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Why limit contraindication to Janssen? Using same criteria revisit EUA/BLA for all C19 quasi-vaccines. Transparency: Emergency ACIP Meeting Dec 16 2021: A second open letter to Dr. Grace Lee, ACIP Chair

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December 16 2021, December 23 2021 (revised)[1]
Comment Tracking Number: (added after submission)
CDC-2021-0133 (only available at start of meeting, but inactive on regulations.gov until 12/17/21)

Dear ACIP Chairperson Dr. Lee,[2]
We refer to the letter to you from one of us (DW) of November 19, submitted to the docket (once a number had been assigned) and published as on Trial Site News.(1) DW remains in anticipation of the pleasure of your reply to that, and this letter, as to your proposed actions. We welcome an honest discussion of our analyses.

To enhance transparency and informed consent, we use the term "quasi-vaccine" (q-vaccine) to disclose the fact that these drugs meet FDA's definition of gene therapy products, and constitute a novel class distinct from classical vaccines.

Key concerns are summarized here under these main headings, with detail below and attached.

- Contraindications warranted for all q-vaccines to include other events (thrombosis, myocarditis, etc.). Focusing on a small subset of events in one q-vaccine is regulatory misdirection.
- Insufficient guidance on coagulopathies for Janssen and other quasi-vaccines
- COVID-19 q-vaccine in children 5-11 years: contraindication and re-evaluation of use warranted
- ACIP should be discussing ever reduced benefit for greater risk: Attempting to boost our way out of new variants is the immunological equivalent of heroin addiction.
- **Full review of the existing EUAs and BLA is warranted due to greater prevalence of AEs as well as death far exceeding the TTS rate for Janssen and the death reports for all three Covid-19 quasi-vaccines.**

Transparency Concerns
We extend earlier remarks concerning your concluding comments at the Nov 19 meeting stressing the importance of transparency in ACIP proceedings and the expression of diverse views. Given the circumstances of how Dec 16 meeting was announced, concerns about opacity are deepened. As before, the late notice, the late-publication of a docket number, the failure of email notifications and late posting of presentation slides, require corrective action.

Based on CDC and FDA decisions, millions in America and around the world are subjected to mandates and other harsh measures that could include imprisonment and loss of employment. The opacity displayed by ACIP not only deepens mistrust within the American public but reverberates around the world. You must be cognizant of your responsibility.

Contraindications warranted for all q-vaccines to include other events (thrombosis, myocarditis etc.)

- Why is the contraindication restricted to a small subset (54 cases of CVST) of a much larger set of many hundreds of thrombosis-related reports for all three quasi-vaccines? Surely this is regulatory misdirection.
- Reporting rates for myo/pericarditis for mRNA **AND** Janssen q-vaccines are as least as high, surely warranting a contraindication. Why is there inadequate guidance regarding myo/pericarditis? The fact sheets instruct patients to tell providers about previous episodes of myocarditis, with no guidance on how to act on this information.
- Can CDC and FDA guarantee no increased risk with subsequent dosing after previous episodes of other AEs?
- An EUA *"Provides for a lower level of evidence than the "effectiveness" standard FDA uses for product approvals"*[3] The same must surely be true of the level of evidence needed to demonstrate lack of safety. Accordingly, safety signals must be acted upon far sooner, out of an abundance of caution.
- We propose the following contraindication:

[1] An earlier version of this document had been prepared and attempts were made to load this to the regulations.gov portal. That document was sent to acip@cdc.gov as well as Dr. Lee. See section 6.1.3.
[2] Revised from cover letter previously sent – see 6.3
[3] https://www.fda.gov/media/154532/download

"Do not administer COMIRNATY, Pfizer-BioNTech or Moderna COVID-19 quasi-vaccines to patients with a history of myocarditis or pericarditis or thrombosis following any other mRNA COVID-19 quasi-vaccines."

- **Full review of the existing EUAs and BLA is warranted due to:**
  - Greater prevalence of AEs for all three q-vaccines than for a rare AE (TTS) for the Janssen q-vaccine.
  - Deaths per million (37-66) reported for all three quasi-vaccines far exceed (24-44 times) the threshold of comfort (1.5/million) set by ACIP member Dr. Sanchez and by FDA in establishing the TTS-related contraindication.

Insufficient guidance on coagulopathies for Janssen and other quasi-vaccines

- The contraindication for use in those with a history of Thrombosis with Thrombocytopenia Syndrome (TTS) **AFTER** Janssen dosing fails to guide on how to avoid TTS in the first place.
- CDC must estimate sub-clinical risks of TTS and other coagulopathies with Janssen and the mRNA q-vaccines.
- CDC must issue guidelines on tests and treatment of TTS and other q-vaccine-related adverse events.
- Why does the contraindication not consider risks of ALL coagulation events for all mix-and-match combinations?
- Why has it taken FDA this long to act on safety signals we provided at least 8 weeks ago?
- Now that FDA has enabled estimation of VAERS underreporting for myocarditis, can CDC estimate this for TTS?
- How can CDC/ACIP make any recommendations based on data FDA has failed to verify? (Janssen booster, Pfizer children, molnupiravir safety)
- Why is FDA not consulting with VRBPAC on these issues?
- Does ACIP understand that according to the founder of BioNTech, DNA-based quasi-vaccines may carry a risk of insertional mutagenesis?
- In re-assessing the risk-benefit ratio for all q-vaccines, has reduced effectiveness against omicron been considered?

COVID-19 q-vaccine in children 5-11 years: contraindication and re-evaluation of use warranted

- Early CDC figures reveal rates of myocarditis in 5-11 year-olds (5.21/MM 2nd dose) higher than for TTS (3.8/MM), warranting a contraindication for use after any episode of myocarditis.
- Pfizer's children's' study efficacy data have not been verified by FDA. Where is Pfizer's study on subclinical myocarditis and troponin levels?
- Our analysis of the VAERS data reveals discrepancies (in both directions) with CDC's analysis. There is an alarming number of cases (including one death) of administration of q-vaccine to a subject of inappropriate age.
- This is a gene therapy product with unevaluated long-term risks.
- According to the Australian government's "Nonclinical Evaluation Report," the Pfizer quasi-vaccine was not proposed for pediatric use. Had it been, studies in juvenile animals would have been submitted.(2)
- FDA's risk-benefit is flawed by 26 times in the wrong direction: Risk is at least 4x greater than benefit: including:
  - Overestimate of cases prevented based on Pfizer's data by 2.25-2.9x
  - No accounting for seroprevalence benefit (88% -Merck, 81% - Pfizer), waning immunity.
  - Adjusting for preliminary CDC data on myocarditis in 5-11 year-olds still does not yield a benefit of quasi-vaccination, especially when low activity against omicron is considered.
- A changed Pfizer formulation (for adults and children) differs from that used in trials.
  - Improved stability may increase effective dosing, worsening safety profile
  - Change in surface properties of LNP may alter injection site uptake and distribution, thereby affecting safety and efficacy.
- Use of Pfizer drug in children 5-11 is akin to using a child car seat with poor regulatory oversight.

ACIP should be discussing reduced benefit for greater risk: Immunological equivalent of heroin addiction. pCoQS

- Exposing subjects to risks associated with booster q-vaccination without understanding benefits is irresponsible.
- No data on the toxicity of cumulative dosing/boosting and the non-natural nucleosides used in the mRNA drugs.
- Reduced benefit for greater risk: Attempting to boost our way out of new variants is the immunological equivalent of heroin addiction.
- Concerning lag-dependent correlations between vaccine coverage and all-cause mortality, especially in children.
- The range and number of adverse events demands an integrated approach. Accordingly, we have adopted the terms: post Covid Vaccine Syndrome (pCoVS) or post Covid Quasi-Vaccine Syndrome (pCoQS).

Respectfully

David Wiseman PhD, MRPharmS Jessica Rose PhD, MSc., BSc. Josh Guetzkow, PhD Hervé Seligmann PhD

Contents

1. Contraindications warranted for all q-vaccines and include other events (thrombosis, myocarditis etc.)

The contraindication added by FDA is for subjects who have already experienced TTS after dosing with the Janssen drug. The contraindication is of little benefit to those who already died from TTS and makes no attempt to avert TTS *ab initio*. Nonetheless, the contraindication prudently estimates an elevated risk of TTS in those who survived an initial episode. The same prudence should therefore be exercised for any other adverse event, particularly those deemed serious (such as myocardial infarction and coagulopathies), regardless of whether a causal like has been definitely established. Can CDC say with certainty that there is no risk of repeated vaccine-associated myocarditis occurring after a prior episode?

In viewing the VAERS reports below, the percentage use of the three drugs in the USA (by number of people fully vaccinated) is approximately[4] Pfizer 56%: Moderna 36%: Janssen 8%. The VAERS searches below have included only US /Territories/unknown. We have not excluded Covid-19 related diagnoses. We provide links for the search strategies. However, note that as VAERS is updated, results will differ.

1.1. Frequency of myo/pericarditis in VAERS

A search (12/19/21) of VAERS[5] for terms: 10028606 (MYOCARDITIS), 10028650 (MYOPERICARDITIS), 10034484 (PERICARDITIS) reveals 3405 unique events. This does not include at least a 4.8x underreporting for myocarditis within VAERS (see 2.6).

Messages:
- VAERS data in CDC WONDER are updated every Friday. Hence, results for the same query can change from week to week.
- These results are for 3,405 total events.
- Rows with zero Events Reported are hidden. Use Quick Options above to show zero rows.

Symptoms	Vaccine Manufacturer	Events Reported	Percent (of 3,405)
MYOCARDITIS	JANSSEN	65	1.91%
MYOCARDITIS	MODERNA	761	22.35%
MYOCARDITIS	PFIZER\BIONTECH	1,530	44.93%
MYOCARDITIS	UNKNOWN MANUFACTURER	6	0.18%
MYOCARDITIS	Total	**2,362**	**69.37%**
PERICARDITIS	JANSSEN	86	2.53%
PERICARDITIS	MODERNA	590	17.33%
PERICARDITIS	PFIZER\BIONTECH	998	29.31%
PERICARDITIS	UNKNOWN MANUFACTURER	6	0.18%
PERICARDITIS	Total	**1,680**	**49.34%**
Total		**4,042**	**118.71%**

Note: Submitting a report to VAERS does not mean that healthcare personnel or the vaccine caused or contributed to the adverse event (possible side effect).

1.2. Frequency of TTS and related events in VAERS

A search for all symptoms containing the word "thrombosis"[6] yielded numbers of reports far higher than those for myocarditis or pericarditis for all three manufacturers. Accordingly, it is unclear why FDA's contraindication is restricted to TTS and only to Janssen.

[4] https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total.
[5] Covid-19 vaccines by manufacturer, search link: https://wonder.cdc.gov/controller/saved/D8/D260F937
[6] https://wonder.cdc.gov/controller/saved/D8/D260F948

- VAERS data in CDC WONDER are updated every Friday. Hence, results for the same query can change from week to week.
- These results are for 7,535 total events.
- Rows with zero Events Reported are hidden. Use Quick Options above to show zero rows.

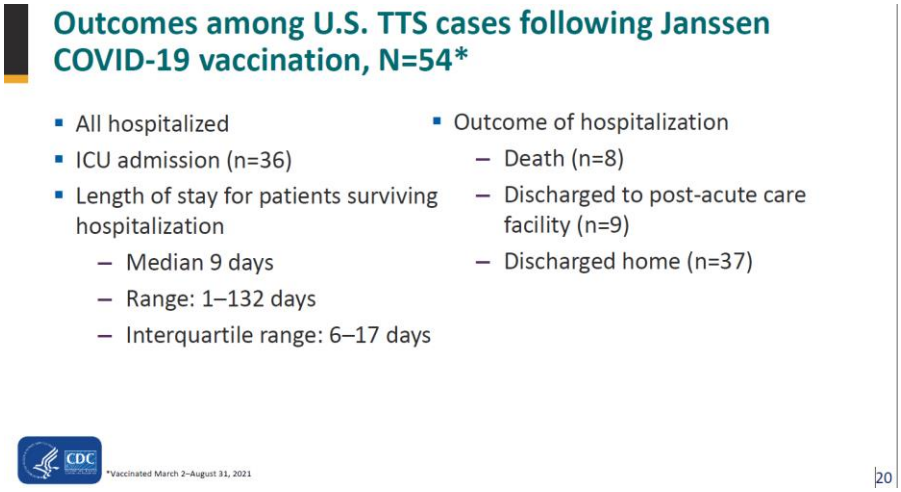
Vaccine Manufacturer	Events Reported	Percent (of 7,535)
JANSSEN	1,804	23.94%
MODERNA	2,810	37.29%
PFIZER\BIONTECH	3,543	47.02%
UNKNOWN MANUFACTURER	32	0.42%
Total	**8,189**	**108.68%**

Nonetheless, focusing on THROMBOCYTOPENIA, a search[7] for 10043554 (THROMBOCYTOPENIA) or 10086158 (THROMBOSIS WITH THROMBOCYTOPENIA SYNDROME) yielded numbers lower than for the above search. Specifically for TTS (THROMBOSIS WITH THROMBOCYTOPENIA SYNDROME), we found only 4 events for Janssen. Note that the number of events for THROMBOCYTOPENIA was nonetheless quite high for the two other drugs. Again, the question should be asked as to why FDA is focused on TTS and not on THROMBOCYTOPENIA more generally.

- VAERS data in CDC WONDER are updated every Friday. Hence, results for the same query can change from week to week.
- These results are for 682 total events.
- Rows with zero Events Reported are hidden. Use Quick Options above to show zero rows.

Symptoms	Vaccine Manufacturer	Events Reported	Percent (of 682)
THROMBOCYTOPENIA	JANSSEN	134	19.65%
THROMBOCYTOPENIA	MODERNA	270	39.59%
THROMBOCYTOPENIA	PFIZER\BIONTECH	398	58.36%
THROMBOCYTOPENIA	UNKNOWN MANUFACTURER	3	0.44%
THROMBOCYTOPENIA	**Total**	**805**	**118.04%**
THROMBOSIS WITH THROMBOCYTOPENIA SYNDROME	JANSSEN	4	0.59%
THROMBOSIS WITH THROMBOCYTOPENIA SYNDROME	**Total**	**4**	**0.59%**
Total		**809**	**118.62%**

This figure of 4 TTS events conflicts with the figure of 54 events described by CDC's Dr. See,[8] at the December 16 ACIP meeting.



Dr. See described CDC's methodology for finding cases of TTS within VAERS:

[7] https://wonder.cdc.gov/controller/saved/D8/D260F946

[8] https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-12-16/02-COVID-See-508.pdf

Case finding in VAERS for TTS following COVID-19 vaccines

- VAERS database search conducted daily for possible TTS reports
  - Healthcare providers directly contacted CDC with potential TTS
  - CDC initiates an investigation and facilitates submission of a VAERS report
- Medical records requested for all potential TTS case reports to confirm thrombosis with laboratory evidence of thrombocytopenia, using working case definition, reviewed by CDC and FDA medical officers
- CISA experts, including hematology/neurology, confirm clinical syndrome consistent with TTS and rule out other causes of thrombosis and thrombocytopenia

VAERS CISA

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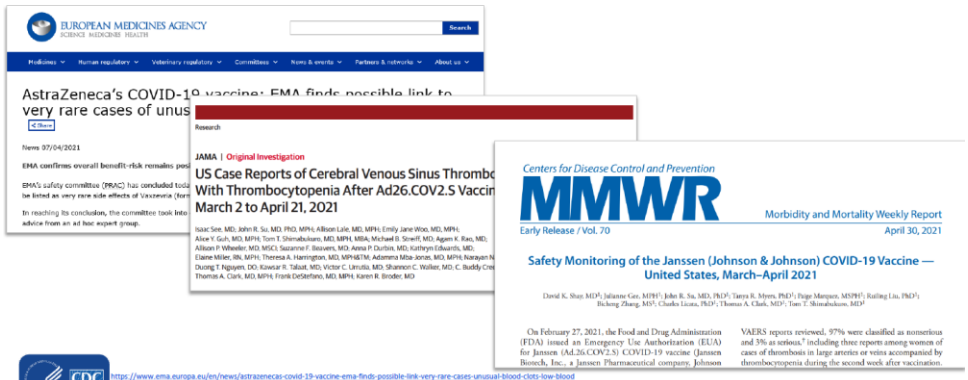
However, this does not explain the discrepancy. It was noted by Dr. See that TTS is a new syndrome recognized after events associated with adenovirus-vectored vaccines.

Thrombosis with thrombocytopenia syndrome (TTS): new syndrome recognized after adenoviral-vectored COVID-19 vaccines

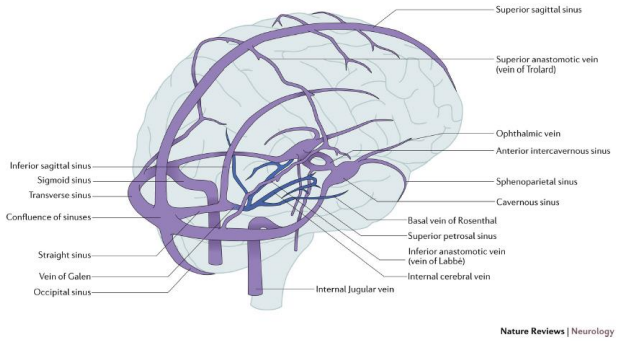


https://www.ema.europa.eu/en/news/astrazenecas-covid-19-vaccine-ema-finds-possible-link-very-rare-cases-unusual-blood-clots-low-blood
https://jamanetwork.com/journals/jama/fullarticle/2779731
https://www.cdc.gov/mmwr/volumes/70/wr/mm7018e2.htm?s_cid=mm7018e2_w

5

Here CDC linked TTS with Cerebral Venous Sinus Thrombosis (CVST), although TTS may manifest itself elsewhere in the body in arteries and veins.(3)

Cerebral Venous Sinus Thrombosis (CVST)



Nature Reviews | Neurology

Source: Silvis SM et al, Nature Reviews Neurology 13, 555-565 (2017).

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A search[9] for CEREBRAL VENOUS SINUS THROMBOSIS (CVST), or possibly related terms, yielded 60 CVST events for Janssen. This appears more in line with CDC's estimate of 54 TTS events. Events for the mRNA quasi-vaccines were relatively low when considering their much higher usage.

These results are for 443 total events.
Rows with zero Events Reported are hidden. Use Quick Options above to show zero rows.

Symptoms	Vaccine Manufacturer	Events Reported	Percent (of 443)
CEREBRAL THROMBOSIS	JANSSEN	45	10.16%
CEREBRAL THROMBOSIS	MODERNA	80	18.06%
CEREBRAL THROMBOSIS	PFIZER\BIONTECH	86	19.41%
CEREBRAL THROMBOSIS	UNKNOWN MANUFACTURER	3	0.68%
CEREBRAL THROMBOSIS	**Total**	**214**	**48.31%**
CEREBRAL VENOUS SINUS THROMBOSIS	JANSSEN	60	13.54%
CEREBRAL VENOUS SINUS THROMBOSIS	MODERNA	69	15.58%
CEREBRAL VENOUS SINUS THROMBOSIS	PFIZER\BIONTECH	75	16.93%
CEREBRAL VENOUS SINUS THROMBOSIS	UNKNOWN MANUFACTURER	1	0.23%
CEREBRAL VENOUS SINUS THROMBOSIS	**Total**	**205**	**46.28%**
CEREBRAL VENOUS THROMBOSIS	JANSSEN	14	3.16%
CEREBRAL VENOUS THROMBOSIS	MODERNA	13	2.93%
CEREBRAL VENOUS THROMBOSIS	PFIZER\BIONTECH	22	4.97%
CEREBRAL VENOUS THROMBOSIS	**Total**	**49**	**11.06%**
SUPERIOR SAGITTAL SINUS THROMBOSIS	JANSSEN	12	2.71%
SUPERIOR SAGITTAL SINUS THROMBOSIS	MODERNA	11	2.48%
SUPERIOR SAGITTAL SINUS THROMBOSIS	PFIZER\BIONTECH	16	3.61%
SUPERIOR SAGITTAL SINUS THROMBOSIS	**Total**	**39**	**8.80%**
THROMBOSIS WITH THROMBOCYTOPENIA SYNDROME	JANSSEN	4	0.90%
THROMBOSIS WITH THROMBOCYTOPENIA SYNDROME	**Total**	**4**	**0.90%**
Total		**511**	**115.35%**

Restricting the above search to Janssen,[10] yielded the following with minimal overlap (i.e. 268 events reported from 250 unique events), suggesting TTS/CVST reports higher than 54.

These results are for 250 total events.

Symptoms	Events Reported	Percent (of 250)
CEREBRAL THROMBOSIS	45	18.00%
CEREBRAL VENOUS SINUS THROMBOSIS	60	24.00%
CEREBRAL VENOUS THROMBOSIS	13	5.20%
SUPERIOR SAGITTAL SINUS THROMBOSIS	12	4.80%
THROMBOCYTOPENIA	134	53.60%
THROMBOSIS WITH THROMBOCYTOPENIA SYNDROME	4	1.60%
Total	**268**	**107.20%**

Restricting the search to only CVST and TTS[11] yielded 63 unique events.

These results are for 63 total events.

Symptoms	Events Reported	Percent (of 63)
CEREBRAL VENOUS SINUS THROMBOSIS	60	95.24%
THROMBOSIS WITH THROMBOCYTOPENIA SYNDROME	4	6.35%
Total	**64**	**101.59%**

[9] https://wonder.cdc.gov/controller/saved/D8/D260F957
[10] https://wonder.cdc.gov/controller/saved/D8/D260F958
[11] https://wonder.cdc.gov/controller/saved/D8/D260F961

Allowing for slightly different reporting periods, this is a similar number to the 54 TTS cases described by Dr. See, suggesting that based on post-VAERS case review, most of the 50/54 of the TTS cases were reclassed from CVST.

Given that CVST is not the only manifestation of TTS(3), widening the scope of TTS to other thrombotic events, might require issuing a contra-indication regarding non-TTS thrombosis. This in turn begs the question as to why FDA have ignored other thrombosis-related events, including those for Pfizer and Moderna quasi-vaccines.

1.3. Inadequate labeling and CDC guidance on myocarditis, despite greater frequency than TTS

Given rates of myo/pericarditis much higher than TTS, there is inadequate labeling and guidance for the mRNA drugs. Myocarditis has prompted the inclusion of the following statement in both the COMIRNATY label(4) and the fact sheet for providers of the Pfizer drug:(5)

"Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose"

The fact sheet for recipients(6) of the Pfizer drug states: (added highlight)

WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU GET THE VACCINE?
Tell the vaccination provider about all of your medical conditions, including if you:

- have any allergies
- have had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- have a fever
- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects your immune system
- are pregnant or plan to become pregnant
- are breastfeeding
- have received another COVID-19 vaccine
- have ever fainted in association with an injection

What purpose is served instructing patients to inform providers about myocarditis after a mRNA quasi-vaccine if there is no corresponding action or decision tree given to providers? The fact sheet for providers of the Pfizer drug(5) states:

Myocarditis and Pericarditis
Post marketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose. The observed risk is higher among males under 40 years of age than among females and older males. The observed risk is highest in males 12 through 17 years of age. Although some cases required intensive care support, available data from short-term follow-up suggest that most individuals have had resolution of symptoms with conservative management. Information is not yet available about potential long-term sequelae. The CDC has published considerations related to myocarditis and pericarditis after vaccination, including for vaccination of individuals with a history of myocarditis or pericarditis (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html).

There is similar language for the Moderna quasi-vaccine.(7)

How many cases require intensive care support?

There is no guidance given to providers in this document as to how to deal with a patient with prior quasi-vaccine-associated myocarditis. The referenced CDC Clinical Considerations(8) provide no guidance either. Is CDC confident that prior q-vaccine associated (or other) myocarditis carries no risk associated with subsequent dosing? Where are the data? Why is there no contraindication for the mRNA q-vaccines, for example:

> ***"Do not administer COMIRNATY, Pfizer-BioNTech or Moderna COVID-19 quasi-vaccines to patients with a history of myocarditis or pericarditis or thrombosis following any other mRNA COVID-19 quasi-vaccines."***

Even though the myocarditis VAERS reports are greater for the mRNA drugs, myocarditis has still been reported for Janssen. Given that the number of myo/pericarditis events reported for Janssen is similar to the number of TTS reports, surely a myo-pericarditis contraindication is also warranted for the Janssen quasi-vaccine?

2. Insufficient guidance on coagulopathies for Janssen and other quasi-vaccines

2.1. New contraindication limited to those with post-Janssen TTS – no information on pre-initial dose risks

This ACIP meeting follows the announcement[12] by FDA on December 14th regarding the contraindication which states in the FACT SHEET FOR HEALTHCARE PROVIDERS:

"Do not administer the Janssen COVID-19 Vaccine to individuals with a history of thrombosis with thrombocytopenia following the Janssen COVID-19 Vaccine or any other adenovirus vectored COVID-19 vaccine (e.g., AstraZeneca's COVID-19 vaccine which is not authorized or approved in the United States)"

This contraindication does nothing to avoid a first instance of TTS. It is **limited only** to those with a history of Thrombosis with Thrombocytopenia Syndrome (TTS) after the Janssen (or other adenovirus vector) vaccine. TTS, according to the fact sheet, can occur in males or females across a wide age range, the highest incidence being in females 30-49 years old, with a fatality of about 15%. Other than this, there is little information provided as to other risk factors for TTS prior to **any** dosing.

2.2. No estimate of sub-clinical risk of TTS, other types of coagulation disorders, or risks in mRNA doses

No estimates are provided as to subclinical TTS, nor any attempt to place TTS in the context of a broader category of coagulopathy, embolic or thrombotic events which have been reported in VAERS associated with the Pfizer and Moderna mRNA doses.

2.3. CDC must issue guidelines on diagnostic tests and treatment

To further public trust, CDC must issue guidelines on diagnostic tests and treatment of TTS, as well as other vaccine-related adverse events.

2.4. Contraindication does not consider mix-and-match implications

Although it is unclear how the mechanisms of the different types of coagulation-related events in all three drugs are related, it would seem prudent to extend the contraindication to any **homologous or heterologous** combination of the three q-vaccines where ANY sort of coagulation-related event occurred.

2.5. Why has it taken FDA this long to act on safety signals we provided at least 8 weeks ago?

About eight weeks ago, we submitted(9) comments to the ACIP Meeting of October 20 containing a detailed discussion of our safety signal analysis. We adopted the approach published (10) by scientists from FDA and CDC to normalize the number of events reported in VAERS for the number of people receiving a particular vaccine or doses administered. This figure can be divided by a similar ratio from a reference vaccine to obtain a normalized event ratio (NER). **Table 1** shows high NER signals for death, coagulopathy, embolic/ thrombotic events. Although the ratios for coagulopathy and embolic/thrombotic events are much higher for Janssen than Pfizer and Moderna, the ratios for the latter two are nonetheless high and similar to or greater than the NER values for myocarditis in the mRNA q-vaccines. These values serve as reference points because of the acknowledged association with myocarditis.

Note that for all three quasi-vaccines there is also a significant safety signal for myocardial infarction that could be related in part to dyscoagulation.

[12] www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-december-14-2021

Table 1: ***Normalized Event Ratio (NER) for Covid-19 quasi-Vaccines Compared with Seasonal Flu Vaccines***

	JANSSEN		MODERNA		PFIZER\BIONTECH	
	By dose	By person	By dose	By person	By dose	By person
Death	297	297	170	316	119	225
Life Threatening	110	110	39	72	32	60
Permanent Disability	57	57	24	44	20	38
Congenital Anomaly/Birth Defect	112	112	58	108	51	95
Hospitalized	101	101	43	80	37	70
GBS	19	19	3	5	2	4
Coagulopathy	1427	1428	286	531	218	413
Myocardial Infarction	411	412	232	431	180	339
Myo/peri carditis	181	181	170	317	217	410
Embolic Thrombotic	610	610	151	280	113	213
Serious	92	92	41	76	34	65
Not serious	46	46	27	51	16	31

Using VAERS data as of 10/13/21, we obtained the numbers of reports for various event types and categories using the "USA/Territories/Unknown" filter and for ages 6 and above. We stratified by Covid q-vaccine type and compared event rates with those for seasonal flu vaccines from the 2015/16 to 2019/20 seasons. Flu and Covid-19 (q-)vaccine coverage data were obtained from CDC, and population estimates where needed from https://usafacts.org/. We calculated NER for the Covid-19 q-vaccines against seasonal flu vaccine. We normalized both for the number of doses administered and the number of people having at least one dose.

We made an even earlier submission to FDA for the September 17 VRBPAC meeting in which we described safety signals for coagulopathy (all q-vaccines combined).(11) We not only used the NER, but also the PRR ratio described in the VAERS SOP.(12) Although we believe that method to be inferior, safety signals still met the Evans criteria.(13)

Table 2: ***COVID-19 vs. Flu (q-)Vaccines: Normalized Event Ratio vs. Disproportionality Signal Analysis as Proportion of All Reports or events***

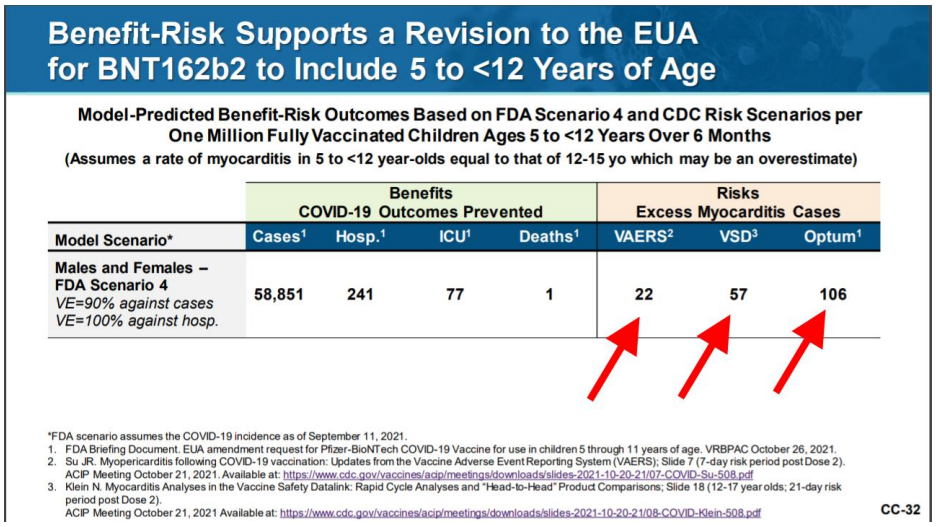
	SERIOUS EVENTS			DEATHS			GBS			COAGULOPATHY			Myocardial Infarction		
Ages	NER dose	PRR event	PRR report	NER dose	PRR event	PRR report	NER dose	PRR event	PRR report	NER dose	PRR event	PRR report	NER dose	PRR event	PRR report
10-17	34	1.66	1.35	32	1.52	1.24	7	0.34	0.28	74	3.56	2.89	n.e.	n.e.	n.e.
18-49	25	0.87	0.99	64	2.22	2.52	3	0.09	0.1	226	7.78	8.82	403	13.92	15.78
50-64	26	1.23	1.45	85	4.01	4.74	3	0.12	0.14	239	11.19	13.22	121	5.68	6.71
65+	30	2.34	2.76	98	7.77	9.16	3	0.22	0.26	370	31.34	36.97	88	7.01	8.27
10+	28	1.31	1.52	91	4.24	4.93	3	0.13	0.15	276	12.77	14.84	126	5.83	6.78

Note: The PRR is the ratio of the proportion of a particular event or event type out of all reports (or events) for COVID-19 to the proportion of all reports (or events) for the combined 2015-2019 flu seasons. Orange shading indicates a statistically significant difference between the proportion of COVID-19 proportion of COVID-19 and flu reports for that age group and event type (chi squared test. Flu reporting rates represent the total reports to VAERS across the 2015/16-2019/20 flu seasons for each age group. Covid-19 reporting rates include all reports to VAERS for COVID-19 vaccines for each age group as of Aug. 6, 2021. The Normalized Event Ratio shown is calculated according to the number of doses given.
The "coagulopathy" category includes a set of 26 preferred terms (PT) for thromboembolic events (although the category does not include coagulopathy PT). The full list of PT's for GBS, coagulopathy and acute myocardial infarctions can be found in Table 4.6 of the VAERS SOP document.(12)

2.6. There is likely at least a 4.8x under-reporting in VAERSs

Risk-benefit analyses have little meaning without understanding the degree of under-reporting in VAERS, or similar systems. Key information is re-iterated from the November 19 letter.

At the October 26 VRBPAC meeting an exchange took place between CDC's Dr Cohn and FDA's Dr. Yang in which Dr. Yang revealed that because VAERS is under-reported, FDA used a database (Optum), apparently unknown to CDC. youtu.be/laaL0_xKmmA?t=21807 Does it not concern ACIP that unlike CDC, Pfizer DID know about this database, attested by this Pfizer slide? [13]



Benefit-Risk Supports a Revision to the EUA for BNT162b2 to Include 5 to <12 Years of Age

Model-Predicted Benefit-Risk Outcomes Based on FDA Scenario 4 and CDC Risk Scenarios per One Million Fully Vaccinated Children Ages 5 to <12 Years Over 6 Months

(Assumes a rate of myocarditis in 5 to <12 year-olds equal to that of 12-15 yo which may be an overestimate)

	Benefits COVID-19 Outcomes Prevented				Risks Excess Myocarditis Cases		
Model Scenario*	Cases[1]	Hosp.[1]	ICU[1]	Deaths[1]	VAERS[2]	VSD[3]	Optum[1]
Males and Females – FDA Scenario 4 *VE=90% against cases VE=100% against hosp.*	58,851	241	77	1	22	57	106

*FDA scenario assumes the COVID-19 incidence as of September 11, 2021.

1. FDA Briefing Document. EUA amendment request for Pfizer-BioNTech COVID-19 Vaccine for use in children 5 through 11 years of age. VRBPAC October 26, 2021.
2. Su JR. Myopericarditis following COVID-19 vaccination: Updates from the Vaccine Adverse Event Reporting System (VAERS); Slide 7 (7-day risk period post Dose 2). ACIP Meeting October 21, 2021. Available at: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/07-COVID-Su-508.pdf
3. Klein N. Myocarditis Analyses in the Vaccine Safety Datalink: Rapid Cycle Analyses and "Head-to-Head" Product Comparisons; Slide 18 (12-17 year olds; 21-day risk period post Dose 2). ACIP Meeting October 21, 2021 Available at: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/08-COVID-Klein-508.pdf

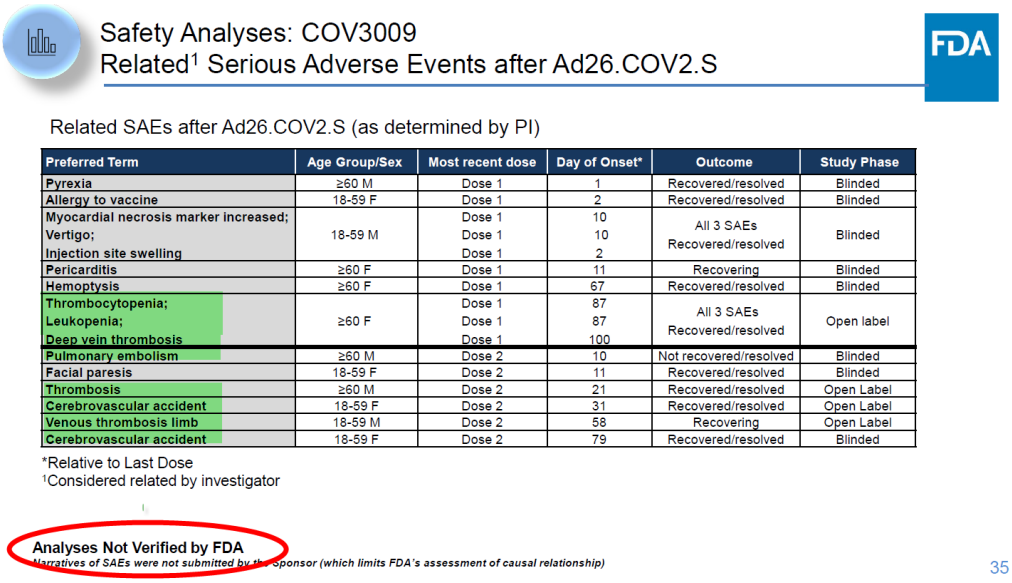
CC-32

Slide 32 from Pfizer's Dr. Gruber (arrows added)

This slide reveals at least a 4.8x VAERS underreporting for myocarditis? What does this mean for other AEs such as those being considered today?

2.7. Why did FDA not verify Janssen's efficacy or safety data for its 2nd dose submission? Does it not concern ACIP that recommendations are being made based on unverified data?

Adding to the above concern as to why it has taken at least 8 weeks for FDA to take this action, is FDA's disclosure in the Oct 15 VRBPAC meeting that it had not verified much of Janssen's safety or efficacy analysis, as seen the presentation slides,[14] including 8 in the safety part of the presentation, for example, this one: (highlights added)



Safety Analyses: COV3009
Related[1] Serious Adverse Events after Ad26.COV2.S

FDA

Related SAEs after Ad26.COV2.S (as determined by PI)

Preferred Term	Age Group/Sex	Most recent dose	Day of Onset*	Outcome	Study Phase
Pyrexia	≥60 M	Dose 1	1	Recovered/resolved	Blinded
Allergy to vaccine	18-59 F	Dose 1	2	Recovered/resolved	Blinded
Myocardial necrosis marker increased; Vertigo; Injection site swelling	18-59 M	Dose 1 Dose 1 Dose 1	10 10 2	All 3 SAEs Recovered/resolved	Blinded
Pericarditis	≥60 F	Dose 1	11	Recovering	Blinded
Hemoptysis	≥60 F	Dose 1	67	Recovered/resolved	Blinded
Thrombocytopenia; Leukopenia; Deep vein thrombosis	≥60 F	Dose 1 Dose 1 Dose 1	87 87 100	All 3 SAEs Recovered/resolved	Open label
Pulmonary embolism	≥60 M	Dose 2	10	Not recovered/resolved	Blinded
Facial paresis	18-59 F	Dose 2	11	Recovered/resolved	Blinded
Thrombosis	≥60 M	Dose 2	21	Recovered/resolved	Open Label
Cerebrovascular accident	18-59 F	Dose 2	31	Recovered/resolved	Open Label
Venous thrombosis limb	18-59 M	Dose 2	58	Recovering	Open Label
Cerebrovascular accident	18-59 F	Dose 2	79	Recovered/resolved	Blinded

*Relative to Last Dose
[1]Considered related by investigator

Analyses Not Verified by FDA
Narratives of SAEs were not submitted by the Sponsor (which limits FDA's assessment of causal relationship)

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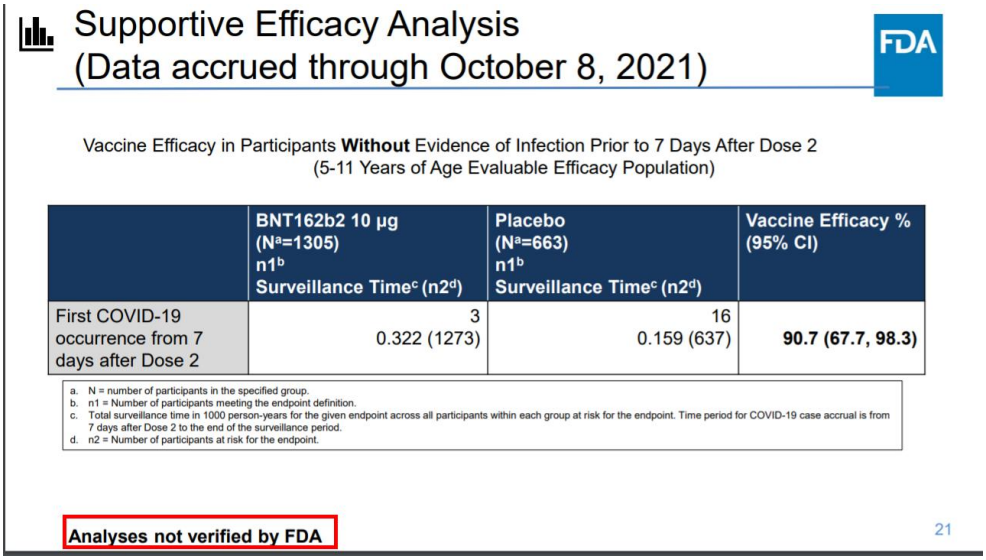
This deficiency was challenged by VRBPAC member Dr. Chatterjee.[15] FDA's Drs. Fink and Marks justified this based on the intense public interest on boosters and the urgent need for a meeting where a small immunogenicity study of 200 or so

[13] fda.gov/media/153513/download
[14] https://www.fda.gov/media/153130/download
[15] https://youtu.be/c-H40GrvWz4?t=11801

subjects was expected requiring only a short review. Instead, a study with some 30,000 subjects was submitted whose detailed review by FDA would have taken several weeks. The answer is difficult to reconcile with the ongoing discussions alluded to FDA and the fact that this 2-dose study was described in Janssen's EUA briefing document of February 26, 2021.[16]

We have previously notified CDC of this lapse on the part of FDA(9) and do so again now. We are now aware of two other instances of a failure to conduct the most basic of functions on the part of FDA. Without an assurance that the data can even be verified, no other decision can take place, and certainly none that could lead to mandates.

Firstly, in the VRBPAC meeting of October 26 (EUA for Pfizer in children 5-11), key analyses were not verified by FDA, for example here:[17] (highlight added)



Supportive Efficacy Analysis
(Data accrued through October 8, 2021)

FDA

Vaccine Efficacy in Participants **Without** Evidence of Infection Prior to 7 Days After Dose 2
(5-11 Years of Age Evaluable Efficacy Population)

	BNT162b2 10 µg (N[a]=1305) n1[b] Surveillance Time[c] (n2[d])	Placebo (N[a]=663) n1[b] Surveillance Time[c] (n2[d])	Vaccine Efficacy % (95% CI)
First COVID-19 occurrence from 7 days after Dose 2	3 0.322 (1273)	16 0.159 (637)	**90.7 (67.7, 98.3)**

a. N = number of participants in the specified group.
b. n1 = Number of participants meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of participants at risk for the endpoint.

Analyses not verified by FDA

21

Even data errors in a small number of subjects, could lead to large interpretative errors.

Secondly, in the AMBAC advisory meeting of November 30 to consider the EUA for molnupiravir, FDA stated[18] *"We have not verified the sponsor's [safety] analyses."*

2.8. Why is FDA not consulting with VRBPAC?

Given the seriousness of the issues, why is FDA not consulting its advisory committee? A search of the FDA advisory committee meeting schedule failed to yield (6.1.4) a listing of a parallel FDA VRBPAC meeting.

2.9. No satisfactory explanation as to why this (and other quasi-vaccines) are not being regulated as gene therapy products: risk of insertional mutagenesis with DNA-based doses

Part of any risk-benefit analysis must consider long term adverse events. Please refer to our previous submission on this topic.(9) Moderna, Inc., acknowledged in their 2Q 2020 SEC filing(14)[19] that *"Currently, mRNA is considered a gene therapy product by the FDA."*

Although he attempted to justify why mRNA should not be regulated as a gene therapy product, Dr. Ugur Sahin, the founder of BioNTech, stated that ***"****One would expect the classification of an mRNA drug to be a biologic, a gene therapy or a somatic cell therapy.****"***(15) He also stated that *"mRNA-based therapeutics, unlike plasmid DNA and viral vectors, do not integrate*

[16] https://www.fda.gov/media/146217/download
[17] https://www.fda.gov/media/153510/download
[18] https://www.youtube.com/watch?v=fR9FNSJT64M&t=10195s. Note that these comments were spoken ol and not on written slide.
[19] Moderna's 2Q2020 SEC filing is dated August 6 2020, and states that the phase 1 study began March 16, 2020, with the phase 2 study being fully enrolled by July 8, 2020. Enrollment for the phase 3 study began July 27, 2020, as also reflected in for clinicaltrials.gov. Each phase would have been cleared by FDA. The start date given in clinicaltrials.gov for Pfizer's trial was April 29 2020 and for J&J Sept 7 2020.

into the genome and therefore do not pose the risk of insertional mutagenesis," implying that there **is such a risk for DNA based therapeutics**.

Is CDC aware of preclinical studies to assess this risk? Will CDC factor this into their risk benefit analysis?

2.10. Informed consent, including representations made by CDC in its promotional materials, must disclose that the Janssen, Pfizer and Moderna quasi-vaccines are gene therapy products.

With the various unknown risks associated with gene therapy products, we suggest that CDC **is abusing the trust of the public** by failing to disclose that these quasi-vaccines are gene therapy products. At a recent international conference, Stefan Oelrich, President, Bayer Pharmaceuticals Division (World Health Summit, Berlin, October 24-26, 2021) stated:
"*I always like to say if we had surveyed two years ago in the public - would you be willing to take a gene or cell therapy and inject into your body? we would have probably had 95% refusal rate."*[20]

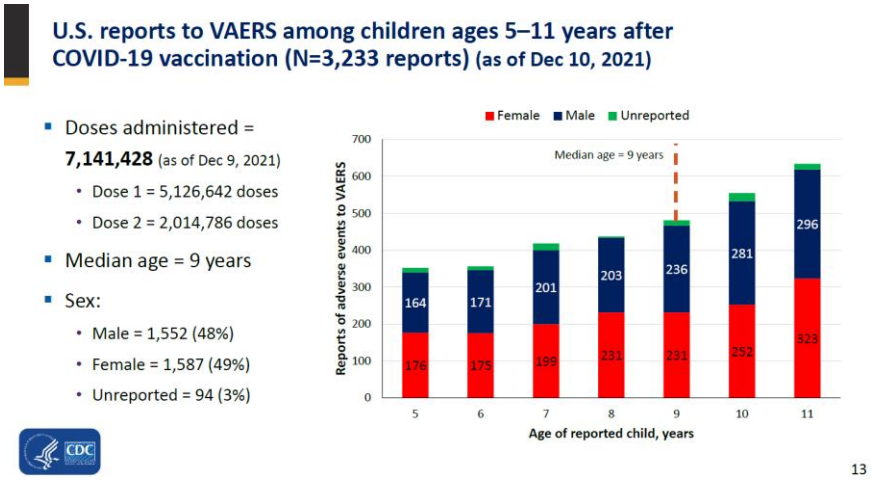
3. COVID-19 quasi-vaccine in children 5-11 years: contraindication and re-evaluation of use warranted

ACIP is invited to watch a recent presentation given[21] to the World Council for Health. To summarize, there are significant concerns regarding the children's 5-11 vaccine program.

Concerns regarding the gene therapy nature of these quasi-vaccines (see 2.9) and the failure of FDA to verify the analyses for the Pfizer children's dose (see 2.7) are described above. The latter is particularly important in the light of only 16 and 3 outcome events in placebo and BNT162b2 groups respectively. Even small errors may have dramatic effects on estimates of efficacy. Other main concerns requiring a re-evaluation of CDC's decision framework are:

3.1. Recent updates from v-safe and VAERS in children 5-11 warrant a contra-indication

An update of VAERS reports was provided at the December 16 meeting by CDC's Dr. John Su.[22].With only 41.232 participants in v-safe, data are limited. Dr. Su presented VAERS data as of December 9, 2021 based on a total of 7.1 million doses (5.1 million first doses; 2 million second doses), yielding 3,233 AE reports. There were two deaths.



[20] https://www.youtube.com/watch?v=OJFKBritLlc&t=5845s
[21] https://worldcouncilforhealth.org/multimedia/david-wiseman-recklessness/
[22] https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-12-16/05-COVID-Su-508.pdf

3.1.1. Unable to replicate CDC update from VAERS: total number and type of event.

We found a higher number of reports (3917) as of December 17th and due to how VAERS data are overwritten every week, we were unable to replicate the data as of December 9th. We found other differences, in both directions, but are unable to explain them by just a one week lag time. This discrepancy may be partly explained by an additional week of reporting. **We welcome contact with CDC to understand the source of this discrepancy in order that we may correct our analysis.** Strangely, the number of reports of increased troponin ***decreased*** from 10 to 2.

For serious AEs, CDC's analysis (left) is shown below side by side with ours (right)[23] (discrepancies highlighted).

CDC Analysis

Most frequent adverse events among serious reports to VAERS following COVID-19 vaccination, children ages 5–11 years (n=81) (as of Dec 10, 2021)

Rank	Adverse event (not mutually exclusive)	n (%)
1	Fever	21 (26)
2	Vomiting	17 (21)
3	Chest pain	11 (14)
4	C-reactive protein increased	10 (12)
5	Echocardiogram normal	10 (12)
6	Troponin increased	10 (12)
7	Intensive care	8 (10)
8	Respiratory viral panel	8 (10)
9	Seizure*	8 (10)
10	Blood test	7 (9)

* Upon review, seizure reports include: assessed as syncope (1), febrile seizure (1), history of seizures (2), potential seizure disorder (1); new onset seizure (3)

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Our Analysis

Most frequent adverse events among serious reports to VAERS following COVID-19 injection, children ages 5-11 years (N=317) (as of December 17, 2021)

Rank	Adverse event (not mutually exclusive)	N (%)
1	Fever/Pyrexia	22 (6.9)
2	Vomiting	12 (3.8)
3	Chest pain	33 (10.4)
4	C-reactive protein increased	12 (3.8)
5	Echocradiogram normal	13 (4.1)
6	Troponin increased	2 (0.6)
7	Intensive care	4 (1.3)
8	Respiratory viral panel	1 (0.3)
9	Seizure	14 (4.4)
10	Blood test	18 (5.7)

Apparrent difference

Similarly, for non-serious SAEs:

CDC Analysis

Most frequent adverse events among non-serious reports to VAERS following COVID-19 vaccination, children ages 5–11 years (n=3,152) (as of Dec 10, 2021)

Rank	Adverse event (not mutually exclusive)*	n (%)
1	Incorrect dose administered	581 (18)
2	No adverse event	573 (18)
3	Product preparation issue	386 (12)
4	Vomiting	269 (9)
5	Fever	235 (7)
6	Syncope	219 (7)
7	Dizziness	205 (6)
8	Headache	204 (6)
9	Fatigue	175 (6)
10	Product administered to patient of inappropriate age	165 (5)

* Reported adverse events reflect vaccination errors and symptoms observed during preauthorization clinical trials

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Our Analysis

Most frequent adverse events among non-serious reports to VAERS following COVID-19 injection, children ages 5-11 years (N=3,600) (as of December 17, 2021)

Rank	Adverse event (not mutually exclusive)	N (%)
1	Incorrect dose administered	530 (14.7)
2	No adverse event	727 (20.2)
3	Product preparation issue	296 (8.2)
4	Vomiting	211 (5.9)
5	Fever	187 (5.2)
6	Syncope	196 (5.4)
7	Dizziness	211 (5.9)
8	Headache	205 (5.7)
9	Fatigue	179 (5)
10	Product administered to patient of inappropriate age	1018 (28.2)

Differs by >100
Differs by 25-99

3.1.2. Alarming number of instances of product administered to patients of inappropriate age

Most alarming is the large number of non-serious reports of product administered to a patient of inappropriate age (n=1018) in 5-11 year-olds. Looking more broadly at all ages 0-17, we found 2259 non-serious reports of age-inappropriate dosing[24] for the Pfizer quasi-vaccine.

Additionally, there were five "serious" events associated with age-inappropriate dosing. We found one report (ID 1696757) of a death in an 11 year 8 month old child to whom was administered the Pfizer quasi vaccine on 9/14/21, with no medical history, history of allergy or concomitant medications. There were four other reports of serious events classed as age-inappropriate administration:

- VAERS ID 1912259 A 9 year-old who was hospitalized with vomiting, severe stomach distention, and difficulty in walking, the same (or possibly next day) after q-vaccination. The report states that the child received the pediatric dose, but is classified as: PRODUCT ADMINISTERED TO PATIENT OF INAPPROPRIATE AGE. No history noted.

[23] In an effort to replicate the figures provided in the ACIP meeting, we excluded VAERS IDs that did not show clear administration with a covid-19 product. The original algorithm filters according to VAX_TYPE not VAX_MANU which catches some records with "NA." To err on the side of caution, all records with "NA"s in column vector VAX_MANU were omitted.

[24] https://wonder.cdc.gov/controller/saved/D8/D262F279

- VAERS ID 1349581 - A 15 year old in April 2021 (before use in 12-15 year olds was authorized May 2021). This child developed TTP (thrombotic thrombocytopenic purpura) about 10 days after the first dose. No history noted.
- VAERS ID 1155731 in a 16 year old records a report of stroke 6 days after dosing with prior surgical repair of truncus arteriosus and anticoagulation for >10 years without issue. Although the child is recorded as being 16 years old (appropriate for the EUA of December 2020) the event is classified as PRODUCT ADMINISTERED TO PATIENT OF INAPPROPRIATE AGE.
- VAERS ID 1708721 in a 2.67 year old in September 2021 receiving both the Pfizer and Janssen quasi-vaccines. The nature of the event was not noted other than being classed as Serious and as Congenital Anomaly / Birth Defect.

For Moderna there were 5 serious and 6071 non-serious reports.[25] For Janssen there were 1 serious and 1042 non-serious events[26] after age-inappropriate administration.

Given the possibility of a serious injury, surely all instances of age-inappropriate administration should be classed as serious, regardless of outcome. It is remarkable that given attempts by public health officials to impugn the safety of ivermectin because of adverse events resulting from the inappropriate use of high doses of ivermectin obtained from animal formulations, no efforts have been made to curb the age- inappropriate use of the quasi-vaccines.

3.1.3. Other AE categories not captured in CDC's update.

The range of event types are shown in Table 3.

Table 3: Number of events by event type reported in VAERS for 5-11 year olds for Pfizer (Dec 17)

Event type	Number of events
neurological	631
immunological	896
cardiovascular	881
reproductive	9
death (as CDC)	2
hospitalization	68
emergency room visit	275
life threatening	15
disability	9
birth defect	0

An integrated approach that considers more broadly these events as a collective whole, rather than as separate isolated event types, is surely warranted, given the number and range of event types reported for this (and other) quasi-vaccines.

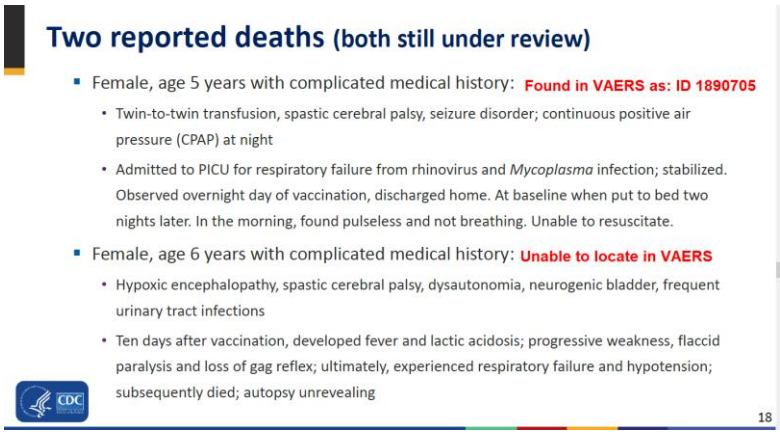
To reflect this approach, we have adopted the terms:

post Covid Vaccine Syndrome a(pCoVS)
post Covid Quasi-Vaccine Syndrome (pCoQS)

3.1.4.Deaths

CDC described two deaths (still under review) (annotated):

[25] https://wonder.cdc.gov/controller/saved/D8/D262F281
[26] https://wonder.cdc.gov/controller/saved/D8/D262F284



We were able to retrieve the record for the first of these as VAERS ID 1890705 (below). We were unable to locate the second of these cases. There was a third death of the 11 years, 8 month child given the Pfizer quasi-vaccine inappropriately (VAERS ID 1696757 described in 3.1.1 above). Although this administration was technically inappropriate, the closeness in age of this child to the age range (>12) for the full-dose (30ug) indication should give cause for concern for the higher dose. for that higher dose.

Details for VAERS ID: 1890705-1

Event Information			
Patient Age	5.00	Sex	Female
State / Territory	Iowa	Date Report Completed	2021-11-22
Date Vaccinated	2021-11-18	Date Report Received	2021-11-22
Date of Onset	2021-11-22	Date Died	2021-11-22
Days to onset	4		
Vaccine Administered By	Private	Vaccine Purchased By	Not Applicable *
Mfr/Imm Project Number	NONE	Report Form Version	2
Recovered	No	Serious	Yes

* VAERS 2.0 Report Form Only
** VAERS-1 Report Form Only
"Not Applicable" will appear when information is not available on this report form version.

Event Categories	
Death	Yes
Life Threatening	No
Permanent Disability	No
Congenital Anomaly / Birth Defect *	No
Hospitalized	No
Days in Hospital	None
Existing Hospitalization Prolonged	No
Emergency Room / Office Visit **	N/A
Emergency Room *	No
Office Visit *	No

* VAERS 2.0 Report Form Only
** VAERS-1 Report Form Only
"N/A" will appear when information is not available on this report form version.

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19 VACCINE	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER\BIONTECH	fk5127	1	IM	RA

Symptom
BLOOD GASES ABNORMAL
BLOOD PH DECREASED
CARBON DIOXIDE INCREASED
DEATH
INTENSIVE CARE
PULSE ABSENT
RESPIRATORY ARREST
RESUSCITATION

Adverse Event Description
Due to patient's complex PMH, provider asked that patient be monitored overnight after administration of COVID vaccine. Patient was moved from PICU to general peds floor due to improvement in condition on Thursday. Vaccine was administered that evening. Patient did well. Remained on room air. Was discharged home on Saturday. On Monday morning, father checked on patient and she was found pulseless and not breathing. It is unclear whether or not patient was placed on home CPAP during the night. EMS called. Patient arrived to ED as a CPR in progress. Patient presented with a pH of <6. Last known well 9pm the evening prior. Patient expired at 11/22/21 at 11:05 CST.

Lab Data	Current Illness	Adverse Events After Prior Vaccinations
Blood gas was done indicating pH<6, high CO2.	Recent admission for rhino/enterovirus, mycoplasma pneumoniae ab+ for acute respiratory failure.	

Medications At Time Of Vaccination	History/Allergies
albuterol nebs, baclofen, vitamin D, flonase, glycopyrrolate, levetiracetam, nystatin topical, phenobarbital, Miralax, azithromycin, PRN tylenol and ibuprofen	PMH of twin to twin transfusion born at erm, neuroimaging showed significant loss of gray-white matter, hydrocephalus s/p VP shunt, spastic CP, seizure disorder. Use CPAP at home at night.,none known

Note: Submitting a report to VAERS does not mean that healthcare personnel or the vaccine caused or contributed to the adverse event (possible side effect).

Top New Report Notes Citation

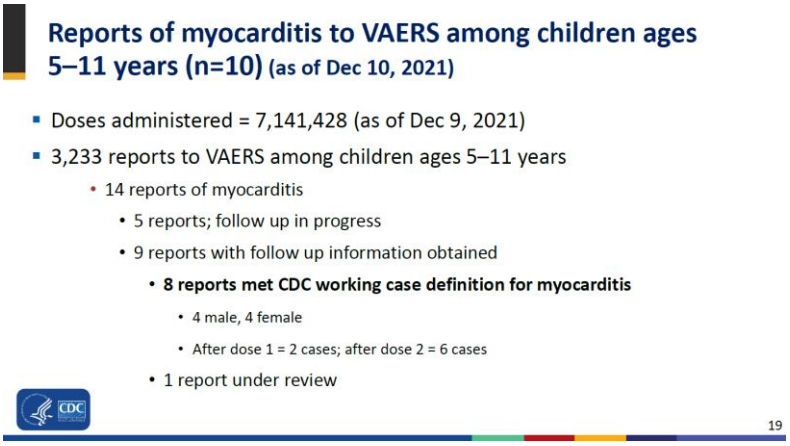
Notes:

Caveats:

Data contains VAERS reports processed as of 12/10/2021. The VAERS data in WONDER are updated weekly, yet the VAERS system receives continuous updates including revisions and new reports for preceding time periods. Duplicate event reports and/or reports determined to be false are removed from VAERS. More information.

3.1.5.Myocarditis in 5-11 year olds

Compared with the 14 reports of myocarditis described by CDC, we found 67, if "chest pain" was included in the search terms, and only 5 if this was omitted.[27] Unable to reconcile the two analyses, let us consider the 14 cases of myocarditis reported in CDC's presentation. Of the 9 where follow up information was obtained, 8 met the CDC working definition of myocarditis. 1 report was under review, and an additional 5 were still in follow-up. It is not unreasonable to consider that all 14 cases met the definition.



In the absence of detail but extrapolating from the 8 cases meeting the CDC definition, we will assume the following:

- Approximately equal male:female mix
- 1:3 ratio of events reported for 1st dose vs. 2nd dose
- That, exercising prudence, all 14 reports meet the case definition.
- We have not adjusted for any under- or delayed reporting.

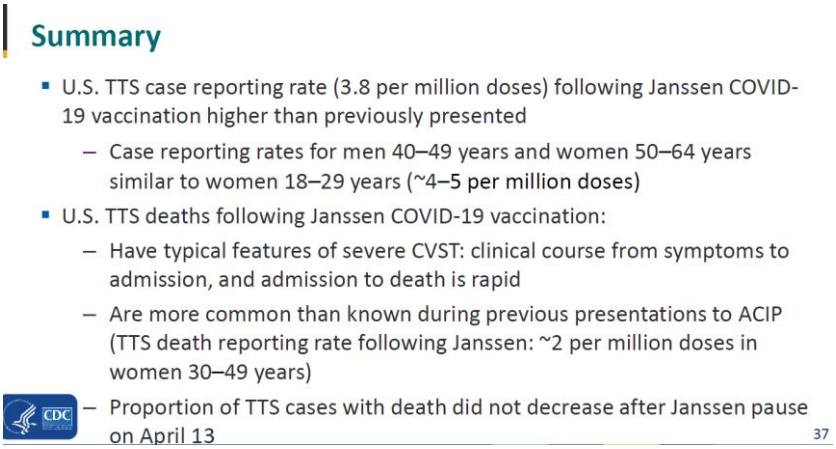
This yielded 3.5 cases after 1st dose and 10.5 cases after second dose. Considering 5.1 million first doses and 2 million second doses, yielded incidence rates of 0.68 events/million first doses and 5.21 events/ million second doses. These figures can be compared with [data provided by CDC's Dr. Matthew Oster] at the October 26th meeting of FDA's VRBPAC[28] in his slides 4 and 5 of which are excerpted below. Mixed gender population rates have been annotated.

Reporting rates (per 1 million doses administered) of myocarditis after Pfizer mRNA COVID-19 quasi-vaccine
From Dr. Matthew Oster, CDC, Oct 26 2021

	Mixed		(Males)		(Females)	
Ages	D1	D2	Dose 1	Dose 2	Dose 1	Dose 2
12-15	2.3	21.9	4.2	39.9	0.4	3.9
16-17	2.85	38.5	5.7	69.1	0.0	7.9
18-24	1.25	19.65	2.3	36.8	0.2	2.5
25-29	0.75	6.0	1.3	10.8	0.2	1.2
30-39	0.55	2.95	0.5	5.2	0.6	0.7
40-49	0.2	1.55	0.3	2.0	0.1	1.1
50-64	0.25	0.4	0.2	0.3	0.3	0.5
65+	0.15	0.2	0.2	0.1	0.1	0.3

Since FDA issued a contraindication for the Janssen quasi-vaccine based on the incidence of TTS at 3.8 cases/MM (below),

[27] We used the Medra terms described by CDC – see slide 17 in www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/07-COVID-Su-508.pdf. It is possible that there have been revisions to these terms.
[28] https://www.fda.gov/media/153514/download

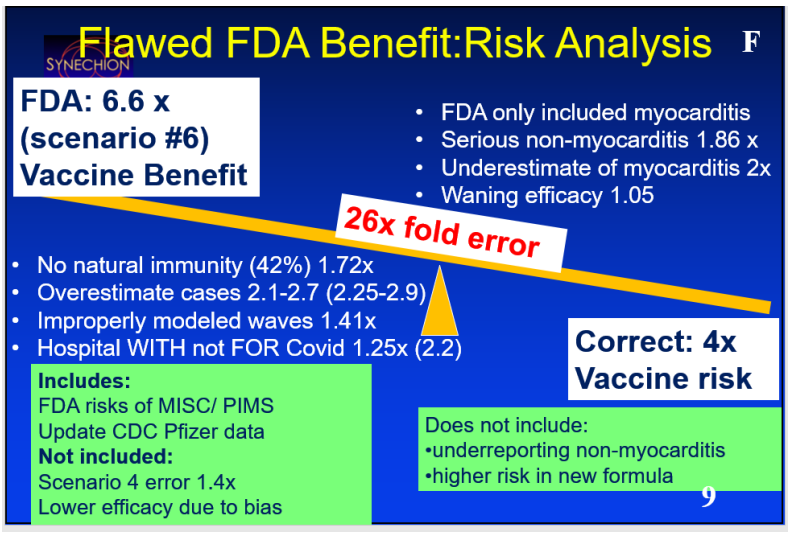


surely the higher rate of myocarditis after a second Pfizer quasi-vaccine of 5.21 cases/ million demands a similar contraindication. Can CDC and FDA guarantee that a serious event would not occur after a prior episode? As discussed above, the wording for a contraindication is proposed:

"Do not administer COMIRNATY, Pfizer-BioNTech or Moderna COVID-19 quasi-vaccines to patients with a history of myocarditis or pericarditis or thrombosis following any other mRNA COVID-19 quasi-vaccines."

3.2. Flawed risk-benefit analysis off by 26 times in the wrong direction:4x risk>benefit

We calculate that FDA's risk-benefit analysis[29] is incorrect by at least 26 times.

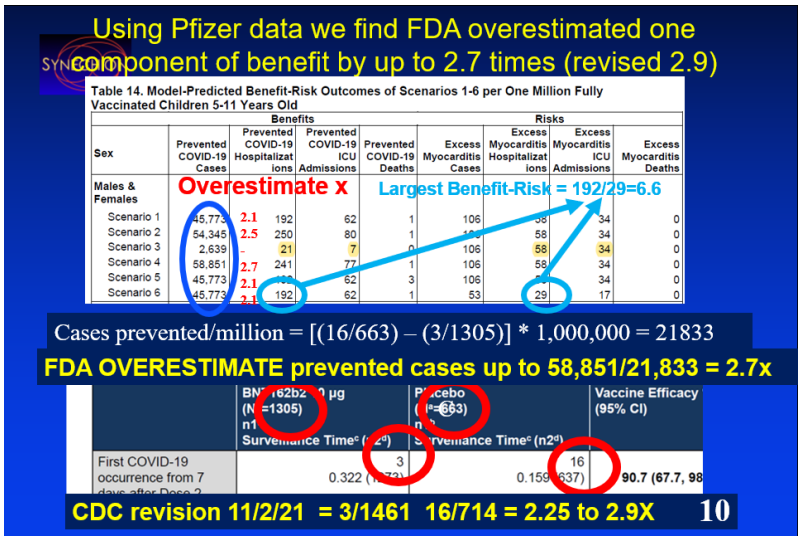


This does not take into account overestimates of initial effectiveness, reduced effectiveness against omicron or other factors listed in the slide.

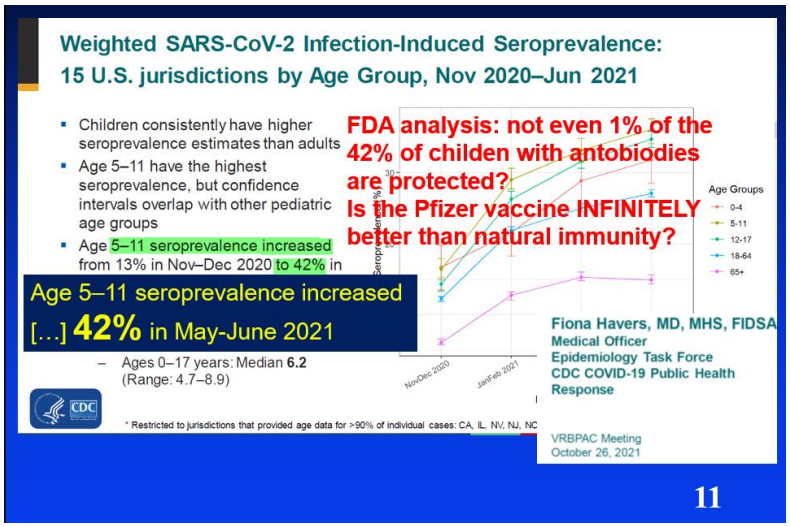
Based on the information provided by CDC on myocarditis in children 5-11 (see 3.1), the risk of myocarditis after first and second doses in children 5-11 based on these limited data appears to be similar to the risks in 25–29-year-olds. This is about a quarter of the figure used in most of FDA's risk benefit analyses (22/million). We do not know if the current figures are subject to the same degree of under-reporting suggested by the -4.8x - analysis). Even though this lowers our estimate of risk over benefit, the balance still disfavors quasi-vaccination, especially when one considers long term risks and reduced effectiveness against the omicron variant.

To illustrate just two other areas of error, the number of cases prevented appears overestimated by FDA by 2.25 to 2.9 times.

[29] https://www.fda.gov/media/153447/download

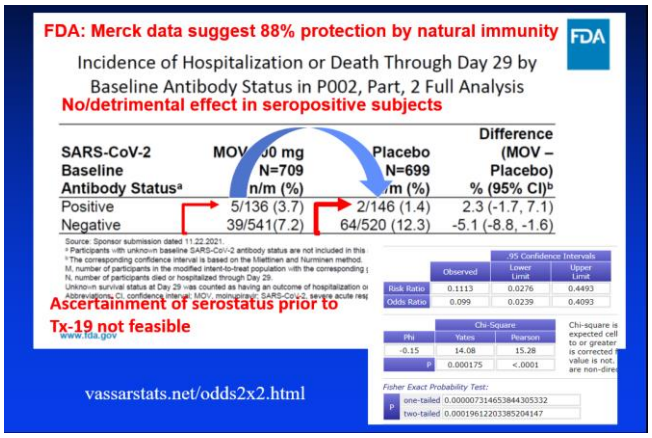


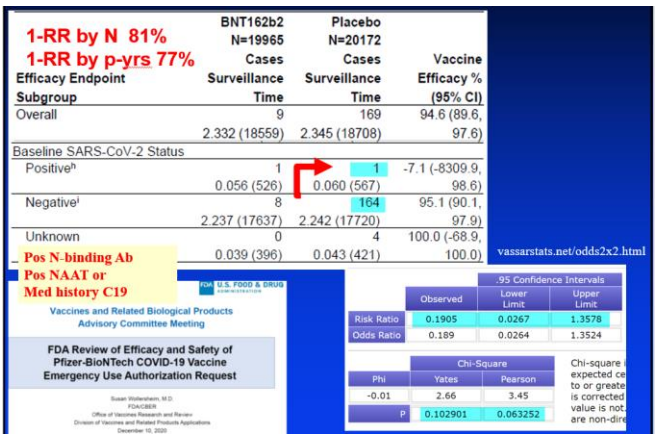
FDA have not allowed for ANY beneficial effect of seroprevalence:



Interestingly, data in Merck's molnupiravir EUA submission suggest an 88% protective effect of seroprevalence in an adult population, as shown in this FDA slide from[30] the recent AMBAC advisory meeting (annotations and statistics added). Similar data can be discerned from FDA's review of Pfizer's EUA[31] submission on December 10, 2020.

[30] https://www.fda.gov/media/154473/download
[31] https://www.fda.gov/media/144337/download





3.3. Changed untested Pfizer formulation for everyone

Pfizer have changed their formulation for both adults and children.[32] This was authorized (16) by FDA based only on analytical comparability. All of Pfizer's clinical studies, including the children's doses, were performed using the old PBS buffer rather than the new tris buffer.

There are two main ways a formulation change could affect safety and efficacy:

- By improving stability (the stated purpose for the change), the effective dose injected may be higher for more people, because less product has been degraded by difficult-to-maintain low temperature conditions. This could worsen the safety profile.
- Adsorption of small quantities of the tris molecule by hydrogen bonding to the ionizable lipids on the surface of the lipid nanoparticles, could affect the distribution of the LNP and cell transfection. No in vivo or in vitro safety or efficacy studies were provided to support this change.

3.4. The Pfizer quasi-vaccine was never intended for use in children 5-11

According to the Australian government's "Nonclinical Evaluation Report: BNT162b2 [mRNA] COVID-19 vaccine (COMIRNATY™" the Pfizer quasi-vaccine was not proposed for pediatric use. Had it been, studies in juvenile animals would have been submitted.(2)

> ***Paediatric use***
>
> BNT162b2 is not proposed for paediatric use and no specific studies in juvenile animals were submitted.

If there is now pediatric use, why are no appropriate animal studies forthcoming?

3.5. Use of Pfizer drug in children 5-11 is akin to using a car seat with poor regulatory oversight

Given the concerns about unverified data, a flawed risk benefit analysis and a changed formulation, using the Pfizer drug in children 5-11 is akin to using a child safety seat whose label states the following:

[32] https://cacmap.fda.gov/media/150386/download

We welcome CDC's comments.

4. What should ACIP be discussing?

Conspicuous by their absence from the agenda[33] were the following items:

4.1. Effectiveness of current quasi-vaccines against omicron to 30-48%?

Some news media report that the efficacy against the omicron variant may be as low as 30-48%.[34] What is CDC's estimate of this? How does this affect CDC's estimates of risk-benefit analysis? The presentation at the meeting was inadequate, as is CDC's current information page.[35] The suggestion of exposing subjects to strongly suspected risks associated with use of booster quasi-vaccination without an understanding of what benefit may accrue, is irresponsible.

4.2. Effect of cumulative dosing on safety

With the prospect of boosting doses every three months,[36] the effect of cumulative dosing on toxicity has not been studied. Dr. Katalin Karikó, one of the founders of BioNTech was quoted as saying:

"I would say that mRNA is better suited for diseases where treatment for short duration is sufficiently curative, so the toxicities caused by delivery materials are less likely to occur"[37]

Other risks (e.g. autoimmune anti-RNA antibodies, toxicity of nucleoside analogs) of cumulative dosing are discussed in a review by BioNtech founders.(15)

"However, mounting evidence suggests that patients with systemic lupus erythematosus and other autoimmune diseases can develop anti-self RNA autoantibodies that have a role in the induction and progression of autoimmunity. Thus, under certain circumstances, such as ***long-term repetitive systemic application of mRNAs, anti-RNA antibodies may potentially form and mediate immune pathology."***

*"In clinical trial design****, the potential toxicity of nucleoside analogues*** *should be addressed diligently by conservative dose-escalation regimens and close assessment of risk organs. Safety monitoring has to consider that adverse effects may only occur after* ***prolonged treatment with nucleoside analogues****."*

4.3. Attempting to boost our way out of new variants – the immunological equivalent of heroin addiction.

Given waning immunity, ever more vaccine resistant virus variants, and an increased, unevaluated risk of cumulative dosing, results in greater risk for reduced benefit. This can be thought of as the immunological equivalent of heroin addiction.

4.4. Deaths per million (37-66) reported for all three quasi-vaccines far exceed the threshold of comfort (1.5/million) set by an ACIP member and by FDA in establishing the TTS-related contraindication

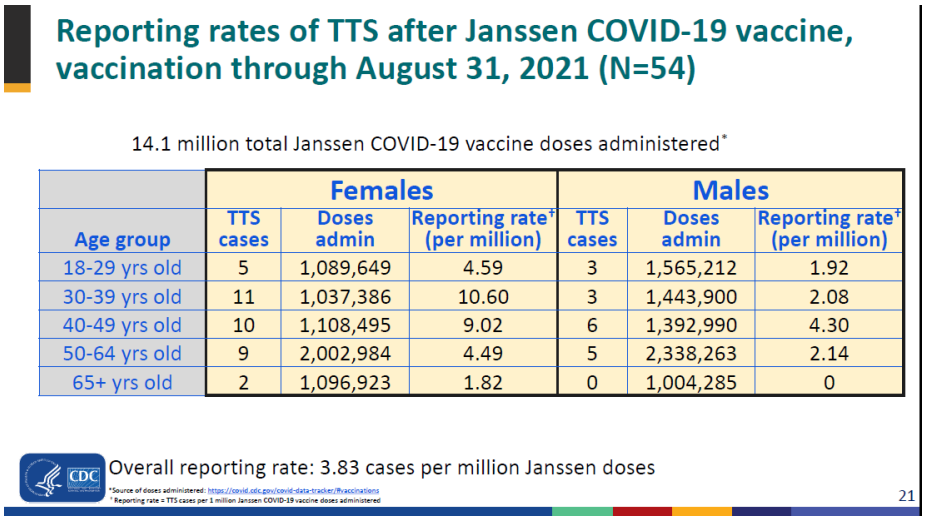
[33] www.cdc.gov/vaccines/acip/meetings/downloads/agenda-archive/agenda-2021-12-16-508.pdf
[34] https://news.yahoo.com/vaccines-appear-weak-blocking-omicron-203342248.html?fr=sycsrp_catchall
[35] https://www.cdc.gov/coronavirus/2019-ncov/variants/omicron-variant.html
[36] https://www.msn.com/en-us/news/world/uk-to-offer-booster-shots-to-all-adults-just-3-months-after-their-second-dose/ar-AARgL5Z
[37] https://www.statnews.com/2016/09/13/moderna-therapeutics-biotech-mrna/

Dr. Pablo Sanchez (Professor of Pediatrics, Ohio State University, Neonatologist, Pediatric Infectious Diseases at Nationwide Children's) voiced his concern with recommending a quasi-vaccine with a fatality rate of 1.5 per million.

In context, the transcript of his remarks at the ACIP meeting[38] reads: (highlighted)

	129:24 *This is a -- it's a very difficult decision making process here. And really, I just -- I just cannot recommend a vaccine that has a -- it's associated with a condition that may lead to death. I think we have other vaccines that, you know, we can't --it's not all about ease. I mean, you know, we can no longer talk* *about just a single dose because like it's been pointed out, it is not a single dose vaccine anymore. And we recommend boosters.* *And, you know, so if we say then that would be preferred only for those who for some reason have contraindications to the messenger RNA vaccines, then I think we should do that. I can see that. But I -- you know, we have other therapies too. I mean, I hate to say this, but you know, there's monoclonals and there's now pills that are being looked at for, you know, for early disease.* ***I just have a real problem with the recommendation for anyone to give a vaccine that in one per 1000 --100,000 women and 30 to 49 years old, will have a condition with a case fatality rate of 15%.*** *And so I really have a problem. I -- I am not recommending it to any of my patients parents. And I tell them to stay away from it. The AstraZeneca [inaudible] vaccine has seen some cases in -- with a second dose. And it may be the same thing, as we -- as --as more of these booster doses for the Janssen product is given. I agree with Dr. Long that if we are going to keep this - this vaccine on a you know, on -- on, you know, if we're going to keep it available, I really think that we should say should be limited to such and such people. And with the knowledge beforehand that it is --that this is a possibility. I just have a lot of problems with this vaccine right now. Thank you.*	

The event rate of 1/100,000 is based on the 10.6 rate per million doses for females 30-39 shown n the presentation of Dr. See.



Reporting rates of TTS after Janssen COVID-19 vaccine, vaccination through August 31, 2021 (N=54)

14.1 million total Janssen COVID-19 vaccine doses administered*

	Females			Males		
Age group	TTS cases	Doses admin	Reporting rate† (per million)	TTS cases	Doses admin	Reporting rate† (per million)
18-29 yrs old	5	1,089,649	4.59	3	1,565,212	1.92
30-39 yrs old	11	1,037,386	10.60	3	1,443,900	2.08
40-49 yrs old	10	1,108,495	9.02	6	1,392,990	4.30
50-64 yrs old	9	2,002,984	4.49	5	2,338,263	2.14
65+ yrs old	2	1,096,923	1.82	0	1,004,285	0

Overall reporting rate: 3.83 cases per million Janssen doses

*Source of doses administered: https://covid.cdc.gov/covid-data-tracker/#vaccinations

†Reporting rate = TTS cases per 1 million Janssen COVID-19 vaccine doses administered

21

We have calculated the number of deaths reported for each of the quasi-vaccines. To permit comparability different products, and whether one, two or three doses had been used, we have expressed results in terms of number of deaths per 100,000 people having at least one dose.

Using figures from CDC[39] (12/22/21) for the number of doses of each type administered, numbers of people fully and booster q-vaccinated, we calculated the number of people having at least one dose of each quasi-vaccine. We then searched VAERS[40] (12/22/21) by Event Category (USA/ Territories/ Unknown) to yield the number of reports of deaths, which were then normalized per 1 million people given at least one dose (**Table 4**).

[38] YouTube-generated transcript with minor edits - https://youtu.be/g1X5IL9vM64?t=7762

[39] https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total

[40] https://wonder.cdc.gov/controller/saved/D8/D262F092

Table 4: Deaths reported to VAERS per million people receiving at least one dose of quasi-vaccine (USA)

	A *	B *	C *	D **	E #	F	G ##
	Doses Given	**N Fully Vaxed**	**N Booster**	**N one dose only**	**N >=1 dose**	**Deaths**	**Deaths /million**
Pfizer	290,516,041	115,159,988	34,071,622	26,124,443	141,284,431	5,215	37
Moderna	190,503,920	73,256,771	28,117,114	15,873,264	89,130,035	4,479	50
Janssen	17,484,508	16,264,948	976,963	242,597 *	16,507,545	1,084	66

* From CDC: https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total

** D= A-C-(2 x B) (for Pfizer and Moderna). D = A-C-B for Janssen. Note that, likely due to reporting errors, this figure should be zero for Janssen. This is a conservative estimate as it increases the denominator.

\# E=B+D

\## G=F *1000,000/E

An EUA *"Provides for a lower level of evidence than the "effectiveness" standard FDA uses for product approvals"*[41] The same must surely be true of the level of evidence needed to demonstrate lack of safety. Accordingly, even though causality cannot be inferred from VAERS, safety signals must be acted upon far sooner, out of an abundance of caution and until proven otherwise we must assume that these deaths are in fact related to the use of the quasi-vaccines. These estimates do not allow for underreporting, which we conservatively estimate at 4.8x (see 2.6).

Even without adjusting for underreporting the estimates of deaths/million of 37) Pfizer, 50 (Moderna) and 66 (Janssen) far exceed the threshold of comfort (1.5 deaths/million) not only set by ACIP's Dr. Sanchez, but also implied by the establishment by FDA of the TTS-related contraindication.

We note that if the deaths reported represented background deaths, deaths would be constant by onset time. They are clearly not, as this search shows:[42]

[41] https://www.fda.gov/media/154532/download

[42] https://wonder.cdc.gov/controller/saved/D8/D262F420

Messages:

- VAERS data in CDC WONDER are updated every Friday. Hence, results for the same query can change from week to week.
- These results are for 3,492 total events.
- Rows with zero Events Reported are hidden. Use Quick Options above to show zero rows.

Vaccine Manufacturer	Event Category	Onset Interval	Events Reported	Percent (of 3,492)
JANSSEN	Death	0 days	49	1.40%
		1 day	68	1.95%
		2 days	36	1.03%
		3 days	33	0.95%
		4 days	20	0.57%
		5 days	15	0.43%
		6 days	23	0.66%
		7 days	22	0.63%
		Total	**266**	**7.62%**
	Total		**266**	**7.62%**
MODERNA	Death	0 days	444	12.71%
		1 day	562	16.09%
		2 days	251	7.19%
		3 days	145	4.15%
		4 days	113	3.24%
		5 days	119	3.41%
		6 days	60	1.72%
		7 days	108	3.09%
		Total	**1,802**	**51.60%**
	Total		**1,802**	**51.60%**
PFIZER\BIONTECH	Death	0 days	394	11.28%
		1 day	431	12.34%
		2 days	211	6.04%
		3 days	144	4.12%
		4 days	147	4.21%
		5 days	107	3.06%
		6 days	89	2.55%
		7 days	78	2.23%
		Total	**1,601**	**45.85%**
	Total		**1,601**	**45.85%**
UNKNOWN MANUFACTURER	Death	0 days	3	0.09%
		1 day	5	0.14%
		2 days	5	0.14%
		3 days	1	0.03%
		4 days	2	0.06%
		5 days	1	0.03%
		7 days	1	0.03%
		Total	**18**	**0.52%**
	Total		**18**	**0.52%**
Total			**3,687**	**105.58%**

Note: Submitting a report to VAERS does not mean that healthcare personnel or the vaccine caused or contributed to the adverse event (possible side effect).

4.5. Correlations between Covid vaccination coverage and all-cause mortality, at various lag times.

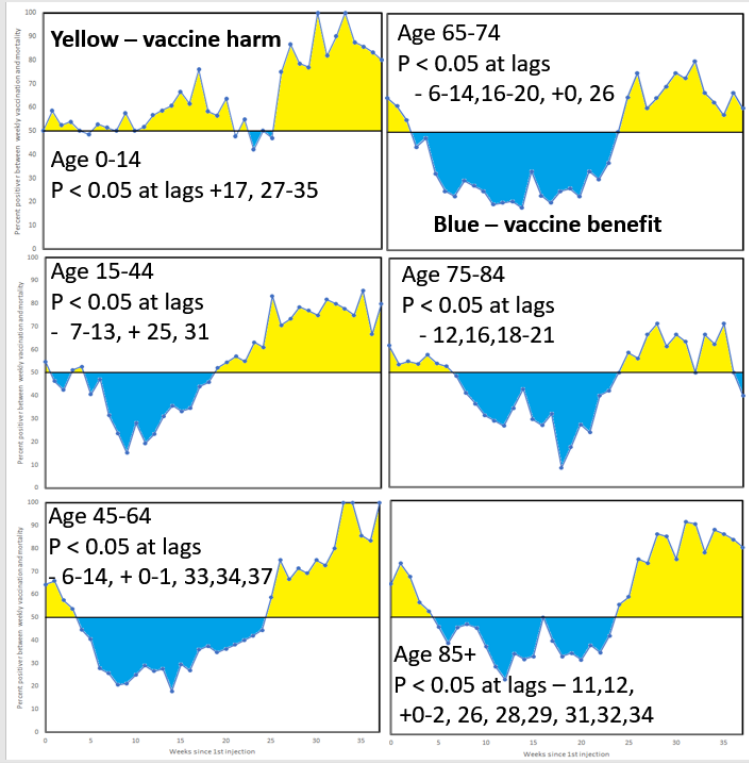
The analysis below conducted by Dr. Hervé Seligmann used data from 23 European countries in Euromomo.eu, plotting a z-score normalized measure of all-cause mortality with the percentage of the population receiving vaccines. Correlations were determined for each week starting January 2021 and for all lag times between week (to week 36) of vaccination and week of death.

A positive correlation suggests a detrimental association between vaccination and death rates, A negative correlation suggests an beneficial association. For each lag time (x axis), the percentage of positive correlations of all correlations possible for each lag time were plotted on the y axis. Regions where this number exceeds 50% (i.e. more positive correlations than negative), suggesting an overall detriment, were colored yellow. Regions where this number is less than 50% (i.e. more negative correlations than positive), suggesting an overall benefit, were colored blue. Data were stratified by age group for deaths, correlating against all-population vaccination.

All- cause deaths appear to correlate with % vaccination in a definite pattern. After an initial detrimental phase of about 4 weeks, there followed a beneficial phase of about 20 weeks. This was then followed by a detrimental phase. This was true for all adult sub-groups. Noteworthy is the suggestion of almost pervasive detriment of adult vaccination on children under 14, most of whom were not vaccinated when this analysis was conducted.

This analysis is consistent with that of CDC's estimate of all-cause mortality benefit over a period of about 7-8 months (17) which masks the initial short detrimental period and does not enter the later detrimental period. Further work is continuing

using this methodology.(18) Other analyses(19) from the UK, although hampered by poor and inconsistent data, also suggest a detriment of vaccination on all-cause mortality at least in some age bands.



Ages	%+	P<0.05 -	P<0.05+	Adv1	Adv2
0-14	59.3*	14	46*	20	26
15-44	46.5*	25*	25*	4	19
45-64	44.3*	35*	31*	3	25
65-74	39.8*	30*	17	2	24
75-84	44.6*	22	4	6	24
85+	50.9	21	15	4	24

All cause mortality is correlated with % vaccination.
From 0-~6 weeks after d1 – deaths INCREASE
From 4-6 to about 25 weeks, deaths DECREASE
> ~25 weeks, deaths INCREASE

For all age groups, except in children 0-14 (mostly unvaxed), DEATHS almost always increase.

X axis – lag time from 1st dose
Y axis – % positive weekly correlations

Data from 23 European countries via Euromomo
Dr. Herve Seligmann

5. Oral remarks provided by Dr. David Wiseman to the Dec 16 ACIP meeting (added in revision)
Available at https://youtu.be/GqWvBm2fwX8?t=11209 and https://youtu.be/SHCjUCYl6JM?t=808

"The concluding comments at the last meeting advocated for transparency and expression of diverse views. I wrote a letter to you then, and await the pleasure of your reply. I have submitted additional comments.

Given the circumstances of this meeting, concerns about opacity are deepened. Having only now seen the presentations, in particular Dr. Oliver's which was only posted around the time she began, I am simply shocked.

I am not a fan of any of the Covid vaccines, but my old employer and sometime client I believe is the vehicle here of regulatory misdirection.
You are simply asking the wrong questions.

Our own analyses suggest a limited window of all-cause mortality benefit outside of which at both ends, there appear to be significant detriments.

*Although TTS is important, there are unexplained safety signals for **all vaccines** far stronger, including dyscoagulation, death and myocardial infarction. We submitted this weeks ago our analyses to FDA and CDC.*

According to the founder of BioNTech, the DNA-based vaccines may carry a risk of insertional mutagenesis.

Also critical is that some key Pfizer and Jansen analyses have not been verified by FDA (ditto for molnupiravir). How can you make any decisions at all?

In addition to re-evaluating the use of ALL vaccines, you must consider

- *Estimates of VE reduction against omicron to 30-48%?*
- *Toxicity of cumulative dosing*

- *Reduced benefit for greater risk: Attempting to boost our way out of new variants is the immunological equivalent of heroin addiction.*
- *What is the sub-clinical risk of TTS or other dyscoagulation*
- *These drugs are not classical vaccines, but gene therapy drugs.*
- *that CDC is not accurately representing the nature of these vaccines, depriving Americans of fully informed consent?*

Children: additional concerns

- *Unverified data and FDA's risk- benefit flawed by 26 times in wrong direction: At least 4x risk > benefit.*
- *Changed Pfizer formulation (for everyone) differs from that used in trials.*
    - *Improved stability may increase effective dose, worsening safety profile*
    - *The change may distribution, thereby affecting safety and efficacy.*
- *Use of Pfizer drug in children is akin to using a car seat with poor regulatory oversight.*

The eyes of the world are on you. Your decisions being mirrored in other countries. Millions, are subject to mandates and other harsh measures including imprisonment and loss of employment. The opacity here deepens mistrust within America and reverberates globally. Would ACIP want to be responsible for long term detriments as well as unjust imprisonment, based on reliance of flawed data?

In the spirit of transparency and diverse views, I am happy to take questions."

6. Lack of ACIP transparency and adequate discussion of diverse opinions

No email notification, inability to submit written comments to a docket number, no Federal Register notice do not contribute to transparency or the airing of divergent views.

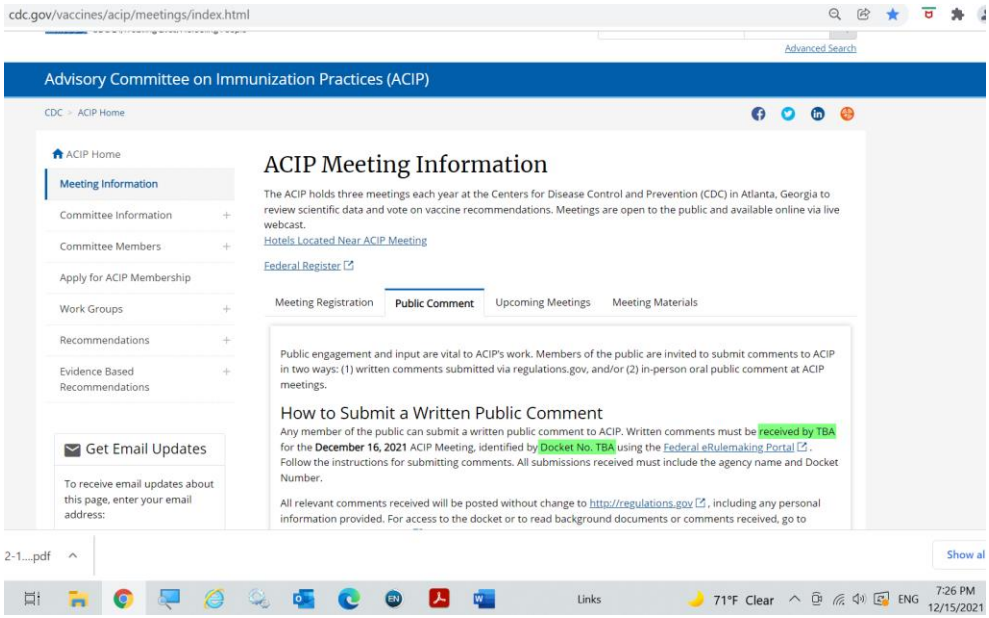
1. Meeting, docket and agenda details must be posted much sooner along with slide presentations.
2. To effectively provide for the sharing of diverse opinions, ACIP must invite qualified doctors and scientists to make substantive presentations with full committee discussion, rather than as a paltry 3-minute statement selected by lottery.
3. To effectively provide for the sharing of diverse opinions ACIP would invite qualified individuals with diverse pinions to become voting committee members.

6.1. Inadequate and incomplete notification of meeting details

6.1.1.Meeting notification does not provide docket number for written comment submission

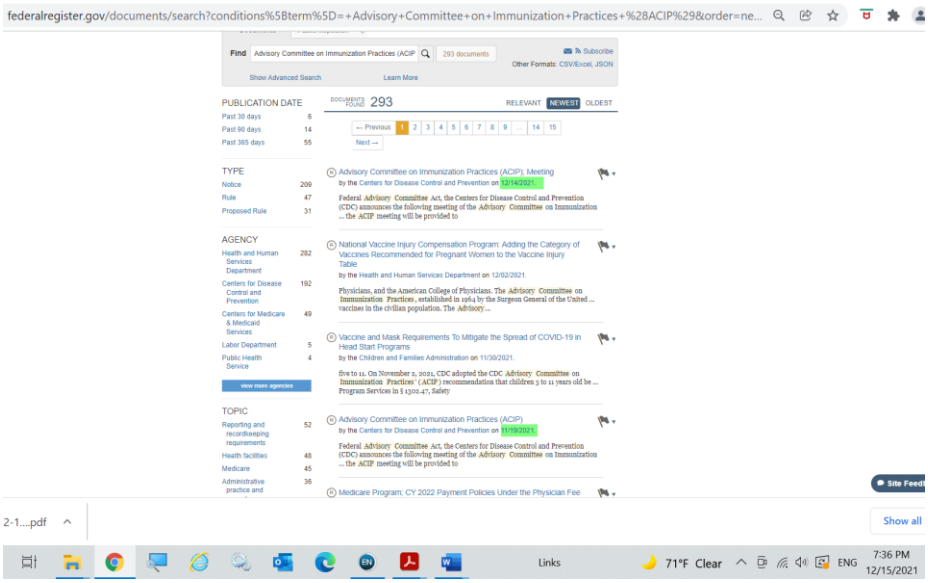
The meeting notification posted at: www.cdc.gov/vaccines/acip/meetings/index.html as of 7.26pm CST 12/15/21 (no change 12/23/21) contained insufficient information to permit submission of a written comment, with a deadline and docket number noted as "TBA." (only at the start of the meeting was this provided in a presentation slide, not on the web site).

Any member of the public can submit a written public comment to ACIP. Written comments must be received by TBA for the December 16, 2021 ACIP Meeting, identified by Docket No. TBA using the Federal eRulemaking Portalexternal icon. Follow the instructions for submitting comments. All submissions received must include the agency name and Docket Number.

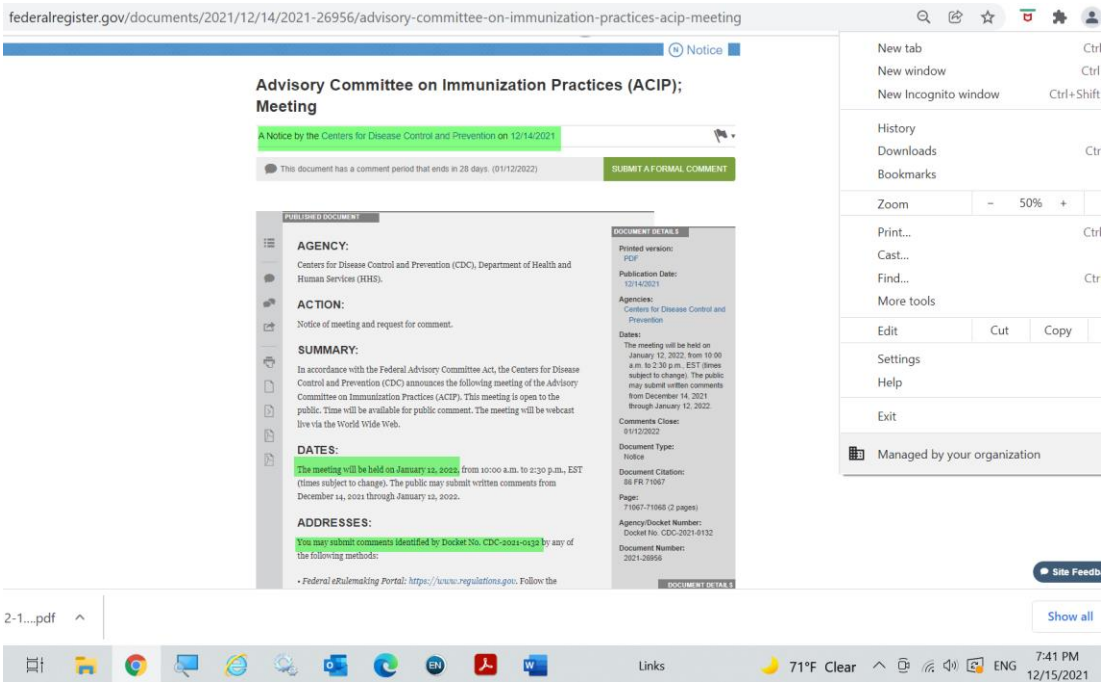


6.1.2.Federal Register does not contain an announcement about the December 16 meeting

Prior to the meeting, a link was provided on the ACIP page to the Federal Register: https://www.federalregister.gov/, Using that link and searching for: "Advisory Committee on Immunization Practices (ACIP)" with the "Newest" filter, yielded announcements for a meeting on January 12th 2022 as well as the recent meeting of November 19th 2021.



Here are the details for the Jan 12th meeting. Note that a docket number had been assigned for that meeting but not the meeting of December 16th.



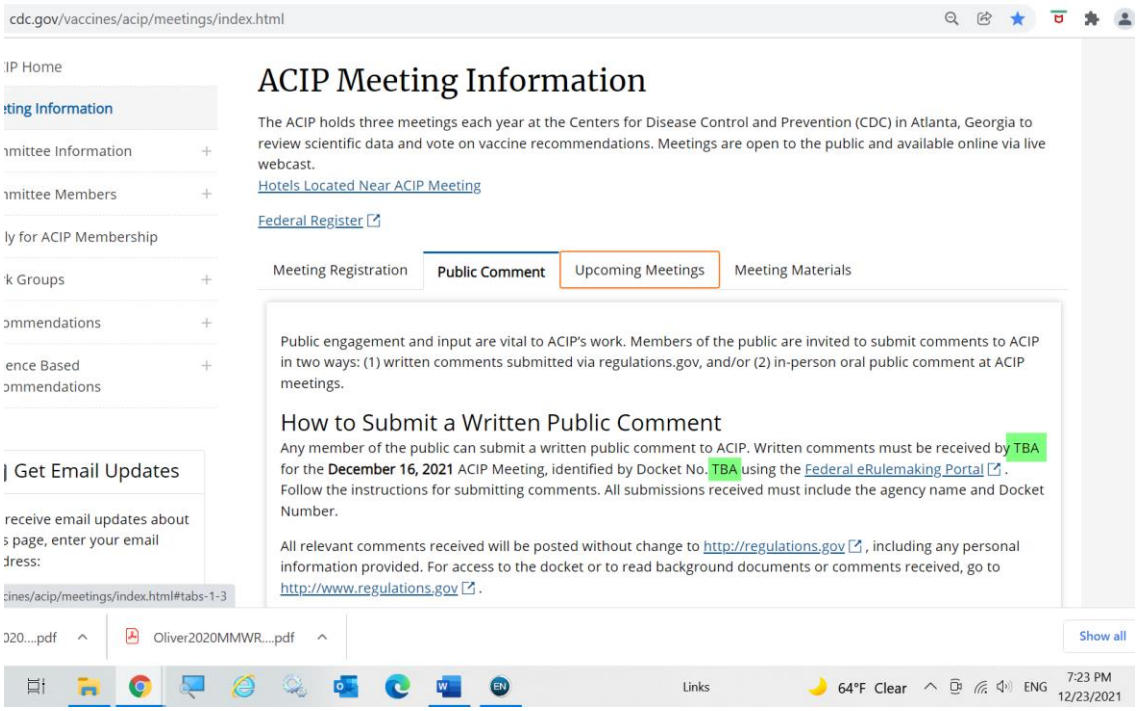
6.1.3.Revised instructions for submission to docket (REV)

At the start of the meeting one of the CDC presenters provided docket number CDC-2021-0133 on one of the slides. An attempt was made to upload to that docket number, but it had not been initiated in the regulations.gov system. Writing to ACIP elicited this reply.

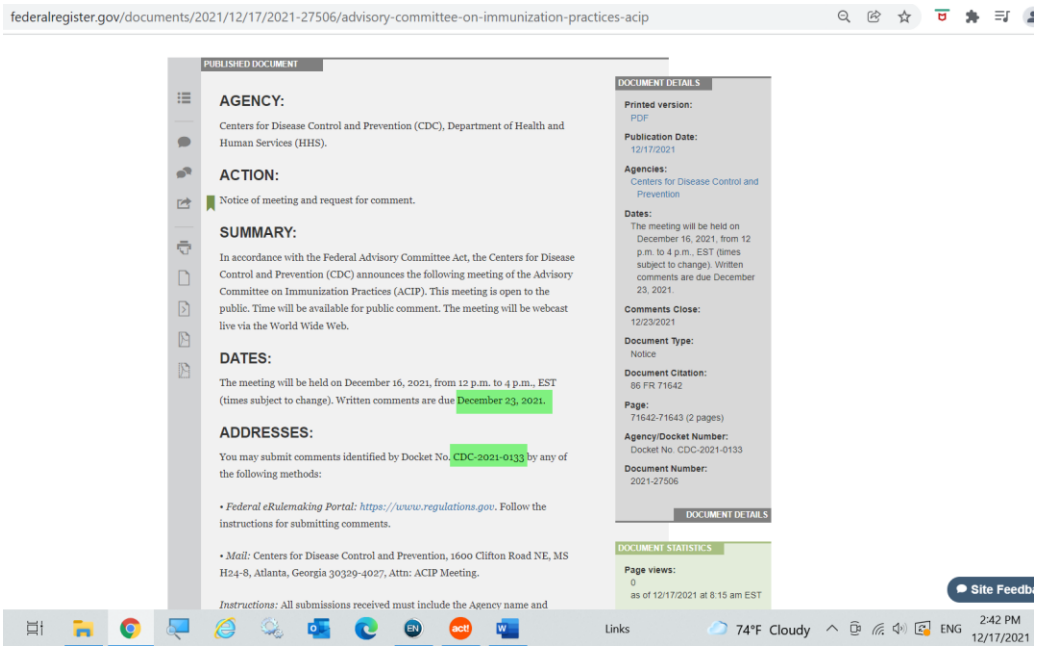
> **Advisory Committee on Immunization Practices (CDC)** (acip@cdc.gov)To:you + 1 more Thu, Dec 16, 2021 12:04 pm
> Hello,
> The docket will open once the FRN has published, it is scheduled to publish on December 17, 2021. Please submit all written comments to www.regulations.gov
> Thank you,
> ACIP Secretariat
>
> **From:** David Wiseman <synechion@aol.com>
> **Sent:** Thursday, December 16, 2021 12:38 PM
> **To:** Advisory Committee on Immunization Practices (CDC) <acip@cdc.gov>; gmlee@stanford.edu
> **Subject:** Re: ACIP Oral Comments TODAY, DEC 16th: unable to upload comments
>
> Dear Dr. Lee and ACIP
> The docket number was only provided in a slide at the start of the meeting as CDC-2021-0133 (please confirm this is correct), However regulations.gov does not show this, nor does a search there yields this meeting.
> I am therefore submitting my comments by email. Summary below - see also attached.
> Thank you.
> David Wiseman PhD, MRPharmS

As of 12/23/21 the docket number had still not been provided on the ACIP web site:[43]

[43] https://www.cdc.gov/vaccines/acip/meetings/index.html



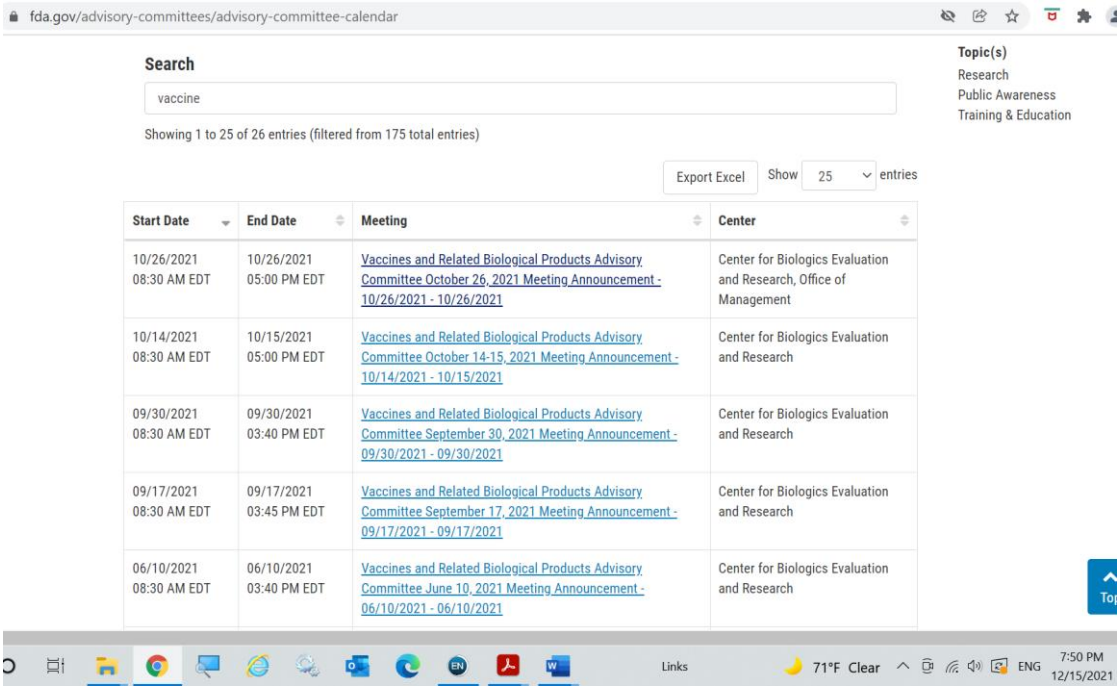
The Federal Register did contain this information.



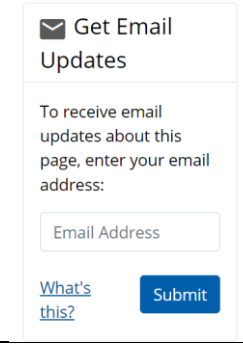
6.1.4. There appears to be no parallel FDA VRBPAC meeting scheduled

A search of the FDA advisory committee meeting schedule failed to yield a listing of a parallel FDA VRBPAC meeting. Noted is the announcement[44] by FDA on December 14th regarding the contraindication for use of the Janssen COVID-19 Vaccine in those with a history of thrombosis with thrombocytopenia following the Janssen COVID-19 Vaccine or any other adenovirus-vectored COVID-19 vaccine.

[44] www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-december-14-2021



6.2. Confirmation of subscription to ACIP notifications



An active subscription to the ACIP notices, including announcements about meetings, was confirmed, with the message "your email address is already in use"

The most frequent schedule is only quarterly. This must be addressed.

DW is subscribed to receive ACIP email alerts and did not receive any and asks once again for your personal assurance of not being on a blacklist.

6.3. Text of original cover letter sent 12/16/21

"Dear ACIP Chairperson Dr. Lee,

I am sending this email to your email address as well as to acip@cdc.gov. I refer to my previous letter to you of November 19, submitted to the docket (once a number had been assigned) and published as an open letter on Trial Site News.(1) I remain in anticipation of the pleasure of your reply.

Transparency Concerns

Before I address the content of the meeting, I extend my earlier remarks concerning your concluding comments at the Nov 19 meeting which stressed the importance for ACIP proceedings to be transparent and to allow for diverse views to be expressed. Given the circumstances of how the current (Dec 16) meeting has been announced, my concerns about opacity are only deepened.

The eyes of the world are on CDC and FDA. Based on your decisions being mirrored in other countries, millions of Americans and people around the world, especially in Austria and Australia are being subject to mandates and other harsh measures that could include imprisonment and loss of employment. The lack of transparency displayed by ACIP, not only deepens mistrust within the American public, but will reverberate around the world. Would you or the ACIP committee members want to be responsible for the unjust imprisonment of a person, based on reliance of flawed data?

Benefit/risk assessment for Janssen COVID-19 vaccines,: key points and questions

- FDA's announcement of a contraindication for use in those with a history of Thrombosis with Thrombocytopenia Syndrome (TTS) fails to guide on how to avoid TTS in the first place.
- CDC must estimate sub-clinical risk of TTS, other coagulopathies, and these risks with mRNA products.
- CDC must issue guidelines on diagnostic tests and treatment of TTS and other vaccine-relateds.

- The contraindication does not consider risks of ALL coagulation events for all mix-and-match combinations?
- Why has it taken FDA this long to act on safety signals we provided at least 8 weeks ago?
- Now that FDA has enabled estimation of VAERS underreporting, can CDC estimate this for TTS?
- How can CDC/ACIP make any recommendations on data FDA has failed to verify? (Janssen booster, Pfizer children, molnupiravir safety)
- Why is FDA not consulting with VRBPAC on these issues?
- Does ACIP understand that these products are not classical vaccines, but gene therapy drugs?
- Does ACIP understand that according to the founder of BioNTech, the DNA-based vaccines may carry a risk of insertional mutagenesis?
- Is ACIP unconcerned that CDC is not accurately representing the nature of these vaccines to the American people, depriving them of fully informed consent?

COVID-19 vaccine safety surveillance in children 5-11 years of age: key concerns

- Pfizer's childrens' study efficacy data unverified by FDA
- Gene therapy product with unevaluated long-term risks
- FDA's risk- benefit flawed by 26 times in wrong direction: At least 4x risk > benefit: including:
    - Overestimate of cases prevented based on Pfizer's data by 2.25-2.9x
    - No accounting for seroprevalence benefit (88% according to Merck data)
- Changed Pfizer formulation (for adults and children) differs from that used in trials.
    - Improved stability may increase effective dosing, worsening safety profile
    - Change in surface properties of LNP may alter injection site uptake and distribution, thereby affecting safety and efficacy.
- Use of Pfizer drug in children 5-11 is akin to using a car seat with poor regulatory oversight.

ACIP should be discussing

- Possible reduction of effectiveness against omicron below to 30-48%?
- The effect of cumulative dosing on toxicity
- Reduced benefit for greater risk: Attempting to boost our way out of new variants is the immunological equvalent of heroin addiction.

A detailed discussion is given below and attached.
Respectfully
David Wiseman PhD, MRPharmS"

6.4. References

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https://downloads.regulations.gov/CDC-2021-0125-0003/attachment_1.pdf

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9. Wiseman D, Guetzkow, J,, Seligmann H. Booster Doses for Moderna and Janssen Vaccines. Written comments submitted to: Advisory Committee on Immunization Practices (ACIP), October 20-21, 2021 Meeting and Vaccines and Related Biological Products Advisory Committee (VRBPAC), October 26, 2021,. 2021 October 20. at https://www.regulations.gov/comment/CDC-2021-0098-0071

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