.
Thanks,
Lauri

From: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) <yxo4@cdc.gov>
Sent: Wednesday, July 21, 2021 12:51 PM
To: Cohn, Amanda (CDC/DDID/NCIRD/OD) <anc0@cdc.gov>; Hicks, Lauri (CDC/DDID/NCEZID/DHQP) <auq3@cdc.gov>
Cc: Dooling, Kathleen L. (CDC/DDID/NCIRD/DVD) <vic9@cdc.gov>
Subject: Immunocompromised slides

Amanda and Lauri:

Attached are the (mostly) cleared immunocompromised slides with our current language. I'm going to send them to Doran, but thought you guys may want to share with Marion/Peter just to make sure all our FDA-bases are covered.

Happy to make any adjustments as needed to the language around FDA and 'regulatory allowance' (Doran's words from our call yesterday.

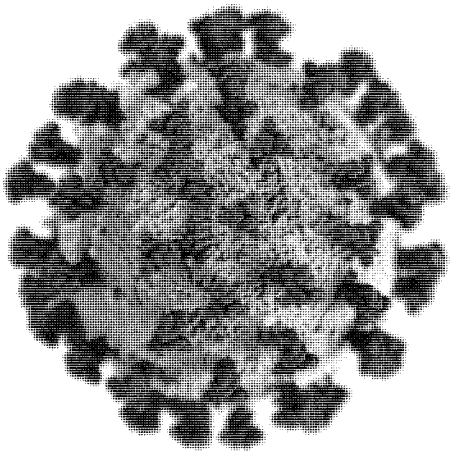
Thanks!
Sara

Sara Oliver, MD, MSPH
LCDR, U.S. Public Health Service
Lead, ACIP COVID-19 Vaccine Work Group
Vaccine Task Force
Centers for Disease Control and Prevention
phone: 404-639-1204
email: yxo4@cdc.gov

Obtained via FOIA by Judicial Watch, Inc.

COVID-19 vaccine use in immunocompromised people

Sara Oliver MD, MSPH
ACIP Meeting
July 22, 2021



cdc.gov/coronavirus

Obtained via FOIA by Judicial Watch, Inc.

Outline

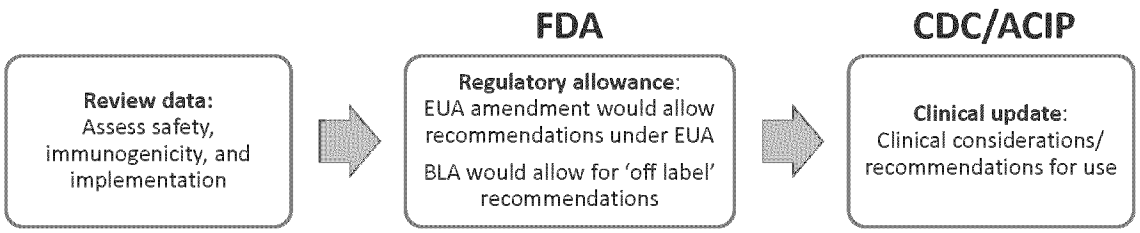
1) COVID-19 vaccine response among immunocompromised people

2) Response to an additional dose of COVID-19 vaccine among immunocompromised people

3) Frequently asked questions about vaccination of immunocompromised people

Obtained via FOIA by Judicial Watch, Inc.

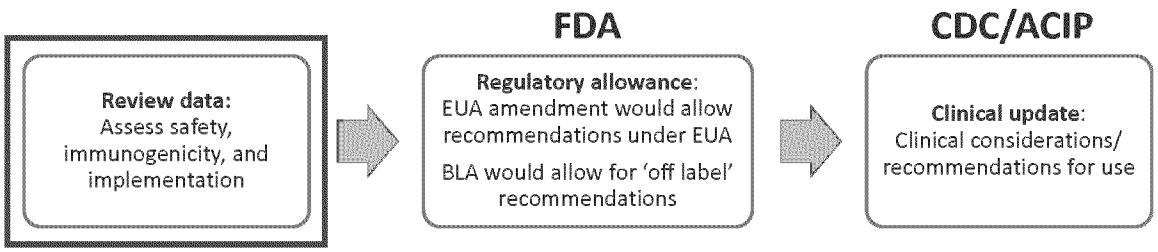
Additional doses in immunocompromised people



EUA= Emergency Use Authorization; BLA= Biologics License Application

Obtained via FOIA by Judicial Watch, Inc.

Additional doses in immunocompromised people



EUA= Emergency Use Authorization; BLA= Biologics License Application

Obtained via FOIA by Judicial Watch, Inc.

COVID-19 vaccine response in immunocompromised people:

What do we know now?

Obtained via FOIA by Judicial Watch, Inc.

Immunocompromised people and SARS-CoV-2 infection

- Immunocompromised people comprise ~2.7% of U.S. adults[1]
  - Solid tumor and hematologic malignancies
  - Receipt of solid-organ or hematopoietic stem cell transplant
  - Some people with primary immunodeficiency
  - Some people living with HIV
  - Treatment with medications such as cancer chemotherapeutic agents, TNF blockers, certain biologic agents (e.g., rituximab), and high-dose corticosteroids

1. Harpaz et al. Prevalence of Immunosuppression Among U.S. Adults, 2013. JAMA 2016

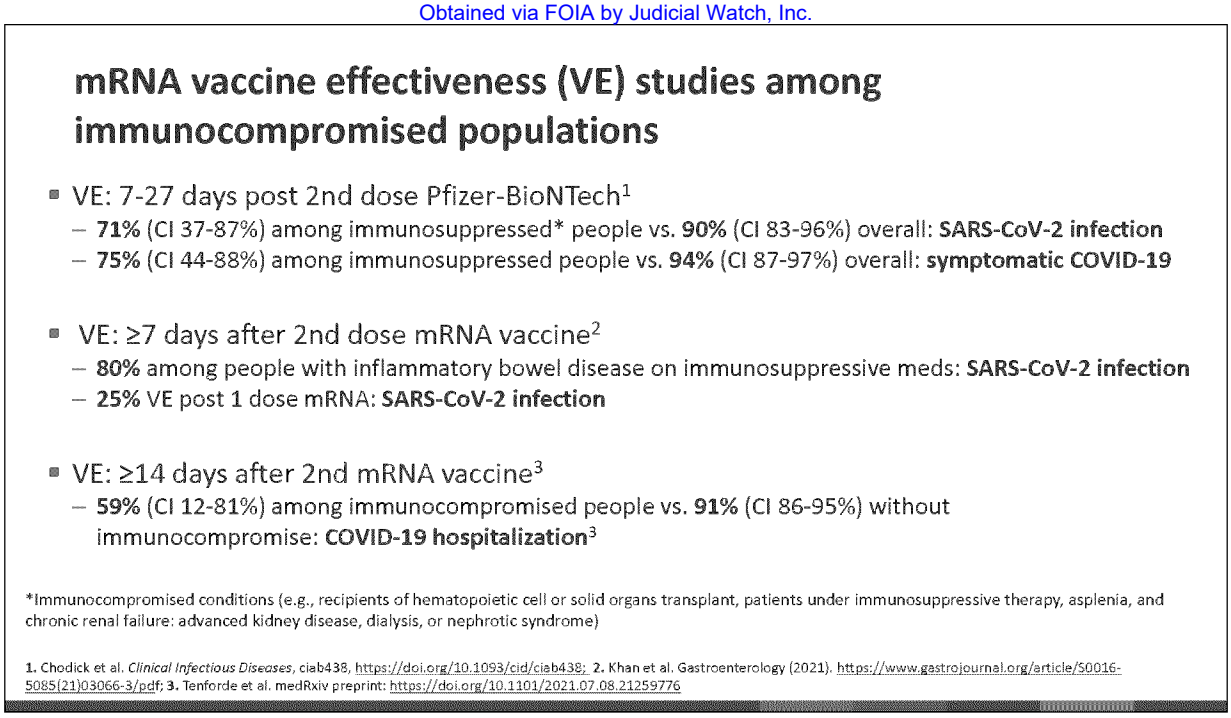
Obtained via FOIA by Judicial Watch, Inc.

Immunocompromised people and SARS-CoV-2 infection

- More likely to get severely ill from COVID-19[1, 2]
- Higher risk for:
  - Prolonged SARS-CoV-2 infection and shedding[3-7 14-16]
  - Viral evolution during infection and treatment (hospitalized patients)[3,6,8-10,14,17]
  - Low antibody/neutralization titers to SARS-CoV-2 variants[12]
- More likely to transmit SARS-CoV-2 to household contacts[11]
- High proportion of vaccine breakthrough cases occur among immunocompromised people:
  - **44%** among hospitalized patients in United States[13]
  - **40%** in Israel[18]

See reference slide at end

Obtained via FOIA by Judicial Watch, Inc.



Immunocompromised Inclusion criteria:

1) Chodick et al. : A large health provider in Israel that were vaccinated with at least 1 dose of BNT162b2. Immunocompromised conditions (eg, recipients of hematopoietic cell or solid organs transplant, patients under immunosuppressive therapy, asplenia, and chronic renal failure: advanced kidney disease, dialysis, or nephrotic syndrome)

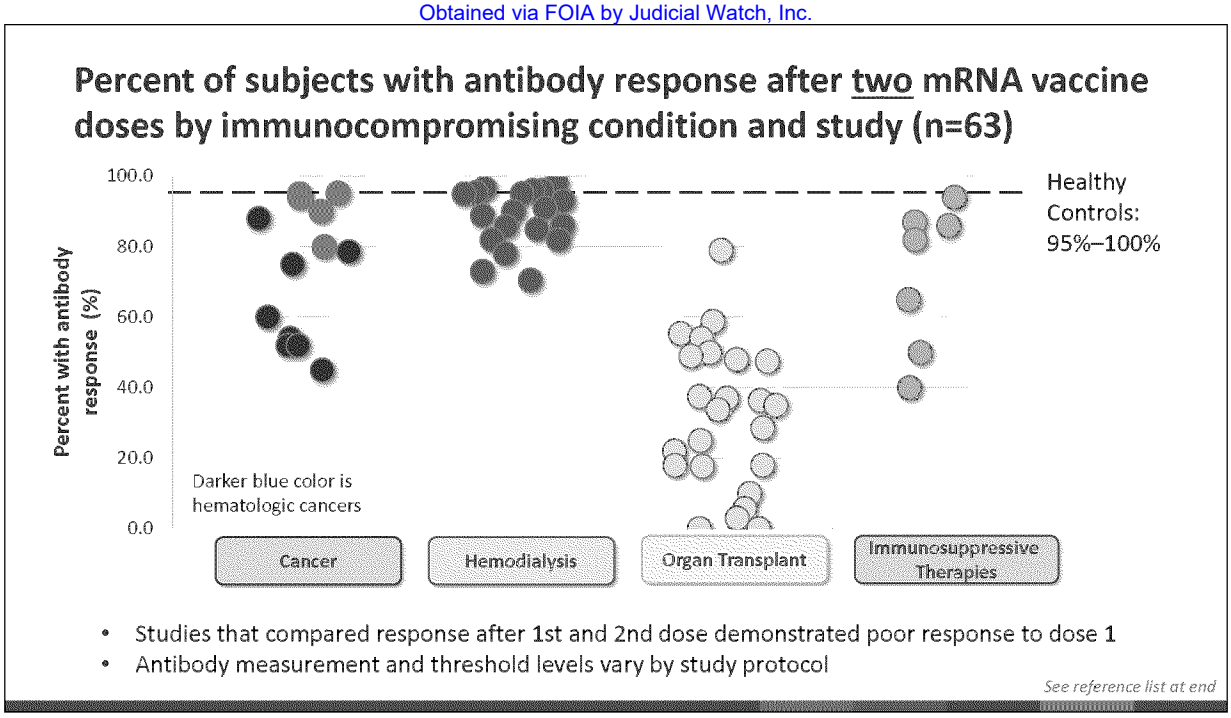
2) Khan et al. :Veterans Health Administration with IBD diagnosed before December 18, 2020, the start date of the Veterans Health Administration patient vaccination program. IBD medication exposures included mesalamine, thiopurines, anti-tumor necrosis factor biologic agents, vedolizumab, ustekinumab, tofacitinib, methotrexate, and corticosteroid use.

3) Tenforde et al. : including immunocompromising conditions as stated Grijalva CG, Feldstein LR, Talbot HK, et al. Influenza Vaccine Effectiveness for Prevention of Severe Influenza-Associated Illness among Adults in the United States, 2019-2020: A testnegative study. Clin Infect Dis 2021.
Immunocompromising condition: Active solid organ cancer without metastases (active cancer defined as treatment for the cancer or newly diagnosed cancer in the past 6 months), active solid organ cancer without metastases (active cancer defined as treatment for the cancer or newly diagnosed cancer in the past 6 months), active hematologic cancer (such as leukemia / lymphoma / myeloma) or active cancer defined as treatment for the cancer or newly diagnosed cancer in the past 6 months, human immunodeficiency virus (HIV) infection without AIDS, AIDS, congenital immunodeficiency syndrome, prior splenectomy, prior solid organ transplant, immunosuppressive medication, systemic lupus erythematosus, rheumatoid arthritis, psoriasis, scleroderma, inflammatory bowel disease including Crohn's disease or ulcerative colitis

71% (95%CI:37%-87%)
90% (95%CI:79%- 95%)
In Israel, retrospective cohort (n=25,459) from Maccabi Healthcare Services (MHS), a state-mandated sick fund, covering 2.6 million-member or 25% of residents in Israel

Nationwide Veterans Affairs cohort of patients with IBD (n=14,697)

Obtained via FOIA by Judicial Watch, Inc.



This graph shows the percent antibody response after two mRNA vaccine doses by different types of immunocompromising condition. Studies of people with cancer is shown in blue, with hematologic cancers shown in a darker blue, which ranged 45% to 95%, with larger impacts seen among people with hematologic cancers. Studies of people on hemodialysis are shown in green and ranged 98-70.5%. Studies of people with solid organ transplants had the largest defects in antibody response, ranging 0% to 79%. Studies of people being treated for autoimmune or inflammatory disorders ranged 40% to 94%. For reference, healthy controls, where included in these studies, ranged 95% to 100%. Almost all studies that assessed response after the 1st and 2nd vaccine dose demonstrated poor response of people who were immunosuppressed to a single mRNA dose. Next slide

Percent Antibody Response Range:
Cancer: 95-45%
Solid Cancers: 95-80%
Hematologic 88-45%
Hemodialysis: 98-71%
Organ Transplant: 79-0%
autoimmune or inflammatory disorders ranged 40% to 94%
Healthy Controls: 95-100%

Obtained via FOIA by Judicial Watch, Inc.

Response to an additional dose of COVID-19 vaccine in immunocompromised people:

The emerging data

Obtained via FOIA by Judicial Watch, Inc.

Comparing evidence 3rd mRNA COVID-19 vaccine dose in immunosuppressed people with seropositive response

Study	Patient Population	2nd Dose			3rd Dose among		
		Sample Size	Seronegative N (%)	Seropositive N (%)	Sample Size (seronegative)	Seronegative N (%)	Seropositive N (%)
Kamar et al.	Recipients of solid-organ transplant	99	59 (60)	40 (40)	59	33 (56)	**26 (44)**
Werbel et al.*	Recipients of solid-organ transplant	30	24 (80)	6 (20)	24	16 (67)	**8 (33)**
Longlune et al.	Patients on hemodialysis	82	13 (16)	69 (84)	12	7 (58)	**5 (42)**
Maxime et al.	Patients on hemodialysis	106	66 (62)	40 (38)	12	6 (50)	**6 (50)**

* Recipients received homologous mRNA prime followed by either a single Moderna, Pfizer, or Janssen boost

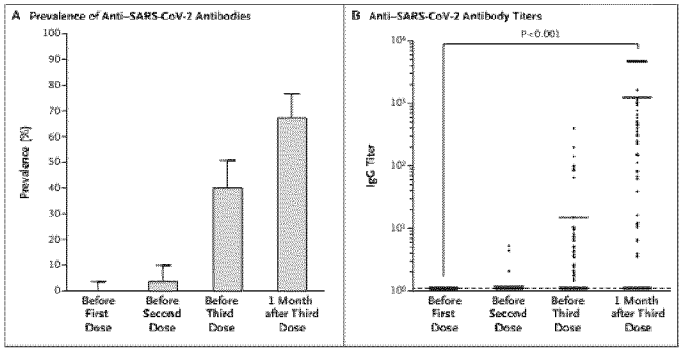
- Among those who had **no detectable antibody** response to an initial mRNA vaccine series, **33-50% developed an antibody response to an additional dose**

See references list at end

This slides shows 4 studies that looked at the seropositivity antibody response in immunocompromised populations after a second and third dose of an mRNA vaccine. In these studies, the percent of people who were seropositive after a 3rd dose ranged from 33-50% .

Obtained via FOIA by Judicial Watch, Inc.

Three doses of an mRNA COVID-19 vaccine in solid-organ transplant recipients



- No serious adverse events were reported after administration of the 3rd dose, and no acute rejection episodes occurred (n=99)

Kamar et al. (2021) NEJM Three Doses of an mRNA Covid-19 Vaccine in Solid-Organ Transplant Recipients (nejm.org)

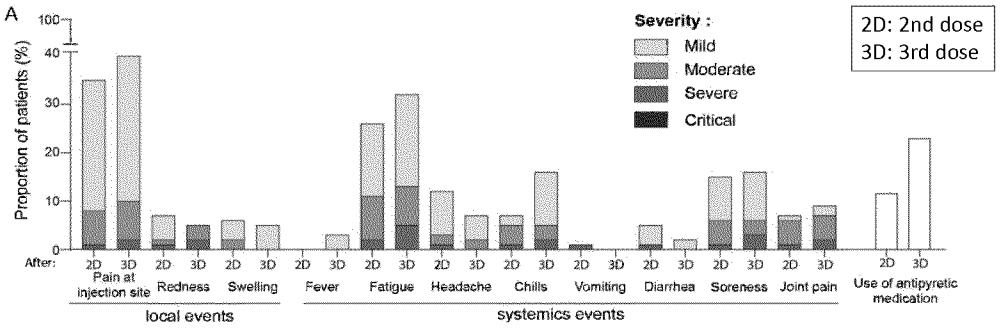
Panel A: shows the prevalence of anti–severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) antibodies before and after vaccination in the study population.
Panel B: shows anti–SARS-CoV-2 antibody titers before and after vaccination in the study population.

Overall, in this organ transplanted study population, the prevalence of anti–SARS-CoV-2 antibodies were: 40% (40 of 99 patients) before the 3rd dose, and 68% (67 of 99 patients) 4 weeks after the 3rd dose. Among the 59 patients who had been seronegative before the 3rd dose, 26 (44%) were seropositive at 4 weeks after the 3rd dose.

Obtained via FOIA by Judicial Watch, Inc.

Reactogenicity of 3rd mRNA vaccine dose in cohort of patients on hemodialysis (n=63*)

- No patients developed critical side effects requiring hospitalization
- Symptoms reported were consistent with previous doses and the intensity of the symptoms was mostly mild or moderate



*Sample included patients who had an optimal and suboptimal antibody response to primary mRNA series and chose to receive a 3rd dose

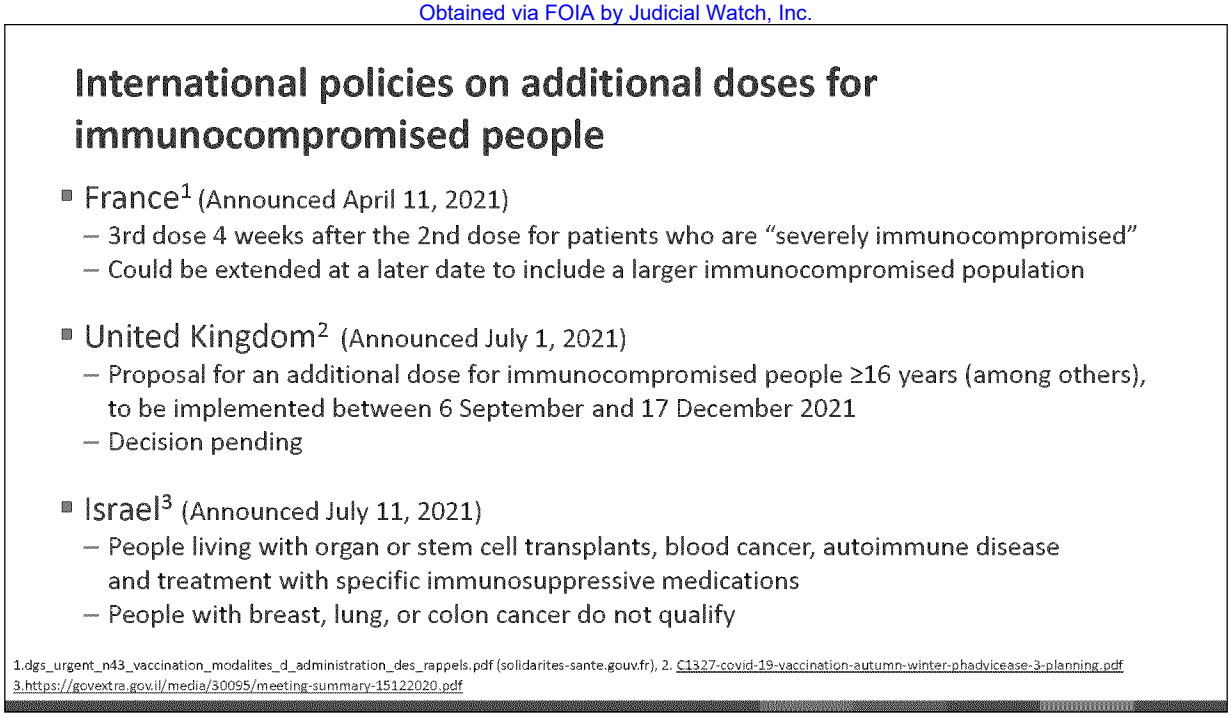
Maxime et al. (2021) medRxiv doi: https://doi.org/10.1101/2021.07.02.21259913

Reactogenicity to the 3rd dose of mRNA vaccine in MHD patients

A. Proportion of MHD patients who developed local and systemic adverse events after 2D and after 3D dose of vaccine are represented. Severity of the adverse event is color-coded (0-4) according to the scale detailed in the material and method section.

B. The number and the severity of local and systemic adverse events that occurred after 2D and 3D of vaccine are compared.

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What populations are included in these policy's:
French: "[S]everely immunocompromised people (solid organ transplants, recent bone marrow transplants, dialysis patients, patients with autoimmune diseases under strong immunosuppressive treatment such as anti-CD20 or anti-metabolites). Recommendations will be made later on the need for a 3rd dose for patients with patients with chronic kidney disease not on dialysis, cancer patients and patients with medical conditions autoimmune under other immunosuppressive therapy."

United Kingdom: "adults who are severely immunosuppressed"

Israel: immunocompromised patients, including oncological and hematological patients, organ transplants, patients suffering from rheumatic and inflammatory diseases, and those treated with anti-inflammatory drugs

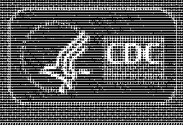
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Summary

- Immunocompromised people are at increased risk of poor outcomes from COVID-19
- Studies indicate a reduced antibody response in immunocompromised people following a primary vaccine series, compared to healthy vaccine recipients
- Emerging data suggest that an additional COVID-19 vaccine dose in immunocompromised people enhances antibody response and increases the proportion who respond
- In small studies, the reactogenicity of the 3rd dose of mRNA vaccine was similar to prior doses

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Frequently asked questions about vaccination of immunocompromised people



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Which immunocompromised groups should be considered for an additional dose once authorized by FDA?

- Conditions and treatments associated with *moderate to severe* immune compromise*
  - Solid tumor and hematologic malignancies
  - Receipt of solid-organ or hematopoietic stem cell transplant
  - Some people with primary immunodeficiency
  - Some people living with HIV
  - Treatment with medications such as cancer chemotherapeutic agents, TNF blockers, certain biologic agents (e.g., rituximab), and high-dose corticosteroids
- Chronic conditions associated with *varying* degrees of immune deficit, such as asplenia and chronic renal disease*
- Different medical conditions and treatments can result in widely varying degrees of immunosuppression. A patient's clinical team is best able to assess the degree of altered immunocompetence and optimal timing of vaccination

*General Best Practice Guidelines for Immunization and CDC Yellow Book can be consulted for detailed information

Obtained via FOIA by Judicial Watch, Inc.

Should immunocompromised people undergo antibody testing following COVID-19 vaccination?

- Utility of serologic testing or cellular immune testing to assess immune response to COVID-19 vaccination has not been established
- Exact correlation between antibody level and protection from COVID-19 remains unclear
- Commercial antibody and cellular immune testing may not be consistent across laboratories
- Serologic testing or cellular immune testing outside of the context of research studies is **not recommended in the United States at this time**

Obtained via FOIA by Judicial Watch, Inc.

Are there data to support mixed-dose series in immunocompromised people: for example, Janssen followed by mRNA COVID-19 vaccine?

- Studies from Europe have assessed heterologous primary series (AstraZeneca and Pfizer-BioNTech) in the general adult population and found immunogenicity to be at least equivalent to homologous series [1-5]
  - Large UK trial (Com-COV) found that one dose of AstraZeneca + one dose of Pfizer-BioNTech resulted in superior immunogenicity compared with two doses of AstraZeneca vaccine but lower antibodies than 2 doses of Pfizer-BioNTech; increase in systemic reactogenicity observed with heterologous schedules[5]
- Evidence is needed regarding the safety and immunogenicity of using a mixed-dose approach for Janssen (FDA-authorized adenoviral vector vaccine) + mRNA vaccine in immunocompromised people

1. Borobia et al. Reactogenicity and Immunogenicity of BNT162b2 in Subjects Having Received a First Dose of ChAdOx1s: Initial Results of a Randomized, Adaptive, Phase 2 Trial (CombiVacS). Available at SSRN: https://ssrn.com/abstract=3854768 **2.** Shaw et al. Heterologous prime-boost COVID-19 vaccination: initial reactogenicity data, ISSN 0140-6736, https://doi.org/10.1016/S0140-6736(21)01115-6 **3.** Hillus et al. Safety, reactogenicity, and immunogenicity of homologous and heterologous prime-boost immunization with ChAdOx1-nCoV19 and BNT162b2: a prospective cohort study. medRxiv; 2021. DOI: 10.1101/2021.05.19.21257334. **4.** Schmidt et al. medRxiv preprint (June 15 2021): https://doi.org/10.1101/2021.06.13.21258859 Click to add text **5.** Liu et al. Lancet preprint (June 25, 2021): http://dx.doi.org/10.2139/ssrn.3874014

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Following COVID-19 vaccination, what infection prevention measures should immunocompromised people maintain?

- Immunocompromised people should be counseled about potential for reduced immune responses to COVID-19 vaccination and need to follow prevention measures*
  - Wear a mask
  - Stay 6 feet apart from others they don't live with
  - Avoid crowds and poorly ventilated indoor spaces until advised otherwise by their healthcare provider
- Close contacts of immunocompromised people should be encouraged to be vaccinated against COVID-19

* https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html

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Is there a role for monoclonal antibody use in immunocompromised people?

- Monoclonal antibodies are currently authorized by FDA for emergency use in persons with SARS-CoV-2 infection who are at high risk for progressing to severe COVID-19 and/or hospitalization

- Monoclonal antibodies are not yet authorized for SARS-CoV-2 infection prophylaxis

https://www.fda.gov/drugs/coronavirus-covid-19-drugs/coronavirus-treatment-acceleration-program-ctap#dashboard

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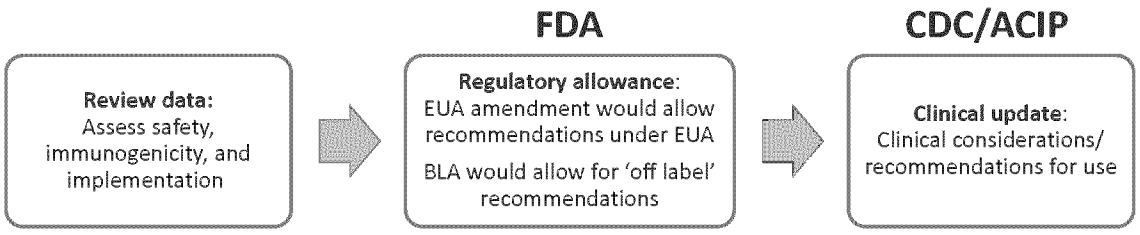
What are the implications of the Emergency Use Authorizations (EUAs) for the COVID-19 vaccines, with respect to considerations for an additional dose in immunocompromised persons?

- FDA has authorized mRNA vaccines as a 2-dose series and Janssen COVID-19 vaccine as a single dose; until sufficient evidence accrues to warrant either an amendment to the EUA or a BLA, additional doses are not recommended

EUA= Emergency Use Authorization; BLA= Biologics License Application

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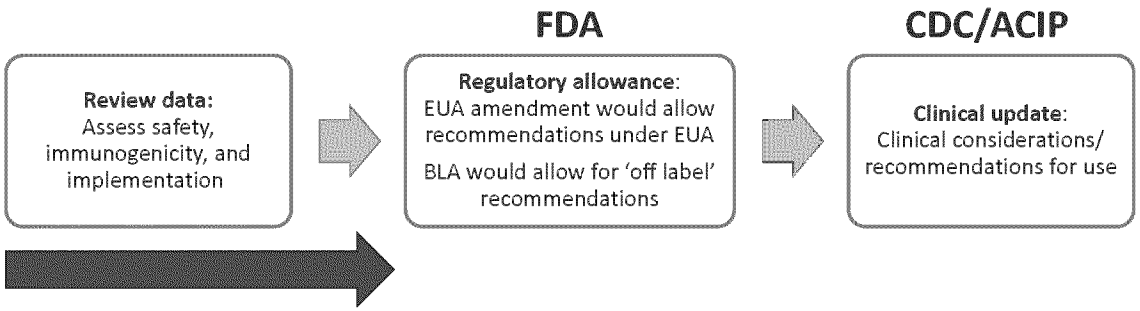
Additional doses in immunocompromised people



EUA= Emergency Use Authorization; BLA= Biologics License Application

Obtained via FOIA by Judicial Watch, Inc.

Additional doses in immunocompromised people



Now:

Immunocompromised people should continue to **follow infection prevention measures**:

Wear a mask, stay 6 feet apart from others, avoid crowds and poorly ventilated spaces

Close contacts (≥12 years old) of immunocompromised people should be **vaccinated against COVID-19**

EUA= Emergency Use Authorization; BLA= Biologics License Application

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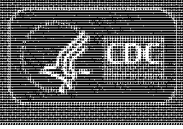
Additional COVID-19 vaccine dose in immunocompromised people: Next steps

- Assess additional studies of safety and immunogenicity of additional dose in immunocompromised people
- Assess additional studies and expert opinion regarding the subpopulations of immunocompromised people who may benefit most from an additional dose
- Determine acceptable intervals and mix and match schedules
- Await FDA amendment of EUA or BLA allowing an additional dose of COVID-19 vaccine

EUA= Emergency Use Authorization; BLA= Biologics License Application

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Questions for ACIP



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Questions for ACIP

1. What additional data do ACIP need to inform these discussions?

2. Thoughts on the focus of "moderate to severe" immunocompromised populations, once authorized/approved?

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Acknowledgements

- Nicole Reisman
- Mary Chamberland
- Kathleen Dooling
- Jack Gersten
- Heather Scobie
- Kristine Schmit
- Lauri Hicks
- Stephen Hadler
- Jessica MacNeil
- Danielle Moulia
- Eddie Shanley
- Hannah Rosenblum
- Monica Godfrey

- Vaccine Task Force
- Epi Task Force
- Respiratory Viruses Branch

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References

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References for slides 9: immunocompromised populations [4]

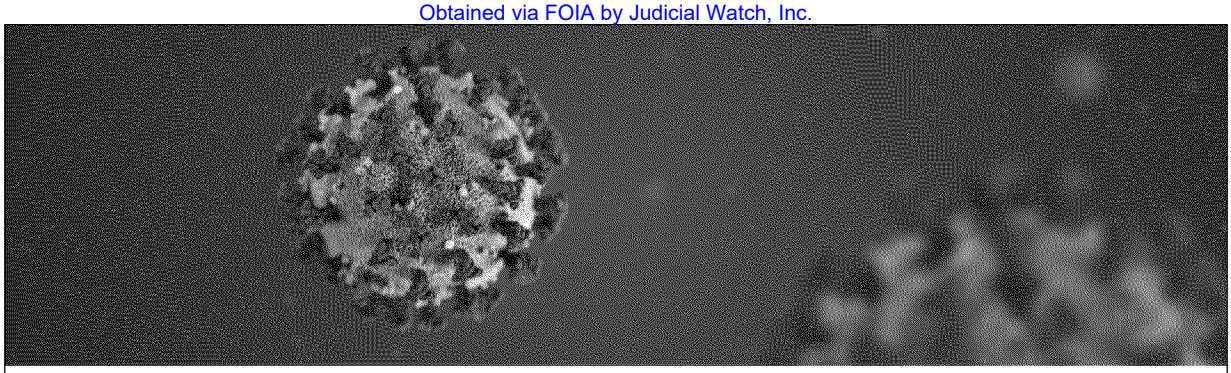
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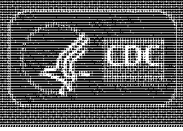


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Subject: RE: STOP REPLY ALL PLEASE - Re: COVID-19 vaccine dangers; CDC's "Vaccines do not cause autism" lie, taken down; NH commission exposes FCC corruption, cellular radiation dangers

The original email did not come from me. I did not construct this huge email list. I just responded and asked to be removed.

Please do not send any emails to me!!!!

You should write to the person mentioned first below, who was the sender:
Vinu Arumugham (b) (6) @yahoo.com>

Bw Peter G

Dear All,

It appears the original email came from pcg@scientificfreedom.dk.

Please email directly to remove yourself from the list. Otherwise, we will get 251 individual emails. I am most certain this is not what we want.

Thanks- Kristen

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From: "cbrechot@usf.edu" <cbrechot@usf.edu>
Date: Tuesday, February 2, 2021 at 9:24 AM
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Subject: RE: COVID-19 vaccine dangers; CDC's "Vaccines do not cause autism" lie, taken down; NH commission exposes FCC corruption, cellular radiation dangers

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Subject: Re: COVID-19 vaccine dangers; CDC's "Vaccines do not cause autism" lie, taken down; NH commission exposes FCC corruption, cellular radiation dangers

Prof. Gøtzsche,

Let me clarify that we are not discussing vaccine vs. no vaccine. We are discussing dirty, sickening vaccines vs. clean safe, effective vaccines.

Regarding autism, you are talking about the wrong vaccine. We have shown beyond all doubt, using **reliable mechanistic evidence** that milk protein contaminated vaccines (DTaP/TdaP, Prevnar 13, ActHiB) cause the vast majority (75%) of autism cases.

Autism pathogenesis: Piecing it all together, from end to beginning ...
https://doi.org/10.5281/zenodo.1477515

Immunization with homologous xenogeneic (animal/plant/fungal) antigens causes the development of autoimmune diseases. Known for at least 45 years.

Vaccine-Induced Autoimmunity in the Dog

"the most likely sources of cross-reactive epitopes are bovine serum and cell culture components. These are present in almost all vaccines as residu-al components of the cell culture necessary to generate vaccine viruses and may purposely be added to the vaccine as a stabilizer. In the presence of an adjuvant, these bovine products stimulate a strong im-mune response and induce antibodies that cross-react with conserved canine antigens."

Xenogeneic therapeutic cancer vaccines as breakers of immune tolerance for clinical application: to use or not to use?
pubmed.ncbi.nlm.nih.gov/24837511/

Oncologists immunize with xenogeneic antigens to break immune tolerance (cause autoimmunity) to make your immune system attack your own cancer cells.

Regular vaccines such as the measles vaccines are contaminated with animal proteins (chicken) and therefore cause numerous autoimmune disorders including type 1 diabetes.

Correlation of type 1 diabetes trends in European countries to the number of bovine insulin and GAD65 contaminated chick embryo cell culture containing vaccines in the schedule, as predicted by the autoimmunity mechanism involving immunization with homologous xenogeneic antigens and EPIT as a potential treatment
https://doi.org/10.5281/zenodo.1870364

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The US IOM pointed out that epidemiological studies are useless in 93% of the cases. Mechanistic studies proved reliable.

Institute of Medicine: Most epidemiological vaccine safety studies are useless

https://doi.org/10.5281/zenodo.3244496

The Pandemrix vaccine made in Europe had higher levels of contamination with H1N1 nucleoproteins than the Arepanrix vaccine manufactured by the same company (GSK) in Canada. Pandemrix therefore caused way more cases of narcolepsy. Do you know the level of chicken protein contamination in Danish vs. US vaccines? How can you then apply studies done in Denmark to any other country?

Big picture of the damage vaccines do:

Vaccines and Biologics injury table based on mechanistic evidence – Feb 2020

Covering over 125 conditionshttps://zenodo.org/record/3647593/files/vbitr2_final.pdf?download=1

The organized suppression of vaccine safety science:

Retraction of scientific papers: the case of vaccine research
https://www.tandfonline.com/doi/full/10.1080/09581596.2021.1878109

Thanks,

Vinu

On 1/31/21 11:47 PM, pcg@scientificfreedom.dk wrote:

I have no knowledge of this huge email list and do not know why I was put on it. But I assume I will be taken off it because of what I write below. Please read it.

The idea that vaccines may cause autism was launched by Andrew Wakefield in relation to a fraudulent study published in Lancet in 1998 that has been retracted. Large observational studies from my country, Denmark, have shown convincingly that the Emperor has no clothes. I analyse this in detail in my 2020 book, Vaccines: truth, lies and controversy. It is an e-book but will come out soon on Skyhorse, New York, as a print book with an updated corona chapter that ends with the riots on 6 January 2021 at Capitol Hill.

Wakefield's horrendous fraud, which has caused many deaths, concerned the MMR vaccine. These are excerpts from my book, the chapter on measles:

According to the WHO, there were 110,000 measles deaths in 2017, and most were in children under the age of five.[3] Vaccination resulted in an 80% drop in measles deaths between 2000 and 2017 preventing an estimated 21 million deaths.

Measles outbreaks also provide strong support for the benefits of the vaccine. In the United States, there was a resurgence of measles in 1989-1990, which primarily involved unvaccinated racial and ethnic minority children less than five years of age residing in inner-city areas.[40] There were 66 (0.1%) cases of encephalitis. A provisional total of 41 measles-associated deaths was reported in 1989 (2.3 deaths per 1000 cases), which increased to 89 (3.2 per 1000 cases) in 1990. In 2000, the CDC declared measles eradicated in the United States but there have been several outbreaks since due to imported cases.[41] In 2018, no less than 17 outbreaks occurred. One, in New York, was due to people who had been to Israel, and it included 182 cases in orthodox Jewish communities with a vaccination rate of only 50%.[42]
It is not possible to say exactly what the risk is of dying from measles. As noted earlier, the death risk is related to the infectious dose, which is higher in settings with overcrowding. We can only say what it has been in outbreaks, and a commonly used estimate is 2 deaths per 1000 cases. But it can be much worse. During an epidemic in Copenhagen in 1887, at least 5% of the children, or 50 per 1000 cases, died.[43] The mortality was probably even higher because only those who died

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while they had a rash counted. In Wien, at the beginning of the 20th century, the mortality was 11% among the poorest and 0.6% among the richest.
An outbreak in Madagascar that started in 2018 had in April 2019 caused over 1200 deaths, which is about 1% of those infected.[44] Only about 60% of the population is vaccinated.

We should all get vaccinated against measles and get our children vaccinated, with very few exceptions. Contraindications for the vaccine include a history of severe allergic reaction to any component of the vaccine including neomycin, pregnancy (measles illness during pregnancy results in a higher risk of premature labour, spontaneous abortion, and low-birthweight infants), and severe immunosuppression.[34]

On Swedish TV, in 2020, Wakefield lied horrendously about measles: "Exposure in childhood is safe and conveys lifelong immunity."

The reference is:

Dokumentär
Anna Nordbeck och Malin Olofsson
Dokument inifrån: VACCINKRIGARNA
https://www.svtplay.se/dokument-inifran-vaccinkrigarna
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Subject: COVID-19 vaccine dangers; CDC's "Vaccines do not cause autism" lie, taken down; NH commission exposes FCC corruption, cellular radiation dangers

Obtained via FOIA by Judicial Watch, Inc.

Vaccines absolutely do cause autism

The CDC has flip-flopped twice in ~5 months on the fraudulent claim that "Vaccines do not cause autism", on their website. It suggests that the CDC's vaccine/autism claims are based on the conjunction of Jupiter and Saturn, not science.

They were forced to take the false claim down because ICAN demonstrated there was **ZERO** science behind that claim.

The CDC Finally Capitulated To ICAN's Legal Demands and Removed the Claim that "Vaccines Do Not Cause Autism" From Its Website!

https://www.icandecide.org/ican_press/the-cdc-finally-capitulated-to-icans-legal-demands-and-removed-the-claim-that-vaccines-do-not-cause-autism-from-its-website/

THE CDC JUST SOLIDIFIED THAT ITS DECISIONS ARE NOT DRIVEN BY SCIENCE

https://www.icandecide.org/ican_press/the-cdc-just-solidified-that-its-decisions-are-not-driven-by-science/

FACT: Milk protein contaminated vaccines (DTap/Tdap/Prevnar 13/ActHiB) cause at least 75% of autism cases.

Autism pathogenesis: Piecing it all together, from end to beginning ...
https://doi.org/10.5281/zenodo.1477515

CDC caught lying, again about the COVID-19 vaccine this time.

CDC Investigation

http://fullmeasure.news/news/cover-story/cdc-investigation

Vaccine mandates are based on a lie; Repeal all mandates immediately; Try the corrupted liars who created mandates, for CRIMES AGAINST HUMANITY

"Administration of parenterally administered vaccines alone typically does not result in potent mucosal immunity that might interrupt infection or transmission"

SARS-CoV-2 Vaccines: Much Accomplished, Much to Learn

www.acpjournals.org/doi/10.7326/M21-0111

So Fauci admits now that **ALL** injected vaccines are for individual protection only. **No herd/community immunity.** So no vaccine mandates are justifiable for **ANY** injected vaccine.

And of course this also means the vaccinated can become infected super-spreaders as occurs with the failed flu shot and failed pertussis vaccines.

Yan J, Grantham M, Pantelic J, de Mesquita PJ, Albert B, Liu F, et al. Infectious virus in exhaled breath of symptomatic seasonal influenza cases from a college community. Adamson W, Beato-Arribas B, Bischoff W, Booth W, Cauchemez S, Ehrman S, et al., editors. Proc Natl Acad Sci. National Academy of Sciences; 2018;

The potential role of subclinical Bordetella Pertussis colonization in the etiology of multiple sclerosis
pubmed.ncbi.nlm.nih.gov/26724970/

This is the consequence of **insanely injecting** antigens of pathogens whose natural routes of exposure are mucosal surfaces in the nose, mouth or eyes.

NOTICE!

By authority of the Nuremberg Code on Medical Experimentation, I do hereby exercise my right to refuse to submit to or to administer the Covid-19 vaccine. The United States Government has prosecuted, convicted

Obtained via FOIA by Judicial Watch, Inc.
and executed Medical Doctors who have violated the Nuremberg Code on Medical Experimentation. Aiders and abettors of Nuremberg Crimes are equally guilty and have also been prosecuted, convicted, and executed.

Francis A. Boyle
Professor of Law.

My comment in the Annals of Internal Medicine, against Fauci's "SARS-CoV-2 Vaccines: Much Accomplished, Much to Learn"

https://www.acpjournals.org/doi/10.7326/M21-0111

Vinu Arumugham Independent 18 January 2021

These vaccines are unsafe, unnecessary and must be immediately withdrawn

The vaccine safety claims made by the authors are unsupported by evidence. Vaccines must be designed for safety. These vaccines were not designed at all. So they are unsafe by definition. I predicted the allergic sensitization and autoimmunity risks with these vaccines which have now been confirmed.

The Pfizer/BioNTech vaccine is unnecessary, unsafe and should not be authorized.

https://www.regulations.gov/document?D=FDA-2020-N-1898-0039

Robert F Kennedy Jr. warned the FDA months back about the risk of allergic reactions due to the use of polyethylene glycol (PEG) in the vaccines.
https://childrenshealthdefense.org/defender/pfizer-covid-vaccine-allergic-reactions/

The FDA/VRBPAC ignored us and authorized these horrendously dangerous vaccines.

Recently, Dr. Peter Marks of the FDA admitted that the population was sensitized by PEG-containing pharmaceutical preparations (that include other vaccines/injections).

https://www.wsj.com/articles/scientists-eye-potential-culprit-for-covid-19-vaccine-allergic-reactions-11608901200?mod=hp_lead_pos2

"What we're learning now is that those **allergic reactions could be somewhat more common** than the highly uncommon that we thought they were **because people do get exposed to polyethylene glycol in various pharmaceutical preparations,**" - Peter Marks, Director, CBER,FDA.

We of course already knew that any vaccine/injection that has enough allergen to cause a reaction, has more than enough allergen to guarantee sensitization/priming (causing the development of new allergy).

Evidence that Food Proteins in Vaccines Cause the Development of Food Allergies and Its Implications for Vaccine Policy

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3571073

www.sciencemag.org/news/2020/12/suspicions-grow-nanoparticles-pfizer-s-covid-19-vaccine-trigger-rare-allergic-reactions

Obtained via FOIA by Judicial Watch, Inc.

"he worries anti-PEG antibodies triggered by the first shot could increase the risk of an allergic reaction to the second or to PEGylated drugs."

- Janos Szebeni, an immunologist at Semmelweis University

So now, these vaccines have sensitized millions to PEG. The goal is to sensitize/boost PEG allergy in a 100 million more in the next 100 days.

PEG is contaminated with 1,4-dioxane, a carcinogen.

https://www.fda.gov/cosmetics/potential-contaminants-cosmetics/14-dioxane-cosmetics-manufacturing-byproduct

As predicted, Pfizer COVID-19 vaccine induced autoimmunity (thrombocytopenia) killed a Florida doctor. This is just the tip of the iceberg. Thousands of cases of vaccine induced autoimmune diseases may take months/years to be diagnosed and will be dismissed as unrelated to the vaccine.

https://www.nytimes.com/2021/01/12/health/covid-vaccine-death.html

Only a few lots were tested in the trial. No one has a clue what other lots will do. 100-fold variation of contaminants in vaccines makes trials and epidemiological studies worthless as I detailed in my comments in the Annals of Internal Medicine before. Vaccine safety remains an oxymoron.

https://www.acpjournals.org/doi/10.7326/m18-2101

California calls for pause of 330,000 doses, investigation after allergic reactions to Moderna vaccine batch

https://www.mercurynews.com/2021/01/18/coronavirus-california-calls-for-pause-investigation-after-allergic-reactions-to-moderna-vaccine-batch/

What's worse? Effective, life-saving, cheap, safe medicines such as famotidine/cetirizine/ivermectin are being ignored in this blind race to vaccinate at any cost.

Immunological mechanisms explaining the role of vaccines, IgE, mast cells, histamine, elevating ferritin, IL-6, D-dimer, VEGF levels in COVID-19 and dengue, potential treatments such as mast cell stabilizers, antihistamines: Predictions and confirmations

https://europepmc.org/article/PPR/PPR241819

Big picture of the damage vaccines do:

Vaccines and Biologics injury table based on mechanistic evidence – Feb 2020

Covering over 125 conditionshttps://zenodo.org/record/3647593/files/vbitr2_final.pdf?download=1

The organized suppression of vaccine safety science:

Retraction of scientific papers: the case of vaccine research
https://www.tandfonline.com/doi/full/10.1080/09581596.2021.1878109

The WHO's flip-flopping "science" competes with CDC's incompetence

WHO Recommends Against Moderna, Pfizer Vaccines for Most Pregnant Women

Obtained via FOIA by Judicial Watch, Inc.

https://www.wsj.com/articles/who-recommends-against-moderna-pfizer-vaccines-for-most-pregnant-women-11611775138

Pregnant Women May Receive Covid Vaccines Safely, W.H.O. Says
https://www.nytimes.com/2021/01/29/health/covid-vaccine-pregnancy.html

Moderna's COVID-19 vaccine now recommended for pregnant women, WHO says in guidance reversal

https://www.foxnews.com/health/moderna-covid-vaccine-pregnant-women-who-guidance-reversal

Not to be outdone by the flip-flopping CDC, WHO did a flip-flop on COVID-19 vaccine during pregnancy.

Latest evidence that there is ZERO science behind vaccines or vaccine safety. They just pull their "science" out of a hat. Follow the money.

These flip-flopping, lying, organized criminals at the CDC/WHO, are the "reputable sources" for your "fact-checkers".

The New Hampshire Commission report below has ripped FCC's 5G (and all other cellular) RF safety claims:

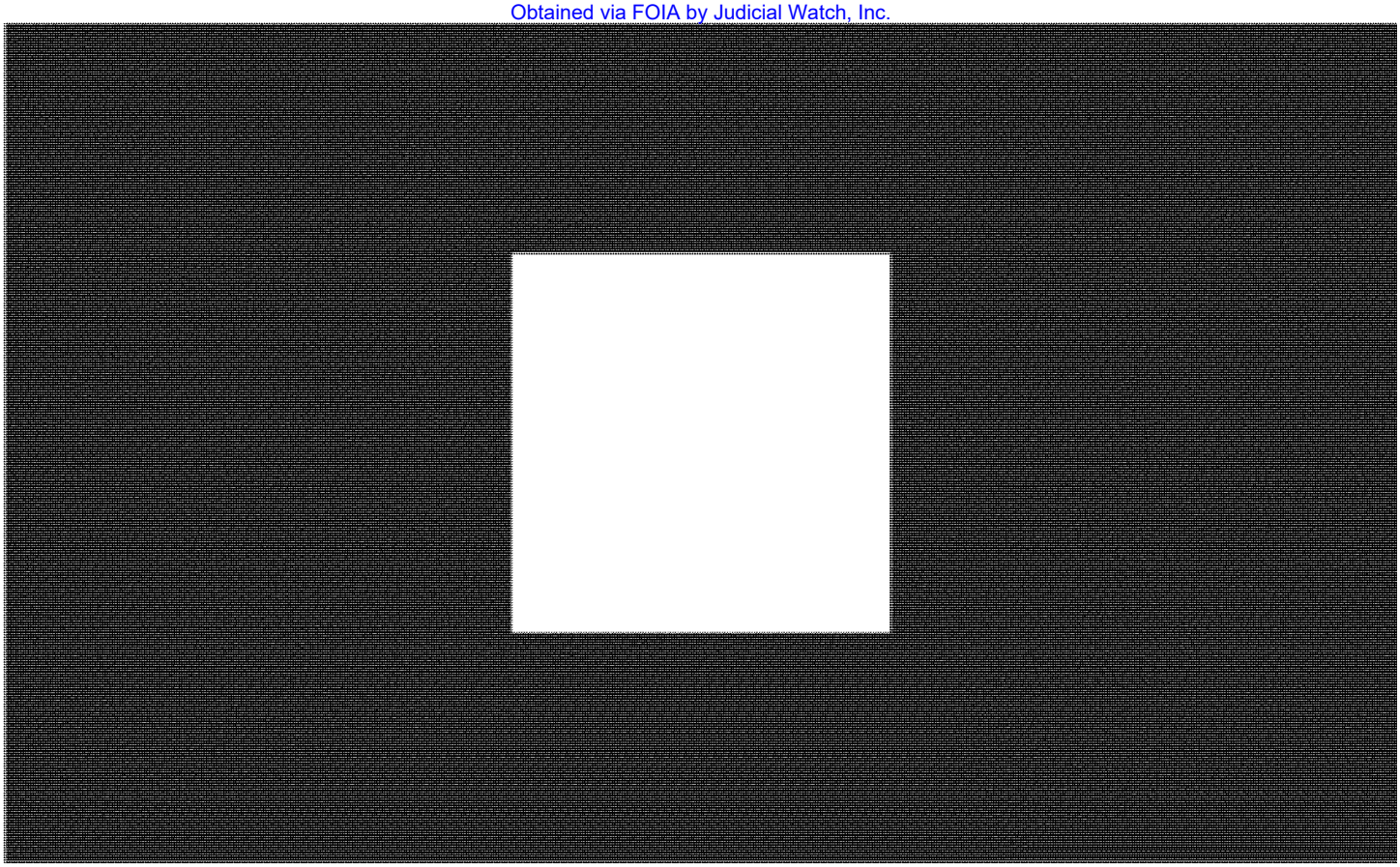
Final Report of the Commission to Study The Environmental and Health Effects of Evolving 5G Technology

http://www.gencourt.state.nh.us/statstudcomm/committees/1474/reports/5G%20final%20report.pdf

"RECOMMENDATION 1- Propose a resolution of the House to the US Congress and Executive Branch to **require the Federal Communication Commission (FCC) to commission an independent review** of the current radiofrequency (RF) standards of the electromagnetic radiation in the 300MHz to 300GHz microwave spectrum as well as a health study to assess and recommend mitigation for the health risks associated with the use of cellular communications and data transmittal."

"A likely explanation as to why **regulatory agencies have opted to ignore the body of scientific evidence demonstrating the negative impact of cellphone radiation** is that **those agencies are "captured"** (see Harvard University publication entitled, "Captured Agency: How the Federal Communications Commission Is Dominated by the Industries It Presumably Regulates" linked in Appendix G). This report documents how **the leadership roles in some agencies (the FCC in particular) are filled by individuals with strong industry ties** and hence are more **focused on industry interests than the health of citizens**"

Obtained via FOIA by Judicial Watch, Inc.



Major Litigation Updates & Recent Local Victories

It's been a strong week for our movement!

There are a lot of exciting things to report on this week, so let's dive right in...

Lake Tahoe, CA - Landmark Federal Lawsuit Filed to Block Saturation of Lake Tahoe Region with Cell Towers

Obtained via FOIA by Judicial Watch, Inc.

Hundreds of hazardous, unsightly wireless antennas and cell towers are quickly blanketing the Lake Tahoe, California region.

Three environmental non-profits and Monica Eisenstecken, a lifelong resident of South Lake Tahoe, have filed a potentially **precedent-setting litigation** against the Tahoe Regional Planning Agency, Verizon Wireless, the Tahoe Prosperity Center, and a local property owner...all in an effort **to protect one of the world's greatest natural treasures from a looming telecom takeover.**

Read Today's Press Release

Obtained via FOIA by Judicial Watch, Inc.

Visit the New Tahoe Safe Tech Website

Support the Landmark Litigation

D.C. Court of Appeals - Environmental Health Trust et al. v. FCC Oral Arguments, January 25th, 2021

Obtained via FOIA by Judicial Watch, Inc.

"A federal appeals panel in Washington voiced skepticism that the Federal Communications Commission had adequately considered dangerous health effects when it established guidelines for radiation emission from cell towers and wireless devices."
- Bloomberg Law

Congratulations to both the Environmental Health Trust and the Children's Health Defense for their tireless efforts challenging the FCC's outdated and insufficient wireless radiation public exposure guidelines.

Following yesterday's fabulous presentation, we are hopeful the judges will rule against the FCC.

Obtained via FOIA by Judicial Watch, Inc.

Read the News

Listen to Recording of the Oral Arguments

RECENT VICTORIES

FLORIDA

1. Palm Coast, FL defeats 150-foot cell tower to be installed in the heart of the city's oldest neighborhood.

Read the news here.

Obtained via FOIA by Judicial Watch, Inc.

2. Lakeland, FL defeats 110-foot cell tower slated to be installed mere feet from homes. This is the second cell tower in three months that has been defeated by Lakeland representatives due to resident opposition.

Read the news here.

Obtained via FOIA by Judicial Watch, Inc.

NEW JERSEY

3. Lavallette, NJ Borough Council approves five "small cell" antennas with challenging conditions: certification from the U.S. Department of Defense and the Federal Aviation Administration that 5G frequencies emitted by the equipment will not interfere with critical avionics equipment. Lavallette is situated just a few miles from one of the country's most active military air bases - Joint Base McGuire-Dix-Lakehurst.

Read the news here.

Obtained via FOIA by Judicial Watch, Inc.

CALIFORNIA

4. Petaluma, CA defeats Verizon application to install 16 wireless antennas at the Petaluma Creamery, just 75 feet from homes. Read the legal memorandum in opposition to Verizon's application here.

Obtained via FOIA by Judicial Watch, Inc.

SOUTH CAROLINA

5. Residents in Mt. Pleasant, SC defeat a cell tower to be installed next to the Long Point playground.

Read the news here.

Obtained via FOIA by Judicial Watch, Inc.

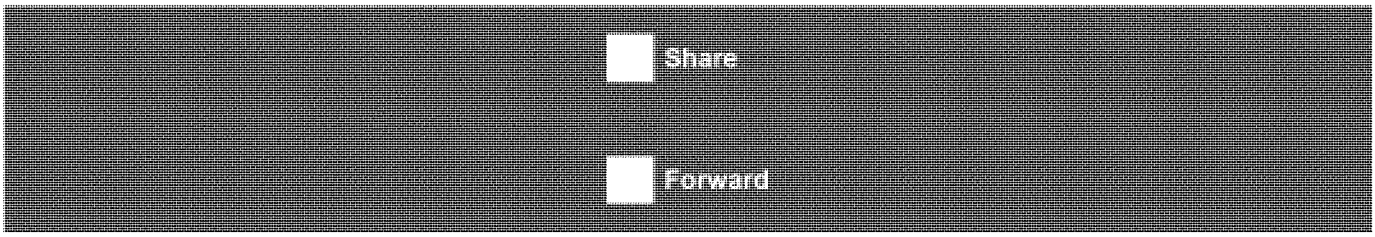
As always, let's keep raking in the wins and working together to protect our communities from the telecom industry's ever-growing wireless footprint.

If you need assistance pushing back against 5G and/or other wireless infrastructure deployments in your area, please don't hesitate to reply to this email or call us at 516-883-0887.

-The 5G Crisis Team

Contribute to 5G Crisis

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Contact us:
Email report@5gcrisis.com
Call 516-883-0887

Want to change how you receive these emails?
You can or .

Thanks,
Vinu

[EXTERNAL EMAIL] DO NOT CLICK links or attachments unless you recognize the sender and know the content is safe.

Obtained via FOIA by Judicial Watch, Inc.

From: Vinu Arumugham (b) (6) @yahoo.com]
Sent: 2/2/2021 2:15:14 PM
To: pcg@scientificfreedom.dk; Golding, Hana [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0619807f66f6406d9ece442207c82c95-goldingh]; Khurana, Surender [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6215b7e342d4622be59fa3d58501a6f-Khurana]; sli49@emory.edu; elizabeth.deatrick@niaid.nih.gov; pwilson1@medicine.bsd.uchicago.edu; agewirtz@gsu.edu; megan.hahn@fda.hhs.gov; goldmanb@stanford.edu; mario.cortese@stanford.edu; nroupha@emory.edu; alan.embry@nih.gov; alex@lji.org; neuron@cell.com; jlandsberg@cell.com; agoldstein@cell.com; mzirlinger@cell.com; tdobie@cell.com; mfurman@cell.com; ckonen@cell.com; eniederst@cell.com; uschridde@cell.com; jshaw@cell.com; eporro@cell.com; emarcus@cell.com; jeffrey.sonnenfeld@yale.edu; info@eeoc.gov; ofo.eeoc@eeoc.gov; FOIA@eeoc.gov; eeoc.traininginstitute@eeoc.gov; inspector.general@eeoc.gov; richard.hatchett@cepi.net; fg17882@bristol.ac.uk; ripley.ballou@gskbio.com; nicole.lurie@cepi.net; 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jmcollins@wisc.edu; jaconwell@wisc.edu; nbarnes2@wisc.edu; kcurtis@ssc.wisc.edu; mcurtis3@wisc.edu; jeason2@wisc.edu; ehrenthal@wisc.edu; felwert@ssc.wisc.edu; cengelman@wisc.edu; mengelman@ssc.wisc.edu; jason.fletcher@wisc.edu; cfu@ssc.wisc.edu; fujimura@ssc.wisc.edu; tgerber@ssc.wisc.edu; cde@ssc.wisc.edu; grantm@ssc.wisc.edu; jan.greenberg@wisc.edu; jmgregory@ssc.wisc.edu; egrodsky@ssc.wisc.edu; sarah.halpernmeekin@wisc.edu; jenny.a.higgins@wisc.edu; lpjacobs@wisc.edu; fjones4@wisc.edu; hyunseung@stat.wisc.edu; dkaplan@education.wisc.edu; jkennan@ssc.wisc.edu; ajk@medicine.wisc.edu; mlight@ssc.wisc.edu; logan@ssc.wisc.edu; kmagnuson@wisc.edu; marsha.mailick@wisc.edu; kmalecki@wisc.edu; mmassoglia@ssc.wisc.edu; drmeyer1@wisc.edu; cmommaerts@wisc.edu; amukherjee@wisc.edu; jmullahy@wisc.edu; jnobles@ssc.wisc.edu; robrien@lafollette.wisc.edu; palloni@wisc.edu; patz@wisc.edu; ppeppard@wisc.edu; jraymo@ssc.wisc.edu; ferey@wisc.edu; sarobert@wisc.edu; schaeffer@ssc.wisc.edu; lschechter@wisc.edu; aschneider4@wisc.edu; cschwart@ssc.wisc.edu; aseshadr@ssc.wisc.edu; smeeding@lafollette.wisc.edu; econjeff@ssc.wisc.edu; psteiner@wisc.edu; ctaber@ssc.wisc.edu; tjernstroem@wisc.edu; walker@ssc.wisc.edu; wallace@lafollette.wisc.edu; tbwalsh@wisc.edu; yang.wang@lafollette.wisc.edu; mjwiswall@wisc.edu; wolfe@lafollette.wisc.edu; ysxiong2@wisc.edu; jzhu@stat.wisc.edu; ashivani@seas.upenn.edu; rbeck@jaeb.org; (b) (6) @gmail.com; t1dstats@jaeb.org; willi@email.chop.edu; weinstor@upstate.edu; paul.wadwa@cuanschutz.edu; jennifer.sherr@yale.edu; rmonzavi@chla.usc.edu; Laurel.Messer@cuanschutz.edu; sarah.corathers@cchmc.org; Amy.Criego@ParkNicollet.com; maclements@cmh.edu; inquires@sda.gov.cn; yerw@bjmu.edu.cn; yxy@xjtu.edu.cn; cfetpyhj@vip.sina.com; caodesheng@chinadaily.com.cn; yanwl@fudan.edu.cn; yiwang@shmu.edu.cn; zhangyp@chinacdc.cn; maojh88@zju.edu.cn; gisou.vandergoot@epfl.ch; nicola.harris@epfl.ch; andrea.ablasser@epfl.ch; patrick.aebischer@epfl.ch; johan.auwerx@epfl.ch; olaf.blanke@epfl.ch; melanie.blokesch@epfl.ch; cathrin.brisken@epfl.ch; philipp.bucher@epfl.ch; stewart.cole@epfl.ch; daniel.constam@epfl.ch; gregoire.courtine@epfl.ch; matteo.dalperaro@epfl.ch; paolo.delosrios@epfl.ch; michele.depalma@epfl.ch; bart.deplancke@epfl.ch; denis.duboule@epfl.ch; wulfram.gerstner@epfl.ch; pierre.gonczy@epfl.ch; johannes.graeff@epfl.ch; douglas.hanahan@epfl.ch; oliver.hantschel@epfl.ch; vassily.hatzimanikatis@epfl.ch; michael.herzog@epfl.ch; kathryn.hess@epfl.ch; joerg.huelsken@epfl.ch; friedhelm.hummel@epfl.ch; hilal.lashuel@epfl.ch; theo.lasser@epfl.ch; bruno.lemaitre@epfl.ch; joachim.lingner@epfl.ch; matthias.lutolf@epfl.ch; pierre.magistretti@epfl.ch; suliana.manley@epfl.ch; henry.markram@epfl.ch; brian.mccabe@epfl.ch; john.mckinney@epfl.ch; etienne.meylan@epfl.ch; felix.naef@epfl.ch; olaia.naveiras@epfl.ch; andrew.oates@epfl.ch; elisa.oricchio@epfl.ch; alexandre.persat@epfl.ch; carl.petersen@epfl.ch; freddy.radtke@epfl.ch; pavan.ramdya@epfl.ch; marcel.salathe@epfl.ch; carmen.sandi@epfl.ch; 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Subject: Re: COVID-19 vaccine dangers; CDC's "Vaccines do not cause autism" lie, taken down; NH commission exposes FCC corruption, cellular radiation dangers

All those who requested have been removed from future threads.

Prof. Gøtzsche,

"we would surely have heard about it."

You just did!

Thanks,

Vinu

On 2/2/21 1:10 AM, pcg@scientificfreedom.dk wrote:

If there had been any reliable evidence that "milk protein contaminated vaccines (DTaP/TdaP, Prevnar 13, ActHiB) cause the vast majority (75%) of autism cases", we would surely have heard about it.

Please delete me from your email list

Peter C Gøtzsche
Professor and Director
Institute for Scientific Freedom
Copenhagen
https://www.scientificfreedom.dk/ and https://www.deadlymedicines.dk/
Twitter: @PGtzsche1

From: Vinu Arumugham <(b) (6) @yahoo.com>
Sent: 01 February 2021 20:11
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Subject: Re: COVID-19 vaccine dangers; CDC's "Vaccines do not cause autism" lie, taken down; NH commission exposes FCC corruption, cellular radiation dangers

Prof. Gøtzsche,

Let me clarify that we are not discussing vaccine vs. no vaccine. We are discussing dirty, sickening vaccines vs. clean safe, effective vaccines.

Regarding autism, you are talking about the wrong vaccine. We have shown beyond all doubt, using **reliable mechanistic evidence** that milk protein contaminated vaccines (DTaP/TdaP, Prevnar 13, ActHiB) cause the vast majority (75%) of autism cases.

Autism pathogenesis: Piecing it all together, from end to beginning ...
https://doi.org/10.5281/zenodo.1477515

Immunization with homologous xenogeneic (animal/plant/fungal) antigens causes the development of autoimmune diseases. Known for at least 45 years.

Vaccine-Induced Autoimmunity in the Dog

"the most likely sources of cross-reactive epitopes are bovine serum and cell culture components. These are present in almost all vaccines as residu-al components of the cell culture necessary to generate vaccine viruses and may purposely be added to the vaccine as a stabilizer. In the presence of an adjuvant, these bovine products stimulate a strong im-mune response and induce antibodies that cross-react with conserved canine antigens."

Xenogeneic therapeutic cancer vaccines as breakers of immune tolerance for clinical application: to use or not to use?
pubmed.ncbi.nlm.nih.gov/24837511/

Oncologists immunize with xenogeneic antigens to break immune tolerance (cause autoimmunity) to make your immune system attack your own cancer cells.

Regular vaccines such as the measles vaccines are contaminated with animal proteins (chicken) and therefore cause numerous autoimmune disorders including type 1 diabetes.

Correlation of type 1 diabetes trends in European countries to the number of bovine insulin and GAD65 contaminated chick embryo cell culture containing vaccines in the schedule, as predicted by the autoimmunity mechanism involving immunization with homologous xenogeneic antigens and EPIT as a potential treatment
https://doi.org/10.5281/zenodo.1870364

The US IOM pointed out that epidemiological studies are useless in 93% of the cases. Mechanistic studies proved reliable.

Institute of Medicine: Most epidemiological vaccine safety studies are useless

https://doi.org/10.5281/zenodo.3244496

The Pandemrix vaccine made in Europe had higher levels of contamination with H1N1 nucleoproteins than the Arepanrix vaccine manufactured by the same company (GSK) in Canada. Pandemrix therefore caused way more cases of narcolepsy. Do you know the level of chicken protein contamination in Danish vs. US vaccines? How can you then apply studies done in Denmark to any other country?

Big picture of the damage vaccines do:

Vaccines and Biologics injury table based on mechanistic evidence – Feb 2020

Covering over 125 conditionshttps://zenodo.org/record/3647593/files/vbitr2_final.pdf?download=1

Obtained via FOIA by Judicial Watch, Inc.

The organized suppression of vaccine safety science:

Retraction of scientific papers: the case of vaccine research
https://www.tandfonline.com/doi/full/10.1080/09581596.2021.1878109

Thanks,

Vinu

On 1/31/21 11:47 PM, pcg@scientificfreedom.dk wrote:

I have no knowledge of this huge email list and do not know why I was put on it. But I assume I will be taken off it because of what I write below. Please read it.

The idea that vaccines may cause autism was launched by Andrew Wakefield in relation to a fraudulent study published in Lancet in 1998 that has been retracted. Large observational studies from my country, Denmark, have shown convincingly that the Emperor has no clothes. I analyse this in detail in my 2020 book, Vaccines: truth, lies and controversy. It is an e-book but will come out soon on Skyhorse, New York, as a print book with an updated corona chapter that ends with the riots on 6 January 2021 at Capitol Hill.

Wakefield's horrendous fraud, which has caused many deaths, concerned the MMR vaccine. These are excerpts from my book, the chapter on measles:

According to the WHO, there were 110,000 measles deaths in 2017, and most were in children under the age of five.[3] Vaccination resulted in an 80% drop in measles deaths between 2000 and 2017 preventing an estimated 21 million deaths.

Measles outbreaks also provide strong support for the benefits of the vaccine. In the United States, there was a resurgence of measles in 1989-1990, which primarily involved unvaccinated racial and ethnic minority children less than five years of age residing in inner-city areas.[40] There were 66 (0.1%) cases of encephalitis. A provisional total of 41 measles-associated deaths was reported in 1989 (2.3 deaths per 1000 cases), which increased to 89 (3.2 per 1000 cases) in 1990. In 2000, the CDC declared measles eradicated in the United States but there have been several outbreaks since due to imported cases.[41] In 2018, no less than 17 outbreaks occurred. One, in New York, was due to people who had been to Israel, and it included 182 cases in orthodox Jewish communities with a vaccination rate of only 50%.[42]
It is not possible to say exactly what the risk is of dying from measles. As noted earlier, the death risk is related to the infectious dose, which is higher in settings with overcrowding. We can only say what it has been in outbreaks, and a commonly used estimate is 2 deaths per 1000 cases. But it can be much worse. During an epidemic in Copenhagen in 1887, at least 5% of the children, or 50 per 1000 cases, died.[43] The mortality was probably even higher because only those who died while they had a rash counted. In Wien, at the beginning of the 20th century, the mortality was 11% among the poorest and 0.6% among the richest.
An outbreak in Madagascar that started in 2018 had in April 2019 caused over 1200 deaths, which is about 1% of those infected.[44] Only about 60% of the population is vaccinated.
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We should all get vaccinated against measles and get our children vaccinated, with very few exceptions. Contraindications for the vaccine include a history of severe allergic reaction to any component of the vaccine including neomycin, pregnancy (measles illness during pregnancy results in a higher risk of premature labour, spontaneous abortion, and low-birthweight infants), and severe immunosuppression.[34]

Obtained via FOIA by Judicial Watch, Inc.
On Swedish TV, in 2020, Wakefield lied horrendously about measles: "Exposure in childhood is safe and conveys lifelong immunity."
<!--[if !supportLineBreakNewLine]-->
<!--[endif]-->
The reference is:

Dokumentär
Anna Nordbeck och Malin Olofsson
Dokument inifrån: VACCINKRIGARNA
https://www.svtplay.se/dokument-inifran-vaccinkrigarna
SVT

Bw

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Subject: COVID-19 vaccine dangers; CDC's "Vaccines do not cause autism" lie, taken down; NH commission exposes FCC corruption, cellular radiation dangers

Vaccines absolutely do cause autism

The CDC has flip-flopped twice in ~5 months on the fraudulent claim that "Vaccines do not cause autism", on their website. It suggests that the CDC's vaccine/autism claims are based on the conjunction of Jupiter and Saturn, not science.

They were forced to take the false claim down because ICAN demonstrated there was **ZERO** science behind that claim.

The CDC Finally Capitulated To ICAN's Legal Demands and Removed the Claim that "Vaccines Do Not Cause Autism" From Its Website!

https://www.icandecide.org/ican_press/the-cdc-finally-capitulated-to-icans-legal-demands-and-removed-the-claim-that-vaccines-do-not-cause-autism-from-its-website/

THE CDC JUST SOLIDIFIED THAT ITS DECISIONS ARE NOT DRIVEN BY SCIENCE

Obtained via FOIA by Judicial Watch, Inc.

https://www.icandecide.org/ican_press/the-cdc-just-solidified-that-its-decisions-are-not-driven-by-science/

FACT: Milk protein contaminated vaccines (DTap/Tdap/Prevnar 13/ActHiB) cause at least 75% of autism cases.

Autism pathogenesis: Piecing it all together, from end to beginning ...
https://doi.org/10.5281/zenodo.1477515

CDC caught lying, again about the COVID-19 vaccine this time.

CDC Investigation

http://fullmeasure.news/news/cover-story/cdc-investigation

Vaccine mandates are based on a lie; Repeal all mandates immediately; Try the corrupted liars who created mandates, for CRIMES AGAINST HUMANITY

"Administration of parenterally administered vaccines alone typically does not result in potent mucosal immunity that might interrupt infection or transmission"

SARS-CoV-2 Vaccines: Much Accomplished, Much to Learn

www.acpjournals.org/doi/10.7326/M21-0111

So Fauci admits now that **ALL** injected vaccines are for individual protection only. **No herd/community immunity.** So no vaccine mandates are justifiable for **ANY** injected vaccine.

And of course this also means the vaccinated can become infected super-spreaders as occurs with the failed flu shot and failed pertussis vaccines.

Yan J, Grantham M, Pantelic J, de Mesquita PJ, Albert B, Liu F, et al. Infectious virus in exhaled breath of symptomatic seasonal influenza cases from a college community. Adamson W, Beato-Arribas B, Bischoff W, Booth W, Cauchemez S, Ehrman S, et al., editors. Proc Natl Acad Sci. National Academy of Sciences; 2018;

The potential role of subclinical Bordetella Pertussis colonization in the etiology of multiple sclerosis
pubmed.ncbi.nlm.nih.gov/26724970/

This is the consequence of **insanely injecting** antigens of pathogens whose natural routes of exposure are mucosal surfaces in the nose, mouth or eyes.

NOTICE!

By authority of the Nuremberg Code on Medical Experimentation, I do hereby exercise my right to refuse to submit to or to administer the Covid-19 vaccine. The United States Government has prosecuted, convicted and executed Medical Doctors who have violated the Nuremberg Code on Medical Experimentation. Aiders and abettors of Nuremberg Crimes are equally guilty and have also been prosecuted, convicted, and executed.

Francis A. Boyle
Professor of Law.

My comment in the Annals of Internal Medicine, against Fauci's "SARS-CoV-2 Vaccines: Much Accomplished, Much to Learn"

https://www.acpjournals.org/doi/10.7326/M21-0111

Vinu Arumugham Independent 18 January 2021

These vaccines are unsafe, unnecessary and must be immediately withdrawn

Obtained via FOIA by Judicial Watch, Inc.

The vaccine safety claims made by the authors are unsupported by evidence. Vaccines must be designed for safety. These vaccines were not designed at all. So they are unsafe by definition. I predicted the allergic sensitization and autoimmunity risks with these vaccines which have now been confirmed.

The Pfizer/BioNTech vaccine is unnecessary, unsafe and should not be authorized.

https://www.regulations.gov/document?D=FDA-2020-N-1898-0039

Robert F Kennedy Jr. warned the FDA months back about the risk of allergic reactions due to the use of polyethylene glycol (PEG) in the vaccines.
https://childrenshealthdefense.org/defender/pfizer-covid-vaccine-allergic-reactions/

The FDA/VRBPAC ignored us and authorized these horrendously dangerous vaccines.

Recently, Dr. Peter Marks of the FDA admitted that the population was sensitized by PEG-containing pharmaceutical preparations (that include other vaccines/injections).

https://www.wsj.com/articles/scientists-eye-potential-culprit-for-covid-19-vaccine-allergic-reactions-11608901200?mod=hp_lead_pos2

"What we're learning now is that those **allergic reactions could be somewhat more common** than the highly uncommon that we thought they were **because people do get exposed to polyethylene glycol in various pharmaceutical preparations,**" - Peter Marks, Director, CBER,FDA.

We of course already knew that any vaccine/injection that has enough allergen to cause a reaction, has more than enough allergen to guarantee sensitization/priming (causing the development of new allergy).

Evidence that Food Proteins in Vaccines Cause the Development of Food Allergies and Its Implications for Vaccine Policy

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3571073

www.sciencemag.org/news/2020/12/suspicions-grow-nanoparticles-pfizer-s-covid-19-vaccine-trigger-rare-allergic-reactions

"he worries anti-PEG antibodies triggered by the first shot could increase the risk of an allergic reaction to the second or to PEGylated drugs."

- Janos Szebeni, an immunologist at Semmelweis University

So now, these vaccines have sensitized millions to PEG. The goal is to sensitize/boost PEG allergy in a 100 million more in the next 100 days.

PEG is contaminated with 1,4-dioxane, a carcinogen.

https://www.fda.gov/cosmetics/potential-contaminants-cosmetics/14-dioxane-cosmetics-manufacturing-byproduct

Obtained via FOIA by Judicial Watch, Inc.

As predicted, Pfizer COVID-19 vaccine induced autoimmunity (thrombocytopenia) killed a Florida doctor. This is just the tip of the iceberg. Thousands of cases of vaccine induced autoimmune diseases may take months/years to be diagnosed and will be dismissed as unrelated to the vaccine.

https://www.nytimes.com/2021/01/12/health/covid-vaccine-death.html

Only a few lots were tested in the trial. No one has a clue what other lots will do. 100-fold variation of contaminants in vaccines makes trials and epidemiological studies worthless as I detailed in my comments in the Annals of Internal Medicine before. Vaccine safety remains an oxymoron.

https://www.acpjournals.org/doi/10.7326/m18-2101

California calls for pause of 330,000 doses, investigation after allergic reactions to Moderna vaccine batch

https://www.mercurynews.com/2021/01/18/coronavirus-california-calls-for-pause-investigation-after-allergic-reactions-to-moderna-vaccine-batch/

What's worse? Effective, life-saving, cheap, safe medicines such as famotidine/cetirizine/ivermectin are being ignored in this blind race to vaccinate at any cost.

Immunological mechanisms explaining the role of vaccines, IgE, mast cells, histamine, elevating ferritin, IL-6, D-dimer, VEGF levels in COVID-19 and dengue, potential treatments such as mast cell stabilizers, antihistamines: Predictions and confirmations

https://europepmc.org/article/PPR/PPR241819

Big picture of the damage vaccines do:

Vaccines and Biologics injury table based on mechanistic evidence – Feb 2020

Covering over 125 conditionshttps://zenodo.org/record/3647593/files/vbitr2_final.pdf?download=1

The organized suppression of vaccine safety science:

Retraction of scientific papers: the case of vaccine research
https://www.tandfonline.com/doi/full/10.1080/09581596.2021.1878109

The WHO's flip-flopping "science" competes with CDC's incompetence

WHO Recommends Against Moderna, Pfizer Vaccines for Most Pregnant Women

https://www.wsj.com/articles/who-recommends-against-moderna-pfizer-vaccines-for-most-pregnant-women-11611775138

Pregnant Women May Receive Covid Vaccines Safely, W.H.O. Says
https://www.nytimes.com/2021/01/29/health/covid-vaccine-pregnancy.html

Moderna's COVID-19 vaccine now recommended for pregnant women, WHO says in guidance reversal

https://www.foxnews.com/health/moderna-covid-vaccine-pregnant-women-who-guidance-reversal

Not to be outdone by the flip-flopping CDC, WHO did a flip-flop on COVID-19 vaccine during pregnancy.

Latest evidence that there is ZERO science behind vaccines or vaccine safety. They just pull their "science" out of a hat. Follow the money.

Obtained via FOIA by Judicial Watch, Inc.

These flip-flopping, lying, organized criminals at the CDC/WHO, are the "reputable sources" for your "fact-checkers".

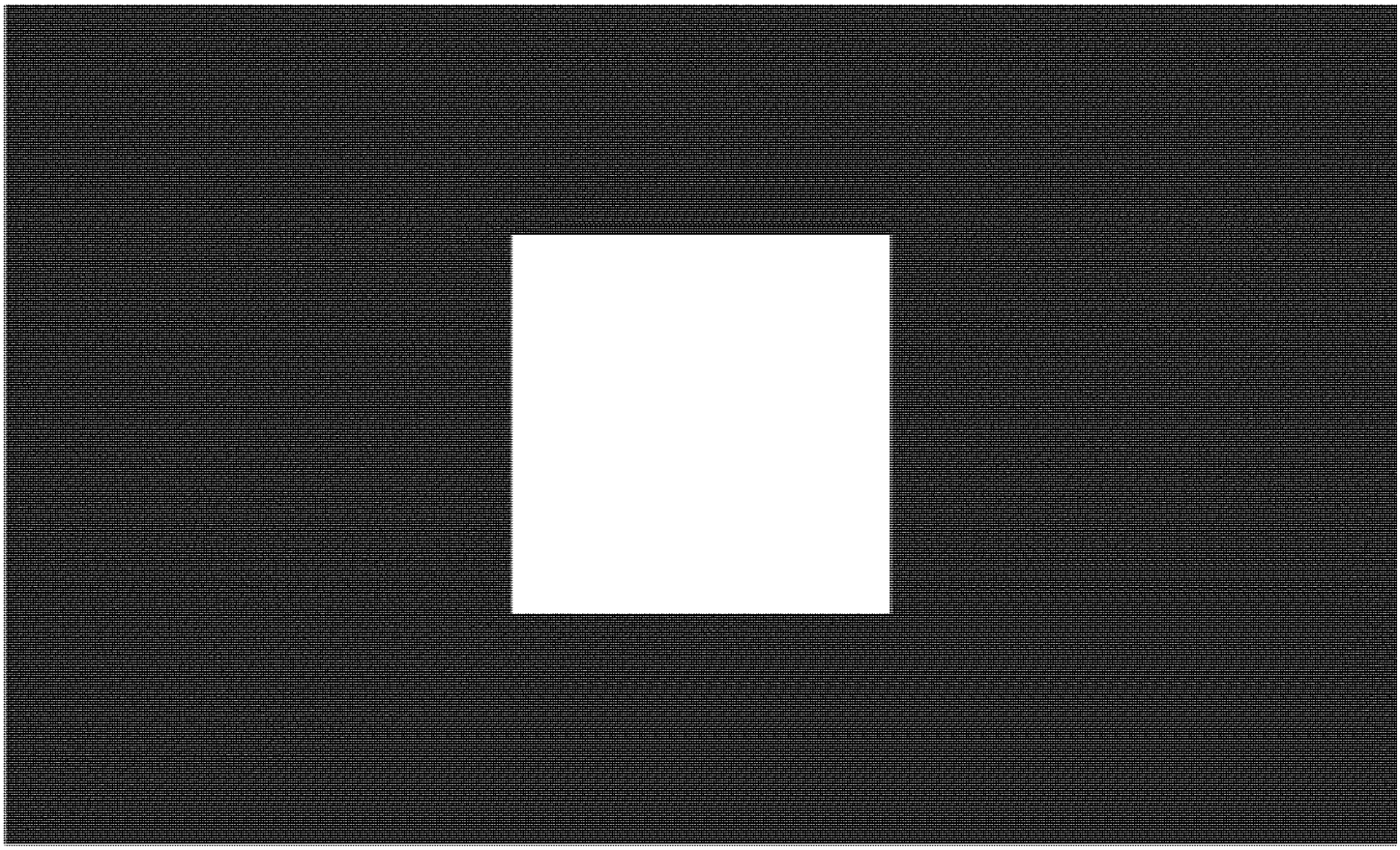
The New Hampshire Commission report below has ripped FCC's 5G (and all other cellular) RF safety claims:

Final Report of the Commission to Study The Environmental and Health Effects of Evolving 5G Technology

http://www.gencourt.state.nh.us/statstudcomm/committees/1474/reports/5G%20final%20report.pdf

"RECOMMENDATION 1- Propose a resolution of the House to the US Congress and Executive Branch to **require the Federal Communication Commission (FCC) to commission an independent review** of the current radiofrequency (RF) standards of the electromagnetic radiation in the 300MHz to 300GHz microwave spectrum as well as a health study to assess and recommend mitigation for the health risks associated with the use of cellular communications and data transmittal."

"A likely explanation as to why **regulatory agencies have opted to ignore the body of scientific evidence demonstrating the negative impact of cellphone radiation** is that **those agencies are "captured"** (see Harvard University publication entitled, "Captured Agency: How the Federal Communications Commission Is Dominated by the Industries It Presumably Regulates" linked in Appendix G). This report documents how **the leadership roles in some agencies (the FCC in particular) are filled by individuals with strong industry ties** and hence are more **focused on industry interests than the health of citizens**"



Obtained via FOIA by Judicial Watch, Inc.

Major Litigation Updates & Recent Local Victories

It's been a strong week for our movement!

There are a lot of exciting things to report on this week, so let's dive right in...

Lake Tahoe, CA - Landmark Federal Lawsuit Filed to Block Saturation of Lake Tahoe Region with Cell Towers

Obtained via FOIA by Judicial Watch, Inc.

Hundreds of hazardous, unsightly wireless antennas and cell towers are quickly blanketing the Lake Tahoe, California region.

Three environmental non-profits and Monica Eisenstecken, a lifelong resident of South Lake Tahoe, have filed a potentially **precedent-setting litigation** against the Tahoe Regional Planning Agency, Verizon Wireless, the Tahoe Prosperity Center, and a local property owner...all in an effort **to protect one of the world's greatest natural treasures from a looming telecom takeover.**

Read Today's Press Release

Visit the New Tahoe Safe Tech Website

Support the Landmark Litigation

D.C. Court of Appeals - Environmental Health Trust et al. v. FCC Oral Arguments, January 25th, 2021

Obtained via FOIA by Judicial Watch, Inc.

"A federal appeals panel in Washington voiced skepticism that the Federal Communications Commission had adequately considered dangerous health effects when it established guidelines for radiation emission from cell towers and wireless devices."
- Bloomberg Law

Congratulations to both the Environmental Health Trust and the Children's Health Defense for their tireless efforts challenging the FCC's outdated and insufficient wireless radiation public exposure guidelines.

Following yesterday's fabulous presentation, we are hopeful the judges will rule against the FCC.

Obtained via FOIA by Judicial Watch, Inc.

Read the News

Listen to Recording of the Oral Arguments

RECENT VICTORIES

FLORIDA

1. Palm Coast, FL defeats 150-foot cell tower to be installed in the heart of the city's oldest neighborhood.

Read the news here.

Obtained via FOIA by Judicial Watch, Inc.

2. Lakeland, FL defeats 110-foot cell tower slated to be installed mere feet from homes. This is the second cell tower in three months that has been defeated by Lakeland representatives due to resident opposition.

Read the news here.

Obtained via FOIA by Judicial Watch, Inc.

NEW JERSEY

3. Lavallette, NJ Borough Council approves five "small cell" antennas with challenging conditions: certification from the U.S. Department of Defense and the Federal Aviation Administration that 5G frequencies emitted by the equipment will not interfere with critical avionics equipment. Lavallette is situated just a few miles from one of the country's most active military air bases - Joint Base McGuire-Dix-Lakehurst.

Read the news here.

Obtained via FOIA by Judicial Watch, Inc.

CALIFORNIA

4. Petaluma, CA defeats Verizon application to install 16 wireless antennas at the Petaluma Creamery, just 75 feet from homes. Read the legal memorandum in opposition to Verizon's application here.

Obtained via FOIA by Judicial Watch, Inc.

SOUTH CAROLINA

5. Residents in Mt. Pleasant, SC defeat a cell tower to be installed next to the Long Point playground.

Read the news here.

Obtained via FOIA by Judicial Watch, Inc.

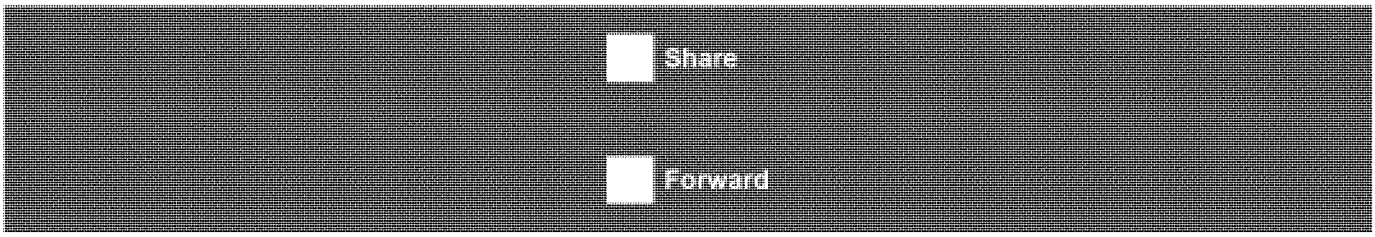
As always, let's keep raking in the wins and working together to protect our communities from the telecom industry's ever-growing wireless footprint.

If you need assistance pushing back against 5G and/or other wireless infrastructure deployments in your area, please don't hesitate to reply to this email or call us at 516-883-0887.

-The 5G Crisis Team

Contribute to 5G Crisis

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Contact us:
Email report@5gcrisis.com
Call 516-883-0887

Want to change how you receive these emails?
You can or .

Thanks,
Vinu

Obtained via FOIA by Judicial Watch, Inc.

From: Kristen Malecki [kmalecki@wisc.edu]
Sent: 2/2/2021 10:30:55 AM
To: cbrechot@usf.edu; Vinu Arumugham (b) (6) @yahoo.com]; pcg@scientificfreedom.dk; Golding, Hana [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0619807f66f6406d9ece442207c82c95-goldingh]; Khurana, Surender [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6215b7e342d4622be59fa3d58501a6f-Khurana]; sli49@emory.edu; elizabeth.deatrick@niaid.nih.gov; pwilson1@medicine.bsd.uchicago.edu; agewirtz@gsu.edu; megan.hahn@fda.hhs.gov; goldmanb@stanford.edu; mario.cortese@stanford.edu; nroupha@emory.edu; alan.embry@nih.gov; alex@lji.org; neuron@cell.com; jlandsberg@cell.com; agoldstein@cell.com; mzirlinger@cell.com; tdobie@cell.com; mfurman@cell.com; ckonen@cell.com; eniederst@cell.com; uschridde@cell.com; jshaw@cell.com; eporro@cell.com; emarcus@cell.com; jeffrey.sonnenfeld@yale.edu; info@eeoc.gov; ofo.eeoc@eeoc.gov; FOIA@eeoc.gov; eeoc.traininginstitute@eeoc.gov; inspector.general@eeoc.gov; richard.hatchett@cepi.net; fg17882@bristol.ac.uk; ripley.ballou@gskbio.com; nicole.lurie@cepi.net; jlg251@georgetown.edu; tom.monath@crozetbiopharma.com; aabimiku@ihv.umaryland.edu; abarrett@utmb.edu; Ananda.Bandyopadhyay@gatesfoundation.org; chappi@hsph.harvard.edu; Connie.s.schmaljohn.civ@mail.mil; Damon, Inger K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=42b35bd733a34c66a5698f43f7026e88-HHS-iad7-cd]; jamesrobinson@uchicago.edu; Jean.Lang@sanofipasteur.com; john.k.billington@gsk.com; kenji.shibuya@kcl.ac.uk; Krause, Philip [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00c6330fea0042fdb5571c3fdef792ed-krause]; mlevine@som.umaryland.edu; moorthyv@who.int; Bryant, Paula R (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3eb42f9318014bbb8c14d39ef311d8f9-HHS-paula.b]; (b) (6) @africaonline.co.ke; yves.levy@aphp.fr; Fenaba Addo [faddo@wisc.edu]; Bradford Barham [bradford.barham@wisc.edu]; LEONELO E BAUTISTA [lebautista@wisc.edu]; Lawrence M Berger [lmberger@wisc.edu]; Will Buckingham [wrbuckin@wisc.edu]; MARGUERITE E BURNS [meburns@wisc.edu]; Marcy Carlson [carlson@ssc.wisc.edu]; J. 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Subject: STOP REPLY ALL PLEASE - Re: COVID-19 vaccine dangers; CDC's "Vaccines do not cause autism" lie, taken down; NH commission exposes FCC corruption, cellular radiation dangers

Dear All,

It appears the original email came from pcg@scientificfreedom.dk.

Please email directly to remove yourself from the list. Otherwise, we will get 251 individual emails. I am most certain this is not what we want.

Thanks- Kristen

From: "cbrechot@usf.edu" <cbrechot@usf.edu>
Date: Tuesday, February 2, 2021 at 9:24 AM
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Subject: RE: COVID-19 vaccine dangers; CDC's "Vaccines do not cause autism" lie, taken down; NH commission exposes FCC corruption, cellular radiation dangers

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Subject: Re: COVID-19 vaccine dangers; CDC's "Vaccines do not cause autism" lie, taken down; NH commission exposes FCC corruption, cellular radiation dangers

Prof. Gøtzsche,

Let me clarify that we are not discussing vaccine vs. no vaccine. We are discussing dirty, sickening vaccines vs. clean safe, effective vaccines.

Regarding autism, you are talking about the wrong vaccine. We have shown beyond all doubt, using **reliable mechanistic evidence** that milk protein contaminated vaccines (DTaP/TdaP, Prevnar 13, ActHiB) cause the vast majority (75%) of autism cases.

Autism pathogenesis: Piecing it all together, from end to beginning ...
https://doi.org/10.5281/zenodo.1477515

Immunization with homologous xenogeneic (animal/plant/fungal) antigens causes the development of autoimmune diseases. Known for at least 45 years.

Vaccine-Induced Autoimmunity in the Dog

"the most likely sources of cross-reactive epitopes are bovine serum and cell culture components. These are present in almost all vaccines as residu-al components of the cell culture necessary to generate vaccine viruses and may purposely be added to the vaccine as a stabilizer. In the presence of an adjuvant, these bovine products stimulate a strong im-mune response and induce antibodies that cross-react with conserved canine antigens."

Xenogeneic therapeutic cancer vaccines as breakers of immune tolerance for clinical application: to use or not to use?
pubmed.ncbi.nlm.nih.gov/24837511/

Oncologists immunize with xenogeneic antigens to break immune tolerance (cause autoimmunity) to make your immune system attack your own cancer cells.

Regular vaccines such as the measles vaccines are contaminated with animal proteins (chicken) and therefore cause numerous autoimmune disorders including type 1 diabetes.

Correlation of type 1 diabetes trends in European countries to the number of bovine insulin and GAD65 contaminated chick embryo cell culture containing vaccines in the schedule, as predicted by the autoimmunity mechanism involving immunization with homologous xenogeneic antigens and EPIT as a potential treatment
https://doi.org/10.5281/zenodo.1870364

The US IOM pointed out that epidemiological studies are useless in 93% of the cases. Mechanistic studies proved reliable.

Institute of Medicine: Most epidemiological vaccine safety studies are useless

https://doi.org/10.5281/zenodo.3244496

The Pandemrix vaccine made in Europe had higher levels of contamination with H1N1 nucleoproteins than the Arepanrix vaccine manufactured by the same company (GSK) in Canada. Pandemrix therefore caused way more cases of narcolepsy. Do you know the level of chicken protein contamination in Danish vs. US vaccines? How can you then apply studies done in Denmark to any other country?

Big picture of the damage vaccines do:

Vaccines and Biologics injury table based on mechanistic evidence – Feb 2020

Covering over 125 conditionshttps://zenodo.org/record/3647593/files/vbitr2_final.pdf?download=1

Obtained via FOIA by Judicial Watch, Inc.

The organized suppression of vaccine safety science:

Retraction of scientific papers: the case of vaccine research
https://www.tandfonline.com/doi/full/10.1080/09581596.2021.1878109

Thanks,

Vinu

On 1/31/21 11:47 PM, pcg@scientificfreedom.dk wrote:

I have no knowledge of this huge email list and do not know why I was put on it. But I assume I will be taken off it because of what I write below. Please read it.

The idea that vaccines may cause autism was launched by Andrew Wakefield in relation to a fraudulent study published in Lancet in 1998 that has been retracted. Large observational studies from my country, Denmark, have shown convincingly that the Emperor has no clothes. I analyse this in detail in my 2020 book, Vaccines: truth, lies and controversy. It is an e-book but will come out soon on Skyhorse, New York, as a print book with an updated corona chapter that ends with the riots on 6 January 2021 at Capitol Hill.

Wakefield's horrendous fraud, which has caused many deaths, concerned the MMR vaccine. These are excerpts from my book, the chapter on measles:

According to the WHO, there were 110,000 measles deaths in 2017, and most were in children under the age of five.[3] Vaccination resulted in an 80% drop in measles deaths between 2000 and 2017 preventing an estimated 21 million deaths.

Measles outbreaks also provide strong support for the benefits of the vaccine. In the United States, there was a resurgence of measles in 1989-1990, which primarily involved unvaccinated racial and ethnic minority children less than five years of age residing in inner-city areas.[40] There were 66 (0.1%) cases of encephalitis. A provisional total of 41 measles-associated deaths was reported in 1989 (2.3 deaths per 1000 cases), which increased to 89 (3.2 per 1000 cases) in 1990. In 2000, the CDC declared measles eradicated in the United States but there have been several outbreaks since due to imported cases.[41] In 2018, no less than 17 outbreaks occurred. One, in New York, was due to people who had been to Israel, and it included 182 cases in orthodox Jewish communities with a vaccination rate of only 50%.[42]
It is not possible to say exactly what the risk is of dying from measles. As noted earlier, the death risk is related to the infectious dose, which is higher in settings with overcrowding. We can only say what it has been in outbreaks, and a commonly used estimate is 2 deaths per 1000 cases. But it can be much worse. During an epidemic in Copenhagen in 1887, at least 5% of the children, or 50 per 1000 cases, died.[43] The mortality was probably even higher because only those who died while they had a rash counted. In Wien, at the beginning of the 20th century, the mortality was 11% among the poorest and 0.6% among the richest.
An outbreak in Madagascar that started in 2018 had in April 2019 caused over 1200 deaths, which is about 1% of those infected.[44] Only about 60% of the population is vaccinated.

We should all get vaccinated against measles and get our children vaccinated, with very few exceptions. Contraindications for the vaccine include a history of severe allergic reaction to any component of the vaccine including neomycin, pregnancy (measles illness during pregnancy results in a higher risk of premature labour, spontaneous abortion, and low-birthweight infants), and severe immunosuppression.[34]

Obtained via FOIA by Judicial Watch, Inc.

On Swedish TV, in 2020, Wakefield lied horrendously about measles: "Exposure in childhood is safe and conveys lifelong immunity."

The reference is:

Dokumentär
Anna Nordbeck och Malin Olofsson
Dokument inifrån: VACCINKRIGARNA
https://www.svtplay.se/dokument-inifran-vaccinkrigarna
SVT

Bw

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Subject: COVID-19 vaccine dangers; CDC's "Vaccines do not cause autism" lie, taken down; NH commission exposes FCC corruption, cellular radiation dangers

Vaccines absolutely do cause autism

The CDC has flip-flopped twice in ~5 months on the fraudulent claim that "Vaccines do not cause autism", on their website. It suggests that the CDC's vaccine/autism claims are based on the conjunction of Jupiter and Saturn, not science.

They were forced to take the false claim down because ICAN demonstrated there was **ZERO** science behind that claim.

The CDC Finally Capitulated To ICAN's Legal Demands and Removed the Claim that "Vaccines Do Not Cause Autism" From Its Website!

https://www.icandecide.org/ican_press/the-cdc-finally-capitulated-to-icans-legal-demands-and-removed-the-claim-that-vaccines-do-not-cause-autism-from-its-website/

THE CDC JUST SOLIDIFIED THAT ITS DECISIONS ARE NOT DRIVEN BY SCIENCE

Obtained via FOIA by Judicial Watch, Inc.

https://www.icandecide.org/ican_press/the-cdc-just-solidified-that-its-decisions-are-not-driven-by-science/

FACT: Milk protein contaminated vaccines (DTap/Tdap/Prevnar 13/ActHiB) cause at least 75% of autism cases.

Autism pathogenesis: Piecing it all together, from end to beginning ...
https://doi.org/10.5281/zenodo.1477515

CDC caught lying, again about the COVID-19 vaccine this time.

CDC Investigation

http://fullmeasure.news/news/cover-story/cdc-investigation

Vaccine mandates are based on a lie; Repeal all mandates immediately; Try the corrupted liars who created mandates, for CRIMES AGAINST HUMANITY

"Administration of parenterally administered vaccines alone typically does not result in potent mucosal immunity that might interrupt infection or transmission"

SARS-CoV-2 Vaccines: Much Accomplished, Much to Learn

www.acpjournals.org/doi/10.7326/M21-0111

So Fauci admits now that **ALL** injected vaccines are for individual protection only. **No herd/community immunity.** So no vaccine mandates are justifiable for **ANY** injected vaccine.

And of course this also means the vaccinated can become infected super-spreaders as occurs with the failed flu shot and failed pertussis vaccines.

Yan J, Grantham M, Pantelic J, de Mesquita PJ, Albert B, Liu F, et al. Infectious virus in exhaled breath of symptomatic seasonal influenza cases from a college community. Adamson W, Beato-Arribas B, Bischoff W, Booth W, Cauchemez S, Ehrman S, et al., editors. Proc Natl Acad Sci. National Academy of Sciences; 2018;

The potential role of subclinical Bordetella Pertussis colonization in the etiology of multiple sclerosis
pubmed.ncbi.nlm.nih.gov/26724970/

This is the consequence of **insanely injecting** antigens of pathogens whose natural routes of exposure are mucosal surfaces in the nose, mouth or eyes.

NOTICE!

By authority of the Nuremberg Code on Medical Experimentation, I do hereby exercise my right to refuse to submit to or to administer the Covid-19 vaccine. The United States Government has prosecuted, convicted and executed Medical Doctors who have violated the Nuremberg Code on Medical Experimentation. Aiders and abettors of Nuremberg Crimes are equally guilty and have also been prosecuted, convicted, and executed.

Francis A. Boyle
Professor of Law.

My comment in the Annals of Internal Medicine, against Fauci's "SARS-CoV-2 Vaccines: Much Accomplished, Much to Learn"

https://www.acpjournals.org/doi/10.7326/M21-0111

Vinu Arumugham Independent 18 January 2021

These vaccines are unsafe, unnecessary and must be immediately withdrawn

Obtained via FOIA by Judicial Watch, Inc.

The vaccine safety claims made by the authors are unsupported by evidence. Vaccines must be designed for safety. These vaccines were not designed at all. So they are unsafe by definition. I predicted the allergic sensitization and autoimmunity risks with these vaccines which have now been confirmed.

The Pfizer/BioNTech vaccine is unnecessary, unsafe and should not be authorized.

https://www.regulations.gov/document?D=FDA-2020-N-1898-0039

Robert F Kennedy Jr. warned the FDA months back about the risk of allergic reactions due to the use of polyethylene glycol (PEG) in the vaccines.
https://childrenshealthdefense.org/defender/pfizer-covid-vaccine-allergic-reactions/

The FDA/VRBPAC ignored us and authorized these horrendously dangerous vaccines.

Recently, Dr. Peter Marks of the FDA admitted that the population was sensitized by PEG-containing pharmaceutical preparations (that include other vaccines/injections).

https://www.wsj.com/articles/scientists-eye-potential-culprit-for-covid-19-vaccine-allergic-reactions-11608901200?mod=hp_lead_pos2

"What we're learning now is that those **allergic reactions could be somewhat more common** than the highly uncommon that we thought they were **because people do get exposed to polyethylene glycol in various pharmaceutical preparations,**" - Peter Marks, Director, CBER,FDA.

We of course already knew that any vaccine/injection that has enough allergen to cause a reaction, has more than enough allergen to guarantee sensitization/priming (causing the development of new allergy).

Evidence that Food Proteins in Vaccines Cause the Development of Food Allergies and Its Implications for Vaccine Policy

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3571073

www.sciencemag.org/news/2020/12/suspicions-grow-nanoparticles-pfizer-s-covid-19-vaccine-trigger-rare-allergic-reactions

"he worries anti-PEG antibodies triggered by the first shot could increase the risk of an allergic reaction to the second or to PEGylated drugs."

- Janos Szebeni, an immunologist at Semmelweis University

So now, these vaccines have sensitized millions to PEG. The goal is to sensitize/boost PEG allergy in a 100 million more in the next 100 days.

PEG is contaminated with 1,4-dioxane, a carcinogen.

https://www.fda.gov/cosmetics/potential-contaminants-cosmetics/14-dioxane-cosmetics-manufacturing-byproduct

Obtained via FOIA by Judicial Watch, Inc.

As predicted, Pfizer COVID-19 vaccine induced autoimmunity (thrombocytopenia) killed a Florida doctor. This is just the tip of the iceberg. Thousands of cases of vaccine induced autoimmune diseases may take months/years to be diagnosed and will be dismissed as unrelated to the vaccine.

https://www.nytimes.com/2021/01/12/health/covid-vaccine-death.html

Only a few lots were tested in the trial. No one has a clue what other lots will do. 100-fold variation of contaminants in vaccines makes trials and epidemiological studies worthless as I detailed in my comments in the Annals of Internal Medicine before. Vaccine safety remains an oxymoron.

https://www.acpjournals.org/doi/10.7326/m18-2101

California calls for pause of 330,000 doses, investigation after allergic reactions to Moderna vaccine batch

https://www.mercurynews.com/2021/01/18/coronavirus-california-calls-for-pause-investigation-after-allergic-reactions-to-moderna-vaccine-batch/

What's worse? Effective, life-saving, cheap, safe medicines such as famotidine/cetirizine/ivermectin are being ignored in this blind race to vaccinate at any cost.

Immunological mechanisms explaining the role of vaccines, IgE, mast cells, histamine, elevating ferritin, IL-6, D-dimer, VEGF levels in COVID-19 and dengue, potential treatments such as mast cell stabilizers, antihistamines: Predictions and confirmations

https://europepmc.org/article/PPR/PPR241819

Big picture of the damage vaccines do:

Vaccines and Biologics injury table based on mechanistic evidence – Feb 2020

Covering over 125 conditionshttps://zenodo.org/record/3647593/files/vbitr2_final.pdf?download=1

The organized suppression of vaccine safety science:

Retraction of scientific papers: the case of vaccine research
https://www.tandfonline.com/doi/full/10.1080/09581596.2021.1878109

The WHO's flip-flopping "science" competes with CDC's incompetence

WHO Recommends Against Moderna, Pfizer Vaccines for Most Pregnant Women

https://www.wsj.com/articles/who-recommends-against-moderna-pfizer-vaccines-for-most-pregnant-women-11611775138

Pregnant Women May Receive Covid Vaccines Safely, W.H.O. Says
https://www.nytimes.com/2021/01/29/health/covid-vaccine-pregnancy.html

Moderna's COVID-19 vaccine now recommended for pregnant women, WHO says in guidance reversal

https://www.foxnews.com/health/moderna-covid-vaccine-pregnant-women-who-guidance-reversal

Not to be outdone by the flip-flopping CDC, WHO did a flip-flop on COVID-19 vaccine during pregnancy.

Latest evidence that there is ZERO science behind vaccines or vaccine safety. They just pull their "science" out of a hat. Follow the money.

Obtained via FOIA by Judicial Watch, Inc.

These flip-flopping, lying, organized criminals at the CDC/WHO, are the "reputable sources" for your "fact-checkers".

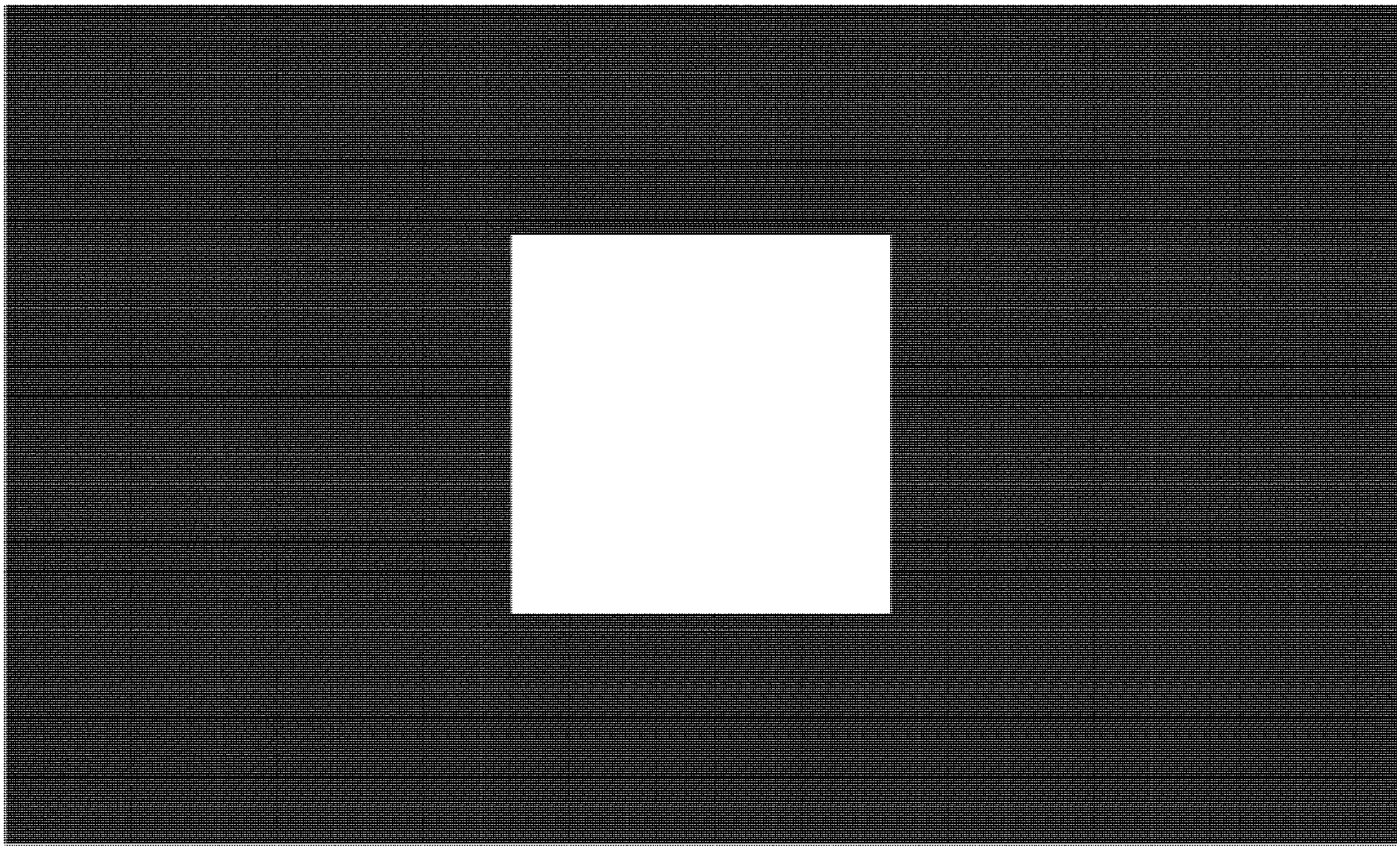
The New Hampshire Commission report below has ripped FCC's 5G (and all other cellular) RF safety claims:

Final Report of the Commission to Study The Environmental and Health Effects of Evolving 5G Technology

http://www.gencourt.state.nh.us/statstudcomm/committees/1474/reports/5G%20final%20report.pdf

"RECOMMENDATION 1- Propose a resolution of the House to the US Congress and Executive Branch to **require the Federal Communication Commission (FCC) to commission an independent review** of the current radiofrequency (RF) standards of the electromagnetic radiation in the 300MHz to 300GHz microwave spectrum as well as a health study to assess and recommend mitigation for the health risks associated with the use of cellular communications and data transmittal."

"A likely explanation as to why **regulatory agencies have opted to ignore the body of scientific evidence demonstrating the negative impact of cellphone radiation** is that **those agencies are "captured"** (see Harvard University publication entitled, "Captured Agency: How the Federal Communications Commission Is Dominated by the Industries It Presumably Regulates" linked in Appendix G). This report documents how **the leadership roles in some agencies (the FCC in particular) are filled by individuals with strong industry ties** and hence are more **focused on industry interests than the health of citizens**"



Obtained via FOIA by Judicial Watch, Inc.

Major Litigation Updates & Recent Local Victories

It's been a strong week for our movement!

There are a lot of exciting things to report on this week, so let's dive right in...

Lake Tahoe, CA - Landmark Federal Lawsuit Filed to Block Saturation of Lake Tahoe Region with Cell Towers

Obtained via FOIA by Judicial Watch, Inc.

Hundreds of hazardous, unsightly wireless antennas and cell towers are quickly blanketing the Lake Tahoe, California region.

Three environmental non-profits and Monica Eisenstecken, a lifelong resident of South Lake Tahoe, have filed a potentially **precedent-setting litigation** against the Tahoe Regional Planning Agency, Verizon Wireless, the Tahoe Prosperity Center, and a local property owner...all in an effort **to protect one of the world's greatest natural treasures from a looming telecom takeover.**

Read Today's Press Release

Visit the New Tahoe Safe Tech Website

Support the Landmark Litigation

D.C. Court of Appeals - Environmental Health Trust et al. v. FCC Oral Arguments, January 25th, 2021

Obtained via FOIA by Judicial Watch, Inc.

"A federal appeals panel in Washington voiced skepticism that the Federal Communications Commission had adequately considered dangerous health effects when it established guidelines for radiation emission from cell towers and wireless devices."
- Bloomberg Law

Congratulations to both the Environmental Health Trust and the Children's Health Defense for their tireless efforts challenging the FCC's outdated and insufficient wireless radiation public exposure guidelines.

Following yesterday's fabulous presentation, we are hopeful the judges will rule against the FCC.

Obtained via FOIA by Judicial Watch, Inc.

Read the News

Listen to Recording of the Oral Arguments

RECENT VICTORIES

FLORIDA

1. Palm Coast, FL defeats 150-foot cell tower to be installed in the heart of the city's oldest neighborhood.

Read the news here.

Obtained via FOIA by Judicial Watch, Inc.

2. Lakeland, FL defeats 110-foot cell tower slated to be installed mere feet from homes. This is the second cell tower in three months that has been defeated by Lakeland representatives due to resident opposition.

Read the news here.

Obtained via FOIA by Judicial Watch, Inc.

NEW JERSEY

3. Lavallette, NJ Borough Council approves five "small cell" antennas with challenging conditions: certification from the U.S. Department of Defense and the Federal Aviation Administration that 5G frequencies emitted by the equipment will not interfere with critical avionics equipment. Lavallette is situated just a few miles from one of the country's most active military air bases - Joint Base McGuire-Dix-Lakehurst.

Read the news here.

Obtained via FOIA by Judicial Watch, Inc.

CALIFORNIA

4. Petaluma, CA defeats Verizon application to install 16 wireless antennas at the Petaluma Creamery, just 75 feet from homes. Read the legal memorandum in opposition to Verizon's application here.

Obtained via FOIA by Judicial Watch, Inc.

SOUTH CAROLINA

5. Residents in Mt. Pleasant, SC defeat a cell tower to be installed next to the Long Point playground.

Read the news here.

Obtained via FOIA by Judicial Watch, Inc.

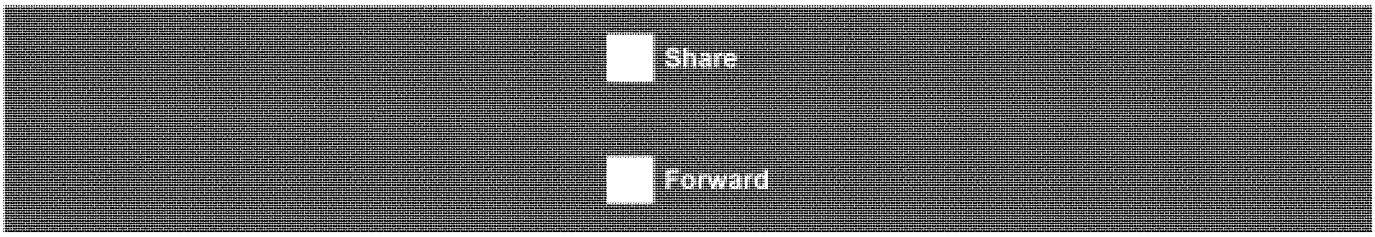
As always, let's keep raking in the wins and working together to protect our communities from the telecom industry's ever-growing wireless footprint.

If you need assistance pushing back against 5G and/or other wireless infrastructure deployments in your area, please don't hesitate to reply to this email or call us at 516-883-0887.

-The 5G Crisis Team

Contribute to 5G Crisis

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Contact us:
Email report@5gcrisis.com
Call 516-883-0887

Want to change how you receive these emails?
You can or .

Thanks,
Vinu

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Subject: RE: COVID-19 vaccine dangers; CDC's "Vaccines do not cause autism" lie, taken down; NH commission exposes FCC corruption, cellular radiation dangers

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Christian Brechot

From: Vinu Arumugham < (b) (6) @yahoo.com>
Sent: Monday, February 1, 2021 2:11 PM
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Subject: Re: COVID-19 vaccine dangers; CDC's "Vaccines do not cause autism" lie, taken down; NH commission exposes FCC corruption, cellular radiation dangers

Prof. Gøtzsche,

Let me clarify that we are not discussing vaccine vs. no vaccine. We are discussing dirty, sickening vaccines vs. clean safe, effective vaccines.

Regarding autism, you are talking about the wrong vaccine. We have shown beyond all doubt, using **reliable mechanistic evidence** that milk protein contaminated vaccines (DTaP/TdaP, Prevnar 13, ActHiB) cause the vast majority (75%) of autism cases.

Autism pathogenesis: Piecing it all together, from end to beginning ...
https://doi.org/10.5281/zenodo.1477515

Obtained via FOIA by Judicial Watch, Inc.

Immunization with homologous xenogeneic (animal/plant/fungal) antigens causes the development of autoimmune diseases. Known for at least 45 years.

Vaccine-Induced Autoimmunity in the Dog

"the most likely sources of cross-reactive epitopes are bovine serum and cell culture components. These are present in almost all vaccines as residu-al components of the cell culture necessary to generate vaccine viruses and may purposely be added to the vaccine as a stabilizer. In the presence of an adjuvant, these bovine products stimulate a strong im-mune response and induce antibodies that cross-react with conserved canine antigens."

Xenogeneic therapeutic cancer vaccines as breakers of immune tolerance for clinical application: to use or not to use?
pubmed.ncbi.nlm.nih.gov/24837511/

Oncologists immunize with xenogeneic antigens to break immune tolerance (cause autoimmunity) to make your immune system attack your own cancer cells.

Regular vaccines such as the measles vaccines are contaminated with animal proteins (chicken) and therefore cause numerous autoimmune disorders including type 1 diabetes.

Correlation of type 1 diabetes trends in European countries to the number of bovine insulin and GAD65 contaminated chick embryo cell culture containing vaccines in the schedule, as predicted by the autoimmunity mechanism involving immunization with homologous xenogeneic antigens and EPIT as a potential treatment
https://doi.org/10.5281/zenodo.1870364

The US IOM pointed out that epidemiological studies are useless in 93% of the cases. Mechanistic studies proved reliable.

Institute of Medicine: Most epidemiological vaccine safety studies are useless

https://doi.org/10.5281/zenodo.3244496

The Pandemrix vaccine made in Europe had higher levels of contamination with H1N1 nucleoproteins than the Arepanrix vaccine manufactured by the same company (GSK) in Canada. Pandemrix therefore caused way more cases of narcolepsy. Do you know the level of chicken protein contamination in Danish vs. US vaccines? How can you then apply studies done in Denmark to any other country?

Big picture of the damage vaccines do:

Vaccines and Biologics injury table based on mechanistic evidence – Feb 2020

Covering over 125 conditionshttps://zenodo.org/record/3647593/files/vbitr2_final.pdf?download=1

The organized suppression of vaccine safety science:

Retraction of scientific papers: the case of vaccine research
https://www.tandfonline.com/doi/full/10.1080/09581596.2021.1878109

Thanks,

Vinu

On 1/31/21 11:47 PM, pcg@scientificfreedom.dk wrote:

I have no knowledge of this huge email list and do not know why I was put on it. But I assume I will be taken off it because of what I write below. Please read it.

The idea that vaccines may cause autism was launched by Andrew Wakefield in relation to a fraudulent study published in Lancet in 1998 that has been retracted. Large observational studies from my country, Denmark, have shown convincingly that the Emperor has no clothes. I analyse this in detail in my 2020 book, Vaccines: truth, lies and controversy. It is an e-book but will come out soon on Skyhorse, New York, as a print book with an updated corona chapter that ends with the riots on 6 January 2021 at Capitol Hill.

Obtained via FOIA by Judicial Watch, Inc.

Wakefield's horrendous fraud, which has caused many deaths, concerned the MMR vaccine. These are excerpts from my book, the chapter on measles:

According to the WHO, there were 110,000 measles deaths in 2017, and most were in children under the age of five.[3] Vaccination resulted in an 80% drop in measles deaths between 2000 and 2017 preventing an estimated 21 million deaths.

Measles outbreaks also provide strong support for the benefits of the vaccine. In the United States, there was a resurgence of measles in 1989-1990, which primarily involved unvaccinated racial and ethnic minority children less than five years of age residing in inner-city areas.[40] There were 66 (0.1%) cases of encephalitis. A provisional total of 41 measles-associated deaths was reported in 1989 (2.3 deaths per 1000 cases), which increased to 89 (3.2 per 1000 cases) in 1990. In 2000, the CDC declared measles eradicated in the United States but there have been several outbreaks since due to imported cases.[41] In 2018, no less than 17 outbreaks occurred. One, in New York, was due to people who had been to Israel, and it included 182 cases in orthodox Jewish communities with a vaccination rate of only 50%.[42]
It is not possible to say exactly what the risk is of dying from measles. As noted earlier, the death risk is related to the infectious dose, which is higher in settings with overcrowding. We can only say what it has been in outbreaks, and a commonly used estimate is 2 deaths per 1000 cases. But it can be much worse. During an epidemic in Copenhagen in 1887, at least 5% of the children, or 50 per 1000 cases, died.[43] The mortality was probably even higher because only those who died while they had a rash counted. In Wien, at the beginning of the 20th century, the mortality was 11% among the poorest and 0.6% among the richest.
An outbreak in Madagascar that started in 2018 had in April 2019 caused over 1200 deaths, which is about 1% of those infected.[44] Only about 60% of the population is vaccinated.

We should all get vaccinated against measles and get our children vaccinated, with very few exceptions. Contraindications for the vaccine include a history of severe allergic reaction to any component of the vaccine including neomycin, pregnancy (measles illness during pregnancy results in a higher risk of premature labour, spontaneous abortion, and low-birthweight infants), and severe immunosuppression.[34]

On Swedish TV, in 2020, Wakefield lied horrendously about measles: "Exposure in childhood is safe and conveys lifelong immunity."

The reference is:

Dokumentär
Anna Nordbeck och Malin Olofsson
Dokument inifrån: VACCINKRIGARNA
https://www.svtplay.se/dokument-inifran-vaccinkrigarna
SVT

Bw

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Subject: COVID-19 vaccine dangers; CDC's "Vaccines do not cause autism" lie, taken down; NH commission exposes FCC corruption, cellular radiation dangers

Vaccines absolutely do cause autism

The CDC has flip-flopped twice in ~5 months on the fraudulent claim that "Vaccines do not cause autism", on their website. It suggests that the CDC's vaccine/autism claims are based on the conjunction of Jupiter and Saturn, not science.

They were forced to take the false claim down because ICAN demonstrated there was **ZERO** science behind that claim.

The CDC Finally Capitulated To ICAN's Legal Demands and Removed the Claim that "Vaccines Do Not Cause Autism" From Its Website!

https://www.icandecide.org/ican_press/the-cdc-finally-capitulated-to-icans-legal-demands-and-removed-the-claim-that-vaccines-do-not-cause-autism-from-its-website/

THE CDC JUST SOLIDIFIED THAT ITS DECISIONS ARE NOT DRIVEN BY SCIENCE

https://www.icandecide.org/ican_press/the-cdc-just-solidified-that-its-decisions-are-not-driven-by-science/

FACT: Milk protein contaminated vaccines (DTap/Tdap/Prevnar 13/ActHiB) cause at least 75% of autism cases.

Autism pathogenesis: Piecing it all together, from end to beginning ...
https://doi.org/10.5281/zenodo.1477515

CDC caught lying, again about the COVID-19 vaccine this time.

CDC Investigation

http://fullmeasure.news/news/cover-story/cdc-investigation

Vaccine mandates are based on a lie; Repeal all mandates immediately; Try the corrupted liars who created mandates, for CRIMES AGAINST HUMANITY

"Administration of parenterally administered vaccines alone typically does not result in potent mucosal immunity that might interrupt infection or transmission"

SARS-CoV-2 Vaccines: Much Accomplished, Much to Learn

www.acpjournals.org/doi/10.7326/M21-0111

Obtained via FOIA by Judicial Watch, Inc.

So Fauci admits now that **ALL** injected vaccines are for individual protection only. **No herd/community immunity.** So no vaccine mandates are justifiable for **ANY** injected vaccine.

And of course this also means the vaccinated can become infected super-spreaders as occurs with the failed flu shot and failed pertussis vaccines.

Yan J, Grantham M, Pantelic J, de Mesquita PJ, Albert B, Liu F, et al. Infectious virus in exhaled breath of symptomatic seasonal influenza cases from a college community. Adamson W, Beato-Arribas B, Bischoff W, Booth W, Cauchemez S, Ehrman S, et al., editors. Proc Natl Acad Sci. National Academy of Sciences; 2018;

The potential role of subclinical Bordetella Pertussis colonization in the etiology of multiple sclerosis
pubmed.ncbi.nlm.nih.gov/26724970/

This is the consequence of **insanely injecting** antigens of pathogens whose natural routes of exposure are mucosal surfaces in the nose, mouth or eyes.

NOTICE!

By authority of the Nuremberg Code on Medical Experimentation, I do hereby exercise my right to refuse to submit to or to administer the Covid-19 vaccine. The United States Government has prosecuted, convicted and executed Medical Doctors who have violated the Nuremberg Code on Medical Experimentation. Aiders and abettors of Nuremberg Crimes are equally guilty and have also been prosecuted, convicted, and executed.

Francis A. Boyle
Professor of Law.

My comment in the Annals of Internal Medicine, against Fauci's "SARS-CoV-2 Vaccines: Much Accomplished, Much to Learn"

https://www.acpjournals.org/doi/10.7326/M21-0111

Vinu Arumugham Independent 18 January 2021

These vaccines are unsafe, unnecessary and must be immediately withdrawn

The vaccine safety claims made by the authors are unsupported by evidence. Vaccines must be designed for safety. These vaccines were not designed at all. So they are unsafe by definition. I predicted the allergic sensitization and autoimmunity risks with these vaccines which have now been confirmed.

The Pfizer/BioNTech vaccine is unnecessary, unsafe and should not be authorized.

https://www.regulations.gov/document?D=FDA-2020-N-1898-0039

Robert F Kennedy Jr. warned the FDA months back about the risk of allergic reactions due to the use of polyethylene glycol (PEG) in the vaccines.
https://childrenshealthdefense.org/defender/pfizer-covid-vaccine-allergic-reactions/

The FDA/VRBPAC ignored us and authorized these horrendously dangerous vaccines.

Recently, Dr. Peter Marks of the FDA admitted that the population was sensitized by PEG-containing pharmaceutical preparations (that include other vaccines/injections).

https://www.wsj.com/articles/scientists-eye-potential-culprit-for-covid-19-vaccine-allergic-reactions-11608901200?mod=hp_lead_pos2

Obtained via FOIA by Judicial Watch, Inc.

"What we're learning now is that those **allergic reactions could be somewhat more common** than the highly uncommon that we thought they were **because people do get exposed to polyethylene glycol in various pharmaceutical preparations,**" - Peter Marks, Director, CBER,FDA.

We of course already knew that any vaccine/injection that has enough allergen to cause a reaction, has more than enough allergen to guarantee sensitization/priming (causing the development of new allergy).

Evidence that Food Proteins in Vaccines Cause the Development of Food Allergies and Its Implications for Vaccine Policy

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3571073

www.sciencemag.org/news/2020/12/suspicions-grow-nanoparticles-pfizer-s-covid-19-vaccine-trigger-rare-allergic-reactions

"he worries anti-PEG antibodies triggered by the first shot could increase the risk of an allergic reaction to the second or to PEGylated drugs."

- Janos Szebeni, an immunologist at Semmelweis University

So now, these vaccines have sensitized millions to PEG. The goal is to sensitize/boost PEG allergy in a 100 million more in the next 100 days.

PEG is contaminated with 1,4-dioxane, a carcinogen.

https://www.fda.gov/cosmetics/potential-contaminants-cosmetics/14-dioxane-cosmetics-manufacturing-byproduct

As predicted, Pfizer COVID-19 vaccine induced autoimmunity (thrombocytopenia) killed a Florida doctor. This is just the tip of the iceberg. Thousands of cases of vaccine induced autoimmune diseases may take months/years to be diagnosed and will be dismissed as unrelated to the vaccine.

https://www.nytimes.com/2021/01/12/health/covid-vaccine-death.html

Only a few lots were tested in the trial. No one has a clue what other lots will do. 100-fold variation of contaminants in vaccines makes trials and epidemiological studies worthless as I detailed in my comments in the Annals of Internal Medicine before. Vaccine safety remains an oxymoron.

https://www.acpjournals.org/doi/10.7326/m18-2101

California calls for pause of 330,000 doses, investigation after allergic reactions to Moderna vaccine batch

https://www.mercurynews.com/2021/01/18/coronavirus-california-calls-for-pause-investigation-after-allergic-reactions-to-moderna-vaccine-batch/

What's worse? Effective, life-saving, cheap, safe medicines such as famotidine/cetirizine/ivermectin are being ignored in this blind race to vaccinate at any cost.

Obtained via FOIA by Judicial Watch, Inc.

Immunological mechanisms explaining the role of vaccines, IgE, mast cells, histamine, elevating ferritin, IL-6, D-dimer, VEGF levels in COVID-19 and dengue, potential treatments such as mast cell stabilizers, antihistamines: Predictions and confirmations

https://europepmc.org/article/PPR/PPR241819

Big picture of the damage vaccines do:

Vaccines and Biologics injury table based on mechanistic evidence – Feb 2020

Covering over 125 conditionshttps://zenodo.org/record/3647593/files/vbitr2_final.pdf?download=1

The organized suppression of vaccine safety science:

Retraction of scientific papers: the case of vaccine research
https://www.tandfonline.com/doi/full/10.1080/09581596.2021.1878109

The WHO's flip-flopping "science" competes with CDC's incompetence

WHO Recommends Against Moderna, Pfizer Vaccines for Most Pregnant Women

https://www.wsj.com/articles/who-recommends-against-moderna-pfizer-vaccines-for-most-pregnant-women-11611775138

Pregnant Women May Receive Covid Vaccines Safely, W.H.O. Says
https://www.nytimes.com/2021/01/29/health/covid-vaccine-pregnancy.html

Moderna's COVID-19 vaccine now recommended for pregnant women, WHO says in guidance reversal

https://www.foxnews.com/health/moderna-covid-vaccine-pregnant-women-who-guidance-reversal

Not to be outdone by the flip-flopping CDC, WHO did a flip-flop on COVID-19 vaccine during pregnancy.

Latest evidence that there is ZERO science behind vaccines or vaccine safety. They just pull their "science" out of a hat. Follow the money.

These flip-flopping, lying, organized criminals at the CDC/WHO, are the "reputable sources" for your "fact-checkers".

The New Hampshire Commission report below has ripped FCC's 5G (and all other cellular) RF safety claims:

Final Report of the Commission to Study The Environmental and Health Effects of Evolving 5G Technology

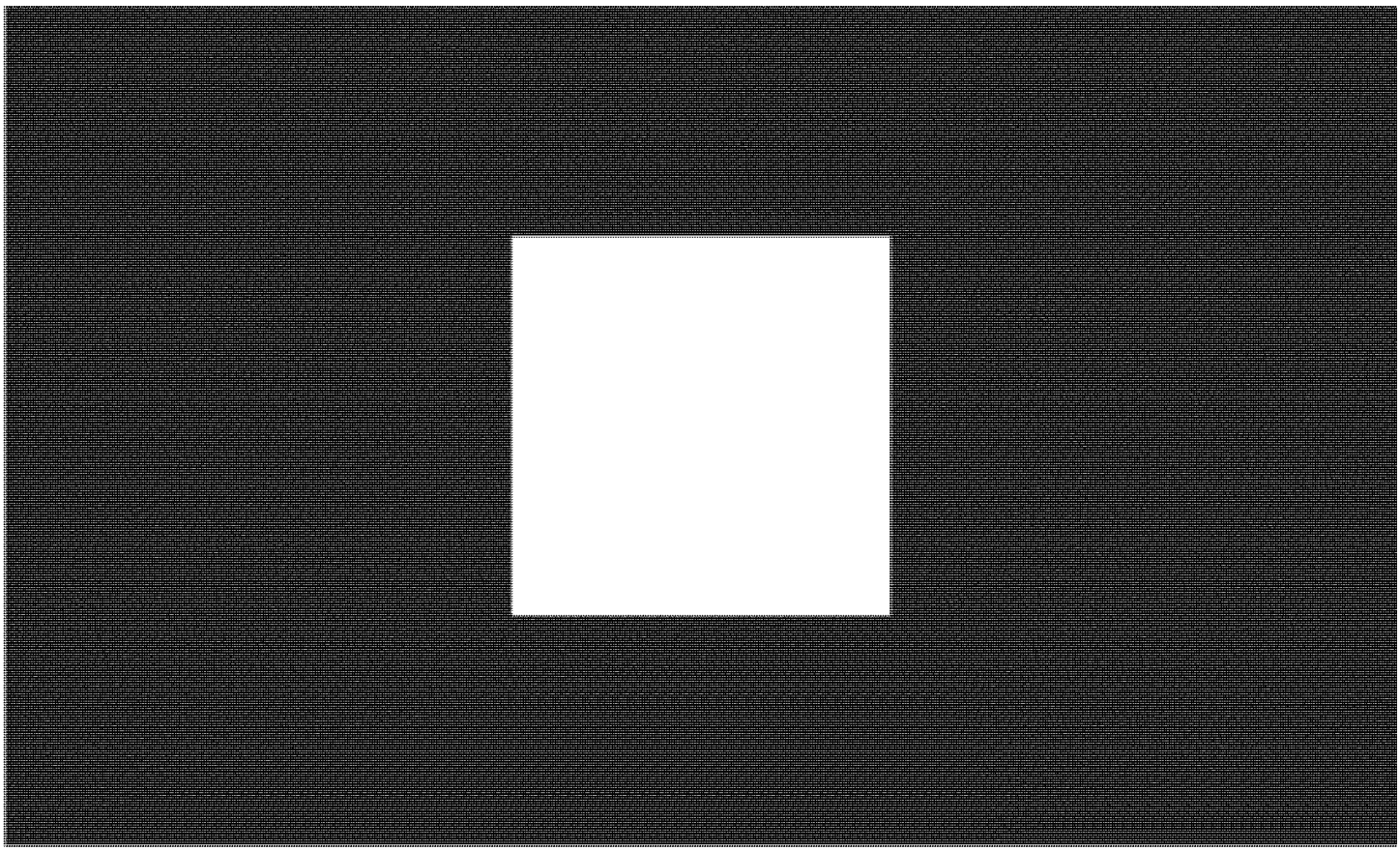
http://www.gencourt.state.nh.us/statstudcomm/committees/1474/reports/5G%20final%20report.pdf

"RECOMMENDATION 1- Propose a resolution of the House to the US Congress and Executive Branch to **require the Federal Communication Commission (FCC) to commission an independent review** of the current radiofrequency (RF) standards of the electromagnetic radiation in the 300MHz to 300GHz microwave spectrum as well as a health study to assess and recommend mitigation for the health risks associated with the use of cellular communications and data transmittal."

"A likely explanation as to why **regulatory agencies have opted to ignore the body of scientific evidence demonstrating the negative impact of cellphone radiation** is that **those agencies are "captured"** (see Harvard University publication entitled, "Captured Agency: How the Federal Communications Commission Is Dominated by the Industries It Presumably Regulates" linked in Appendix G). This report

Obtained via FOIA by Judicial Watch, Inc.

documents how **the leadership roles in some agencies (the FCC in particular) are filled by individuals with strong industry ties** and hence are more **focused on industry interests than the health of citizens**"



Major Litigation Updates & Recent Local Victories

It's been a strong week for our movement!

There are a lot of exciting things to report on this week, so let's dive right in...

Lake Tahoe, CA - Landmark Federal Lawsuit Filed to Block Saturation of Lake Tahoe Region with Cell Towers

Obtained via FOIA by Judicial Watch, Inc.

Hundreds of hazardous, unsightly wireless antennas and cell towers are quickly blanketing the Lake Tahoe, California region.

Three environmental non-profits and Monica Eisenstecken, a lifelong resident of South Lake Tahoe, have filed a potentially **precedent-setting litigation** against the Tahoe Regional Planning Agency, Verizon Wireless, the Tahoe Prosperity Center, and a local property owner...all in an effort **to protect one of the world's greatest natural treasures from a looming telecom takeover.**

Read Today's Press Release

Obtained via FOIA by Judicial Watch, Inc.

Visit the New Tahoe Safe Tech Website

Support the Landmark Litigation

D.C. Court of Appeals - Environmental Health Trust et al. v. FCC Oral Arguments, January 25th, 2021

Obtained via FOIA by Judicial Watch, Inc.

"A federal appeals panel in Washington voiced skepticism that the Federal Communications Commission had adequately considered dangerous health effects when it established guidelines for radiation emission from cell towers and wireless devices."
- Bloomberg Law

Congratulations to both the Environmental Health Trust and the Children's Health Defense for their tireless efforts challenging the FCC's outdated and insufficient wireless radiation public exposure guidelines.

Following yesterday's fabulous presentation, we are hopeful the judges will rule against the FCC.

Obtained via FOIA by Judicial Watch, Inc.

Read the News

Listen to Recording of the Oral Arguments

RECENT VICTORIES

FLORIDA

1. Palm Coast, FL defeats 150-foot cell tower to be installed in the heart of the city's oldest neighborhood.

Read the news here.

Obtained via FOIA by Judicial Watch, Inc.

2. Lakeland, FL defeats 110-foot cell tower slated to be installed mere feet from homes. This is the second cell tower in three months that has been defeated by Lakeland representatives due to resident opposition.

Read the news here.

Obtained via FOIA by Judicial Watch, Inc.

NEW JERSEY

3. Lavallette, NJ Borough Council approves five "small cell" antennas with challenging conditions: certification from the U.S. Department of Defense and the Federal Aviation Administration that 5G frequencies emitted by the equipment will not interfere with critical avionics equipment. Lavallette is situated just a few miles from one of the country's most active military air bases - Joint Base McGuire-Dix-Lakehurst.

Read the news here.

Obtained via FOIA by Judicial Watch, Inc.

CALIFORNIA

4. Petaluma, CA defeats Verizon application to install 16 wireless antennas at the Petaluma Creamery, just 75 feet from homes. Read the legal memorandum in opposition to Verizon's application here.

Obtained via FOIA by Judicial Watch, Inc.

SOUTH CAROLINA

5. Residents in Mt. Pleasant, SC defeat a cell tower to be installed next to the Long Point playground.

Read the news here.

Obtained via FOIA by Judicial Watch, Inc.

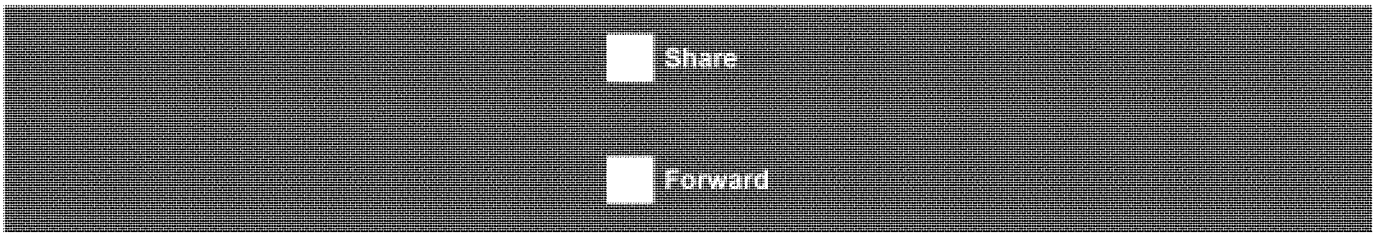
As always, let's keep raking in the wins and working together to protect our communities from the telecom industry's ever-growing wireless footprint.

If you need assistance pushing back against 5G and/or other wireless infrastructure deployments in your area, please don't hesitate to reply to this email or call us at 516-883-0887.

-The 5G Crisis Team

Contribute to 5G Crisis

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Contact us:
Email report@5gcrisis.com
Call 516-883-0887

Want to change how you receive these emails?
You can or .

Thanks,
Vinu

[EXTERNAL EMAIL] DO NOT CLICK links or attachments unless you recognize the sender and know the content is safe.

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From: David Kaplan [david.kaplan@wisc.edu]
Sent: 2/2/2021 10:19:28 AM
To: zhangyp@chinacdc.cn; Courtine Grégoire [gregoire.courtine@epfl.ch]
CC: Nicole Lurie [nicole.lurie@cepi.net]; Marsha Mailick [marsha.mailick@wisc.edu]; trish.greenhalgh@phc.ox.ac.uk; CORINNE D ENGELMAN [corinne.engelman@wisc.edu]; jeffrey.sonnenfeld@yale.edu; Di Pietrantonj Carlo [cdipietrantonj@aslal.it]; pcg@scientificfreedom.dk; Vinu Arumugham [(b) (6)@yahoo.com]; Golding, Hana [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0619807f66f6406d9ece442207c82c95-goldingh]; Khurana, Surender [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6215b7e342d4622be59fa3d58501a6f-Khurana]; sli49@emory.edu; elizabeth.deatrick@niaid.nih.gov; pwilson1@medicine.bsd.uchicago.edu; agewirtz@gsu.edu; megan.hahn@fda.hhs.gov; goldmanb@stanford.edu; mario.cortese@stanford.edu; nroupha@emory.edu; alan.embry@nih.gov; alex@lji.org; neuron@cell.com; jlandsberg@cell.com; agoldstein@cell.com; mzirlinger@cell.com; Ted Dobie [tdobie@cell.com]; mfurman@cell.com; ckonen@cell.com; eniederst@cell.com; uschridde@cell.com; jshaw@cell.com; eporro@cell.com; emarcus@cell.com; info@eeoc.gov; ofo.eeoc@eeoc.gov; FOIA@eeoc.gov; eeoc.traininginstitute@eeoc.gov; inspector.general@eeoc.gov; Richard Hatchett [richard.hatchett@cepi.net]; fg17882@bristol.ac.uk; ripley.ballou@gskbio.com; jlg251@georgetown.edu; tom.monath [tom.monath@crozetbiopharma.com]; Alash'le Abimiku [aabimiku@ihv.umaryland.edu]; Barrett, Alan [abarrett@utmb.edu]; Ananda.Bandyopadhyay@gatesfoundation.org; cbrechot [cbrechot@usf.edu]; chappi@hsph.harvard.edu; Connie [connie.s.schmaljohn.civ@mail.mil]; Damon, Inger K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=42b35bd733a34c66a5698f43f7026e88-HHS-iad7-cd]; jamesrobinson@uchicago.edu; Jean Lang [Jean.Lang@sanofipasteur.com]; john.k.billington@gsk.com; Shibuya, Kenji [kenji.shibuya@kcl.ac.uk]; Krause, Philip [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00c6330fea0042fdb5571c3fdef792ed-krause]; Levine, Myron [Mlevine@som.umaryland.edu]; SATHIYAMOORTHY, Vaseeharan [moorthyv@who.int]; Bryant, Paula R (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3eb42f9318014bbb8c14d39ef311d8f9-HHS-paula.b]; (b) (6)@africaonline.co.ke; yves.levy@aphp.fr; Fenaba Addo [faddo@wisc.edu]; Bradford Barham [bradford.barham@wisc.edu]; LEONELO E BAUTISTA [lebautista@wisc.edu]; Lawrence M Berger [lmberger@wisc.edu]; Will Buckingham [wrbuckin@wisc.edu]; MARGUERITE E BURNS [meburns@wisc.edu]; Marcy Carlson [carlson@ssc.wisc.edu]; J. 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Subject: Re: COVID-19 vaccine dangers; CDC's "Vaccines do not cause autism" lie, taken down; NH commission exposes FCC corruption, cellular radiation dangers

How about not hitting reply all.

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Project page: http://bmer.wceruw.org/index.html

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From: "zhangyp@chinacdc.cn" <zhangyp@chinacdc.cn>
Date: Tuesday, February 2, 2021 at 9:17 AM
To: Courtine Grégoire <gregoire.courtine@epfl.ch>
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Subject: Re: COVID-19 vaccine dangers; CDC's "Vaccines do not cause autism" lie, taken down; NH commission exposes FCC corruption, cellular radiation dangers

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On 02/02/2021 22:56, Courtine Grégoire wrote:

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On 2 Feb 2021, at 15:55, Nicole Lurie <nicole.lurie@cepi.net> wrote:

Me too

Sent from my iPhone

On Feb 2, 2021, at 9:53 AM, Marsha Mailick <marsha.mailick@wisc.edu> wrote:

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On Feb 2, 2021, at 9:41 AM, trish.greenhalgh@phc.ox.ac.uk wrote:

And me.

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Subject: Re: COVID-19 vaccine dangers; CDC's "Vaccines do not cause autism" lie, taken down; NH commission exposes FCC corruption, cellular radiation dangers

Me too.

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Subject: RE: COVID-19 vaccine dangers; CDC's "Vaccines do not cause autism" lie, taken down; NH commission exposes FCC corruption, cellular radiation dangers

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Subject: R: COVID-19 vaccine dangers; CDC's "Vaccines do not cause autism" lie, taken down; NH commission exposes FCC corruption, cellular radiation dangers

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Oggetto: RE: COVID-19 vaccine dangers; CDC's "Vaccines do not cause autism" lie, taken down; NH commission exposes FCC corruption, cellular radiation dangers

If there had been any reliable evidence that “milk protein contaminated vaccines (DTaP/TdaP, Prevnar 13, ActHiB) cause the vast majority (75%) of autism cases”, we would surely have heard about it.

Please delete me from your email list

Peter C Gøtzsche
Professor and Director

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Copenhagen
https://www.scientificfreedom.dk/ and https://www.deadlymedicines.dk/
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Subject: Re: COVID-19 vaccine dangers; CDC's "Vaccines do not cause autism" lie, taken down; NH commission exposes FCC corruption, cellular radiation dangers

Prof. Gøtzsche,

Let me clarify that we are not discussing vaccine vs. no vaccine. We are discussing dirty, sickening vaccines vs. clean safe, effective vaccines.

Regarding autism, you are talking about the wrong vaccine. We have shown beyond all doubt, using **reliable mechanistic evidence** that milk protein contaminated vaccines (DTaP/TdaP, Prevnar 13, ActHiB) cause the vast majority (75%) of autism cases.

Autism pathogenesis: Piecing it all together, from end to beginning …
https://doi.org/10.5281/zenodo.1477515

Immunization with homologous xenogeneic (animal/plant/fungal) antigens causes the development of autoimmune diseases. Known for at least 45 years.

Vaccine-Induced Autoimmunity in the Dog

"the most likely sources of cross-reactive epitopes are bovine serum and cell culture components. These are present in almost all vaccines as residu-al components of the cell culture necessary to generate vaccine viruses and may purposely be added to the vaccine as a stabilizer. In the presence of an adjuvant, these bovine products stimulate a strong im-mune response and induce antibodies that cross-react with conserved canine antigens."

Xenogeneic therapeutic cancer vaccines as breakers of immune tolerance for clinical application: to use or not to use?
pubmed.ncbi.nlm.nih.gov/24837511/

Oncologists immunize with xenogeneic antigens to break immune tolerance (cause autoimmunity) to make your immune system attack your own cancer cells.

Regular vaccines such as the measles vaccines are contaminated with animal proteins (chicken) and therefore cause numerous autoimmune disorders including type 1 diabetes.

Correlation of type 1 diabetes trends in European countries to the number of bovine insulin and GAD65 contaminated chick embryo cell culture containing vaccines in the schedule, as predicted by the autoimmunity mechanism involving immunization with homologous xenogeneic antigens and EPIT as a potential treatment
https://doi.org/10.5281/zenodo.1870364

The US IOM pointed out that epidemiological studies are useless in 93% of the cases. Mechanistic studies proved reliable.

Institute of Medicine: Most epidemiological vaccine safety studies are useless

https://doi.org/10.5281/zenodo.3244496

The Pandemrix vaccine made in Europe had higher levels of contamination with H1N1 nucleoproteins than the Arepanrix vaccine manufactured by the same company (GSK) in Canada. Pandemrix therefore caused way more

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cases of narcolepsy. Do you know the level of chicken protein contamination in Danish vs. US vaccines? How can you then apply studies done in Denmark to any other country?

Big picture of the damage vaccines do:

Vaccines and Biologics injury table based on mechanistic evidence – Feb 2020

Covering over 125 conditionshttps://zenodo.org/record/3647593/files/vbitr2_final.pdf?download=1

The organized suppression of vaccine safety science:

Retraction of scientific papers: the case of vaccine research
https://www.tandfonline.com/doi/full/10.1080/09581596.2021.1878109

Thanks,

Vinu

On 1/31/21 11:47 PM, pcg@scientificfreedom.dk wrote:

I have no knowledge of this huge email list and do not know why I was put on it. But I assume I will be taken off it because of what I write below. Please read it.

The idea that vaccines may cause autism was launched by Andrew Wakefield in relation to a fraudulent study published in Lancet in 1998 that has been retracted. Large observational studies from my country, Denmark, have shown convincingly that the Emperor has no clothes. I analyse this in detail in my 2020 book, Vaccines: truth, lies and controversy. It is an e-book but will come out soon on Skyhorse, New York, as a print book with an updated corona chapter that ends with the riots on 6 January 2021 at Capitol Hill.

Wakefield's horrendous fraud, which has caused many deaths, concerned the MMR vaccine. These are excerpts from my book, the chapter on measles:

According to the WHO, there were 110,000 measles deaths in 2017, and most were in children under the age of five.[3] Vaccination resulted in an 80% drop in measles deaths between 2000 and 2017 preventing an estimated 21 million deaths.

Measles outbreaks also provide strong support for the benefits of the vaccine. In the United States, there was a resurgence of measles in 1989-1990, which primarily involved unvaccinated racial and ethnic minority children less than five years of age residing in inner-city areas.[40] There were 66 (0.1%) cases of encephalitis. A provisional total of 41 measles-associated deaths was reported in 1989 (2.3 deaths per 1000 cases), which increased to 89 (3.2 per 1000 cases) in 1990. In 2000, the CDC declared measles eradicated in the United States but there have been several outbreaks since due to imported cases.[41] In 2018, no less than 17 outbreaks occurred. One, in New York, was due to people who had been to Israel, and it included 182 cases in orthodox Jewish communities with a vaccination rate of only 50%.[42]
It is not possible to say exactly what the risk is of dying from measles. As noted earlier, the death risk is related to the infectious dose, which is higher in settings with overcrowding. We can only say what it has been in outbreaks, and a commonly used estimate is 2 deaths per 1000 cases. But it can be much worse. During an epidemic in Copenhagen in 1887, at least 5% of the children, or 50 per 1000 cases, died.[43] The mortality was probably even higher because only those who died while they had a rash counted. In Wien, at the beginning of the 20th century, the mortality was 11% among the poorest and 0.6% among the richest.
An outbreak in Madagascar that started in 2018 had in April 2019 caused over 1200 deaths, which is about 1% of those infected.[44] Only about 60% of the population is vaccinated.

We should all get vaccinated against measles and get our children vaccinated, with very few exceptions. Contraindications for the vaccine include a history of severe allergic reaction to

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any component of the vaccine including neomycin, pregnancy (measles illness during pregnancy results in a higher risk of premature labour, spontaneous abortion, and low-birthweight infants), and severe immunosuppression.[34]

On Swedish TV, in 2020, Wakefield lied horrendously about measles: "Exposure in childhood is safe and conveys lifelong immunity."

The reference is:

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Anna Nordbeck och Malin Olofsson
Dokument inifrån: VACCINKRIGARNA
https://www.svtplay.se/dokument-inifran-vaccinkrigarna
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From: Vinu Arumugham <(b) (6) @yahoo.com>
Sent: 01 February 2021 01:43
To: goldingh@cber.fda.gov; khuranas@cber.fda.gov; sli49@emory.edu; elizabeth.deatrick@niaid.nih.gov; pwilson1@medicine.bsd.uchicago.edu; agewirtz@gsu.edu; megan.hahn@fda.hhs.gov; goldmanb@stanford.edu; mario.cortese@stanford.edu; nroupha@emory.edu; alan.embry@nih.gov; alex@lji.org; neuron@cell.com; jlandsberg@cell.com; agoldstein@cell.com; mzirlinger@cell.com; tdobie@cell.com; mfurman@cell.com; ckonen@cell.com; eniederst@cell.com; uschridde@cell.com; jshaw@cell.com; eporro@cell.com; emarcus@cell.com; jeffrey.sonnenfeld@yale.edu; info@eeoc.gov; ofo.eeoc@eeoc.gov; FOIA@eeoc.gov; eeoc.traininginstitute@eeoc.gov; inspector.general@eeoc.gov; richard.hatchett@cepi.net; fg17882@bristol.ac.uk; ripley.ballou@gskbio.com; nicole.lurie@cepi.net; jlg251@georgetown.edu;tom.monath@crozetbiopharma.com; aabimiku@ihv.umaryland.edu; abarrett@utmb.edu; Ananda.Bandyopadhyay@gatesfoundation.org; cbrechot@usf.edu; chappi@hsph.harvard.edu; Connie.s.schmaljohn.civ@mail.mil; iad7@cdc.gov; jamesrobinson@uchicago.edu; Jean.Lang@sanofipasteur.com; john.k.billington@gsk.com; kenji.shibuya@kcl.ac.uk; krause@cber.fda.gov; mlevine@som.umaryland.edu; moorthyv@who.int; paula.bryant@nih.gov; (b) (6) @africaonline.co.ke;yves.levy@aphp.fr; faddo@wisc.edu; bradford.barham@wisc.edu; lebautista@wisc.edu; lmberger@wisc.edu; wrbuckin@wisc.edu; meburns@wisc.edu; carlson@ssc.wisc.edu; jmcollins@wisc.edu; jaconwell@wisc.edu; nbarnes2@wisc.edu; kcurtis@ssc.wisc.edu; mcurtis3@wisc.edu; jeason2@wisc.edu; ehrenthal@wisc.edu; felwert@ssc.wisc.edu; cengelman@wisc.edu; mengelman@ssc.wisc.edu; jason.fletcher@wisc.edu;cfu@ssc.wisc.edu; fujimura@ssc.wisc.edu; tgerber@ssc.wisc.edu; cde@ssc.wisc.edu; grantm@ssc.wisc.edu; jan.greenberg@wisc.edu; jmgregory@ssc.wisc.edu; egrodsky@ssc.wisc.edu; sarah.halpernmeekin@wisc.edu;jenny.a.higgins@wisc.edu; lpjacobs@wisc.edu; fjones4@wisc.edu; hyunseung@stat.wisc.edu; dkaplan@education.wisc.edu; jkennan@ssc.wisc.edu; ajk@medicine.wisc.edu; mlight@ssc.wisc.edu;logan@ssc.wisc.edu; kmagnuson@wisc.edu; marsha.mailick@wisc.edu; kmalecki@wisc.edu; mmassoglia@ssc.wisc.edu; drmeyer1@wisc.edu; cmommaerts@wisc.edu; amukherjee@wisc.edu; jmullahy@wisc.edu; jnobles@ssc.wisc.edu; robrien@lafollette.wisc.edu; palloni@wisc.edu; patz@wisc.edu; ppeppard@wisc.edu; jraymo@ssc.wisc.edu; ferey@wisc.edu; sarobert@wisc.edu; schaeffer@ssc.wisc.edu;lschechter@wisc.edu; aschneider4@wisc.edu; cschwart@ssc.wisc.edu; aseshadr@ssc.wisc.edu; smeeding@lafollette.wisc.edu; econjeff@ssc.wisc.edu; psteiner@wisc.edu; ctaber@ssc.wisc.edu; tjernstroem@wisc.e

Obtained via FOIA by Judicial Watch, Inc.

du; walker@ssc.wisc.edu; wallace@lafollette.wisc.edu; tbwalsh@wisc.edu;yang.wang@lafollette.wisc.edu; mjwiswall@wisc.edu; wolfe@lafollette.wisc.edu; ysxiong2@wisc.edu;jzhu@stat.wisc.edu; ashivani@seas.upenn.edu; rbeck@jaeb.org; (b) (6) @gmail.com; t1dstats@jaeb.org;willi@email.chop.edu; weinstor@upstate.edu; paul.wadwa@cuanschutz.edu; jennifer.sherr@yale.edu; rmonzavi@chla.usc.edu; Laurel.Messer@cuanschutz.edu; sarah.corathers@cchmc.org; Amy.Criego@ParkNicollet.com; maclements@cmh.edu; inquires@sda.gov.cn; yerw@bjmu.edu.cn; yxy@xjtu.edu.cn; cfetpyhj@vip.sina.com; caodesheng@chinadaily.com.cn; yanwl@fudan.edu.cn; yiwang@shmu.edu.cn; zhangyp@chinacdc.cn; maojh88@zju.edu.cn; gisou.vandergoot@epfl.ch; nicola.harris@epfl.ch; andrea.ablasser@epfl.ch; patrick.aebischer@epfl.ch; johan.auwerx@epfl.ch;olaf.blanke@epfl.ch; melanie.blokesch@epfl.ch; cathrin.brisken@epfl.ch; philipp.bucher@epfl.ch; stewart.cole@epfl.ch; daniel.constam@epfl.ch; gregoire.courtine@epfl.ch; matteo.dalperaro@epfl.ch; paolo.delosrios@epfl.ch; michele.depalma@epfl.ch; bart.deplancke@epfl.ch; denis.duboule@epfl.ch;wulfram.gerstner@epfl.ch; pierre.gonczy@epfl.ch; johannes.graeff@epfl.ch; douglas.hanahan@epfl.ch; oliver.hantschel@epfl.ch; vassily.hatzimanikatis@epfl.ch; michael.herzog@epfl.ch; kathryn.hess@epfl.ch; joerg.huelsken@epfl.ch; friedhelm.hummel@epfl.ch; hilal.lashuel@epfl.ch; theo.lasser@epfl.ch;bruno.lemaitre@epfl.ch; joachim.lingner@epfl.ch; matthias.lutolf@epfl.ch; pierre.magistretti@epfl.ch; suliana.manley@epfl.ch; henry.markram@epfl.ch; brian.mccabe@epfl.ch; john.mckinney@epfl.ch; etienne.meylan@epfl.ch; felix.naef@epfl.ch; olaia.naveiras@epfl.ch; andrew.oates@epfl.ch;elisa.oricchio@epfl.ch; alexandre.persat@epfl.ch; carl.petersen@epfl.ch; freddy.radtke@epfl.ch; pavan.ramdya@epfl.ch; marcel.salathe@epfl.ch; carmen.sandi@epfl.ch; ralf.schneggenburger@epfl.ch; kristina.schoonjans@epfl.ch; viesturs.simanis@epfl.ch; david.suter@epfl.ch; didier.trono@epfl.ch;nicolas.mermod@unil.ch; beatrice.perrenoud@chuv.ch; awagnon@cmanet.org; accma@accma.org; jgreaves@accma.org; jjackovic@accma.org; grogers@accma.org; ndraper@accma.org; mlum@accma.org; (b) (6) @sbcglobal.net; (b) (6) @gmail.com; sbcms@sbmed.org; nbutler@fmms.org; Kamal.Gadalla@ed.ac.uk;ralph.hector@ed.ac.uk; S.R.Thomson@ed.ac.uk; Paul.Ross@ed.ac.uk; stephanie.mearns@ed.ac.uk; Marie.Bowers@ed.ac.uk; zoe.sawitzki@ed.ac.uk; Sarah.Giachetti@ed.ac.uk; s1316609@sms.ed.ac.uk; cochrane@umcutrecht.nl; editorial-unit@cochrane.org; admin@cochrane.org; CEU Admin <ceu@cochrane.org>;mwilson@cochrane.org; martin.burton@cochrane.nhs.uk; c.farquhar@auckland.ac.nz;j.e.clarkson@dundee.ac.uk; gerald.gartlehner@donau-uni.ac.at; pcg@scientificfreedom.dk; marguerite.a.koster@kp.org; (b) (6) @gmail.com; meerpohl@cochrane.de; santesna@mcmaster.ca;dimitrinka.nikolova@ctu.dk; snezana.djurisic@ctu.dk; (b) (6) @gmail.com; (b) (6) @gmail.com; (b) (6) @gmail.com; vbonfigli@cochrane.org; david@davidhammerstein.org; mburton@cochrane.org; mkoster@cochrane.org; Chris Del Mar <cdelmar@bond.edu.au>; Paul Glasziou <pglaszio@bond.edu.au>; RayMoynihan@bond.edu.au; peter.collignon@act.gov.au; Karla Soares-Weiser <ksoares-weiser@cochrane.org>; Hilary Simmonds <HSimmonds@cochrane.org>; Toby Lasserson <TLasserson@cochrane.org>; Christian Gluud<christian.gluud@ctu.dk>; Christopher Exley <c.exley@keele.ac.uk>; cdipietrantonj@aslal.it; (b) (6) @googlemail.com; sdavies@bmj.com; (b) (6) (b) (6) @btinternet.com; jclarkson@cochrane.org;ncullum@cochrane.org; gfaba@cochrane.org; thowe@cochrane.org; trish.greenhalgh@phc.ox.ac.uk;peter.christian.goetzsche@regionh.dk; governingboardsecretary@cochrane.org; David Tovey<dtovey@cochrane.org>; sara.krauss@ctu.dk; cgluud@ctu.dk; (b) (6) @gmail.com

Subject: COVID-19 vaccine dangers; CDC's "Vaccines do not cause autism" lie, taken down; NH commission exposes FCC corruption, cellular radiation dangers

Vaccines absolutely do cause autism

The CDC has flip-flopped twice in ~5 months on the fraudulent claim that "Vaccines do not cause autism", on their website. It suggests that the CDC's vaccine/autism claims are based on the conjunction of Jupiter and Saturn, not science.

They were forced to take the false claim down because ICAN demonstrated there was **ZERO** science behind that claim.

The CDC Finally Capitulated To ICAN's Legal Demands and Removed the Claim that "Vaccines Do Not Cause Autism" From Its Website!

https://www.icandecide.org/ican_press/the-cdc-finally-capitulated-to-icans-legal-demands-and-removed-the-claim-that-vaccines-do-not-cause-autism-from-its-website/

THE CDC JUST SOLIDIFIED THAT ITS DECISIONS ARE NOT DRIVEN BY SCIENCE

https://www.icandecide.org/ican_press/the-cdc-just-solidified-that-its-decisions-are-not-driven-by-science/

Obtained via FOIA by Judicial Watch, Inc.

FACT: Milk protein contaminated vaccines (DTap/Tdap/Prevnar 13/ActHiB) cause at least 75% of autism cases.

Autism pathogenesis: Piecing it all together, from end to beginning …
https://doi.org/10.5281/zenodo.1477515

CDC caught lying, again about the COVID-19 vaccine this time.

CDC Investigation

http://fullmeasure.news/news/cover-story/cdc-investigation

Vaccine mandates are based on a lie; Repeal all mandates immediately; Try the corrupted liars who created mandates, for CRIMES AGAINST HUMANITY

"Administration of parenterally administered vaccines alone typically does not result in potent mucosal immunity that might interrupt infection or transmission"
SARS-CoV-2 Vaccines: Much Accomplished, Much to Learn
www.acpjournals.org/doi/10.7326/M21-0111
So Fauci admits now that **ALL** injected vaccines are for individual protection only. **No herd/community immunity.** So no vaccine mandates are justifiable for **ANY** injected vaccine.
And of course this also means the vaccinated can become infected super-spreaders as occurs with the failed flu shot and failed pertussis vaccines.
Yan J, Grantham M, Pantelic J, de Mesquita PJ, Albert B, Liu F, et al. Infectious virus in exhaled breath of symptomatic seasonal influenza cases from a college community. Adamson W, Beato-Arribas B, Bischoff W, Booth W, Cauchemez S, Ehrman S, et al., editors. Proc Natl Acad Sci. National Academy of Sciences; 2018;

The potential role of subclinical Bordetella Pertussis colonization in the etiology of multiple sclerosis
pubmed.ncbi.nlm.nih.gov/26724970/

This is the consequence of **insanely injecting** antigens of pathogens whose natural routes of exposure are mucosal surfaces in the nose, mouth or eyes.

NOTICE!

By authority of the Nuremberg Code on Medical Experimentation, I do hereby exercise my right to refuse to submit to or to administer the Covid-19 vaccine. The United States Government has prosecuted, convicted and executed Medical Doctors who have violated the Nuremberg Code on Medical Experimentation. Aiders and abettors of Nuremberg Crimes are equally guilty and have also been prosecuted, convicted, and executed.

Francis A. Boyle
Professor of Law.

My comment in the Annals of Internal Medicine, against Fauci's "SARS-CoV-2 Vaccines: Much Accomplished, Much to Learn"

https://www.acpjournals.org/doi/10.7326/M21-0111

Vinu Arumugham Independent 18 January 2021

These vaccines are unsafe, unnecessary and must be immediately withdrawn

The vaccine safety claims made by the authors are unsupported by evidence. Vaccines must be designed for safety. These vaccines were not designed at all. So they are unsafe by definition. I predicted the allergic sensitization and autoimmunity risks with these vaccines which have now been confirmed.

The Pfizer/BioNTech vaccine is unnecessary, unsafe and should not be authorized.

https://www.regulations.gov/document?D=FDA-2020-N-1898-0039

Obtained via FOIA by Judicial Watch, Inc.

Robert F Kennedy Jr. warned the FDA months back about the risk of allergic reactions due to the use of polyethylene glycol (PEG) in the vaccines.
https://childrenshealthdefense.org/defender/pfizer-covid-vaccine-allergic-reactions/

The FDA/VRBPAC ignored us and authorized these horrendously dangerous vaccines.

Recently, Dr. Peter Marks of the FDA admitted that the population was sensitized by PEG-containing pharmaceutical preparations (that include other vaccines/injections).

https://www.wsj.com/articles/scientists-eye-potential-culprit-for-covid-19-vaccine-allergic-reactions-11608901200?mod=hp_lead_pos2

"What we're learning now is that those **allergic reactions could be somewhat more common** than the highly uncommon that we thought they were **because people do get exposed to polyethylene glycol in various pharmaceutical preparations,**" - Peter Marks, Director, CBER,FDA.

We of course already knew that any vaccine/injection that has enough allergen to cause a reaction, has more than enough allergen to guarantee sensitization/priming (causing the development of new allergy).

Evidence that Food Proteins in Vaccines Cause the Development of Food Allergies and Its Implications for Vaccine Policy

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3571073

www.sciencemag.org/news/2020/12/suspicions-grow-nanoparticles-pfizer-s-covid-19-vaccine-trigger-rare-allergic-reactions

"he worries anti-PEG antibodies triggered by the first shot could increase the risk of an allergic reaction to the second or to PEGylated drugs."

- Janos Szebeni, an immunologist at Semmelweis University

So now, these vaccines have sensitized millions to PEG. The goal is to sensitize/boost PEG allergy in a 100 million more in the next 100 days.

PEG is contaminated with 1,4-dioxane, a carcinogen.

https://www.fda.gov/cosmetics/potential-contaminants-cosmetics/14-dioxane-cosmetics-manufacturing-byproduct

As predicted, Pfizer COVID-19 vaccine induced autoimmunity (thrombocytopenia) killed a Florida doctor. This is just the tip of the iceberg. Thousands of cases of vaccine induced autoimmune diseases may take months/years to be diagnosed and will be dismissed as unrelated to the vaccine.

https://www.nytimes.com/2021/01/12/health/covid-vaccine-death.html

Only a few lots were tested in the trial. No one has a clue what other lots will do. 100-fold variation of contaminants in vaccines makes trials and epidemiological studies worthless as I detailed in my comments in the Annals of Internal Medicine before. Vaccine safety remains an oxymoron.

https://www.acpjournals.org/doi/10.7326/m18-2101

California calls for pause of 330,000 doses, investigation after allergic reactions to Moderna vaccine batch

https://www.mercurynews.com/2021/01/18/coronavirus-california-calls-for-pause-investigation-after-allergic-reactions-to-moderna-vaccine-batch/

What's worse? Effective, life-saving, cheap, safe medicines such as famotidine/cetirizine/ivermectin are being ignored in this blind race to vaccinate at any cost.

Immunological mechanisms explaining the role of vaccines, IgE, mast cells, histamine, elevating ferritin, IL-6, D-dimer, VEGF levels in COVID-19 and dengue, potential treatments such as mast cell stabilizers, antihistamines: Predictions and confirmations

https://europepmc.org/article/PPR/PPR241819

Big picture of the damage vaccines do:

Vaccines and Biologics injury table based on mechanistic evidence – Feb 2020

Covering over 125 conditionshttps://zenodo.org/record/3647593/files/vbitr2_final.pdf?download=1

The organized suppression of vaccine safety science:

Obtained via FOIA by Judicial Watch, Inc.

Retraction of scientific papers: the case of vaccine research
https://www.tandfonline.com/doi/full/10.1080/09581596.2021.1878109

The WHO's flip-flopping "science" competes with CDC's incompetence

WHO Recommends Against Moderna, Pfizer Vaccines for Most Pregnant Women

https://www.wsj.com/articles/who-recommends-against-moderna-pfizer-vaccines-for-most-pregnant-women-11611775138

Pregnant Women May Receive Covid Vaccines Safely, W.H.O. Says
https://www.nytimes.com/2021/01/29/health/covid-vaccine-pregnancy.html

Moderna's COVID-19 vaccine now recommended for pregnant women, WHO says in guidance reversal

https://www.foxnews.com/health/moderna-covid-vaccine-pregnant-women-who-guidance-reversal

Not to be outdone by the flip-flopping CDC, WHO did a flip-flop on COVID-19 vaccine during pregnancy.

Latest evidence that there is ZERO science behind vaccines or vaccine safety. They just pull their "science" out of a hat. Follow the money.

These flip-flopping, lying, organized criminals at the CDC/WHO, are the "reputable sources" for your "fact-checkers".

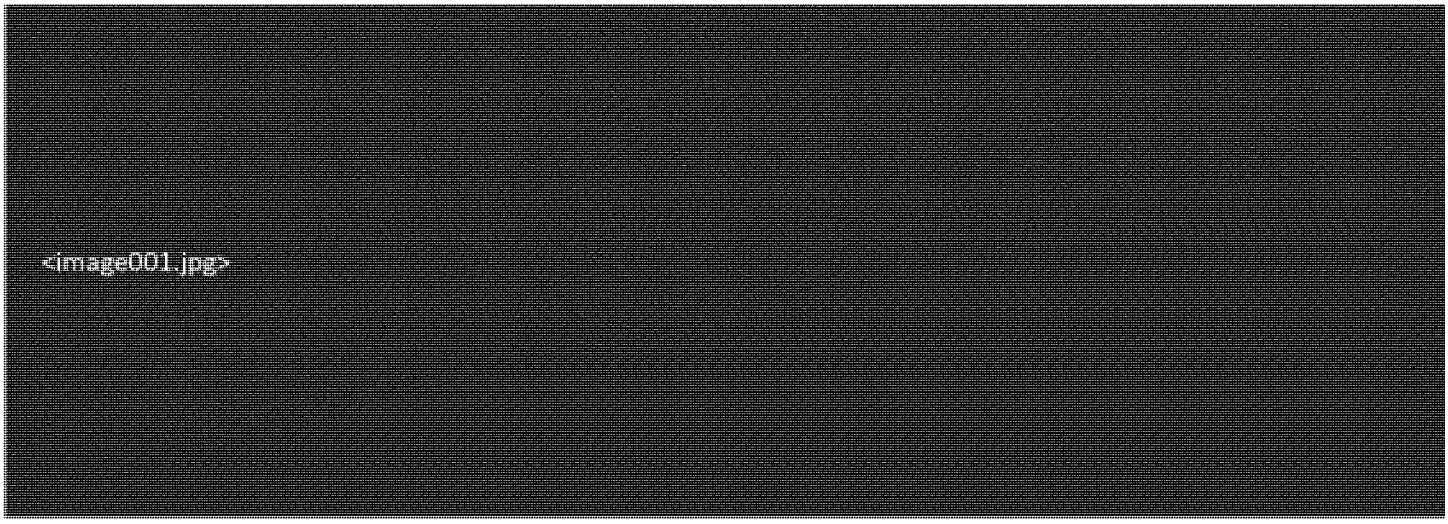
The New Hampshire Commission report below has ripped FCC's 5G (and all other cellular) RF safety claims:

Final Report of the Commission to Study The Environmental and Health Effects of Evolving 5G Technology

http://www.gencourt.state.nh.us/statstudcomm/committees/1474/reports/5G%20final%20report.pdf

"RECOMMENDATION 1- Propose a resolution of the House to the US Congress and Executive Branch to **require the Federal Communication Commission (FCC) to commission an independent review** of the current radiofrequency (RF) standards of the electromagnetic radiation in the 300MHz to 300GHz microwave spectrum as well as a health study to assess and recommend mitigation for the health risks associated with the use of cellular communications and data transmittal."

"A likely explanation as to why **regulatory agencies have opted to ignore the body of scientific evidence demonstrating the negative impact of cellphone radiation** is that **those agencies are "captured"** (see Harvard University publication entitled, "Captured Agency: How the Federal Communications Commission Is Dominated by the Industries It Presumably Regulates" linked in Appendix G). This report documents how **the leadership roles in some agencies (the FCC in particular) are filled by individuals with strong industry ties** and hence are more **focused on industry interests than the health of citizens**"



Obtained via FOIA by Judicial Watch, Inc.

Major Litigation Updates & Recent Local Victories

It's been a strong week for our movement!

There are a lot of exciting things to report on this week, so let's dive right in...

Lake Tahoe, CA - Landmark Federal Lawsuit Filed to Block Saturation of Lake Tahoe Region with Cell Towers

<image002.jpg>

Hundreds of hazardous, unsightly wireless antennas and cell towers are quickly blanketing the Lake Tahoe, California region.

Three environmental non-profits and Monica Eisenstecken, a lifelong resident of South Lake Tahoe, have filed a potentially **precedent-setting litigation** against the Tahoe Regional Planning Agency, Verizon Wireless, the Tahoe Prosperity Center, and a local property owner...all in an effort **to protect one of the world's greatest natural treasures from a looming telecom takeover.**

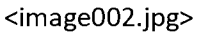
Read Today's Press Release

Visit the New Tahoe Safe Tech Website

Support the Landmark Litigation

Obtained via FOIA by Judicial Watch, Inc.

D.C. Court of Appeals - Environmental Health Trust et al. v. FCC Oral Arguments, January 25th, 2021



"A federal appeals panel in Washington voiced skepticism that the Federal Communications Commission had adequately considered dangerous health effects when it established guidelines for radiation emission from cell towers and wireless devices."
- Bloomberg Law

Congratulations to both the Environmental Health Trust and the Children's Health Defense for their tireless efforts challenging the FCC's outdated and insufficient wireless radiation public exposure guidelines.

Following yesterday's fabulous presentation, we are hopeful the judges will rule against the FCC.

Read the News

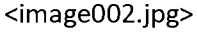
Listen to Recording of the Oral Arguments

RECENT VICTORIES

FLORIDA

1. Palm Coast, FL defeats 150-foot cell tower to be installed in the heart of the city's oldest neighborhood.

Read the news here.



Obtained via FOIA by Judicial Watch, Inc.

2. Lakeland, FL defeats 110-foot cell tower slated to be installed mere feet from homes. This is the second cell tower in three months that has been defeated by Lakeland representatives due to resident opposition.

Read the news here.

<image002.jpg>

NEW JERSEY

3. Lavallette, NJ Borough Council approves five "small cell" antennas with challenging conditions: certification from the U.S. Department of Defense and the Federal Aviation Administration that 5G frequencies emitted by the equipment will not interfere with critical avionics equipment. Lavallette is situated just a few miles from one of the country's most active military air bases - Joint Base McGuire-Dix-Lakehurst.

Read the news here.

<image002.jpg>

CALIFORNIA

4. Petaluma, CA defeats Verizon application to install 16 wireless antennas at the Petaluma Creamery, just 75 feet from homes. Read the legal memorandum in opposition to Verizon's application here.

<image002.jpg>

Obtained via FOIA by Judicial Watch, Inc.

SOUTH CAROLINA

5. Residents in Mt. Pleasant, SC defeat a cell tower to be installed next to the Long Point playground.

Read the news here.

<image003.jpg>

As always, let's keep raking in the wins and working together to protect our communities from the telecom industry's ever-growing wireless footprint.

If you need assistance pushing back against 5G and/or other wireless infrastructure deployments in your area, please don't hesitate to reply to this email or call us at 516-883-0887.

-The 5G Crisis Team

Contribute to 5G Crisis

<image005.jpg>

Share

<image006.jpg>

Forward

<image004.jpg>

Obtained via FOIA by Judicial Watch, Inc.

<image004.jpg>

<image004.jpg>

<image004.jpg>

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Contact us:

Email report@5gcrisis.com

Call 516-883-0887

Want to change how you receive these emails?

You can or .

<image005.jpg>

Thanks,
Vinu

Il contenuto del presente messaggio di posta elettronica, ed ogni eventuale documento a quest'ultimo allegato, è rivolto unicamente al destinatario cui è indirizzato e può contenere dati ed informazioni la cui riservatezza è tutelata. Sono vietati la riproduzione, l'utilizzo e la diffusione dei dati e delle informazioni contenuti nel presente messaggio senza espressa autorizzazione da parte del destinatario. Chiunque abbia ricevuto il presente messaggio per errore è pregato di provvedere senza ritardo a segnalarlo, contattandoci via telefono, fax o e-mail.
Il presente messaggio proviene da un indirizzo di posta elettronica aziendale assegnato al mittente a scopo lavorativo: la relativa casella di posta elettronica è soggetta alle procedure di controllo stabilite dall' ASL AL. Inviate a questo indirizzo solo comunicazioni di natura lavorativa, grazie

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From: LEVY Yves [yves.levy@aphp.fr]
Sent: 2/2/2021 10:14:22 AM
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Subject: Re: COVID-19 vaccine dangers; CDC's "Vaccines do not cause autism" lie, taken down; NH commission exposes FCC corruption, cellular radiation dangers

Me too
Thanks

Pr Yves Levy
Vaccine Research Institute (VRI)
INSERM
Clinical Department of Immunology
CHU Henri Mondor

Le 2 févr. 2021 à 16:09, Magistretti Pierre <pierre.magistretti@epfl.ch> a écrit :

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Please remove me from this list.

Pierre

Pierre J. Magistretti,MD,PhD
Professor
Department of Psychiatry - CHUV/UNIL

Professor Emeritus
Brain Mind Institute, EPFL

NCCR
"The synaptic bases of mental diseases"
http://www.nccr-synapsy.ch

<image001.png>

On 2 févr. 2021, at 15:57, DEBORAH B EHRENTHAL <ehrenthal@wisc.edu> wrote:

Please remove me from this list.

From: "gregoire.courtine@epfl.ch" <gregoire.courtine@epfl.ch>
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Subject: Re: COVID-19 vaccine dangers; CDC's "Vaccines do not cause autism" lie, taken down; NH commission exposes FCC corruption, cellular radiation dangers

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On 2 Feb 2021, at 15:55, Nicole Lurie <nicole.lurie@cepi.net> wrote:

Me too

Sent from my iPhone

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On Feb 2, 2021, at 9:53 AM, Marsha Mailick <marsha.mailick@wisc.edu> wrote:

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On Feb 2, 2021, at 9:41 AM, trish.greenhalgh@phc.ox.ac.uk wrote:

And me.

From: CORINNE D ENGELMAN <corinne.engelman@wisc.edu>
Date: Tuesday, 2 February 2021 at 14:37
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Subject: Re: COVID-19 vaccine dangers; CDC's "Vaccines do not cause autism" lie, taken down; NH commission exposes FCC corruption, cellular radiation dangers

Me too.

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Subject: RE: COVID-19 vaccine dangers; CDC's "Vaccines do not cause autism" lie, taken down; NH commission exposes FCC corruption, cellular radiation dangers

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didier.trono@epfl.ch<didier.trono@epfl.ch>; nicolas.mermod@unil.ch <nicolas.mermod@unil.ch>; beatrice.perrenoud@chuv.ch<beatrice.perrenoud@chuv.ch>; awagnon@cmanet.org <awagnon@cmanet.org>; accma@accma.org <accma@accma.org>;jgreaves@accma.org <jgreaves@accma.org>; jjackovic@accma.org <jjackovic@accma.org>; grogers@accma.org<grogers@accma.org>; ndraper@accma.org <ndraper@accma.org>; mlum@accma.org <mlum@accma.org>; (b) (6) @sbcglobal.net < (b) (6) @sbcglobal.net>; (b) (6) @gmail.com < (b) (6) @gmail.com>; sbcms@sbmed.org<sbcms@sbmed.org>; nbutler@fmms.org <nbutler@fmms.org>; Kamal.Gadalla@ed.ac.uk <Kamal.Gadalla@ed.ac.uk>;ralph.hector@ed.ac.uk <ralph.hector@ed.ac.uk>; S.R.Thomson@ed.ac.uk <S.R.Thomson@ed.ac.uk>; Paul.Ross@ed.ac.uk <Paul.Ross@ed.ac.uk>; stephanie.mearns@ed.ac.uk <stephanie.mearns@ed.ac.uk>; Marie.Bowers@ed.ac.uk<Marie.Bowers@ed.ac.uk>; zoe.sawitzki@ed.ac.uk <zoe.sawitzki@ed.ac.uk>; Sarah.Giachetti@ed.ac.uk<Sarah.Giachetti@ed.ac.uk>; s1316609@sms.ed.ac.uk <s1316609@sms.ed.ac.uk>; 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Oggetto: RE: COVID-19 vaccine dangers; CDC's "Vaccines do not cause autism" lie, taken down; NH commission exposes FCC corruption, cellular radiation dangers

If there had been any reliable evidence that “milk protein contaminated vaccines (DTaP/TdaP, Prevnar 13, ActHiB) cause the vast majority (75%) of autism cases”, we would surely have heard about it.
Please delete me from your email list
Peter C Gøtzsche
Professor and Director
Institute for Scientific Freedom
Copenhagen
https://www.scientificfreedom.dk/ and https://www.deadlymedicines.dk/
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From: Vinu Arumugham < (b) (6) @yahoo.com>
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Subject: Re: COVID-19 vaccine dangers; CDC's "Vaccines do not cause autism" lie, taken down; NH commission exposes FCC corruption, cellular radiation dangers

Prof. Gøtzsche,
Let me clarify that we are not discussing vaccine vs. no vaccine. We are discussing dirty, sickening vaccines vs. clean safe, effective vaccines.
Regarding autism, you are talking about the wrong vaccine. We have shown beyond all doubt, using **reliable mechanistic evidence** that milk protein contaminated vaccines (DTaP/TdaP, Prevnar 13, ActHiB) cause the vast majority (75%) of autism cases.

Autism pathogenesis: Piecing it all together, from end to beginning …
https://doi.org/10.5281/zenodo.1477515
Immunization with homologous xenogeneic (animal/plant/fungal) antigens causes the development of autoimmune diseases. Known for at least 45 years.

Vaccine-Induced Autoimmunity in the Dog

"the most likely sources of cross-reactive epitopes are bovine serum and cell culture components. These are present in almost all vaccines as residu-al components of the cell culture necessary to generate vaccine viruses and may purposely be added to the vaccine as a stabilizer. In the presence of an adjuvant, these bovine products stimulate a strong im-mune response and induce antibodies that cross-react with conserved canine antigens."

Xenogeneic therapeutic cancer vaccines as breakers of immune tolerance for clinical application: to use or not to use?
pubmed.ncbi.nlm.nih.gov/24837511/

Obtained via FOIA by Judicial Watch, Inc.
Oncologists immunize with xenogeneic antigens to break immune tolerance (cause autoimmunity) to make your immune system attack your own cancer cells.
Regular vaccines such as the measles vaccines are contaminated with animal proteins (chicken) and therefore cause numerous autoimmune disorders including type 1 diabetes.
Correlation of type 1 diabetes trends in European countries to the number of bovine insulin and GAD65 contaminated chick embryo cell culture containing vaccines in the schedule, as predicted by the autoimmunity mechanism involving immunization with homologous xenogeneic antigens and EPIT as a potential treatment
https://doi.org/10.5281/zenodo.1870364
The US IOM pointed out that epidemiological studies are useless in 93% of the cases. Mechanistic studies proved reliable.
Institute of Medicine: Most epidemiological vaccine safety studies are useless
https://doi.org/10.5281/zenodo.3244496
The Pandemrix vaccine made in Europe had higher levels of contamination with H1N1 nucleoproteins than the Arepanrix vaccine manufactured by the same company (GSK) in Canada. Pandemrix therefore caused way more cases of narcolepsy. Do you know the level of chicken protein contamination in Danish vs. US vaccines? How can you then apply studies done in Denmark to any other country?
Big picture of the damage vaccines do:
Vaccines and Biologics injury table based on mechanistic evidence – Feb 2020
Covering over 125 conditionshttps://zenodo.org/record/3647593/files/vbitr2_final.pdf?download=1
The organized suppression of vaccine safety science:
Retraction of scientific papers: the case of vaccine research
https://www.tandfonline.com/doi/full/10.1080/09581596.2021.1878109
Thanks,
Vinu
On 1/31/21 11:47 PM, pcg@scientificfreedom.dk wrote:

I have no knowledge of this huge email list and do not know why I was put on it. But I assume I will be taken off it because of what I write below. Please read it.

The idea that vaccines may cause autism was launched by Andrew Wakefield in relation to a fraudulent study published in Lancet in 1998 that has been retracted. Large observational studies from my country, Denmark, have shown convincingly that the Emperor has no clothes. I analyse this in detail in my 2020 book, Vaccines: truth, lies and controversy. It is an e-book but will come out soon on Skyhorse, New York, as a print book with an updated corona chapter that ends with the riots on 6 January 2021 at Capitol Hill.

Wakefield's horrendous fraud, which has caused many deaths, concerned the MMR vaccine. These are excerpts from my book, the chapter on measles:

According to the WHO, there were 110,000 measles deaths in 2017, and most were in children under the age of five.[3] Vaccination resulted in an 80% drop in measles deaths between 2000 and 2017 preventing an estimated 21 million deaths.

Measles outbreaks also provide strong support for the benefits of the vaccine. In the United States, there was a resurgence of measles in 1989-1990, which primarily involved unvaccinated racial and ethnic minority children less than five years of age residing in inner-city areas.[40] There were 66 (0.1%) cases of encephalitis. A provisional total of 41 measles-associated deaths was reported in 1989 (2.3 deaths per 1000 cases), which increased to 89 (3.2 per 1000 cases) in 1990. In 2000, the CDC declared measles eradicated in the United States but there have been several outbreaks since due to imported cases.[41] In 2018, no less than 17 outbreaks occurred. One, in New York, was due to people who had been to Israel, and it included 182 cases in orthodox Jewish communities with a vaccination rate of only 50%.[42]
It is not possible to say exactly what the risk is of dying from measles. As noted earlier, the death risk is related to the infectious dose, which is higher in settings with overcrowding. We can only say what it has been in outbreaks, and a commonly used estimate is 2 deaths per 1000 cases.

Obtained via FOIA by Judicial Watch, Inc.

But it can be much worse. During an epidemic in Copenhagen in 1887, at least 5% of the children, or 50 per 1000 cases, died.[43] The mortality was probably even higher because only those who died while they had a rash counted. In Wien, at the beginning of the 20th century, the mortality was 11% among the poorest and 0.6% among the richest.
An outbreak in Madagascar that started in 2018 had in April 2019 caused over 1200 deaths, which is about 1% of those infected.[44] Only about 60% of the population is vaccinated.

We should all get vaccinated against measles and get our children vaccinated, with very few exceptions. Contraindications for the vaccine include a history of severe allergic reaction to any component of the vaccine including neomycin, pregnancy (measles illness during pregnancy results in a higher risk of premature labour, spontaneous abortion, and low-birthweight infants), and severe immunosuppression.[34]

On Swedish TV, in 2020, Wakefield lied horrendously about measles: "Exposure in childhood is safe and conveys lifelong immunity."

The reference is:

Dokumentär
Anna Nordbeck och Malin Olofsson
Dokument inifrån: VACCINKRIGARNA
https://www.svtplay.se/dokument-inifran-vaccinkrigarna
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From: Vinu Arumugham <(b) (6) @yahoo.com>
Sent: 01 February 2021 01:43
To: goldingh@cber.fda.gov; khuranas@cber.fda.gov; sli49@emory.edu; elizabeth.deatrick@niaid.nih.gov; pwilson1@medicine.bsd.uchicago.edu; agewirtz@gsu.edu; megan.hahn@fda.hhs.gov; goldmanb@stanford.edu; mario.cortese@stanford.edu; nroupha@emory.edu; alan.embry@nih.gov; alex@lji.org; neuron@cell.com; jlandsberg@cell.com; agoldstein@cell.com; mzirlinger@cell.com; tdobie@cell.com; mfurman@cell.com; ckonen@cell.com; eniederst@cell.com; uschridde@cell.com; jshaw@cell.com; eporro@cell.com; emarcus@cell.com; jeffrey.sonnenfeld@yale.edu; info@eeoc.gov; ofo.eeoc@eeoc.gov; FOIA@eeoc.gov; eeoc.traininginstitute@eeoc.gov; inspector.general@eeoc.gov; richard.hatchett@cepi.net; fg17882@bristol.ac.uk; ripley.ballou@gskbio.com; nicole.lurie@cepi.net; jlg251@georgetown.edu;tom.monath@crozetbiopharma.com; aabimiku@ihv.umaryland.edu; abarrett@utmb.edu; Ananda.Bandyopadhyay@gatesfoundation.org; cbrechot@usf.edu; chappi@hsph.harvard.edu; Connie.s.schmaljohn.civ@mail.mil; iad7@cdc.gov; jamesrobinson@uchicago.edu; Jean.Lang@sanofipasteur.com; john.k.billington@gsk.com; kenji.shibuya@kcl.ac.uk; krause@cber.fda.gov; mlevine@som.umaryland.edu; moorthyv@who.int; paula.bryant@nih.gov; (b) (6) @africaonline.co.ke;yves.levy@aphp.fr; faddo@wisc.edu; bradford.barham@wisc.edu; lebautista@wisc.edu; lmberger@wisc.edu; wrbuckin@wisc.edu; meburns@wisc.edu; carlson@ssc.wisc.edu; jmcollins@wisc.edu; jaconwell@wisc.edu; nbarnes2@wisc.edu; kcurtis@ssc.wisc.

Obtained via FOIA by Judicial Watch, Inc.
edu; mcurtis3@wisc.edu; jeason2@wisc.edu; ehrenthal@wisc.edu; felwert@ssc.wisc.edu; cengelman@wisc.edu; mengelman@ssc.wisc.edu; jason.fletcher@wisc.edu;cfu@ssc.wisc.edu; fujimura@ssc.wisc.edu; tgerber@ssc.wisc.edu; cde@ssc.wisc.edu; grantm@ssc.wisc.edu; jan.greenberg@wisc.edu; jmgregory@ssc.wisc.edu; egrodsky@ssc.wisc.edu; sarah.halpernmeekin@wisc.edu;jenny.a.higgins@wisc.edu; lpjacobs@wisc.edu; fjones4@wisc.edu; hyunseung@stat.wisc.edu; dkaplan@education.wisc.edu; jkennan@ssc.wisc.edu; ajk@medicine.wisc.edu; mlight@ssc.wisc.edu;logan@ssc.wisc.edu; kmagnuson@wisc.edu; marsha.mailick@wisc.edu; kmalecki@wisc.edu; mmassoglia@ssc.wisc.edu; drmeyer1@wisc.edu ; cmommaerts@wisc.edu; amukherjee@wisc.edu; jmullahy@wisc.edu; jnobles@ssc.wisc.edu; robrien@lafollette.wisc.edu; palloni@wisc.edu; patz@wisc.edu; ppeppard@wisc.edu; jraymo@ssc.wisc.edu; ferey@wisc.edu; sarobert@wisc.edu ; schaeffer@ssc.wisc.edu;lschechter@wisc.edu; aschneider4@wisc.edu; cschwart@ssc.wisc.edu; aseshadr@ssc.wisc.edu ; smeeding@lafollette.wisc.edu; econjeff@ssc.wisc.edu; psteiner@wisc.edu; ctaber@ssc.wisc.edu; tjernstroem@wisc.edu; walker@ssc.wisc.edu; wallace@lafollette.wisc.edu; tbwalsh@wisc.edu;yang.wang@lafollette.wisc.edu; mjwiswall@wisc.edu; wolfe@lafollette.wisc.edu; ysxiong2@wisc.edu;jzhu@stat.wisc.edu; ashivani@seas.upenn.edu; rbeck@jaeb.org; (b) (6) @gmail.com; t1dstats@jaeb.org;willi@email.chop.edu; weinstor@upstate.edu; paul.wadwa@cuanschutz.edu; jennifer.sherr@yale.edu; rmonzavi@chla.usc.edu; Laurel.Messer@cuanschutz.edu; sarah.corathers@cchmc.org; Amy.Criego@ParkNicollet.com; maclements@cmh.edu; inquires@sda.gov.cn; yerw@bjmu.edu.cn; yxy@xjtu.edu.cn; cfetpyhj@vip.sina.com; caodesheng@chinadaily.com.cn; yanwl@fudan.edu.cn; yiwang@shmu.edu.cn; zhangyp@chinacdc.cn; maojh88@zju.edu.cn; gisou.vandergoot@epfl.ch; nicola.harris@epfl.ch; andrea.ablasser@epfl.ch; patrick.aebischer@epfl.ch; johan.auwerx@epfl.ch;olaf.blanke@epfl.ch; melanie.blokesch@epfl.ch; cathrin.brisken@epfl.ch; philipp.bucher@epfl.ch; stewart.cole@epfl.ch; daniel.constam@epfl.ch; gregoire.courtine@epfl.ch; matteo.dalperaro@epfl.ch; paolo.delosrios@epfl.ch; michele.depalma@epfl.ch; bart.deplancke@epfl.ch; denis.duboule@epfl.ch;wulfram.gerstner@epfl.ch; pierre.gonczy@epfl.ch; johannes.graeff@epfl.ch; douglas.hanahan@epfl.ch; oliver.hantschel@epfl.ch; vassily.hatzimanikatis@epfl.ch; michael.herzog@epfl.ch; kathryn.hess@epfl.ch; joerg.huelsken@epfl.ch; friedhelm.hummel@epfl.ch; hilal.lashuel@epfl.ch; theo.lasser@epfl.ch;bruno.lemaitre@epfl.ch; joachim.lingner@epfl.ch; matthias.lutolf@epfl.ch; pierre.magistretti@epfl.ch; suliana.manley@epfl.ch; henry.markram@epfl.ch; brian.mccabe@epfl.ch; john.mckinney@epfl.ch; etienne.meylan@epfl.ch; felix.naef@epfl.ch; olaia.naveiras@epfl.ch; andrew.oates@epfl.ch;elisa.oricchio@epfl.ch; alexandre.persat@epfl.ch; carl.petersen@epfl.ch; freddy.radtke@epfl.ch; pavan.ramdya@epfl.ch; marcel.salathe@epfl.ch ; carmen.sandi@epfl.ch; ralf.schneggenburger@epfl.ch; kristina.schoonjans@epfl.ch; viesturs.simanis@epfl.ch; david.suter@epfl.ch; didier.trono@epfl.ch;nicolas.mermod@unil.ch; beatrice.perrenoud@chuv.ch; awagnon@cmanet.org; accma@accma.org; jgreaves@accma.org; jjackovic@accma.org; grogers@accma.org; ndraper@accma.org; mlum@accma.org ; (b) (6) @sbcglobal.net; (b) (6) @gmail.com; sbcms@sbmed.org; nbutler@fmms.org; Kamal.Gadalla@ed.ac.uk;ralph.hector@ed.ac.uk; S.R.Thomson@ed.ac.uk; Paul.Ross@ed.ac.uk; stephanie.mearns@ed.ac.uk; Marie.Bowers@ed.ac.uk; zoe.sawitzki@ed.ac.uk; Sarah.Giachetti@ed.ac.uk; s1316609@sms.ed.ac.uk; cochrane@umcutrecht.nl; editorial-unit@cochrane.org; admin@cochrane.org; CEU Admin <ceu@cochrane.org>;mwilson@cochrane.org; martin.burton@cochrane.nhs.uk; c.farquhar@auckland.ac.nz;j.e.clarkson@dundee.ac.uk; gerald.gartlehner@donau-uni.ac.at; pcg@scientificfreedom.dk; marguerite.a.koster@kp.org; (b) (6) @gmail.com; meerpohl@cochrane.de; santesna@mcmaster.ca;dimitrinka.nikolova@ctu.dk; snezana.djurisic@ctu.dk; (b) (6) @gmail.com; (b) (6) @gmail.com; (b) (6) @gmail.com; vbonfigli@cochrane.org; david@davidhammerstein.org; mburton@cochrane.org; mkoster@cochrane.org; Chris Del Mar <cdelmar@bond.edu.au>; Paul Glasziou <pglaszio@bond.edu.au>; RayMoynihan@bond.edu.au; peter.collignon@act.gov.au; Karla Soares-Weiser <ksoares-weiser@cochrane.org>; Hilary Simmonds <HSimmonds@cochrane.org>; Toby Lasserson <TLasserson@cochrane.org>; Christian Gluud<christian.gluud@ctu.dk>; Christopher Exley <c.exley@keele.ac.uk>; cdipietrantonj@aslal.it; (b) (6) @googlemail.com; sdavies@bmj.com; (b) (6) (b) (6)@btinternet.com; jclarkson@cochrane.org;ncullum@cochrane.org; gfaba@cochrane.org; thowe@cochrane.org; trish.greenhalgh@phc.ox.ac.uk;peter.christian.goetzsche@regionh.dk; governingboardsecretary@cochrane.org; David Tovey<dtovey@cochrane.org>; sara.krauss@ctu.dk; cgluud@ctu.dk; (b) (6) @gmail.com

Subject: COVID-19 vaccine dangers; CDC's "Vaccines do not cause autism" lie, taken down; NH commission exposes FCC corruption, cellular radiation dangers

Vaccines absolutely do cause autism

The CDC has flip-flopped twice in ~5 months on the fraudulent claim that "Vaccines do not cause autism", on their website. It suggests that the CDC's vaccine/autism claims are based on the conjunction of Jupiter and Saturn, not science.

Obtained via FOIA by Judicial Watch, Inc.
They were forced to take the false claim down because ICAN demonstrated there was **ZERO** science behind that claim.
The CDC Finally Capitulated To ICAN's Legal Demands and Removed the Claim that "Vaccines Do Not Cause Autism" From Its Website!
https://www.icandecide.org/ican_press/the-cdc-finally-capitulated-to-icans-legal-demands-and-removed-the-claim-that-vaccines-do-not-cause-autism-from-its-website/
THE CDC JUST SOLIDIFIED THAT ITS DECISIONS ARE NOT DRIVEN BY SCIENCE
https://www.icandecide.org/ican_press/the-cdc-just-solidified-that-its-decisions-are-not-driven-by-science/
FACT: Milk protein contaminated vaccines (DTap/Tdap/Prevnar 13/ActHiB) cause at least 75% of autism cases.
Autism pathogenesis: Piecing it all together, from end to beginning …
https://doi.org/10.5281/zenodo.1477515
CDC caught lying, again about the COVID-19 vaccine this time.
CDC Investigation
http://fullmeasure.news/news/cover-story/cdc-investigation

Vaccine mandates are based on a lie; Repeal all mandates immediately; Try the corrupted liars who created mandates, for CRIMES AGAINST HUMANITY
"Administration of parenterally administered vaccines alone typically does not result in potent mucosal immunity that might interrupt infection or transmission"
SARS-CoV-2 Vaccines: Much Accomplished, Much to Learn
www.acpjournals.org/doi/10.7326/M21-0111
So Fauci admits now that **ALL** injected vaccines are for individual protection only. **No herd/community immunity.** So no vaccine mandates are justifiable for **ANY** injected vaccine.
And of course this also means the vaccinated can become infected super-spreaders as occurs with the failed flu shot and failed pertussis vaccines.
Yan J, Grantham M, Pantelic J, de Mesquita PJ, Albert B, Liu F, et al. Infectious virus in exhaled breath of symptomatic seasonal influenza cases from a college community. Adamson W, Beato-Arribas B, Bischoff W, Booth W, Cauchemez S, Ehrman S, et al., editors. Proc Natl Acad Sci. National Academy of Sciences; 2018;

The potential role of subclinical Bordetella Pertussis colonization in the etiology of multiple sclerosis
pubmed.ncbi.nlm.nih.gov/26724970/

This is the consequence of **insanely injecting** antigens of pathogens whose natural routes of exposure are mucosal surfaces in the nose, mouth or eyes.

NOTICE!
By authority of the Nuremberg Code on Medical Experimentation, I do hereby exercise my right to refuse to submit to or to administer the Covid-19 vaccine. The United States Government has prosecuted, convicted and executed Medical Doctors who have violated the Nuremberg Code on Medical Experimentation. Aiders and abettors of Nuremberg Crimes are equally guilty and have also been prosecuted, convicted, and executed.
Francis A. Boyle
Professor of Law.

My comment in the Annals of Internal Medicine, against Fauci's "SARS-CoV-2 Vaccines: Much Accomplished, Much to Learn"

https://www.acpjournals.org/doi/10.7326/M21-0111

Vinu Arumugham Independent 18 January 2021

These vaccines are unsafe, unnecessary and must be immediately withdrawn

Obtained via FOIA by Judicial Watch, Inc.

The vaccine safety claims made by the authors are unsupported by evidence. Vaccines must be designed for safety. These vaccines were not designed at all. So they are unsafe by definition. I predicted the allergic sensitization and autoimmunity risks with these vaccines which have now been confirmed.

The Pfizer/BioNTech vaccine is unnecessary, unsafe and should not be authorized.
https://www.regulations.gov/document?D=FDA-2020-N-1898-0039

Robert F Kennedy Jr. warned the FDA months back about the risk of allergic reactions due to the use of polyethylene glycol (PEG) in the vaccines.
https://childrenshealthdefense.org/defender/pfizer-covid-vaccine-allergic-reactions/

The FDA/VRBPAC ignored us and authorized these horrendously dangerous vaccines.

Recently, Dr. Peter Marks of the FDA admitted that the population was sensitized by PEG-containing pharmaceutical preparations (that include other vaccines/injections).
https://www.wsj.com/articles/scientists-eye-potential-culprit-for-covid-19-vaccine-allergic-reactions-11608901200?mod=hp_lead_pos2

"What we're learning now is that those **allergic reactions could be somewhat more common** than the highly uncommon that we thought they were **because people do get exposed to polyethylene glycol in various pharmaceutical preparations,**" - Peter Marks, Director, CBER,FDA.

We of course already knew that any vaccine/injection that has enough allergen to cause a reaction, has more than enough allergen to guarantee sensitization/priming (causing the development of new allergy).

Evidence that Food Proteins in Vaccines Cause the Development of Food Allergies and Its Implications for Vaccine Policy
https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3571073

www.sciencemag.org/news/2020/12/suspicions-grow-nanoparticles-pfizer-s-covid-19-vaccine-trigger-rare-allergic-reactions

"he worries anti-PEG antibodies triggered by the first shot could increase the risk of an allergic reaction to the second or to PEGylated drugs."
- Janos Szebeni, an immunologist at Semmelweis University

So now, these vaccines have sensitized millions to PEG. The goal is to sensitize/boost PEG allergy in a 100 million more in the next 100 days.

PEG is contaminated with 1,4-dioxane, a carcinogen.
https://www.fda.gov/cosmetics/potential-contaminants-cosmetics/14-dioxane-cosmetics-manufacturing-byproduct

As predicted, Pfizer COVID-19 vaccine induced autoimmunity (thrombocytopenia) killed a Florida doctor. This is just the tip of the iceberg. Thousands of cases of vaccine induced autoimmune diseases may take months/years to be diagnosed and will be dismissed as unrelated to the vaccine.
https://www.nytimes.com/2021/01/12/health/covid-vaccine-death.html

Only a few lots were tested in the trial. No one has a clue what other lots will do. 100-fold variation of contaminants in vaccines makes trials and epidemiological studies worthless as I detailed in my comments in the Annals of Internal Medicine before. Vaccine safety remains an oxymoron.
https://www.acpjournals.org/doi/10.7326/m18-2101

California calls for pause of 330,000 doses, investigation after allergic reactions to Moderna vaccine batch
https://www.mercurynews.com/2021/01/18/coronavirus-california-calls-for-pause-investigation-after-allergic-reactions-to-moderna-vaccine-batch/

What's worse? Effective, life-saving, cheap, safe medicines such as famotidine/cetirizine/ivermectin are being ignored in this blind race to vaccinate at any cost.

Immunological mechanisms explaining the role of vaccines, IgE, mast cells, histamine, elevating ferritin, IL-6, D-dimer, VEGF levels in COVID-19 and dengue, potential treatments such as mast cell stabilizers, antihistamines: Predictions and confirmations
https://europepmc.org/article/PPR/PPR241819

Big picture of the damage vaccines do:

Vaccines and Biologics injury table based on mechanistic evidence – Feb 2020
Covering over 125 conditionshttps://zenodo.org/record/3647593/files/vbitr2_final.pdf?download=1

The organized suppression of vaccine safety science:

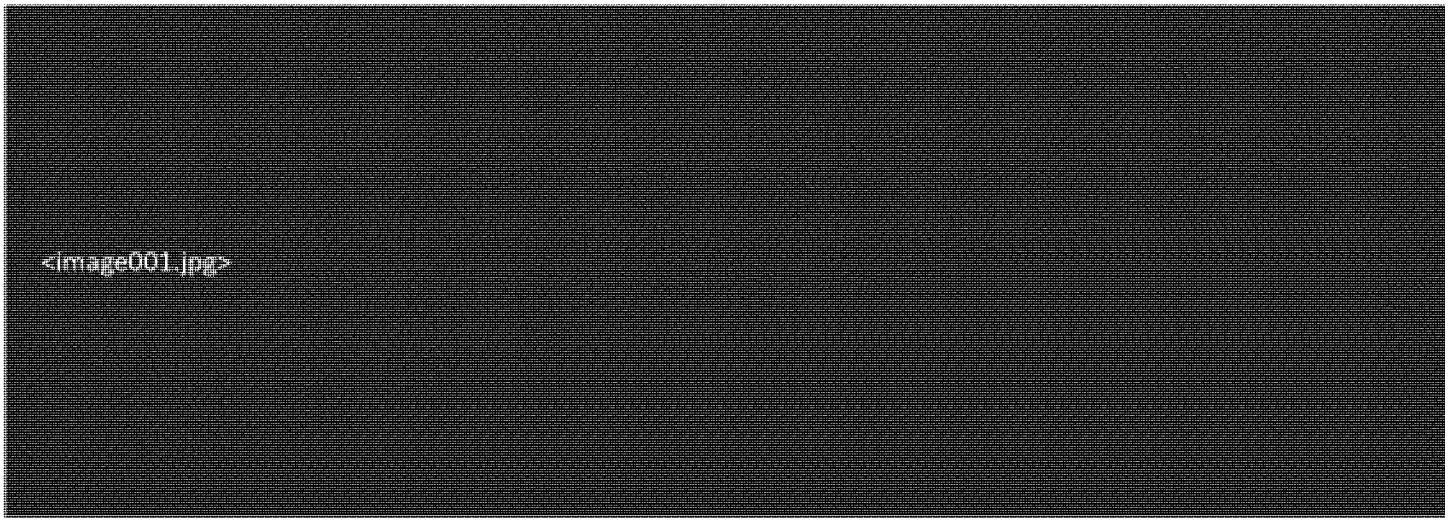
Retraction of scientific papers: the case of vaccine research
https://www.tandfonline.com/doi/full/10.1080/09581596.2021.1878109

The WHO's flip-flopping "science" competes with CDC's incompetence

WHO Recommends Against Moderna, Pfizer Vaccines for Most Pregnant Women

Obtained via FOIA by Judicial Watch, Inc.
https://www.wsj.com/articles/who-recommends-against-moderna-pfizer-vaccines-for-most-pregnant-women-11611775138
Pregnant Women May Receive Covid Vaccines Safely, W.H.O. Says
https://www.nytimes.com/2021/01/29/health/covid-vaccine-pregnancy.html
Moderna's COVID-19 vaccine now recommended for pregnant women, WHO says in guidance reversal
https://www.foxnews.com/health/moderna-covid-vaccine-pregnant-women-who-guidance-reversal
Not to be outdone by the flip-flopping CDC, WHO did a flip-flop on COVID-19 vaccine during pregnancy.
Latest evidence that there is ZERO science behind vaccines or vaccine safety. They just pull their "science" out of a hat. Follow the money.
These flip-flopping, lying, organized criminals at the CDC/WHO, are the "reputable sources" for your "fact-checkers".

The New Hampshire Commission report below has ripped FCC's 5G (and all other cellular) RF safety claims:
Final Report of the Commission to Study The Environmental and Health Effects of Evolving 5G Technology
http://www.gencourt.state.nh.us/statstudcomm/committees/1474/reports/5G%20final%20report.pdf
"RECOMMENDATION 1- Propose a resolution of the House to the US Congress and Executive Branch to **require the Federal Communication Commission (FCC) to commission an independent review** of the current radiofrequency (RF) standards of the electromagnetic radiation in the 300MHz to 300GHz microwave spectrum as well as a health study to assess and recommend mitigation for the health risks associated with the use of cellular communications and data transmittal."
"A likely explanation as to why **regulatory agencies have opted to ignore the body of scientific evidence demonstrating the negative impact of cellphone radiation** is that **those agencies are "captured"** (see Harvard University publication entitled, "Captured Agency: How the Federal Communications Commission Is Dominated by the Industries It Presumably Regulates" linked in Appendix G). This report documents how **the leadership roles in some agencies (the FCC in particular) are filled by individuals with strong industry ties** and hence are more **focused on industry interests than the health of citizens**"



Major Litigation Updates & Recent Local Victories

It's been a strong week for our movement!

There are a lot of exciting things to report on this week, so let's dive right in...

Obtained via FOIA by Judicial Watch, Inc.

Lake Tahoe, CA - Landmark Federal Lawsuit Filed to Block Saturation of Lake Tahoe Region with Cell Towers

<image002.jpg>

Hundreds of hazardous, unsightly wireless antennas and cell towers are quickly blanketing the Lake Tahoe, California region.

Three environmental non-profits and Monica Eisenstecken, a lifelong resident of South Lake Tahoe, have filed a potentially **precedent-setting litigation** against the Tahoe Regional Planning Agency, Verizon Wireless, the Tahoe Prosperity Center, and a local property owner...all in an effort **to protect one of the world's greatest natural treasures from a looming telecom takeover.**

Read Today's Press Release

Visit the New Tahoe Safe Tech Website

Support the Landmark Litigation

D.C. Court of Appeals - Environmental Health Trust et al. v. FCC Oral Arguments, January 25th, 2021

<image002.jpg>

Obtained via FOIA by Judicial Watch, Inc.

"A federal appeals panel in Washington voiced skepticism that the Federal Communications Commission had adequately considered dangerous health effects when it established guidelines for radiation emission from cell towers and wireless devices."
- Bloomberg Law

Congratulations to both the Environmental Health Trust and the Children's Health Defense for their tireless efforts challenging the FCC's outdated and insufficient wireless radiation public exposure guidelines.

Following yesterday's fabulous presentation, we are hopeful the judges will rule against the FCC.

Read the News

Listen to Recording of the Oral Arguments

RECENT VICTORIES

FLORIDA

1. Palm Coast, FL defeats 150-foot cell tower to be installed in the heart of the city's oldest neighborhood.

Read the news here.

<image002.jpg>

2. Lakeland, FL defeats 110-foot cell tower slated to be installed mere feet from homes. This is the second cell tower in three months that has been defeated by Lakeland representatives due to resident opposition.

Read the news here.

Obtained via FOIA by Judicial Watch, Inc.

<image002.jpg>

NEW JERSEY

3. Lavallette, NJ Borough Council approves five "small cell" antennas with challenging conditions: certification from the U.S. Department of Defense and the Federal Aviation Administration that 5G frequencies emitted by the equipment will not interfere with critical avionics equipment. Lavallette is situated just a few miles from one of the country's most active military air bases - Joint Base McGuire-Dix-Lakehurst.

Read the news here.

<image002.jpg>

CALIFORNIA

4. Petaluma, CA defeats Verizon application to install 16 wireless antennas at the Petaluma Creamery, just 75 feet from homes. Read the legal memorandum in opposition to Verizon's application here.

<image002.jpg>

SOUTH CAROLINA

5. Residents in Mt. Pleasant, SC defeat a cell tower to be installed next to the Long Point playground.

Obtained via FOIA by Judicial Watch, Inc.

Read the news here.

<image003.jpg>

As always, let's keep raking in the wins and working together to protect our communities from the telecom industry's ever-growing wireless footprint.

If you need assistance pushing back against 5G and/or other wireless infrastructure deployments in your area, please don't hesitate to reply to this email or call us at 516-883-0887.

-The 5G Crisis Team

Contribute to 5G Crisis

<image004.jpg>

Share

<image004.jpg>

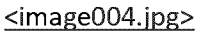
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Obtained via FOIA by Judicial Watch, Inc.



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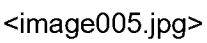
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Email report@5gcrisis.com

Call 516-883-0887

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Thanks,
Vinu

Il contenuto del presente messaggio di posta elettronica, ed ogni eventuale documento a quest'ultimo allegato, è rivolto unicamente al destinatario cui è indirizzato e può contenere dati ed informazioni la cui riservatezza è tutelata. Sono vietati la riproduzione, l'utilizzo e la diffusione dei dati e delle informazioni contenuti nel presente messaggio senza espressa autorizzazione da parte del destinatario. Chiunque abbia ricevuto il presente messaggio per errore è pregato di provvedere senza ritardo a segnalarlo, contattandoci via telefono, fax o e-mail.
Il presente messaggio proviene da un indirizzo di posta elettronica aziendale assegnato al mittente a scopo lavorativo: la relativa casella di posta elettronica è soggetta alle procedure di controllo stabilite dall' ASL AL. Inviate a questo indirizzo solo comunicazioni di natura lavorativa, grazie

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Il contenuto del presente messaggio di posta elettronica, ed ogni eventuale documento a quest'ultimo allegato, è rivolto unicamente al destinatario cui è indirizzato e può contenere dati ed informazioni la cui riservatezza è tutelata. Sono vietati la riproduzione, l'utilizzo e la diffusione dei dati e delle informazioni contenuti nel presente messaggio senza espressa autorizzazione da parte del destinatario. Chiunque abbia ricevuto il presente messaggio per errore è pregato di provvedere senza ritardo a segnalarlo, contattandoci via telefono, fax o e-mail.
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Obtained via FOIA by Judicial Watch, Inc.



Obtained via FOIA by Judicial Watch, Inc.

From: DEBORAH B EHRENTHAL [ehrenthal@wisc.edu]
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Subject: Re: COVID-19 vaccine dangers; CDC's "Vaccines do not cause autism" lie, taken down; NH commission exposes FCC corruption, cellular radiation dangers

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Subject: Re: COVID-19 vaccine dangers; CDC's "Vaccines do not cause autism" lie, taken down; NH commission exposes FCC corruption, cellular radiation dangers

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On 2 Feb 2021, at 15:55, Nicole Lurie <nicole.lurie@cepi.net> wrote:

Me too

Sent from my iPhone

On Feb 2, 2021, at 9:53 AM, Marsha Mailick <marsha.mailick@wisc.edu> wrote:

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On Feb 2, 2021, at 9:41 AM, trish.greenhalgh@phc.ox.ac.uk wrote:

And me.

From: CORINNE D ENGELMAN <corinne.engelman@wisc.edu>
Date: Tuesday, 2 February 2021 at 14:37
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Subject: Re: COVID-19 vaccine dangers; CDC's "Vaccines do not cause autism" lie, taken down; NH commission exposes FCC corruption, cellular radiation dangers

Me too.

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Subject: RE: COVID-19 vaccine dangers; CDC's "Vaccines do not cause autism" lie, taken down; NH commission exposes FCC corruption, cellular radiation dangers

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Oggetto: RE: COVID-19 vaccine dangers; CDC's "Vaccines do not cause autism" lie, taken down; NH commission exposes FCC corruption, cellular radiation dangers

If there had been any reliable evidence that “milk protein contaminated vaccines (DTaP/TdaP, Prevnar 13, ActHiB) cause the vast majority (75%) of autism cases”, we would surely have heard about it.

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Peter C Gøtzsche
Professor and Director
Institute for Scientific Freedom
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Subject: Re: COVID-19 vaccine dangers; CDC's "Vaccines do not cause autism" lie, taken down; NH commission exposes FCC corruption, cellular radiation dangers

Prof. Gøtzsche,

Let me clarify that we are not discussing vaccine vs. no vaccine. We are discussing dirty, sickening vaccines vs. clean safe, effective vaccines.

Regarding autism, you are talking about the wrong vaccine. We have shown beyond all doubt, using **reliable mechanistic evidence** that milk protein contaminated vaccines (DTaP/TdaP, Prevnar 13, ActHiB) cause the vast majority (75%) of autism cases.

Autism pathogenesis: Piecing it all together, from end to beginning …
https://doi.org/10.5281/zenodo.1477515

Obtained via FOIA by Judicial Watch, Inc.

Immunization with homologous xenogeneic (animal/plant/fungal) antigens causes the development of autoimmune diseases. Known for at least 45 years.

Vaccine-Induced Autoimmunity in the Dog

"the most likely sources of cross-reactive epitopes are bovine serum and cell culture components. These are present in almost all vaccines as residu-al components of the cell culture necessary to generate vaccine viruses and may purposely be added to the vaccine as a stabilizer. In the presence of an adjuvant, these bovine products stimulate a strong im-mune response and induce antibodies that cross-react with conserved canine antigens."

Xenogeneic therapeutic cancer vaccines as breakers of immune tolerance for clinical application: to use or not to use?
pubmed.ncbi.nlm.nih.gov/24837511/

Oncologists immunize with xenogeneic antigens to break immune tolerance (cause autoimmunity) to make your immune system attack your own cancer cells.

Regular vaccines such as the measles vaccines are contaminated with animal proteins (chicken) and therefore cause numerous autoimmune disorders including type 1 diabetes.

Correlation of type 1 diabetes trends in European countries to the number of bovine insulin and GAD65 contaminated chick embryo cell culture containing vaccines in the schedule, as predicted by the autoimmunity mechanism involving immunization with homologous xenogeneic antigens and EPIT as a potential treatment
https://doi.org/10.5281/zenodo.1870364

The US IOM pointed out that epidemiological studies are useless in 93% of the cases. Mechanistic studies proved reliable.

Institute of Medicine: Most epidemiological vaccine safety studies are useless

https://doi.org/10.5281/zenodo.3244496

The Pandemrix vaccine made in Europe had higher levels of contamination with H1N1 nucleoproteins than the Arepanrix vaccine manufactured by the same company (GSK) in Canada. Pandemrix therefore caused way more cases of narcolepsy. Do you know the level of chicken protein contamination in Danish vs. US vaccines? How can you then apply studies done in Denmark to any other country?

Big picture of the damage vaccines do:

Vaccines and Biologics injury table based on mechanistic evidence – Feb 2020

Covering over 125 conditionshttps://zenodo.org/record/3647593/files/vbitr2_final.pdf?download=1

The organized suppression of vaccine safety science:

Retraction of scientific papers: the case of vaccine research
https://www.tandfonline.com/doi/full/10.1080/09581596.2021.1878109

Thanks,

Vinu

On 1/31/21 11:47 PM, pcg@scientificfreedom.dk wrote:

I have no knowledge of this huge email list and do not know why I was put on it. But I assume I will be taken off it because of what I write below. Please read it.

The idea that vaccines may cause autism was launched by Andrew Wakefield in relation to a fraudulent study published in Lancet in 1998 that has been retracted. Large observational studies from my country, Denmark, have shown convincingly that the Emperor has no clothes. I analyse this in detail in my 2020 book, Vaccines: truth, lies and controversy. It is an e-book but will come out soon on Skyhorse, New York, as a print book with an updated corona chapter that ends with the riots on 6 January 2021 at Capitol Hill.

Wakefield's horrendous fraud, which has caused many deaths, concerned the MMR vaccine. These are excerpts from my book, the chapter on measles:

Obtained via FOIA by Judicial Watch, Inc.

According to the WHO, there were 110,000 measles deaths in 2017, and most were in children under the age of five.[3] Vaccination resulted in an 80% drop in measles deaths between 2000 and 2017 preventing an estimated 21 million deaths.

Measles outbreaks also provide strong support for the benefits of the vaccine. In the United States, there was a resurgence of measles in 1989-1990, which primarily involved unvaccinated racial and ethnic minority children less than five years of age residing in inner-city areas.[40] There were 66 (0.1%) cases of encephalitis. A provisional total of 41 measles-associated deaths was reported in 1989 (2.3 deaths per 1000 cases), which increased to 89 (3.2 per 1000 cases) in 1990. In 2000, the CDC declared measles eradicated in the United States but there have been several outbreaks since due to imported cases.[41] In 2018, no less than 17 outbreaks occurred. One, in New York, was due to people who had been to Israel, and it included 182 cases in orthodox Jewish communities with a vaccination rate of only 50%.[42]
It is not possible to say exactly what the risk is of dying from measles. As noted earlier, the death risk is related to the infectious dose, which is higher in settings with overcrowding. We can only say what it has been in outbreaks, and a commonly used estimate is 2 deaths per 1000 cases. But it can be much worse. During an epidemic in Copenhagen in 1887, at least 5% of the children, or 50 per 1000 cases, died.[43] The mortality was probably even higher because only those who died while they had a rash counted. In Wien, at the beginning of the 20th century, the mortality was 11% among the poorest and 0.6% among the richest.
An outbreak in Madagascar that started in 2018 had in April 2019 caused over 1200 deaths, which is about 1% of those infected.[44] Only about 60% of the population is vaccinated.

We should all get vaccinated against measles and get our children vaccinated, with very few exceptions. Contraindications for the vaccine include a history of severe allergic reaction to any component of the vaccine including neomycin, pregnancy (measles illness during pregnancy results in a higher risk of premature labour, spontaneous abortion, and low-birthweight infants), and severe immunosuppression.[34]

On Swedish TV, in 2020, Wakefield lied horrendously about measles: "Exposure in childhood is safe and conveys lifelong immunity."

The reference is:

Dokumentär
Anna Nordbeck och Malin Olofsson
Dokument inifrån: VACCINKRIGARNA
https://www.svtplay.se/dokument-inifran-vaccinkrigarna
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Sent: 01 February 2021 01:43
To: goldingh@cber.fda.gov; khuranas@cber.fda.gov; sli49@emory.edu; elizabeth.deatrick@niaid.nih.gov; pwilson1@medicine.bsd.uchicago.edu; agewirtz@gsu.edu; megan.hahn@fda.hhs.gov; goldmanb@stanford.edu; mario.cortese@stanford.edu; nroupha@emory.edu; alan.embry@nih.gov; alex@lji.org; neuron@cell.com; jlandsberg@cell.com; agoldstein@cell.com; mzirlinger@cell.com; tdobie@cell.com; mfurman@cell.com; ckonen@cell.com; eniederst@cell.com; uschridde@cell.com; jshaw@cell.com; eporro@cell.com; emarcus@cell.com; jeffrey.sonnenfeld@yale.edu; info@eeoc.gov; ofo.eeoc@eeoc.gov; FOIA@eeoc.gov; eeoc.traininginstitute@eeoc.gov; inspector.general@eeoc.gov; richard.hatchett@cepi.net; fg17882@bristol.ac.uk; ripley.ballou@gskbio.com; nicole.lurie@cepi.net; jlg251@georgetown.edu;tom.monath@crozetbiopharma.com; aabimiku@ihv.umaryland.edu; abarrett@utmb.edu; Ananda.Bandyopadhyay@gatesfoundation.org; cbrechot@usf.edu; chappi@hsph.harvard.edu; Connie.s.schmaljohn.civ@mail.mil; iad7@cdc.gov; jamesrobinson@uchicago.edu; Jean.Lang@sanofipasteur.com; john.k.billington@gsk.com; kenji.shibuya@kcl.ac.uk; krause@cber.fda.gov; mlevine@som.umaryland.edu; moorthyv@who.int; paula.bryant@nih.gov; (b) (6) @africaonline.co.ke;yves.levy@aphp.fr; faddo@wisc.edu; bradford.barham@wisc.edu; lebautista@wisc.edu; lmberger@wisc.edu; wrbuckin@wisc.edu; meburns@wisc.edu; carlson@ssc.wisc.edu; jmcollins@wisc.edu; jaconwell@wisc.edu; nbarnes2@wisc.edu; kcurtis@ssc.wisc.edu; mcurtis3@wisc.edu; jeason2@wisc.edu; ehrenthal@wisc.edu; felwert@ssc.wisc.edu; cengelman@wisc.edu; mengelman@ssc.wisc.edu; jason.fletcher@wisc.edu;cfu@ssc.wisc.edu; fujimura@ssc.wisc.edu; tgerber@ssc.wisc.edu; cde@ssc.wisc.edu; grantm@ssc.wisc.edu; jan.greenberg@wisc.edu; jmgregory@ssc.wisc.edu; egrodsky@ssc.wisc.edu; sarah.halpernmeekin@wisc.edu;jenny.a.higgins@wisc.edu; lpjacobs@wisc.edu; fjones4@wisc.edu; hyunseung@stat.wisc.edu; dkaplan@education.wisc.edu; jkennan@ssc.wisc.edu; ajk@medicine.wisc.edu; mlight@ssc.wisc.edu;logan@ssc.wisc.edu; kmagnuson@wisc.edu; marsha.mailick@wisc.edu; kmalecki@wisc.edu; mmassoglia@ssc.wisc.edu; drmeyer1@wisc.edu; cmommaerts@wisc.edu; amukherjee@wisc.edu; jmullahy@wisc.edu; jnobles@ssc.wisc.edu; robrien@lafollette.wisc.edu; palloni@wisc.edu; patz@wisc.edu; ppeppard@wisc.edu; jraymo@ssc.wisc.edu; ferey@wisc.edu; sarobert@wisc.edu; schaeffer@ssc.wisc.edu;lschechter@wisc.edu; aschneider4@wisc.edu; cschwart@ssc.wisc.edu; aseshadr@ssc.wisc.edu; smeeding@lafollette.wisc.edu; econjeff@ssc.wisc.edu; psteiner@wisc.edu; ctaber@ssc.wisc.edu; tjernstroem@wisc.edu; walker@ssc.wisc.edu; wallace@lafollette.wisc.edu; tbwalsh@wisc.edu;yang.wang@lafollette.wisc.edu; mjwiswall@wisc.edu; wolfe@lafollette.wisc.edu; ysxiong2@wisc.edu;jzhu@stat.wisc.edu; ashivani@seas.upenn.edu; rbeck@jaeb.org; (b) (6) @gmail.com; t1dstats@jaeb.org;willi@email.chop.edu; weinstor@upstate.edu; paul.wadwa@cuanschutz.edu; jennifer.sherr@yale.edu; rmonzavi@chla.usc.edu; Laurel.Messer@cuanschutz.edu; sarah.corathers@cchmc.org; Amy.Criego@ParkNicollet.com; maclements@cmh.edu; inquires@sda.gov.cn; yerw@bjmu.edu.cn; yxy@xjtu.edu.cn; cfetpyhj@vip.sina.com; caodesheng@chinadaily.com.cn; yanwl@fudan.edu.cn; yiwang@shmu.edu.cn; zhangyp@chinacdc.cn; maojh88@zju.edu.cn; gisou.vandergoot@epfl.ch; nicola.harris@epfl.ch; andrea.ablasser@epfl.ch; patrick.aebischer@epfl.ch; johan.auwerx@epfl.ch;olaf.blanke@epfl.ch; melanie.blokesch@epfl.ch; cathrin.brisken@epfl.ch; philipp.bucher@epfl.ch; stewart.cole@epfl.ch; daniel.constam@epfl.ch; gregoire.courtine@epfl.ch; matteo.dalperaro@epfl.ch; paolo.delosrios@epfl.ch; michele.depalma@epfl.ch; bart.deplancke@epfl.ch; denis.duboule@epfl.ch;wulfram.gerstner@epfl.ch; pierre.gonczy@epfl.ch; johannes.graeff@epfl.ch; douglas.hanahan@epfl.ch; oliver.hantschel@epfl.ch; vassily.hatzimanikatis@epfl.ch; michael.herzog@epfl.ch; kathryn.hess@epfl.ch; joerg.huelsken@epfl.ch; friedhelm.hummel@epfl.ch; hilal.lashuel@epfl.ch; theo.lasser@epfl.ch;bruno.lemaitre@epfl.ch; joachim.lingner@epfl.ch; matthias.lutolf@epfl.ch; pierre.magistretti@epfl.ch; suliana.manley@epfl.ch; henry.markram@epfl.ch; brian.mccabe@epfl.ch; john.mckinney@epfl.ch; etienne.meylan@epfl.ch; felix.naef@epfl.ch; olaia.naveiras@epfl.ch; andrew.oates@epfl.ch;elisa.oricchio@epfl.ch; alexandre.persat@epfl.ch; carl.petersen@epfl.ch; freddy.radtke@epfl.ch; pavan.ramdya@epfl.ch; marcel.salathe@epfl.ch; carmen.sandi@epfl.ch; ralf.schneggenburger@epfl.ch; kristina.schoonjans@epfl.ch; viesturs.simanis@epfl.ch; david.suter@epfl.ch; didier.trono@epfl.ch;nicolas.mermod@unil.ch; beatrice.perrenoud@chuv.ch; awagnon@cmanet.org; accma@accma.org; jgreaves@accma.org; jjackovic@accma.org; grogers@accma.org; ndraper@accma.org; mlum@accma.org; (b) (6) @sbcglobal.net; (b) (6) @gmail.com; sbcms@sbmed.org; nbutler@fmms.org; Kamal.Gadalla@ed.ac.uk;ralph.hector@ed.ac.uk; S.R.Thomson@ed.ac.uk; Paul.Ross@ed.ac.uk; stephanie.mearns@ed.ac.uk; Marie.Bowers@ed.ac.uk; zoe.sawitzki@ed.ac.uk; Sarah.Giachetti@ed.ac.uk; s1316609@sms.ed.ac.uk; cochrane@umcutrecht.nl; editorial-unit@cochrane.org; admin@cochrane.org; CEU Admin <ceu@cochrane.org>;mwilson@cochrane.org; martin.burton@cochrane.nhs.uk; c.farquhar@auckland.ac.nz;j.e.clarkson@dundee.ac.uk; gerald.gartlehner@donau-uni.ac.at; pcg@scientificfreedom.dk; marguerite.a.koster@kp.org; (b) (6) @gmail.com; meerpohl@cochrane.de; sa

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ntesna@mcmaster.ca;dimitrinka.nikolova@ctu.dk; snezana.djurisic@ctu.dk; (b) (6) @gmail.com; (b) (6) @gmail.com; (b) (6) @gmail.com; vbonfigli@cochrane.org; david@davidhammerstein.org; mburton@cochrane.org; mkoster@cochrane.org; Chris Del Mar <cdelmar@bond.edu.au>; Paul Glasziou <pglaszio@bond.edu.au>; RayMoynihan@bond.edu.au; peter.collignon@act.gov.au; Karla Soares-Weiser <ksoares-weiser@cochrane.org>; Hilary Simmonds <HSimmonds@cochrane.org>; Toby Lasserson <TLasserson@cochrane.org>; Christian Gluud<christian.gluud@ctu.dk>; Christopher Exley <c.exley@keele.ac.uk>; cdipietrantonj@aslal.it; (b) (6) @googlemail.com; sdavies@bmj.com; (b) (6) @btinternet.com; jclarkson@cochrane.org;ncullum@cochrane.org; gfaba@cochrane.org; thowe@cochrane.org; trish.g(6)reenhalgh@phc.ox.ac.uk;peter.christian.goetzsche@regionh.dk; governingboardsecretary@cochrane.org; David Tovey<dtovey@cochrane.org>; sara.krauss@ctu.dk; cgluud@ctu.dk; (b) (6) @gmail.com
Subject: COVID-19 vaccine dangers; CDC's "Vaccines do not cause autism" lie, taken down; NH commission exposes FCC corruption, cellular radiation dangers

Vaccines absolutely do cause autism

The CDC has flip-flopped twice in ~5 months on the fraudulent claim that "Vaccines do not cause autism", on their website. It suggests that the CDC's vaccine/autism claims are based on the conjunction of Jupiter and Saturn, not science.

They were forced to take the false claim down because ICAN demonstrated there was **ZERO** science behind that claim.

The CDC Finally Capitulated To ICAN's Legal Demands and Removed the Claim that "Vaccines Do Not Cause Autism" From Its Website!

https://www.icandecide.org/ican_press/the-cdc-finally-capitulated-to-icans-legal-demands-and-removed-the-claim-that-vaccines-do-not-cause-autism-from-its-website/

THE CDC JUST SOLIDIFIED THAT ITS DECISIONS ARE NOT DRIVEN BY SCIENCE

https://www.icandecide.org/ican_press/the-cdc-just-solidified-that-its-decisions-are-not-driven-by-science/

FACT: Milk protein contaminated vaccines (DTap/Tdap/Prevnar 13/ActHiB) cause at least 75% of autism cases.

Autism pathogenesis: Piecing it all together, from end to beginning …
https://doi.org/10.5281/zenodo.1477515

CDC caught lying, again about the COVID-19 vaccine this time.

CDC Investigation

http://fullmeasure.news/news/cover-story/cdc-investigation

Vaccine mandates are based on a lie; Repeal all mandates immediately; Try the corrupted liars who created mandates, for CRIMES AGAINST HUMANITY

"Administration of parenterally administered vaccines alone typically does not result in potent mucosal immunity that might interrupt infection or transmission"
SARS-CoV-2 Vaccines: Much Accomplished, Much to Learn
www.acpjournals.org/doi/10.7326/M21-0111
So Fauci admits now that **ALL** injected vaccines are for individual protection only. **No herd/community immunity.** So no vaccine mandates are justifiable for **ANY** injected vaccine.
And of course this also means the vaccinated can become infected super-spreaders as occurs with the failed flu shot and failed pertussis vaccines.
Yan J, Grantham M, Pantelic J, de Mesquita PJ, Albert B, Liu F, et al. Infectious virus in exhaled breath of symptomatic seasonal influenza cases from a college community. Adamson W, Beato-Arribas B, Bischoff W, Booth W, Cauchemez S, Ehrman S, et al., editors. Proc Natl Acad Sci. National Academy of Sciences; 2018;

The potential role of subclinical Bordetella Pertussis colonization in the etiology of multiple sclerosis
pubmed.ncbi.nlm.nih.gov/26724970/

Obtained via FOIA by Judicial Watch, Inc.

This is the consequence of **insanely injecting** antigens of pathogens whose natural routes of exposure are mucosal surfaces in the nose, mouth or eyes.

NOTICE!

By authority of the Nuremberg Code on Medical Experimentation, I do hereby exercise my right to refuse to submit to or to administer the Covid-19 vaccine. The United States Government has prosecuted, convicted and executed Medical Doctors who have violated the Nuremberg Code on Medical Experimentation. Aiders and abettors of Nuremberg Crimes are equally guilty and have also been prosecuted, convicted, and executed.

Francis A. Boyle
Professor of Law.

My comment in the Annals of Internal Medicine, against Fauci's "SARS-CoV-2 Vaccines: Much Accomplished, Much to Learn"

https://www.acpjournals.org/doi/10.7326/M21-0111

Vinu Arumugham Independent 18 January 2021

These vaccines are unsafe, unnecessary and must be immediately withdrawn

The vaccine safety claims made by the authors are unsupported by evidence. Vaccines must be designed for safety. These vaccines were not designed at all. So they are unsafe by definition. I predicted the allergic sensitization and autoimmunity risks with these vaccines which have now been confirmed.

The Pfizer/BioNTech vaccine is unnecessary, unsafe and should not be authorized.

https://www.regulations.gov/document?D=FDA-2020-N-1898-0039

Robert F Kennedy Jr. warned the FDA months back about the risk of allergic reactions due to the use of polyethylene glycol (PEG) in the vaccines.
https://childrenshealthdefense.org/defender/pfizer-covid-vaccine-allergic-reactions/

The FDA/VRBPAC ignored us and authorized these horrendously dangerous vaccines.

Recently, Dr. Peter Marks of the FDA admitted that the population was sensitized by PEG-containing pharmaceutical preparations (that include other vaccines/injections).

https://www.wsj.com/articles/scientists-eye-potential-culprit-for-covid-19-vaccine-allergic-reactions-11608901200?mod=hp_lead_pos2

"What we're learning now is that those **allergic reactions could be somewhat more common** than the highly uncommon that we thought they were **because people do get exposed to polyethylene glycol in various pharmaceutical preparations,**" - Peter Marks, Director, CBER,FDA.

We of course already knew that any vaccine/injection that has enough allergen to cause a reaction, has more than enough allergen to guarantee sensitization/priming (causing the development of new allergy).

Evidence that Food Proteins in Vaccines Cause the Development of Food Allergies and Its Implications for Vaccine Policy

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3571073

www.sciencemag.org/news/2020/12/suspicions-grow-nanoparticles-pfizer-s-covid-19-vaccine-trigger-rare-allergic-reactions

"he worries anti-PEG antibodies triggered by the first shot could increase the risk of an allergic reaction to the second or to PEGylated drugs."

- Janos Szebeni, an immunologist at Semmelweis University

So now, these vaccines have sensitized millions to PEG. The goal is to sensitize/boost PEG allergy in a 100 million more in the next 100 days.

PEG is contaminated with 1,4-dioxane, a carcinogen.

Obtained via FOIA by Judicial Watch, Inc.
https://www.fda.gov/cosmetics/potential-contaminants-cosmetics/14-dioxane-cosmetics-manufacturing-byproduct

As predicted, Pfizer COVID-19 vaccine induced autoimmunity (thrombocytopenia) killed a Florida doctor. This is just the tip of the iceberg. Thousands of cases of vaccine induced autoimmune diseases may take months/years to be diagnosed and will be dismissed as unrelated to the vaccine.

https://www.nytimes.com/2021/01/12/health/covid-vaccine-death.html

Only a few lots were tested in the trial. No one has a clue what other lots will do. 100-fold variation of contaminants in vaccines makes trials and epidemiological studies worthless as I detailed in my comments in the Annals of Internal Medicine before. Vaccine safety remains an oxymoron.

https://www.acpjournals.org/doi/10.7326/m18-2101

California calls for pause of 330,000 doses, investigation after allergic reactions to Moderna vaccine batch

https://www.mercurynews.com/2021/01/18/coronavirus-california-calls-for-pause-investigation-after-allergic-reactions-to-moderna-vaccine-batch/

What's worse? Effective, life-saving, cheap, safe medicines such as famotidine/cetirizine/ivermectin are being ignored in this blind race to vaccinate at any cost.

Immunological mechanisms explaining the role of vaccines, IgE, mast cells, histamine, elevating ferritin, IL-6, D-dimer, VEGF levels in COVID-19 and dengue, potential treatments such as mast cell stabilizers, antihistamines: Predictions and confirmations

https://europepmc.org/article/PPR/PPR241819

Big picture of the damage vaccines do:

Vaccines and Biologics injury table based on mechanistic evidence – Feb 2020

Covering over 125 conditionshttps://zenodo.org/record/3647593/files/vbitr2_final.pdf?download=1

The organized suppression of vaccine safety science:

Retraction of scientific papers: the case of vaccine research
https://www.tandfonline.com/doi/full/10.1080/09581596.2021.1878109

The WHO's flip-flopping "science" competes with CDC's incompetence

WHO Recommends Against Moderna, Pfizer Vaccines for Most Pregnant Women

https://www.wsj.com/articles/who-recommends-against-moderna-pfizer-vaccines-for-most-pregnant-women-11611775138

Pregnant Women May Receive Covid Vaccines Safely, W.H.O. Says
https://www.nytimes.com/2021/01/29/health/covid-vaccine-pregnancy.html

Moderna's COVID-19 vaccine now recommended for pregnant women, WHO says in guidance reversal

https://www.foxnews.com/health/moderna-covid-vaccine-pregnant-women-who-guidance-reversal

Not to be outdone by the flip-flopping CDC, WHO did a flip-flop on COVID-19 vaccine during pregnancy.

Latest evidence that there is ZERO science behind vaccines or vaccine safety. They just pull their "science" out of a hat. Follow the money.

These flip-flopping, lying, organized criminals at the CDC/WHO, are the "reputable sources" for your "fact-checkers".

The New Hampshire Commission report below has ripped FCC's 5G (and all other cellular) RF safety claims:

Final Report of the Commission to Study The Environmental and Health Effects of Evolving 5G Technology

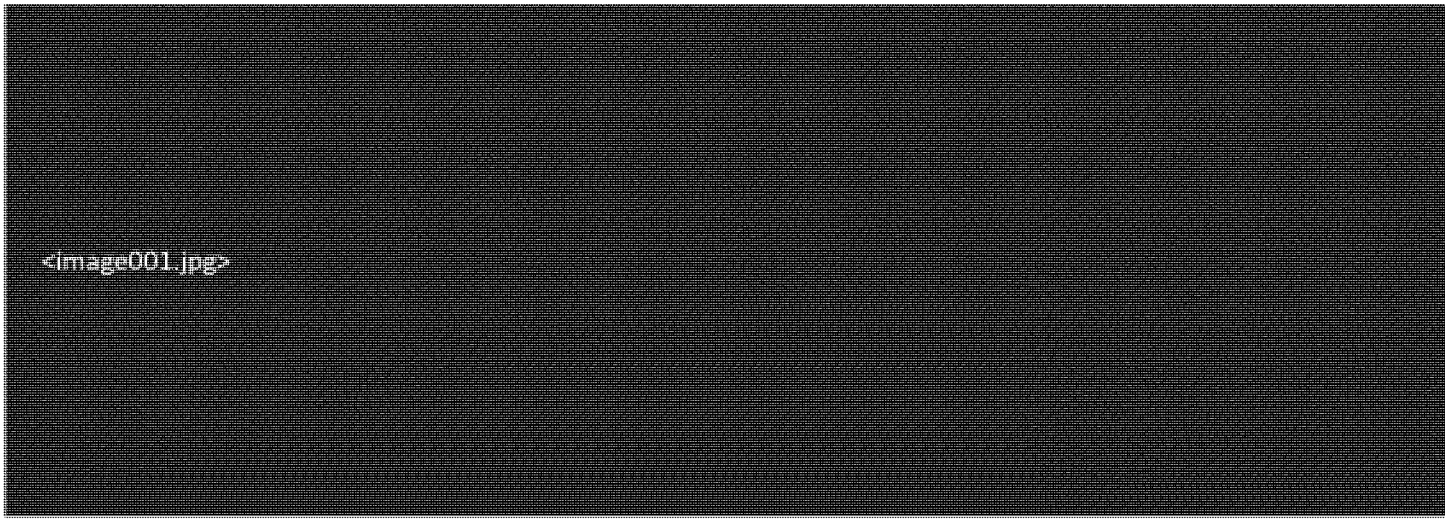
http://www.gencourt.state.nh.us/statstudcomm/committees/1474/reports/5G%20final%20report.pdf

"RECOMMENDATION 1- Propose a resolution of the House to the US Congress and Executive Branch to **require the Federal Communication Commission (FCC) to commission an independent review** of the current radiofrequency (RF) standards of the electromagnetic radiation in the 300MHz to 300GHz microwave

Obtained via FOIA by Judicial Watch, Inc.

spectrum as well as a health study to assess and recommend mitigation for the health risks associated with the use of cellular communications and data transmittal."

"A likely explanation as to why **regulatory agencies have opted to ignore the body of scientific evidence demonstrating the negative impact of cellphone radiation** is that **those agencies are "captured"** (see Harvard University publication entitled, "Captured Agency: How the Federal Communications Commission Is Dominated by the Industries It Presumably Regulates" linked in Appendix G). This report documents how **the leadership roles in some agencies (the FCC in particular) are filled by individuals with strong industry ties** and hence are more **focused on industry interests than the health of citizens**"

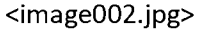


Major Litigation Updates & Recent Local Victories

It's been a strong week for our movement!

There are a lot of exciting things to report on this week, so let's dive right in...

Lake Tahoe, CA - Landmark Federal Lawsuit Filed to Block Saturation of Lake Tahoe Region with Cell Towers



Hundreds of hazardous, unsightly wireless antennas and cell towers are quickly blanketing the Lake Tahoe, California region.

Obtained via FOIA by Judicial Watch, Inc.

Three environmental non-profits and Monica Eisenstecken, a lifelong resident of South Lake Tahoe, have filed a potentially **precedent-setting litigation** against the Tahoe Regional Planning Agency, Verizon Wireless, the Tahoe Prosperity Center, and a local property owner...all in an effort **to protect one of the world's greatest natural treasures from a looming telecom takeover.**

Read Today's Press Release

Visit the New Tahoe Safe Tech Website

Support the Landmark Litigation

D.C. Court of Appeals - Environmental Health Trust et al. v. FCC Oral Arguments, January 25th, 2021

<image002.jpg>

"A federal appeals panel in Washington voiced skepticism that the Federal Communications Commission had adequately considered dangerous health effects when it established guidelines for radiation emission from cell towers and wireless devices."
- Bloomberg Law

Congratulations to both the Environmental Health Trust and the Children's Health Defense for their tireless efforts challenging the FCC's outdated and insufficient wireless radiation public exposure guidelines.

Following yesterday's fabulous presentation, we are hopeful the judges will rule against the FCC.

Obtained via FOIA by Judicial Watch, Inc.

Read the News

Listen to Recording of the Oral Arguments

RECENT VICTORIES

FLORIDA

1. Palm Coast, FL defeats 150-foot cell tower to be installed in the heart of the city's oldest neighborhood.

Read the news here.

<image002.jpg>

2. Lakeland, FL defeats 110-foot cell tower slated to be installed mere feet from homes. This is the second cell tower in three months that has been defeated by Lakeland representatives due to resident opposition.

Read the news here.

<image002.jpg>

NEW JERSEY

3. Lavallette, NJ Borough Council approves five "small cell" antennas with challenging conditions: certification

Obtained via FOIA by Judicial Watch, Inc.

from the U.S. Department of Defense and the Federal Aviation Administration that 5G frequencies emitted by the equipment will not interfere with critical avionics equipment. Lavallette is situated just a few miles from one of the country's most active military air bases - Joint Base McGuire-Dix-Lakehurst.

Read the news here.

<image002.jpg>

CALIFORNIA

4. Petaluma, CA defeats Verizon application to install 16 wireless antennas at the Petaluma Creamery, just 75 feet from homes. Read the legal memorandum in opposition to Verizon's application here.

<image002.jpg>

SOUTH CAROLINA

5. Residents in Mt. Pleasant, SC defeat a cell tower to be installed next to the Long Point playground.

Read the news here.

<image003.jpg>

As always, let's keep raking in the wins and working together to protect our communities from the telecom industry's ever-growing wireless footprint.

Obtained via FOIA by Judicial Watch, Inc.

If you need assistance pushing back against 5G and/or other wireless infrastructure deployments in your area, please don't hesitate to reply to this email or call us at 516-883-0887.

-The 5G Crisis Team

Contribute to 5G Crisis

<image004.jpg>

Share

<image004.jpg>

Forward

<image004.jpg>

<image004.jpg>

<image004.jpg>

<image004.jpg>

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Contact us:

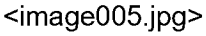
Email report@5gcrisis.com

Call 516-883-0887

Want to change how you receive these emails?

You can or .

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Thanks,
Vinu

Il contenuto del presente messaggio di posta elettronica, ed ogni eventuale documento a quest'ultimo allegato, è rivolto unicamente al destinatario cui è indirizzato e può contenere dati ed informazioni la cui riservatezza è tutelata. Sono vietati la riproduzione, l'utilizzo e la diffusione dei dati e delle informazioni contenuti nel presente messaggio senza espressa autorizzazione da parte del destinatario. Chiunque abbia ricevuto il presente messaggio per errore è pregato di provvedere senza ritardo a segnalarlo, contattandoci via telefono, fax o e-mail.
Il presente messaggio proviene da un indirizzo di posta elettronica aziendale assegnato al mittente a scopo lavorativo: la relativa casella di posta elettronica è soggetta alle procedure di controllo stabilite dall' ASL AL. Inviate a questo indirizzo solo comunicazioni di natura lavorativa, grazie

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From: Hummel Friedhelm Christoph [friedhelm.hummel@epfl.ch]
Sent: 2/2/2021 9:57:48 AM
To: Marsha Mailick [marsha.mailick@wisc.edu]
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Subject: Re: COVID-19 vaccine dangers; CDC's "Vaccines do not cause autism" lie, taken down; NH commission exposes FCC corruption, cellular radiation dangers

Same for me
Thanks

Sent from my iPhone

On 2 Feb 2021, at 15:52, Marsha Mailick <marsha.mailick@wisc.edu> wrote:

Also please remove me from your list

Sent from my iPhone

Obtained via FOIA by Judicial Watch, Inc.

On Feb 2, 2021, at 9:41 AM, trish.greenhalgh@phc.ox.ac.uk wrote:

And me.

From: CORINNE D ENGELMAN <corinne.engelman@wisc.edu>
Date: Tuesday, 2 February 2021 at 14:37
To: "jeffrey.sonnenfeld@yale.edu" <jeffrey.sonnenfeld@yale.edu>, Di Pietrantonj Carlo <cdipietrantonj@aslal.it>, "pcg@scientificfreedom.dk" <pcg@scientificfreedom.dk>, 'Vinu Arumugham' <(b) (6)@yahoo.com>, "goldingh@cber.fda.gov" <goldingh@cber.fda.gov>, "khuranas@cber.fda.gov" <khuranas@cber.fda.gov>, "sli49@emory.edu" <sli49@emory.edu>, "elizabeth.deatrick@niaid.nih.gov" <elizabeth.deatrick@niaid.nih.gov>, "pwilson1@medicine.bsd.uchicago.edu" <pwilson1@medicine.bsd.uchicago.edu>, "agewirtz@gsu.edu" <agewirtz@gsu.edu>, "megan.hahn@fda.hhs.gov" <megan.hahn@fda.hhs.gov>, "goldmanb@stanford.edu" <goldmanb@stanford.edu>, "mario.cortese@stanford.edu" <mario.cortese@stanford.edu>, "nroupha@emory.edu" <nroupha@emory.edu>, "alan.embry@nih.gov" <alan.embry@nih.gov>, "alex@lji.org" <alex@lji.org>, "neuron@cell.com" <neuron@cell.com>, "jlandsberg@cell.com" <jlandsberg@cell.com>, "agoldstein@cell.com" <agoldstein@cell.com>, "mzirlinger@cell.com" <mzirlinger@cell.com>, "tdobie@cell.com" <tdobie@cell.com>, "mfurman@cell.com" <mfurman@cell.com>, "ckonen@cell.com" <ckonen@cell.com>, "eniederst@cell.com" <eniederst@cell.com>, "uschridde@cell.com" <uschridde@cell.com>, "jshaw@cell.com" <jshaw@cell.com>, "eporro@cell.com" <eporro@cell.com>, "emarcus@cell.com" <emarcus@cell.com>, "info@eeoc.gov" <info@eeoc.gov>, "ofo.eeoc@eeoc.gov" <ofo.eeoc@eeoc.gov>, "FOIA@eeoc.gov" <FOIA@eeoc.gov>, "eeoc.traininginstitute@eeoc.gov" <eeoc.traininginstitute@eeoc.gov>, "inspector.general@eeoc.gov" <inspector.general@eeoc.gov>, Richard Hatchett <richard.hatchett@cepi.net>, "fg17882@bristol.ac.uk" <fg17882@bristol.ac.uk>, "ripley.ballou@gskbio.com" <ripley.ballou@gskbio.com>, "nicole.lurie@cepi.net" <nicole.lurie@cepi.net>, "jlg251@georgetown.edu" <jlg251@georgetown.edu>, "tom.monath@crozetbiopharma.com" <tom.monath@crozetbiopharma.com>, "aabimiku@ihv.umaryland.edu" <aabimiku@ihv.umaryland.edu>, "abarrett@utmb.edu" <abarrett@utmb.edu>, "Ananda.Bandyopadhyay@gatesfoundation.org" <Ananda.Bandyopadhyay@gatesfoundation.org>, "cbrechot@usf.edu" <cbrechot@usf.edu>, "chappi@hsph.harvard.edu" <chappi@hsph.harvard.edu>, "Connie.s.schmaljohn.civ@mail.mil" <Connie.s.schmaljohn.civ@mail.mil>, "iad7@cdc.gov" <iad7@cdc.gov>, "jamesrobinson@uchicago.edu" <jamesrobinson@uchicago.edu>, "Jean.Lang@sanofipasteur.com" <Jean.Lang@sanofipasteur.com>, "john.k.billington@gsk.com" <john.k.billington@gsk.com>, "kenji.shibuya@kcl.ac.uk" <kenji.shibuya@kcl.ac.uk>, "krause@cber.fda.gov" <krause@cber.fda.gov>, "mlevine@som.umaryland.edu" <mlevine@som.umaryland.edu>, "moorthyv@who.int" <moorthyv@who.int>, "paula.bryant@nih.gov" <paula.bryant@nih.gov>, (b) (6)@africaonline.co.ke" (b) (6)@africaonline.co.ke>, "yves.levy@aphp.fr" <yves.levy@aphp.fr>, Fenaba Addo <faddo@wisc.edu>, Bradford Barham <bradford.barham@wisc.edu>, LEONELO E BAUTISTA <lebautista@wisc.edu>, Lawrence M Berger <lmberger@wisc.edu>, Will Buckingham <wrbuckin@wisc.edu>, MARGUERITE E BURNS <meburns@wisc.edu>, Marcy Carlson <carlson@ssc.wisc.edu>, "J. Michael Collins" <jmcollins@wisc.edu>, JORDAN CONWELL <jaconwell@wisc.edu>, Nichole Barnes <nbarnes2@wisc.edu>, KATHERINE J CURTIS <kcurtis@ssc.wisc.edu>, Marah Curtis <mcurtis3@wisc.edu>, JOHN EASON <jeason2@wisc.edu>, DEBORAH B EHRENTHAL <ehrenthal@wisc.edu>, FELIX ELWERT <elwert@wisc.edu>, MICHAL ENGELMAN <mengelman@wisc.edu>, Jason M Fletcher <jason.fletcher@wisc.edu>, CHAO FU <cfu@ssc.wisc.edu>, JOAN H FUJIMURA <fujimura@ssc.wisc.edu>, THEODORE P GERBER <tgerber@ssc.wisc.edu>, ". cde account" <cde@ssc.wisc.edu>, Monica J Grant <grantm@ssc.wisc.edu>, Jan Greenberg <jan.greenberg@wisc.edu>, JESSE MCCUNE GREGORY <jmgregory@wisc.edu>, Eric Grodsky <egrodsky@ssc.wisc.edu>, Sarah Halpern-Meekin <sarah.halpernmeekin@wisc.edu>, Jenny Higgins <jenny.a.higgins@wisc.edu>, Lindsay Jacobs

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Subject: Re: COVID-19 vaccine dangers; CDC's "Vaccines do not cause autism" lie, taken down; NH commission exposes FCC corruption, cellular radiation dangers

Me too.

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Subject: RE: COVID-19 vaccine dangers; CDC's "Vaccines do not cause autism" lie, taken down; NH commission exposes FCC corruption, cellular radiation dangers

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Subject: R: COVID-19 vaccine dangers; CDC's "Vaccines do not cause autism" lie, taken down; NH commission exposes FCC corruption, cellular radiation dangers

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Oggetto: RE: COVID-19 vaccine dangers; CDC's "Vaccines do not cause autism" lie, taken down; NH commission exposes FCC corruption, cellular radiation dangers

If there had been any reliable evidence that "milk protein contaminated vaccines (DTaP/TdaP, Prevnar 13, ActHiB) cause the vast majority (75%) of autism cases", we would surely have heard about it.

Please delete me from your email list

Peter C Gøtzsche
Professor and Director
Institute for Scientific Freedom
Copenhagen
https://www.scientificfreedom.dk/ and https://www.deadlymedicines.dk/
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Subject: Re: COVID-19 vaccine dangers; CDC's "Vaccines do not cause autism" lie, taken down; NH commission exposes FCC corruption, cellular radiation dangers

Prof. Gøtzsche,

Let me clarify that we are not discussing vaccine vs. no vaccine. We are discussing dirty, sickening vaccines vs. clean safe, effective vaccines.

Regarding autism, you are talking about the wrong vaccine. We have shown beyond all doubt, using **reliable mechanistic evidence** that milk protein contaminated vaccines (DTaP/TdaP, Prevnar 13, ActHiB) cause the vast majority (75%) of autism cases.

Autism pathogenesis: Piecing it all together, from end to beginning …
https://doi.org/10.5281/zenodo.1477515

Immunization with homologous xenogeneic (animal/plant/fungal) antigens causes the development of autoimmune diseases. Known for at least 45 years.

Vaccine-Induced Autoimmunity in the Dog

Obtained via FOIA by Judicial Watch, Inc.

"the most likely sources of cross-reactive epitopes are bovine serum and cell culture components. These are present in almost all vaccines as residu-al components of the cell culture necessary to generate vaccine viruses and may purposely be added to the vaccine as a stabilizer. In the presence of an adjuvant, these bovine products stimulate a strong im-mune response and induce antibodies that cross-react with conserved canine antigens."

Xenogeneic therapeutic cancer vaccines as breakers of immune tolerance for clinical application: to use or not to use?
pubmed.ncbi.nlm.nih.gov/24837511/

Oncologists immunize with xenogeneic antigens to break immune tolerance (cause autoimmunity) to make your immune system attack your own cancer cells.

Regular vaccines such as the measles vaccines are contaminated with animal proteins (chicken) and therefore cause numerous autoimmune disorders including type 1 diabetes.

Correlation of type 1 diabetes trends in European countries to the number of bovine insulin and GAD65 contaminated chick embryo cell culture containing vaccines in the schedule, as predicted by the autoimmunity mechanism involving immunization with homologous xenogeneic antigens and EPIT as a potential treatment
https://doi.org/10.5281/zenodo.1870364

The US IOM pointed out that epidemiological studies are useless in 93% of the cases. Mechanistic studies proved reliable.

Institute of Medicine: Most epidemiological vaccine safety studies are useless

https://doi.org/10.5281/zenodo.3244496

The Pandemrix vaccine made in Europe had higher levels of contamination with H1N1 nucleoproteins than the Arepanrix vaccine manufactured by the same company (GSK) in Canada. Pandemrix therefore caused way more cases of narcolepsy. Do you know the level of chicken protein contamination in Danish vs. US vaccines? How can you then apply studies done in Denmark to any other country?

Big picture of the damage vaccines do:

Vaccines and Biologics injury table based on mechanistic evidence – Feb 2020

Covering over 125 conditionshttps://zenodo.org/record/3647593/files/vbitr2_final.pdf?download=1

The organized suppression of vaccine safety science:

Retraction of scientific papers: the case of vaccine research
https://www.tandfonline.com/doi/full/10.1080/09581596.2021.1878109

Thanks,

Vinu

On 1/31/21 11:47 PM, pcg@scientificfreedom.dk wrote:

I have no knowledge of this huge email list and do not know why I was put on it. But I assume I will be taken off it because of what I write below. Please read it.

The idea that vaccines may cause autism was launched by Andrew Wakefield in relation to a fraudulent study published in Lancet in 1998 that has been retracted. Large observational studies from my country, Denmark, have shown convincingly that the Emperor has no clothes. I analyse this in detail in my 2020 book, Vaccines: truth, lies and controversy. It is an e-book but will come out soon on Skyhorse, New York, as a print book with an updated corona chapter that ends with the riots on 6 January 2021 at Capitol Hill.

Wakefield's horrendous fraud, which has caused many deaths, concerned the MMR vaccine. These are excerpts from my book, the chapter on measles:

Obtained via FOIA by Judicial Watch, Inc.

According to the WHO, there were 110,000 measles deaths in 2017, and most were in children under the age of five.[3] Vaccination resulted in an 80% drop in measles deaths between 2000 and 2017 preventing an estimated 21 million deaths.

Measles outbreaks also provide strong support for the benefits of the vaccine. In the United States, there was a resurgence of measles in 1989-1990, which primarily involved unvaccinated racial and ethnic minority children less than five years of age residing in inner-city areas.[40] There were 66 (0.1%) cases of encephalitis. A provisional total of 41 measles-associated deaths was reported in 1989 (2.3 deaths per 1000 cases), which increased to 89 (3.2 per 1000 cases) in 1990. In 2000, the CDC declared measles eradicated in the United States but there have been several outbreaks since due to imported cases.[41] In 2018, no less than 17 outbreaks occurred. One, in New York, was due to people who had been to Israel, and it included 182 cases in orthodox Jewish communities with a vaccination rate of only 50%.[42]
It is not possible to say exactly what the risk is of dying from measles. As noted earlier, the death risk is related to the infectious dose, which is higher in settings with overcrowding. We can only say what it has been in outbreaks, and a commonly used estimate is 2 deaths per 1000 cases. But it can be much worse. During an epidemic in Copenhagen in 1887, at least 5% of the children, or 50 per 1000 cases, died.[43] The mortality was probably even higher because only those who died while they had a rash counted. In Wien, at the beginning of the 20th century, the mortality was 11% among the poorest and 0.6% among the richest.
An outbreak in Madagascar that started in 2018 had in April 2019 caused over 1200 deaths, which is about 1% of those infected.[44] Only about 60% of the population is vaccinated.

We should all get vaccinated against measles and get our children vaccinated, with very few exceptions. Contraindications for the vaccine include a history of severe allergic reaction to any component of the vaccine including neomycin, pregnancy (measles illness during pregnancy results in a higher risk of premature labour, spontaneous abortion, and low-birthweight infants), and severe immunosuppression.[34]

On Swedish TV, in 2020, Wakefield lied horrendously about measles: "Exposure in childhood is safe and conveys lifelong immunity."

The reference is:

Dokumentär
Anna Nordbeck och Malin Olofsson
Dokument inifrån: VACCINKRIGARNA
https://www.svtplay.se/dokument-inifran-vaccinkrigarna
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From: Vinu Arumugham <(b) (6) @yahoo.com>
Sent: 01 February 2021 01:43
To: goldingh@cber.fda.gov; khuranas@cber.fda.gov; sli49@emory.edu; elizabeth.deatrick@niaid.nih.gov; pwilson1@medicine.bsd.uchicago.edu; agewirtz@gsu.edu; megan.hahn@fda.hhs.gov; goldmanb@stanford.edu; mario.cortese@stanford.edu; nroupha@emory.edu; alan.embry@nih.gov; alex@lji.org; neuron@cell.com; jlandsberg@cell.com; agoldstein@cell.com; mzirlinger@cell.com; tdobie@cell.com; mfurman@cell.com; ckonen@cell.com; eniederst@cell.com; uschridde@cell.com; jshaw@cell.com; eporro@cell.com; emarcus@cell.com; jeffrey.sonnenfeld@yale.edu; info@eeoc.gov; ofo.eeoc@eeoc.gov; FOIA@eeoc.gov; eeoc.traininginstitute@eeoc.gov; inspector.general@eeoc.gov; richard.hatchett@cepi.net; fg17882@bristol.ac.uk; ripley.ballou@gskbio.com; nicole.lurie@cepi.net; jlg251@georgetown.edu; tom.monath@crozetbiopharma.com; aabimiku@ihv.umaryland.edu; abarrett@utmb.edu; Ananda.Bandyopadhyay@gatesfoundation.org; cbrechot@usf.edu; chappi@hsph.harvard.edu; Connie.s.schmaljohn.civ@mail.mil; iad7@cdc.gov; jamesrobinson@uchicago.edu; Jean.Lang@sanofipasteur.com; john.k.billington@gsk.com; kenji.shibuya@kcl.ac.uk; krause@cber.fda.gov; mlevine@som.umaryland.edu; moorthyv@who.int; paula.bryant@nih.gov; (b) (6) @africaonline.co.ke; yves.levy@aphp.fr; faddo@wisc.edu; bradford.barham@wisc.edu; lebautista@wisc.edu; lmberger@wisc.edu; wrbuckin@wisc.edu; meburns@wisc.edu; carlson@ssc.wisc.edu; jmcollins@wisc.edu; jaconwell@wisc.edu; nbarnes2@wisc.edu; kcurtis@ssc.wisc.edu; mcurtis3@wisc.edu; jeason2@wisc.edu; ehrenthal@wisc.edu; felwert@ssc.wisc.edu; cengelman@wisc.edu; mengelman@ssc.wisc.edu; jason.fletcher@wisc.edu; cfu@ssc.wisc.edu; fujimura@ssc.wisc.edu; tgerber@ssc.wisc.edu; cde@ssc.wisc.edu; grantm@ssc.wisc.edu; jan.greenberg@wisc.edu; jmgregory@ssc.wisc.edu; egrodsky@ssc.wisc.edu; sarah.halpernmeekin@wisc.edu; jenny.a.higgins@wisc.edu; lpjacobs@wisc.edu; fjones4@wisc.edu; hyunseung@stat.wisc.edu; dkaplan@education.wisc.edu; jkennan@ssc.wisc.edu; ajk@medicine.wisc.edu; mlight@ssc.wisc.edu; logan@ssc.wisc.edu; kmagnuson@wisc.edu; marsha.mailick@wisc.edu; kmalecki@wisc.edu; mmassoglia@ssc.wisc.edu; drmeyer1@wisc.edu; cmommaerts@wisc.edu; amukherjee@wisc.edu; jmullahy@wisc.edu; jnobles@ssc.wisc.edu; robrien@lafollette.wisc.edu; palloni@wisc.edu; patz@wisc.edu; ppeppard@wisc.edu; jraymo@ssc.wisc.edu; ferey@wisc.edu; sarobert@wisc.edu; schaeffer@ssc.wisc.edu; lschechter@wisc.edu; aschneider4@wisc.edu; cschwart@ssc.wisc.edu; aseshadr@ssc.wisc.edu; smeeding@lafollette.wisc.edu; econjeff@ssc.wisc.edu; psteiner@wisc.edu; ctaber@ssc.wisc.edu; tjernstroem@wisc.edu; walker@ssc.wisc.edu; wallace@lafollette.wisc.edu; tbwalsh@wisc.edu; yang.wang@lafollette.wisc.edu; mjwiswall@wisc.edu; wolfe@lafollette.wisc.edu; ysxiong2@wisc.edu; jzhu@stat.wisc.edu; ashivani@seas.upenn.edu; rbeck@jaeb.org; (b) (6) @gmail.com; t1dstats@jaeb.org; willi@email.chop.edu; weinstor@upstate.edu; paul.wadwa@cuanschutz.edu; jennifer.sherr@yale.edu; rmonzavi@chla.usc.edu; Laurel.Messer@cuanschutz.edu; sarah.corathers@cchmc.org; Amy.Criego@ParkNicollet.com; maclements@cmh.edu; inquires@sda.gov.cn; yerw@bjmu.edu.cn; yxy@xjtu.edu.cn; cfetpyhj@vip.sina.com; caodesheng@chinadaily.com.cn; yanwl@fudan.edu.cn; yiwang@shmu.edu.cn; zhangyp@chinacdc.cn; maojh88@zju.edu.cn; gisou.vandergoot@epfl.ch; nicola.harris@epfl.ch; andrea.ablasser@epfl.ch; patrick.aebischer@epfl.ch; johan.auwerx@epfl.ch; olaf.blanke@epfl.ch; melanie.blokesch@epfl.ch; cathrin.brisken@epfl.ch; philipp.bucher@epfl.ch; stewart.cole@epfl.ch; daniel.constam@epfl.ch; gregoire.courtine@epfl.ch; matteo.dalperaro@epfl.ch; paolo.delosrios@epfl.ch; michele.depalma@epfl.ch; bart.deplancke@epfl.ch; denis.duboule@epfl.ch; wulfram.gerstner@epfl.ch; pierre.gonczy@epfl.ch; johannes.graeff@epfl.ch; douglas.hanahan@epfl.ch; oliver.hantschel@epfl.ch; vassily.hatzimanikatis@epfl.ch; michael.herzog@epfl.ch; kathryn.hess@epfl.ch; joerg.huelsken@epfl.ch; friedhelm.hummel@epfl.ch; hilal.lashuel@epfl.ch; theo.lasser@epfl.ch; bruno.lemaitre@epfl.ch; joachim.lingner@epfl.ch; matthias.lutolf@epfl.ch; pierre.magistretti@epfl.ch; suliana.manley@epfl.ch; henry.markram@epfl.ch; brian.mccabe@epfl.ch; john.mckinney@epfl.ch; etienne.meylan@epfl.ch; felix.naef@epfl.ch; olaia.naveiras@epfl.ch; andrew.oates@epfl.ch; elisa.oricchio@epfl.ch; alexandre.persat@epfl.ch; carl.petersen@epfl.ch; freddy.radtke@epfl.ch; pavan.ramdya@epfl.ch; marcel.salathe@epfl.ch; carmen.sandi@epfl.ch; ralf.schneggenburger@epfl.ch; kristina.schoonjans@epfl.ch; viesturs.simanis@epfl.ch; david.suter@epfl.ch; didier.trono@epfl.ch; nicolas.mermod@unil.ch; beatrice.perrenoud@chuv.ch; awagnon@cmanet.org; accma@accma.org; jgreaves@accma.org; jjackovic@accma.org; grogers@accma.org; ndraper@accma.org; mlum@accma.org; (b) (6) @sbcglobal.net; (b) (6) @gmail.com; sbcms@sbmed.org; nbutler@fmms.org; Kamal.Gadalla@ed.ac.uk; ralph.hector@ed.ac.uk; S.R.Thomson@ed.ac.uk; Paul.Ross@ed.ac.uk; stephanie.mearns@ed.ac.uk; Marie.Bowers@ed.ac.uk; zoe.sawitzki@ed.ac.uk; Sarah.Giachetti@ed.ac.uk;

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s1316609@sms.ed.ac.uk; cochrane@umcutrecht.nl; editorial-unit@cochrane.org; admin@cochrane.org; CEU Admin <ceu@cochrane.org>; mwilson@cochrane.org; martin.burton@cochrane.nhs.uk; c.farquhar@auckland.ac.nz; j.e.clarkson@dundee.ac.uk; gerald.gartlehner@donau-uni.ac.at; pcg@scientificfreedom.dk; marguerite.a.koster@kp.org; (b) (6) @gmail.com; meerpohl@cochrane.de; santesna@mcmaster.ca; dimitrinka.nikolova@ctu.dk; snezana.djurisic@ctu.dk; (b) (6) @gmail.com; (b) (6) @gmail.com; (b) (6) @gmail.com; vbonfigli@cochrane.org; david@davidhammerstein.org; mburton@cochrane.org; mkoster@cochrane.org; Chris Del Mar <cdelmar@bond.edu.au>; Paul Glasziou <pglaszio@bond.edu.au>; RayMoynihan@bond.edu.au; peter.collignon@act.gov.au; Karla Soares-Weiser <ksoares-weiser@cochrane.org>; Hilary Simmonds <HSimmonds@cochrane.org>; Toby Lasserson <TLasserson@cochrane.org>; Christian Gluud <christian.gluud@ctu.dk>; Christopher Exley <c.exley@keele.ac.uk>; cdipietrantonj@aslal.it; (b) (6) @googlemail.com; sdavies@bmj.com; (b) (6) @btinternet.com; jclarkson@cochrane.org; ncullum@cochrane.org; gfaba@cochrane.org; thowe@cochrane.org; trish.greenhalgh@phc.ox.ac.uk; peter.christian.goetzsche@regionh.dk; governingboardsecretary@cochrane.org; David Tovey <dtovey@cochrane.org>; sara.krauss@ctu.dk; cgluud@ctu.dk; (b) (6) @gmail.com
Subject: COVID-19 vaccine dangers; CDC's "Vaccines do not cause autism" lie, taken down; NH commission exposes FCC corruption, cellular radiation dangers

Vaccines absolutely do cause autism

The CDC has flip-flopped twice in ~5 months on the fraudulent claim that "Vaccines do not cause autism", on their website. It suggests that the CDC's vaccine/autism claims are based on the conjunction of Jupiter and Saturn, not science.

They were forced to take the false claim down because ICAN demonstrated there was **ZERO** science behind that claim.

The CDC Finally Capitulated To ICAN's Legal Demands and Removed the Claim that "Vaccines Do Not Cause Autism" From Its Website!

https://www.icandecide.org/ican_press/the-cdc-finally-capitulated-to-icans-legal-demands-and-removed-the-claim-that-vaccines-do-not-cause-autism-from-its-website/

THE CDC JUST SOLIDIFIED THAT ITS DECISIONS ARE NOT DRIVEN BY SCIENCE

https://www.icandecide.org/ican_press/the-cdc-just-solidified-that-its-decisions-are-not-driven-by-science/

FACT: Milk protein contaminated vaccines (DTap/Tdap/Prevnar 13/ActHiB) cause at least 75% of autism cases.

Autism pathogenesis: Piecing it all together, from end to beginning ...
https://doi.org/10.5281/zenodo.1477515

CDC caught lying, again about the COVID-19 vaccine this time.

CDC Investigation

http://fullmeasure.news/news/cover-story/cdc-investigation

Vaccine mandates are based on a lie; Repeal all mandates immediately; Try the corrupted liars who created mandates, for CRIMES AGAINST HUMANITY
"Administration of parenterally administered vaccines alone typically does not result in potent mucosal immunity that might interrupt infection or transmission"
SARS-CoV-2 Vaccines: Much Accomplished, Much to Learn
www.acpjournals.org/doi/10.7326/M21-0111
So Fauci admits now that **ALL** injected vaccines are for individual protection only. **No herd/community immunity.** So no vaccine mandates are justifiable for **ANY** injected vaccine.
And of course this also means the vaccinated can become infected super-spreaders as occurs with the failed flu shot and failed pertussis vaccines.

Obtained via FOIA by Judicial Watch, Inc.

Yan J, Grantham M, Pantelic J, de Mesquita PJ, Albert B, Liu F, et al. Infectious virus in exhaled breath of symptomatic seasonal influenza cases from a college community. Adamson W, Beato-Arribas B, Bischoff W, Booth W, Cauchemez S, Ehrman S, et al., editors. Proc Natl Acad Sci. National Academy of Sciences; 2018;

The potential role of subclinical Bordetella Pertussis colonization in the etiology of multiple sclerosis
pubmed.ncbi.nlm.nih.gov/26724970/

This is the consequence of **insanely injecting** antigens of pathogens whose natural routes of exposure are mucosal surfaces in the nose, mouth or eyes.

NOTICE!

By authority of the Nuremberg Code on Medical Experimentation, I do hereby exercise my right to refuse to submit to or to administer the Covid-19 vaccine. The United States Government has prosecuted, convicted and executed Medical Doctors who have violated the Nuremberg Code on Medical Experimentation. Aiders and abettors of Nuremberg Crimes are equally guilty and have also been prosecuted, convicted, and executed.

Francis A. Boyle
Professor of Law.

My comment in the Annals of Internal Medicine, against Fauci's "SARS-CoV-2 Vaccines: Much Accomplished, Much to Learn"

https://www.acpjournals.org/doi/10.7326/M21-0111

Vinu Arumugham Independent 18 January 2021

These vaccines are unsafe, unnecessary and must be immediately withdrawn

The vaccine safety claims made by the authors are unsupported by evidence. Vaccines must be designed for safety. These vaccines were not designed at all. So they are unsafe by definition. I predicted the allergic sensitization and autoimmunity risks with these vaccines which have now been confirmed.

The Pfizer/BioNTech vaccine is unnecessary, unsafe and should not be authorized.

https://www.regulations.gov/document?D=FDA-2020-N-1898-0039

Robert F Kennedy Jr. warned the FDA months back about the risk of allergic reactions due to the use of polyethylene glycol (PEG) in the vaccines.
https://childrenshealthdefense.org/defender/pfizer-covid-vaccine-allergic-reactions/

The FDA/VRBPAC ignored us and authorized these horrendously dangerous vaccines.

Recently, Dr. Peter Marks of the FDA admitted that the population was sensitized by PEG-containing pharmaceutical preparations (that include other vaccines/injections).

https://www.wsj.com/articles/scientists-eye-potential-culprit-for-covid-19-vaccine-allergic-reactions-11608901200?mod=hp_lead_pos2

"What we're learning now is that those **allergic reactions could be somewhat more common** than the highly uncommon that we thought they were **because people do get exposed to polyethylene glycol in various pharmaceutical preparations,**" - Peter Marks, Director, CBER,FDA.

We of course already knew that any vaccine/injection that has enough allergen to cause a reaction, has more than enough allergen to guarantee sensitization/priming (causing the development of new allergy).

Obtained via FOIA by Judicial Watch, Inc.

Evidence that Food Proteins in Vaccines Cause the Development of Food Allergies and Its Implications for Vaccine Policy

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3571073

www.sciencemag.org/news/2020/12/suspicions-grow-nanoparticles-pfizer-s-covid-19-vaccine-trigger-rare-allergic-reactions

"he worries anti-PEG antibodies triggered by the first shot could increase the risk of an allergic reaction to the second or to PEGylated drugs."

- Janos Szebeni, an immunologist at Semmelweis University

So now, these vaccines have sensitized millions to PEG. The goal is to sensitize/boost PEG allergy in a 100 million more in the next 100 days.

PEG is contaminated with 1,4-dioxane, a carcinogen.

https://www.fda.gov/cosmetics/potential-contaminants-cosmetics/14-dioxane-cosmetics-manufacturing-byproduct

As predicted, Pfizer COVID-19 vaccine induced autoimmunity (thrombocytopenia) killed a Florida doctor. This is just the tip of the iceberg. Thousands of cases of vaccine induced autoimmune diseases may take months/years to be diagnosed and will be dismissed as unrelated to the vaccine.

https://www.nytimes.com/2021/01/12/health/covid-vaccine-death.html

Only a few lots were tested in the trial. No one has a clue what other lots will do. 100-fold variation of contaminants in vaccines makes trials and epidemiological studies worthless as I detailed in my comments in the Annals of Internal Medicine before. Vaccine safety remains an oxymoron.

https://www.acpjournals.org/doi/10.7326/m18-2101

California calls for pause of 330,000 doses, investigation after allergic reactions to Moderna vaccine batch

https://www.mercurynews.com/2021/01/18/coronavirus-california-calls-for-pause-investigation-after-allergic-reactions-to-moderna-vaccine-batch/

What's worse? Effective, life-saving, cheap, safe medicines such as famotidine/cetirizine/ivermectin are being ignored in this blind race to vaccinate at any cost.

Immunological mechanisms explaining the role of vaccines, IgE, mast cells, histamine, elevating ferritin, IL-6, D-dimer, VEGF levels in COVID-19 and dengue, potential treatments such as mast cell stabilizers, antihistamines: Predictions and confirmations

https://europepmc.org/article/PPR/PPR241819

Big picture of the damage vaccines do:

Vaccines and Biologics injury table based on mechanistic evidence – Feb 2020

Covering over 125 conditionshttps://zenodo.org/record/3647593/files/vbitr2_final.pdf?download=1

The organized suppression of vaccine safety science:

Retraction of scientific papers: the case of vaccine research
https://www.tandfonline.com/doi/full/10.1080/09581596.2021.1878109

The WHO's flip-flopping "science" competes with CDC's incompetence

WHO Recommends Against Moderna, Pfizer Vaccines for Most Pregnant Women

Obtained via FOIA by Judicial Watch, Inc.

https://www.wsj.com/articles/who-recommends-against-moderna-pfizer-vaccines-for-most-pregnant-women-11611775138

Pregnant Women May Receive Covid Vaccines Safely, W.H.O. Says
https://www.nytimes.com/2021/01/29/health/covid-vaccine-pregnancy.html

Moderna's COVID-19 vaccine now recommended for pregnant women, WHO says in guidance reversal

https://www.foxnews.com/health/moderna-covid-vaccine-pregnant-women-who-guidance-reversal

Not to be outdone by the flip-flopping CDC, WHO did a flip-flop on COVID-19 vaccine during pregnancy.

Latest evidence that there is ZERO science behind vaccines or vaccine safety. They just pull their "science" out of a hat. Follow the money.

These flip-flopping, lying, organized criminals at the CDC/WHO, are the "reputable sources" for your "fact-checkers".

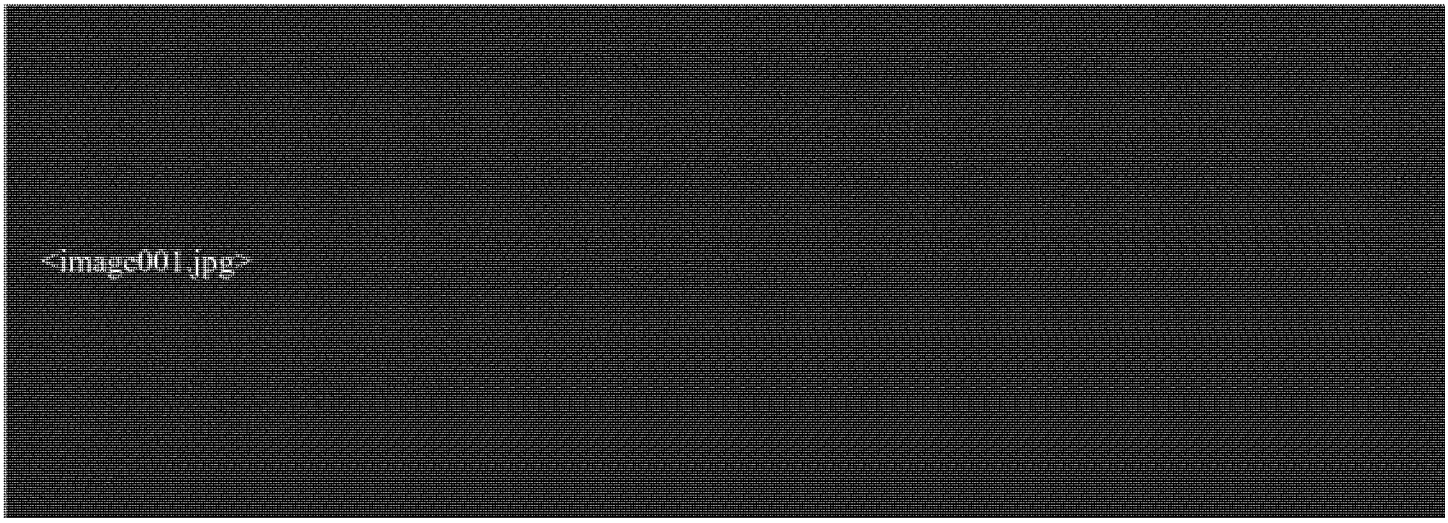
The New Hampshire Commission report below has ripped FCC's 5G (and all other cellular) RF safety claims:

Final Report of the Commission to Study The Environmental and Health Effects of Evolving 5G Technology

http://www.gencourt.state.nh.us/statstudcomm/committees/1474/reports/5G%20final%20report.pdf

"RECOMMENDATION 1- Propose a resolution of the House to the US Congress and Executive Branch to **require the Federal Communication Commission (FCC) to commission an independent review** of the current radiofrequency (RF) standards of the electromagnetic radiation in the 300MHz to 300GHz microwave spectrum as well as a health study to assess and recommend mitigation for the health risks associated with the use of cellular communications and data transmittal."

"A likely explanation as to why **regulatory agencies have opted to ignore the body of scientific evidence demonstrating the negative impact of cellphone radiation** is that **those agencies are "captured"** (see Harvard University publication entitled, "Captured Agency: How the Federal Communications Commission Is Dominated by the Industries It Presumably Regulates" linked in Appendix G). This report documents how **the leadership roles in some agencies (the FCC in particular) are filled by individuals with strong industry ties** and hence are more **focused on industry interests than the health of citizens**"



Obtained via FOIA by Judicial Watch, Inc.

Major Litigation Updates & Recent Local Victories

It's been a strong week for our movement!

There are a lot of exciting things to report on this week, so let's dive right in...

Lake Tahoe, CA - Landmark Federal Lawsuit Filed to Block Saturation of Lake Tahoe Region with Cell Towers

<image002.jpg>

Hundreds of hazardous, unsightly wireless antennas and cell towers are quickly blanketing the Lake Tahoe, California region.

Three environmental non-profits and Monica Eisenstecken, a lifelong resident of South Lake Tahoe, have filed a potentially **precedent-setting litigation** against the Tahoe Regional Planning Agency, Verizon Wireless, the Tahoe Prosperity Center, and a local property owner...all in an effort **to protect one of the world's greatest natural treasures from a looming telecom takeover.**

Read Today's Press Release

Visit the New Tahoe Safe Tech Website

Support the Landmark Litigation

Obtained via FOIA by Judicial Watch, Inc.

D.C. Court of Appeals - Environmental Health Trust et al. v. FCC Oral Arguments, January 25th, 2021

<image002.jpg>

"A federal appeals panel in Washington voiced skepticism that the Federal Communications Commission had adequately considered dangerous health effects when it established guidelines for radiation emission from cell towers and wireless devices."
- Bloomberg Law

Congratulations to both the Environmental Health Trust and the Children's Health Defense for their tireless efforts challenging the FCC's outdated and insufficient wireless radiation public exposure guidelines.

Following yesterday's fabulous presentation, we are hopeful the judges will rule against the FCC.

Read the News

Listen to Recording of the Oral Arguments

RECENT VICTORIES

FLORIDA

1. Palm Coast, FL defeats 150-foot cell tower to be installed in the heart of the city's oldest neighborhood.

Obtained via FOIA by Judicial Watch, Inc.

Read the news here.

<image002.jpg>

2. Lakeland, FL defeats 110-foot cell tower slated to be installed mere feet from homes. This is the second cell tower in three months that has been defeated by Lakeland representatives due to resident opposition.

Read the news here.

<image002.jpg>

NEW JERSEY

3. Lavallette, NJ Borough Council approves five "small cell" antennas with challenging conditions: certification from the U.S. Department of Defense and the Federal Aviation Administration that 5G frequencies emitted by the equipment will not interfere with critical avionics equipment. Lavallette is situated just a few miles from one of the country's most active military air bases - Joint Base McGuire-Dix-Lakehurst.

Read the news here.

<image002.jpg>

CALIFORNIA

Obtained via FOIA by Judicial Watch, Inc.

4. Petaluma, CA defeats Verizon application to install 16 wireless antennas at the Petaluma Creamery, just 75 feet from homes. Read the legal memorandum in opposition to Verizon's application here.

<image002.jpg>

SOUTH CAROLINA

5. Residents in Mt. Pleasant, SC defeat a cell tower to be installed next to the Long Point playground.

Read the news here.

<image003.jpg>

As always, let's keep raking in the wins and working together to protect our communities from the telecom industry's ever-growing wireless footprint.

If you need assistance pushing back against 5G and/or other wireless infrastructure deployments in your area, please don't hesitate to reply to this email or call us at 516-883-0887.

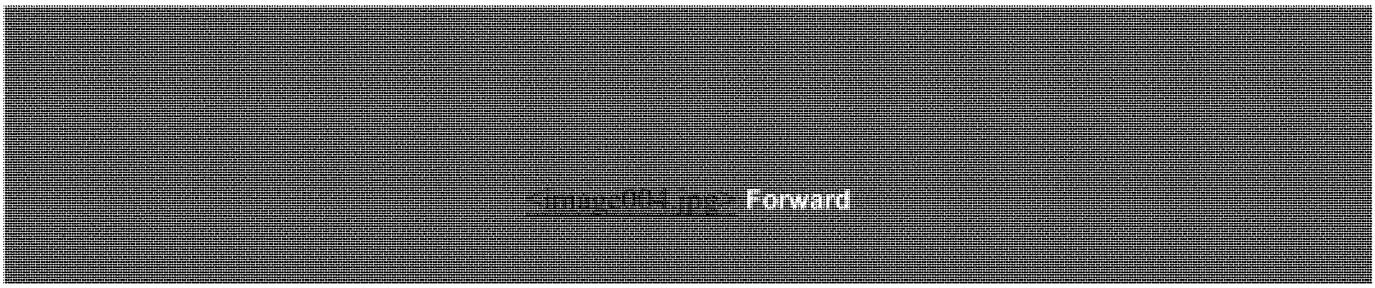
-The 5G Crisis Team

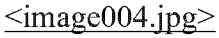
Contribute to 5G Crisis

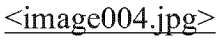
Share

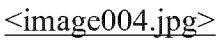
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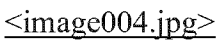
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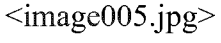




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Email report@5gcrisis.com
Call 516-883-0887

Want to change how you receive these emails?
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Thanks,
Vinu

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Il presente messaggio proviene da un indirizzo di posta elettronica aziendale assegnato al mittente a scopo lavorativo: la relativa casella di posta elettronica è soggetta alle procedure di controllo stabilite dall' ASL AL. Inviate a questo indirizzo solo comunicazioni di natura lavorativa, grazie

Il contenuto del presente messaggio di posta elettronica, ed ogni eventuale documento a quest'ultimo allegato, è rivolto unicamente al destinatario cui è indirizzato e può contenere dati ed informazioni la cui riservatezza è tutelata. Sono vietati la riproduzione, l'utilizzo e la diffusione dei dati e delle informazioni contenuti nel presente messaggio senza espressa autorizzazione da parte del destinatario. Chiunque abbia ricevuto il presente messaggio per errore è pregato di provvedere senza ritardo a segnalarlo, contattandoci via telefono, fax o e-mail.
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Sent: 2/2/2021 10:00:07 AM
To: Marsha Mailick [marsha.mailick@wisc.edu]
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Subject: Re: COVID-19 vaccine dangers; CDC's "Vaccines do not cause autism" lie, taken down; NH commission exposes FCC corruption, cellular radiation dangers

Remove me too

Envoyé de mon iPhone

Le 2 févr. 2021 à 15:52, Marsha Mailick <marsha.mailick@wisc.edu> a écrit :

Also please remove me from your list

Sent from my iPhone

On Feb 2, 2021, at 9:41 AM, trish.greenhalgh@phc.ox.ac.uk wrote:

Obtained via FOIA by Judicial Watch, Inc.

And me.

From: CORINNE D ENGELMAN <corinne.engelman@wisc.edu>
Date: Tuesday, 2 February 2021 at 14:37
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Subject: Re: COVID-19 vaccine dangers; CDC's "Vaccines do not cause autism" lie, taken down; NH commission exposes FCC corruption, cellular radiation dangers

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Me too.

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Subject: RE: COVID-19 vaccine dangers; CDC's "Vaccines do not cause autism" lie, taken down; NH commission exposes FCC corruption, cellular radiation dangers

Me as well.

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Subject: R: COVID-19 vaccine dangers; CDC's "Vaccines do not cause autism" lie, taken down; NH commission exposes FCC corruption, cellular radiation dangers

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Oggetto: RE: COVID-19 vaccine dangers; CDC's "Vaccines do not cause autism" lie, taken down; NH commission exposes FCC corruption, cellular radiation dangers

If there had been any reliable evidence that "milk protein contaminated vaccines (DTaP/TdaP, Prevnar 13, ActHiB) cause the vast majority (75%) of autism cases", we would surely have heard about it.

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Professor and Director
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Subject: Re: COVID-19 vaccine dangers; CDC's "Vaccines do not cause autism" lie, taken down; NH commission exposes FCC corruption, cellular radiation dangers

Prof. Gøtzsche,

Let me clarify that we are not discussing vaccine vs. no vaccine. We are discussing dirty, sickening vaccines vs. clean safe, effective vaccines.

Regarding autism, you are talking about the wrong vaccine. We have shown beyond all doubt, using **reliable mechanistic evidence** that milk protein contaminated vaccines (DTaP/TdaP, Prevnar 13, ActHiB) cause the vast majority (75%) of autism cases.

Autism pathogenesis: Piecing it all together, from end to beginning ...
https://doi.org/10.5281/zenodo.1477515

Immunization with homologous xenogeneic (animal/plant/fungal) antigens causes the development of autoimmune diseases. Known for at least 45 years.

Vaccine-Induced Autoimmunity in the Dog

"the most likely sources of cross-reactive epitopes are bovine serum and cell culture components. These are present in almost all vaccines as residu-al components of the cell culture necessary to generate vaccine viruses and may purposely

Obtained via FOIA by Judicial Watch, Inc.
be added to the vaccine as a stabilizer. In the presence of an adjuvant, these bovine products stimulate a strong immune response and induce antibodies that cross-react with conserved canine antigens."

Xenogeneic therapeutic cancer vaccines as breakers of immune tolerance for clinical application: to use or not to use?
pubmed.ncbi.nlm.nih.gov/24837511/

Oncologists immunize with xenogeneic antigens to break immune tolerance (cause autoimmunity) to make your immune system attack your own cancer cells.

Regular vaccines such as the measles vaccines are contaminated with animal proteins (chicken) and therefore cause numerous autoimmune disorders including type 1 diabetes.

Correlation of type 1 diabetes trends in European countries to the number of bovine insulin and GAD65 contaminated chick embryo cell culture containing vaccines in the schedule, as predicted by the autoimmunity mechanism involving immunization with homologous xenogeneic antigens and EPIT as a potential treatment
https://doi.org/10.5281/zenodo.1870364

The US IOM pointed out that epidemiological studies are useless in 93% of the cases. Mechanistic studies proved reliable.

Institute of Medicine: Most epidemiological vaccine safety studies are useless

https://doi.org/10.5281/zenodo.3244496

The Pandemrix vaccine made in Europe had higher levels of contamination with H1N1 nucleoproteins than the Arepanrix vaccine manufactured by the same company (GSK) in Canada. Pandemrix therefore caused way more cases of narcolepsy. Do you know the level of chicken protein contamination in Danish vs. US vaccines? How can you then apply studies done in Denmark to any other country?

Big picture of the damage vaccines do:

Vaccines and Biologics injury table based on mechanistic evidence – Feb 2020

Covering over 125 conditionshttps://zenodo.org/record/3647593/files/vbitr2_final.pdf?download=1

The organized suppression of vaccine safety science:

Retraction of scientific papers: the case of vaccine research
https://www.tandfonline.com/doi/full/10.1080/09581596.2021.1878109

Thanks,

Vinu

On 1/31/21 11:47 PM, pcg@scientificfreedom.dk wrote:

I have no knowledge of this huge email list and do not know why I was put on it. But I assume I will be taken off it because of what I write below. Please read it.

The idea that vaccines may cause autism was launched by Andrew Wakefield in relation to a fraudulent study published in Lancet in 1998 that has been retracted. Large observational studies from my country, Denmark, have shown convincingly that the Emperor has no clothes. I analyse this in detail in my 2020 book, Vaccines: truth, lies and controversy. It is an e-book but will come out soon on Skyhorse, New York, as a print book with an updated corona chapter that ends with the riots on 6 January 2021 at Capitol Hill.

Wakefield's horrendous fraud, which has caused many deaths, concerned the MMR vaccine. These are excerpts from my book, the chapter on measles:

According to the WHO, there were 110,000 measles deaths in 2017, and most were in children under the age of five.[3] Vaccination resulted in an 80% drop in measles deaths between 2000 and 2017 preventing an estimated 21 million deaths.

Obtained via FOIA by Judicial Watch, Inc.

Measles outbreaks also provide strong support for the benefits of the vaccine. In the United States, there was a resurgence of measles in 1989-1990, which primarily involved unvaccinated racial and ethnic minority children less than five years of age residing in inner-city areas.[40] There were 66 (0.1%) cases of encephalitis. A provisional total of 41 measles-associated deaths was reported in 1989 (2.3 deaths per 1000 cases), which increased to 89 (3.2 per 1000 cases) in 1990. In 2000, the CDC declared measles eradicated in the United States but there have been several outbreaks since due to imported cases.[41] In 2018, no less than 17 outbreaks occurred. One, in New York, was due to people who had been to Israel, and it included 182 cases in orthodox Jewish communities with a vaccination rate of only 50%.[42]

It is not possible to say exactly what the risk is of dying from measles. As noted earlier, the death risk is related to the infectious dose, which is higher in settings with overcrowding. We can only say what it has been in outbreaks, and a commonly used estimate is 2 deaths per 1000 cases. But it can be much worse. During an epidemic in Copenhagen in 1887, at least 5% of the children, or 50 per 1000 cases, died.[43] The mortality was probably even higher because only those who died while they had a rash counted. In Wien, at the beginning of the 20th century, the mortality was 11% among the poorest and 0.6% among the richest.

An outbreak in Madagascar that started in 2018 had in April 2019 caused over 1200 deaths, which is about 1% of those infected.[44] Only about 60% of the population is vaccinated.

We should all get vaccinated against measles and get our children vaccinated, with very few exceptions. Contraindications for the vaccine include a history of severe allergic reaction to any component of the vaccine including neomycin, pregnancy (measles illness during pregnancy results in a higher risk of premature labour, spontaneous abortion, and low-birthweight infants), and severe immunosuppression.[34]

On Swedish TV, in 2020, Wakefield lied horrendously about measles: "Exposure in childhood is safe and conveys lifelong immunity."

The reference is:

Dokumentär
Anna Nordbeck och Malin Olofsson
Dokument inifrån: VACCINKRIGARNA
https://www.svtplay.se/dokument-inifran-vaccinkrigarna
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To: goldingh@cber.fda.gov; khuranas@cber.fda.gov; sli49@emory.edu; elizabeth.deatrick@niaid.nih.gov; pwilson1@medicine.bsd.uchicago.edu; agewirtz@gsu.edu; megan.hahn@fda.hhs.gov; goldmanb@stanford.edu; mario.cortese@stanford.edu; nroupha@emory.edu; alan.embry@nih.gov; alex@lji.org; neuron@cell.com; jlandsberg@cell.com; agoldstein@cell.com; mzirlinger@cell.com; tdobie@cell.com; mfurman@cell.com; ckonen@cell.com; eniederst@cell.com; uschridde@cell.com; jshaw@cell.com; eporro@cell.com; emarcus@cell.com; jeffrey.sonnenfeld@yale.edu; info@eeoc.gov; ofo.eeoc@eeoc.gov; FOIA@eeoc.gov; eeoc.traininginstitute@eeoc.gov; inspector.general@eeoc.gov; richard.hatchett@cepi.net; fg17882@bristol.ac.uk; ripley.ballou@gskbio.com; nicole.lurie@cepi.net; jlg251@georgetown.edu; tom.monath@crozetbiopharma.com; aabimiku@ihv.umaryland.edu; abarrett@utmb.edu; Ananda.Bandyopadhyay@gatesfoundation.org; cbrechot@usf.edu; chappi@hsph.harvard.edu; Connie.s.schmaljohn.civ@mail.mil; iad7@cdc.gov; jamesrobinson@uchicago.edu; Jean.Lang@sanofipasteur.com; john.k.billington@gsk.com; kenji.shibuya@kcl.ac.uk; krause@cber.fda.gov; mlevine@som.umaryland.edu; moorthyv@who.int; paula.bryant@nih.gov; (b) (6) @africaonline.co.ke; yves.levy@aphp.fr; faddo@wisc.edu; bradford.barham@wisc.edu; lebautista@wisc.edu; lmberger@wisc.edu; wrbuckin@wisc.edu; meburns@wisc.edu; carlson@ssc.wisc.edu; jmcollins@wisc.edu; jaconwell@wisc.edu; nbarnes2@wisc.edu; kcurtis@ssc.wisc.edu; mcurtis3@wisc.edu; jeason2@wisc.edu; ehrenthal@wisc.edu; felwert@ssc.wisc.edu; cengelman@wisc.edu; mengelman@ssc.wisc.edu; jason.fletcher@wisc.edu; cfu@ssc.wisc.edu; fujimura@ssc.wisc.edu; tgerber@ssc.wisc.edu; cde@ssc.wisc.edu; grantm@ssc.wisc.edu; jan.greenberg@wisc.edu; jmgregory@ssc.wisc.edu; egrodsky@ssc.wisc.edu; sarah.halpernmeekin@wisc.edu; jenny.a.higgins@wisc.edu; lpjacobs@wisc.edu; fjones4@wisc.edu; hyunseung@stat.wisc.edu; dkaplan@education.wisc.edu; jkennan@ssc.wisc.edu; ajk@medicine.wisc.edu; mlight@ssc.wisc.edu; logan@ssc.wisc.edu; kmagnuson@wisc.edu; 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maclements@cmh.edu; inquires@sda.gov.cn; yerw@bjmu.edu.cn; yxy@xjtu.edu.cn; cfetpyhj@vip.sina.com; caodesheng@chinadaily.com.cn; yanwl@fudan.edu.cn; yiwang@shmu.edu.cn; zhangyp@chinacdc.cn; maojh88@zju.edu.cn; gisou.vandergoot@epfl.ch; nicola.harris@epfl.ch; andrea.ablasser@epfl.ch; patrick.aebischer@epfl.ch; johan.auwerx@epfl.ch; olaf.blanke@epfl.ch; melanie.blokesch@epfl.ch; cathrin.brisken@epfl.ch; philipp.bucher@epfl.ch; stewart.cole@epfl.ch; daniel.constam@epfl.ch; gregoire.courtine@epfl.ch; matteo.dalperaro@epfl.ch; paolo.delosrios@epfl.ch; michele.depalma@epfl.ch; bart.deplancke@epfl.ch; denis.duboule@epfl.ch; wulfram.gerstner@epfl.ch; pierre.gonczy@epfl.ch; johannes.graeff@epfl.ch; douglas.hanahan@epfl.ch; oliver.hantschel@epfl.ch; vassily.hatzimanikatis@epfl.ch; michael.herzog@epfl.ch; kathryn.hess@epfl.ch; joerg.huelsken@epfl.ch; friedhelm.hummel@epfl.ch; hilal.lashuel@epfl.ch; theo.lasser@epfl.ch; bruno.lemaitre@epfl.ch; joachim.lingner@epfl.ch; matthias.lutolf@epfl.ch; pierre.magistretti@epfl.ch; suliana.manley@epfl.ch; henry.markram@epfl.ch; brian.mccabe@epfl.ch; john.mckinney@epfl.ch; etienne.meylan@epfl.ch; felix.naef@epfl.ch; olaia.naveiras@epfl.ch; andrew.oates@epfl.ch; elisa.oricchio@epfl.ch; alexandre.persat@epfl.ch; carl.petersen@epfl.ch; freddy.radtke@epfl.ch; pavan.ramdya@epfl.ch; marcel.salathe@epfl.ch; carmen.sandi@epfl.ch; ralf.schneggenburger@epfl.ch; kristina.schoonjans@epfl.ch; viesturs.simanis@epfl.ch; david.suter@epfl.ch; didier.trono@epfl.ch; nicolas.mermod@unil.ch; beatrice.perrenoud@chuv.ch; awagnon@cmanet.org; accma@accma.org; jgreaves@accma.org; jjackovic@accma.org; grogers@accma.org; ndraper@accma.org; mlum@accma.org; (b) (6) @sbcglobal.net; (b) (6) @gmail.com; sbcms@sbmed.org; nbutler@fmms.org; Kamal.Gadalla@ed.ac.uk; ralph.hector@ed.ac.uk; S.R.Thomson@ed.ac.uk; Paul.Ross@ed.ac.uk; stephanie.mearns@ed.ac.uk; Marie.Bowers@ed.ac.uk; zoe.sawitzki@ed.ac.uk; Sarah.Giachetti@ed.ac.uk; s1316609@sms.ed.ac.uk; cochrane@umcutrecht.nl; editorial-unit@cochrane.org; admin@cochrane.org; CEU Admin <ceu@cochrane.org>; mwilson@cochrane.org; martin.burton@cochrane.nhs.uk; c.farquhar@auckland.ac.nz; j.e.clarkson@dundee.ac.uk; gerald.gartlehner@donau-uni.ac.at; pcg@scientificfreedom.dk; marguerite.a.koster@kp.org; (b) (6) @gmail.com; meerpohl@cochrane.de; santesna@mcmaster.ca;

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dimitrinka.nikolova@ctu.dk; snezana.djurisic@ctu.dk; (b) (6) @gmail.com; (b) (6) @gmail.com; (b) (6) @gmail.com; vbonfigli@cochrane.org; david@davidhammerstein.org; mburton@cochrane.org; mkoster@cochrane.org; Chris Del Mar <cdelmar@bond.edu.au>; Paul Glasziou <pglaszio@bond.edu.au>; RayMoynihan@bond.edu.au; peter.collignon@act.gov.au; Karla Soares-Weiser <ksoares-weiser@cochrane.org>; Hilary Simmonds <HSimmonds@cochrane.org>; Toby Lasserson <TLasserson@cochrane.org>; Christian Gluud <christian.gluud@ctu.dk>; Christopher Exley <c.exley@keele.ac.uk>; cdipietrantonj@aslal.it; (b) (6) @googlemail.com; sdavies@bmj.com; (b) (6) @btinternet.com; jclarkson@cochrane.org; ncullum@cochrane.org; gfaba@cochrane.org; thowe@cochrane.org; trish.greenhalgh@phc.ox.ac.uk; peter.christian.goetzsche@regionh.dk; governingboardsecretary@cochrane.org; David Tovey <dtovey@cochrane.org>; sara.krauss@ctu.dk; cgluud@ctu.dk; (b) (6) @gmail.com
Subject: COVID-19 vaccine dangers; CDC's "Vaccines do not cause autism" lie, taken down; NH commission exposes FCC corruption, cellular radiation dangers

Vaccines absolutely do cause autism

The CDC has flip-flopped twice in ~5 months on the fraudulent claim that "Vaccines do not cause autism", on their website. It suggests that the CDC's vaccine/autism claims are based on the conjunction of Jupiter and Saturn, not science.

They were forced to take the false claim down because ICAN demonstrated there was **ZERO** science behind that claim.

The CDC Finally Capitulated To ICAN's Legal Demands and Removed the Claim that "Vaccines Do Not Cause Autism" From Its Website!

https://www.icandecide.org/ican_press/the-cdc-finally-capitulated-to-icans-legal-demands-and-removed-the-claim-that-vaccines-do-not-cause-autism-from-its-website/

THE CDC JUST SOLIDIFIED THAT ITS DECISIONS ARE NOT DRIVEN BY SCIENCE

https://www.icandecide.org/ican_press/the-cdc-just-solidified-that-its-decisions-are-not-driven-by-science/

FACT: Milk protein contaminated vaccines (DTap/Tdap/Prevnar 13/ActHiB) cause at least 75% of autism cases.

Autism pathogenesis: Piecing it all together, from end to beginning ...
https://doi.org/10.5281/zenodo.1477515

CDC caught lying, again about the COVID-19 vaccine this time.

CDC Investigation

http://fullmeasure.news/news/cover-story/cdc-investigation

Vaccine mandates are based on a lie; Repeal all mandates immediately; Try the corrupted liars who created mandates, for CRIMES AGAINST HUMANITY

"Administration of parenterally administered vaccines alone typically does not result in potent mucosal immunity that might interrupt infection or transmission"
SARS-CoV-2 Vaccines: Much Accomplished, Much to Learn
www.acpjournals.org/doi/10.7326/M21-0111
So Fauci admits now that **ALL** injected vaccines are for individual protection only. **No herd/community immunity.** So no vaccine mandates are justifiable for **ANY** injected vaccine.
And of course this also means the vaccinated can become infected super-spreaders as occurs with the failed flu shot and failed pertussis vaccines.
Yan J, Grantham M, Pantelic J, de Mesquita PJ, Albert B, Liu F, et al. Infectious virus in exhaled breath of symptomatic seasonal influenza cases from a college community. Adamson W, Beato-Arribas B, Bischoff W, Booth W, Cauchemez S, Ehrman S, et al., editors. Proc Natl Acad Sci. National Academy of Sciences; 2018;

The potential role of subclinical Bordetella Pertussis colonization in the etiology of multiple sclerosis

Obtained via FOIA by Judicial Watch, Inc.

pubmed.ncbi.nlm.nih.gov/26724970/

This is the consequence of **insanely injecting** antigens of pathogens whose natural routes of exposure are mucosal surfaces in the nose, mouth or eyes.

NOTICE!

By authority of the Nuremberg Code on Medical Experimentation, I do hereby exercise my right to refuse to submit to or to administer the Covid-19 vaccine. The United States Government has prosecuted, convicted and executed Medical Doctors who have violated the Nuremberg Code on Medical Experimentation. Aiders and abettors of Nuremberg Crimes are equally guilty and have also been prosecuted, convicted, and executed.

Francis A. Boyle
Professor of Law.

My comment in the Annals of Internal Medicine, against Fauci's "SARS-CoV-2 Vaccines: Much Accomplished, Much to Learn"

https://www.acpjournals.org/doi/10.7326/M21-0111

Vinu Arumugham Independent 18 January 2021

These vaccines are unsafe, unnecessary and must be immediately withdrawn

The vaccine safety claims made by the authors are unsupported by evidence. Vaccines must be designed for safety. These vaccines were not designed at all. So they are unsafe by definition. I predicted the allergic sensitization and autoimmunity risks with these vaccines which have now been confirmed.

The Pfizer/BioNTech vaccine is unnecessary, unsafe and should not be authorized.

https://www.regulations.gov/document?D=FDA-2020-N-1898-0039

Robert F Kennedy Jr. warned the FDA months back about the risk of allergic reactions due to the use of polyethylene glycol (PEG) in the vaccines.
https://childrenshealthdefense.org/defender/pfizer-covid-vaccine-allergic-reactions/

The FDA/VRBPAC ignored us and authorized these horrendously dangerous vaccines.

Recently, Dr. Peter Marks of the FDA admitted that the population was sensitized by PEG-containing pharmaceutical preparations (that include other vaccines/injections).

https://www.wsj.com/articles/scientists-eye-potential-culprit-for-covid-19-vaccine-allergic-reactions-11608901200?mod=hp_lead_pos2

"What we're learning now is that those **allergic reactions could be somewhat more common** than the highly uncommon that we thought they were **because people do get exposed to polyethylene glycol in various pharmaceutical preparations,**" - Peter Marks, Director, CBER,FDA.

We of course already knew that any vaccine/injection that has enough allergen to cause a reaction, has more than enough allergen to guarantee sensitization/priming (causing the development of new allergy).

Evidence that Food Proteins in Vaccines Cause the Development of Food Allergies and Its Implications for Vaccine Policy

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3571073

Obtained via FOIA by Judicial Watch, Inc.

www.sciencemag.org/news/2020/12/suspicions-grow-nanoparticles-pfizer-s-covid-19-vaccine-trigger-rare-allergic-reactions

"he worries anti-PEG antibodies triggered by the first shot could increase the risk of an allergic reaction to the second or to PEGylated drugs."

- Janos Szebeni, an immunologist at Semmelweis University

So now, these vaccines have sensitized millions to PEG. The goal is to sensitize/boost PEG allergy in a 100 million more in the next 100 days.

PEG is contaminated with 1,4-dioxane, a carcinogen.

https://www.fda.gov/cosmetics/potential-contaminants-cosmetics/14-dioxane-cosmetics-manufacturing-byproduct

As predicted, Pfizer COVID-19 vaccine induced autoimmunity (thrombocytopenia) killed a Florida doctor. This is just the tip of the iceberg. Thousands of cases of vaccine induced autoimmune diseases may take months/years to be diagnosed and will be dismissed as unrelated to the vaccine.

https://www.nytimes.com/2021/01/12/health/covid-vaccine-death.html

Only a few lots were tested in the trial. No one has a clue what other lots will do. 100-fold variation of contaminants in vaccines makes trials and epidemiological studies worthless as I detailed in my comments in the Annals of Internal Medicine before. Vaccine safety remains an oxymoron.

https://www.acpjournals.org/doi/10.7326/m18-2101

California calls for pause of 330,000 doses, investigation after allergic reactions to Moderna vaccine batch

https://www.mercurynews.com/2021/01/18/coronavirus-california-calls-for-pause-investigation-after-allergic-reactions-to-moderna-vaccine-batch/

What's worse? Effective, life-saving, cheap, safe medicines such as famotidine/cetirizine/ivermectin are being ignored in this blind race to vaccinate at any cost.

Immunological mechanisms explaining the role of vaccines, IgE, mast cells, histamine, elevating ferritin, IL-6, D-dimer, VEGF levels in COVID-19 and dengue, potential treatments such as mast cell stabilizers, antihistamines: Predictions and confirmations

https://europepmc.org/article/PPR/PPR241819

Big picture of the damage vaccines do:

Vaccines and Biologics injury table based on mechanistic evidence – Feb 2020

Covering over 125 conditionshttps://zenodo.org/record/3647593/files/vbitr2_final.pdf?download=1

The organized suppression of vaccine safety science:

Retraction of scientific papers: the case of vaccine research
https://www.tandfonline.com/doi/full/10.1080/09581596.2021.1878109

The WHO's flip-flopping "science" competes with CDC's incompetence

WHO Recommends Against Moderna, Pfizer Vaccines for Most Pregnant Women

https://www.wsj.com/articles/who-recommends-against-moderna-pfizer-vaccines-for-most-pregnant-women-11611775138

Pregnant Women May Receive Covid Vaccines Safely, W.H.O. Says
https://www.nytimes.com/2021/01/29/health/covid-vaccine-pregnancy.html

Obtained via FOIA by Judicial Watch, Inc.

Moderna's COVID-19 vaccine now recommended for pregnant women, WHO says in guidance reversal

https://www.foxnews.com/health/moderna-covid-vaccine-pregnant-women-who-guidance-reversal

Not to be outdone by the flip-flopping CDC, WHO did a flip-flop on COVID-19 vaccine during pregnancy.

Latest evidence that there is ZERO science behind vaccines or vaccine safety. They just pull their "science" out of a hat. Follow the money.

These flip-flopping, lying, organized criminals at the CDC/WHO, are the "reputable sources" for your "fact-checkers".

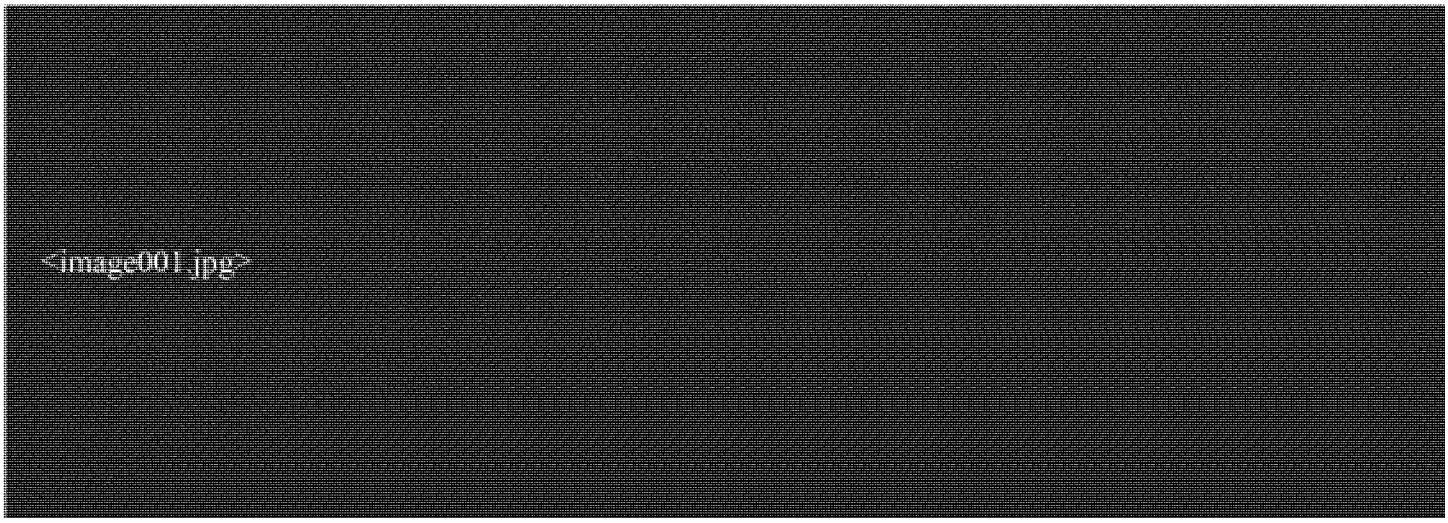
The New Hampshire Commission report below has ripped FCC's 5G (and all other cellular) RF safety claims:

Final Report of the Commission to Study The Environmental and Health Effects of Evolving 5G Technology

http://www.gencourt.state.nh.us/statstudcomm/committees/1474/reports/5G%20final%20report.pdf

"RECOMMENDATION 1- Propose a resolution of the House to the US Congress and Executive Branch to **require the Federal Communication Commission (FCC) to commission an independent review** of the current radiofrequency (RF) standards of the electromagnetic radiation in the 300MHz to 300GHz microwave spectrum as well as a health study to assess and recommend mitigation for the health risks associated with the use of cellular communications and data transmittal."

"A likely explanation as to why **regulatory agencies have opted to ignore the body of scientific evidence demonstrating the negative impact of cellphone radiation** is that **those agencies are "captured"** (see Harvard University publication entitled, "Captured Agency: How the Federal Communications Commission Is Dominated by the Industries It Presumably Regulates" linked in Appendix G). This report documents how **the leadership roles in some agencies (the FCC in particular) are filled by individuals with strong industry ties** and hence are more **focused on industry interests than the health of citizens**"



Major Litigation Updates & Recent Local Victories

It's been a strong week for our movement!

Obtained via FOIA by Judicial Watch, Inc.

There are a lot of exciting things to report on this week, so let's dive right in...

Lake Tahoe, CA - Landmark Federal Lawsuit Filed to Block Saturation of Lake Tahoe Region with Cell Towers

<image002.jpg>

Hundreds of hazardous, unsightly wireless antennas and cell towers are quickly blanketing the Lake Tahoe, California region.

Three environmental non-profits and Monica Eisenstecken, a lifelong resident of South Lake Tahoe, have filed a potentially **precedent-setting litigation** against the Tahoe Regional Planning Agency, Verizon Wireless, the Tahoe Prosperity Center, and a local property owner...all in an effort **to protect one of the world's greatest natural treasures from a looming telecom takeover.**

Read Today's Press Release

Visit the New Tahoe Safe Tech Website

Support the Landmark Litigation

Obtained via FOIA by Judicial Watch, Inc.

D.C. Court of Appeals - Environmental Health Trust et al. v. FCC Oral Arguments, January 25th, 2021

<image002.jpg>

"A federal appeals panel in Washington voiced skepticism that the Federal Communications Commission had adequately considered dangerous health effects when it established guidelines for radiation emission from cell towers and wireless devices."
- Bloomberg Law

Congratulations to both the Environmental Health Trust and the Children's Health Defense for their tireless efforts challenging the FCC's outdated and insufficient wireless radiation public exposure guidelines.

Following yesterday's fabulous presentation, we are hopeful the judges will rule against the FCC.

Read the News

Listen to Recording of the Oral Arguments

RECENT VICTORIES

FLORIDA

1. Palm Coast, FL defeats 150-foot cell tower to be installed in the heart of the city's oldest neighborhood.

Read the news here.

Obtained via FOIA by Judicial Watch, Inc.

<image002.jpg>

2. Lakeland, FL defeats 110-foot cell tower slated to be installed mere feet from homes. This is the second cell tower in three months that has been defeated by Lakeland representatives due to resident opposition.

Read the news here.

<image002.jpg>

NEW JERSEY

3. Lavallette, NJ Borough Council approves five "small cell" antennas with challenging conditions: certification from the U.S. Department of Defense and the Federal Aviation Administration that 5G frequencies emitted by the equipment will not interfere with critical avionics equipment. Lavallette is situated just a few miles from one of the country's most active military air bases - Joint Base McGuire-Dix-Lakehurst.

Read the news here.

<image002.jpg>

CALIFORNIA

4. Petaluma, CA defeats Verizon application to install 16 wireless antennas at the Petaluma Creamery, just 75 feet from homes. Read the legal memorandum in opposition to Verizon's application here.

Obtained via FOIA by Judicial Watch, Inc.

<image002.jpg>

SOUTH CAROLINA

5. Residents in Mt. Pleasant, SC defeat a cell tower to be installed next to the Long Point playground.

Read the news here.

<image003.jpg>

As always, let's keep raking in the wins and working together to protect our communities from the telecom industry's ever-growing wireless footprint.

If you need assistance pushing back against 5G and/or other wireless infrastructure deployments in your area, please don't hesitate to reply to this email or call us at 516-883-0887.

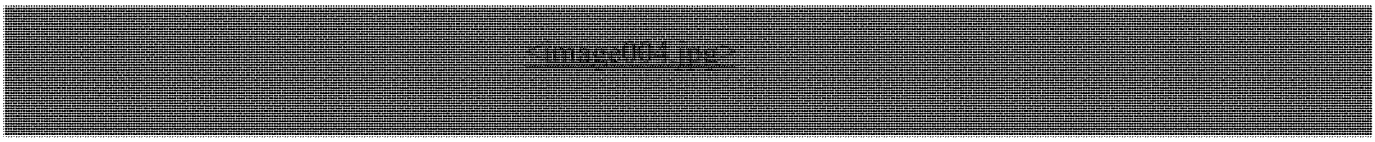
-The 5G Crisis Team

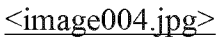
Contribute to 5G Crisis

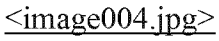
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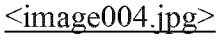
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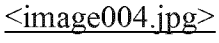
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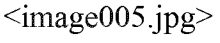




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Il presente messaggio proviene da un indirizzo di posta elettronica aziendale assegnato al mittente a scopo lavorativo: la relativa casella di posta elettronica è soggetta alle procedure di controllo stabilite dall' ASL AL. Inviate a questo indirizzo solo comunicazioni di natura lavorativa, grazie

Obtained via FOIA by Judicial Watch, Inc.

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