ACIP May 19 2022. Data again withheld on safety and waning efficacy in consideration of 5-11 year boosting.

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(corrected for typos)
CDC-2022-0065

CDC convened this meeting of ACIP following the EUA amendment by FDA[1] on May 17 2022 expanding the eligibility for the Pfizer-BioNTech COVID-19 vaccine booster dose to children ages 5-11 years at least five months after completion of a primary series. Responding to the policy question posed by CDC, and "based on the balance of benefits and risks," ACIP voted in favor of the following Interim Recommendation:

"A single Pfizer-BioNTech COVID-19 vaccine booter dose is recommended for persons ages 5-11 years at least 5 months after the primary series, under the FDA's Emergency Use Authorization.
FDA's decision was based on data generated in a subset of children participating in the same clinical trial (C4591007) that supported the original EUA for a primary series in this age group in October 2021.

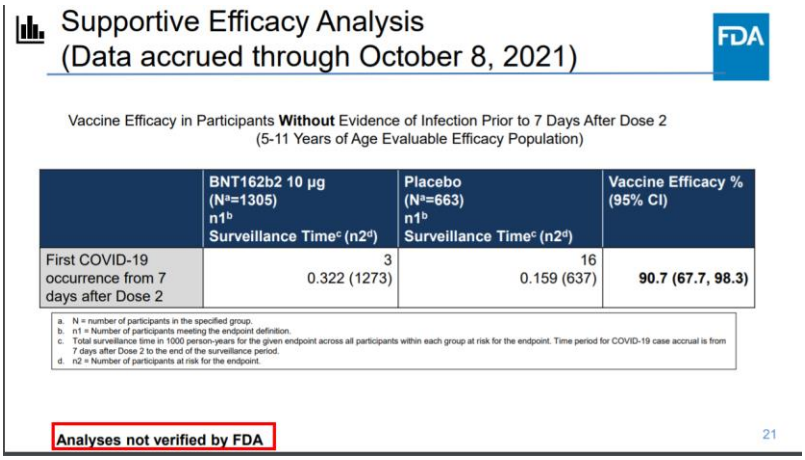
For the evaluation of safety 401 children were followed for 1 month after a booster (3rd) dose was given at least five months (range 5 to 9 months) after completing a two-dose primary series. The sponsor reported that this analysis did not raise any new safety concerns. No cases of anaphylaxis, myocarditis/pericarditis, Bell's palsy (or facial paralysis/paresis) or appendicitis were observed.

For effectiveness, antibody responses (immunogenicity) were evaluated in 67 study participants who received a booster dose 7 to 9 months after completing the primary series. The change in neutralizing antibody against the wild type Wuhan strain levels from before dosing to one month after dosing for the third dose was compared with the change occurring before the first dose and one month after the second dose of the primary series. Another 30 subjects contributed to another assay against the B.1.1.529 (Omicron) strain.

We note the following:

- As we have noted before,(1) key data was not shown to ACIP to provide a full picture of the risks and benefits.
- Pfizer's safety evaluation relied on a small number of children (401) followed for only a short time (1 month). The original primary series evaluation involved approximately 4600 subjects followed for up to 3.3 months.
- Effectiveness was judged based on immunobinding data. FDA and CDC officials in numerous public meetings since September 2021 have stated without equivocation that there is no immune correlate of protection.
- Immunogenicity was established using an assay (stated to be validated) involving the Wuhan strain in only 67 subjects. This activity is largely irrelevant given the most recent Omicron variant. The assessment of antibody response against Omicron was performed in only 30 subjects, in an assay who validation status was not disclosed.
- Given FDA's admitted failure to validate key data for the primary series, as well as for the Janssen booster dose, the decision for FDA to issue this amendment without a public VRBPAC meeting is concerning.
  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:[2] (highlight added). Even data errors in a small number of subjects, could lead to large interpretative errors.

[1] www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-expands-eligibility-pfizer-biontech-covid-19-vaccine-booster-dose
[2] https://www.fda.gov/media/153510/download



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

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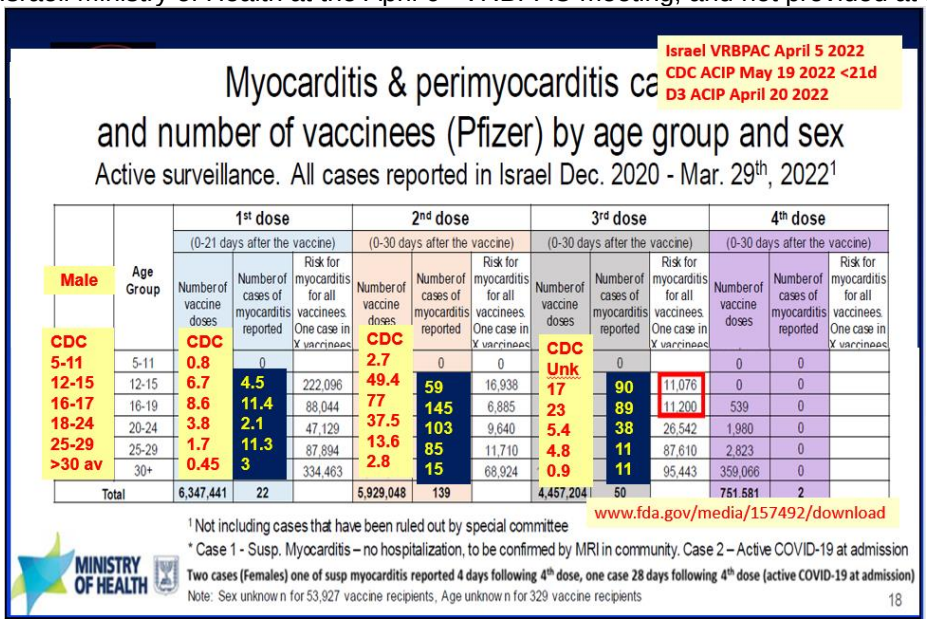
- No clinical efficacy data were provided.
- CDC showed its own data[3] (2) describing the waning of a primary series response in various pediatric (<18) populations to ineffective levels well before the 5 month period set for the booster interval by this EUA amendment. In this data set, VE become negative at around 7 months. Other data presented by CDC also showed waning VE, but these studies were ether small, or had too short a follow up period. Other data from Denmark (3) and New York (children 5-11) (4) not shown to ACIP describing earlier negative VE against Omicron were not shown to ACIP.
- CDC suggested that evidence of protection in older populations by boosters against on severe outcomes, would be replicated in children. However, data presented by the Israeli Ministry of Health at the April 6th VRBPAC meeting showing that even this effect wanes,(5) were not provided to the committee.
- CDC were asked directly by ACIP member Dr. Long about the rates of myocarditis following boosters in older children. CDC stated that the magnitude of risk is substantially lower than after the second dose. Data were referred to descriptively but not provided. CDC published a myocarditis rate of 11.4/million in 12-17 year old males(6), lower than rates of 17.2/million (12-15 years) and 23.2/million (16-17 years) presented at the ACIP meeting of April 20th 2022.(5) These rates are far lower than the alarmingly high rates of about 90/million for each of these two groups presented by the Israeli Ministry of Health at the April 6th VRBPAC meeting, and not provided at all to ACIP.



Israel VRBPAC April 5 2022
CDC ACIP May 19 2022 <21d
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Myocarditis & perimyocarditis ca
and number of vaccinees (Pfizer) by age group and sex
Active surveillance. All cases reported in Israel Dec. 2020 - Mar. 29th, 2022[1]

Male	Age Group	1st dose (0-21 days after the vaccine)			2nd dose (0-30 days after the vaccine)			3rd dose (0-30 days after the vaccine)			4th dose (0-30 days after the vaccine)		
		Number of vaccine doses	Number of cases of myocarditis reported	Risk for myocarditis for all vaccinees. One case in X vaccinees	Number of vaccine doses	Number of cases of myocarditis reported	Risk for myocarditis for all vaccinees. One case in X vaccinees	Number of vaccine doses	Number of cases of myocarditis reported	Risk for myocarditis for all vaccinees. One case in X vaccinees	Number of vaccine doses	Number of cases of myocarditis reported	Risk for myocarditis for all vaccinees. One case in X vaccinees
CDC		CDC			CDC			CDC					
5-11	5-11	0.8	0		2.7	0	0	Unk	0		0	0	
12-15	12-15	6.7	4.5	222,096	49.4	59	16,938	17	90	11,076	0	0	
16-19	16-19	8.6	11.4	88,044	77	145	6,885	23	89	11,200	539	0	
18-24	20-24	3.8	2.1	47,129	37.5	103	9,640	5.4	38	26,542	1,980	0	
25-29	25-29	1.7	11.3	87,894	13.6	85	11,710	4.8	11	87,610	2,823	0	
>30 av	30+	0.45	3	334,463	2.8	15	68,924	0.9	11	95,443	359,066	0	
Total		6,347,441	22		5,929,048	139		4,457,204	50		751,581	2	

www.fda.gov/media/157492/download

[1] Not including cases that have been ruled out by special committee
* Case 1 - Susp. Myocarditis – no hospitalization, to be confirmed by MRI in community. Case 2 – Active COVID-19 at admission
Two cases (Females) one of susp myocarditis reported 4 days following 4th dose, one case 28 days following 4th dose (active COVID-19 at admission)
Note: Sex unknown for 53,927 vaccine recipients, Age unknown for 329 vaccine recipients

MINISTRY OF HEALTH

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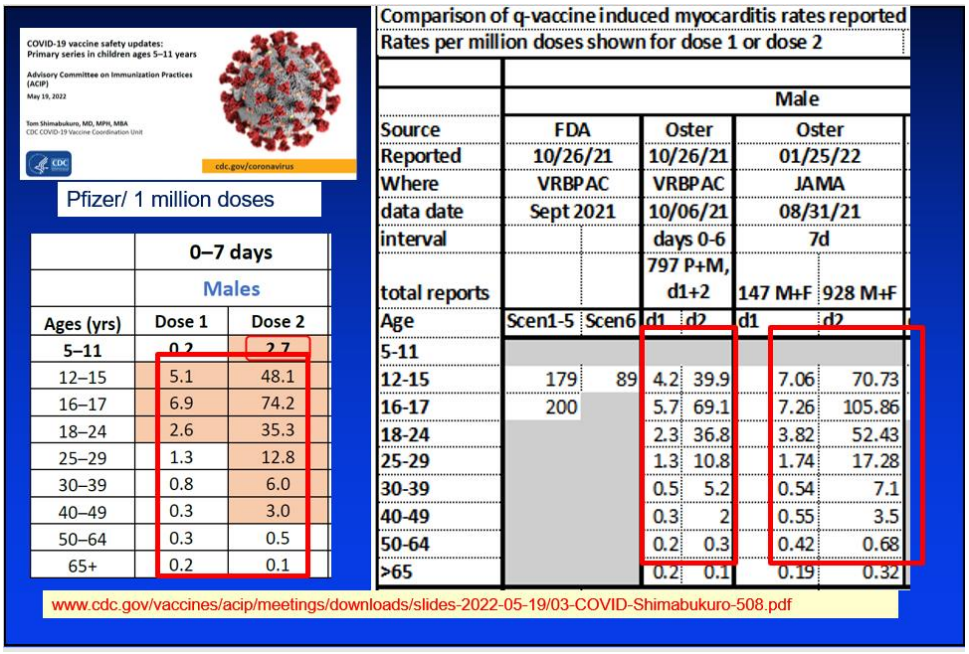
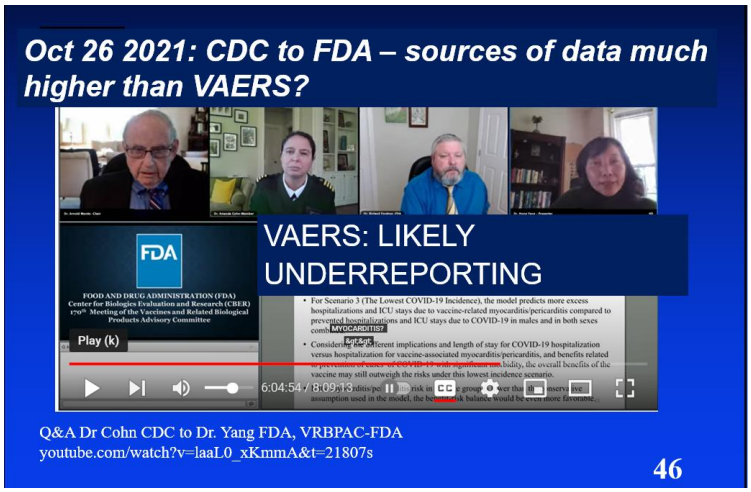
- CDC continue to provide divergent versions of their data. For the primary series, the rates above are similar to those previously described by CDC at the October 26th 2021 VRBPAC meeting and the ACIP meeting of January 5th. They are however lower than the rates published by CDC staff in JAMA (7) shown below.

[3] www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-05-19/02-COVID-Link-Gelles-508.pdf



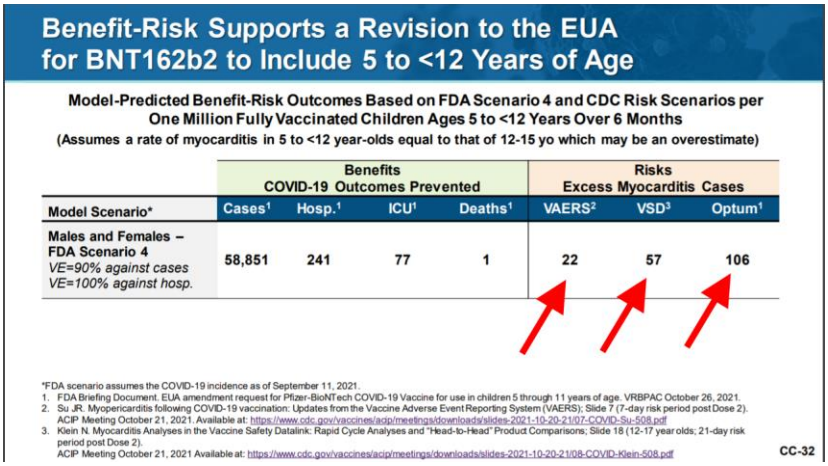
- CDC continues to ignore under- and mis-reporting in VAERS to support its Risk-Benefit estimates. FDA, including in a recent paper,(8) have specifically acknowledged the underreporting by VAERS, on which these CDC numbers are primarily based. FDA prefer the Optum database. We have detailed this issue previously.(1) This is also documented in the video record of the October 26 VRBPAC meeting youtu.be/laaL0_xKmmA?t=21807



(Annotated screenshot from October 26 VRBPAC meeting. Exchange between CDC's Dr. Cohn and FDA's Dr. Yang).

and in this Pfizer slide [4] revealing at least a 4.8x VAERS underreporting for myocarditis?

[4] fda.gov/media/153513/download



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

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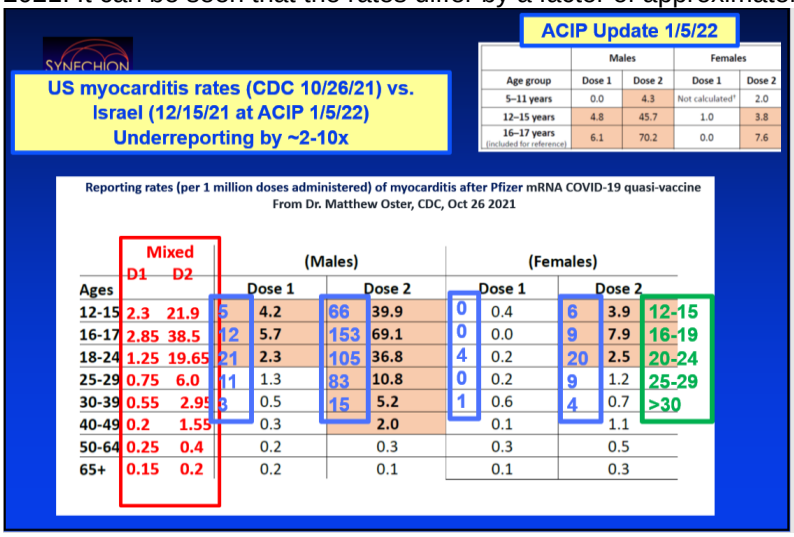
Slide 32 from Pfizer's Dr. Gruber (arrows added)

To estimate VAERS underreporting for Covid-19 vaccines, we used a method published (9) by CDC scientists, reporting this to FDA in September 2021.(10) The numbers of deaths tentatively associated with the Pfizer vaccine may be 4.9-15 times higher than reported. The number of life-threatening events may be 24-64 times higher than reported. An additional source for an estimate of VAERS underreporting for Covid-19 quasi vaccines is another paper from CDC (11) which compared VAERS reports with another database maintained by CDC called vsafe.[5] This is a voluntary tracking system that functions through a smart phone app. CDC reported that only around 40,000 children (5-11) had been enrolled in vsafe, despite around 6 million children being vaccinated. In this highly motivated population and despite CDC encouragement, only 2 of 13 vsafe participants reported their children's hospitalizations to VAERS, yielding a conservative 6.5 fold underreporting factor.

Also consistent with these estimates are estimates we have made using data presented at the January 5th CDC-ACIP meeting from the Israeli Ministry of Health,[6] who, unlike CDC, were actively monitoring for cases of myocarditis. The slide below compares Israel's myocarditis rates (blue annotations) with CDC estimates made from VAERS in October 2021. It can be seen that the rates differ by a factor of approximately 2-10.



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US myocarditis rates (CDC 10/26/21) vs. Israel (12/15/21 at ACIP 1/5/22) Underreporting by ~2-10x

ACIP Update 1/5/22

	Males		Females	
Age group	Dose 1	Dose 2	Dose 1	Dose 2
5–11 years	0.0	4.3	Not calculated[†]	2.0
12–15 years	4.8	45.7	1.0	3.8
16–17 years (included for reference)	6.1	70.2	0.0	7.6

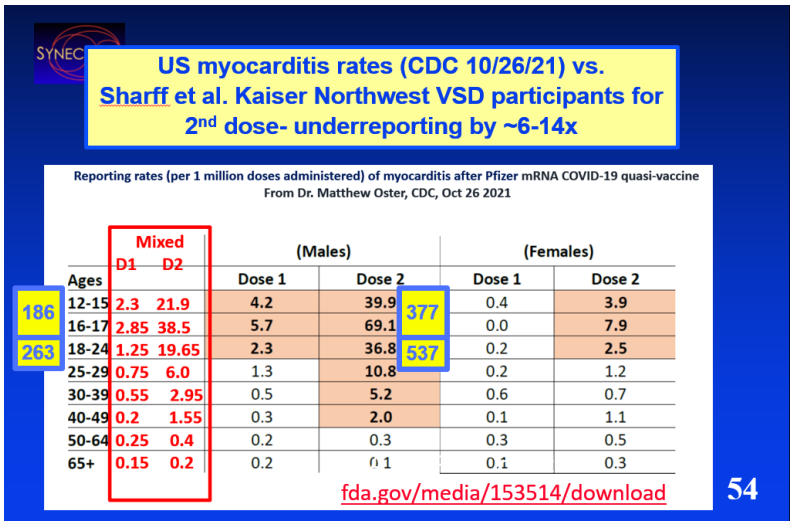
Reporting rates (per 1 million doses administered) of myocarditis after Pfizer mRNA COVID-19 quasi-vaccine From Dr. Matthew Oster, CDC, Oct 26 2021

Ages	Mixed D1	Mixed D2		(Males) Dose 1		(Males) Dose 2		(Females) Dose 1		(Females) Dose 2	
12-15	2.3	21.9	5	4.2	66	39.9	0	0.4	6	3.9	12-15
16-17	2.85	38.5	12	5.7	153	69.1	0	0.0	9	7.9	16-19
18-24	1.25	19.65	21	2.3	105	36.8	4	0.2	20	2.5	20-24
25-29	0.75	6.0	11	1.3	83	10.8	0	0.2	9	1.2	25-29
30-39	0.55	2.95	3	0.5	15	5.2	1	0.6	4	0.7	>30
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	

Lastly, another source of credible data concerning underreporting in VAERS comes from the Kaiser-Permanente group in Oregon.(12) This is an important source because it is one of the centers that contribute data to CDC's VSD (Vaccine Safety Datalink) program, another safety monitoring system used by CDC. This is based on actual medical records, rather than (as for VAERS), spontaneous reports. The authors determined that incomplete ICD10 coding as well as delays in hospital claims data resulted in discrepancies with the VSD data. The rates they described for myocarditis suggest VAERS underreporting of between 6 and 14 times.

[5] www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html

[6] Slide 28 of www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-01-05/06_COVID_Oliver_2022-01-05.pdf



Comparison of myocarditis rates described by Sharff et al., (12) and CDC (VRBPAC Meeting October 26 2021)[Error! Bookmark not defined.]

- Pfizer committed to a study on subclinical myocarditis and troponin levels. This has not yet been produced.
- CDC appear to have recognized that MIS-C may occur in vaccinated children. ACIP's Dr. Long raised the possibility, that myocarditis and/or MIS-C may be partly accounted for by vaccination following Covid-19 infection. CDC provided only unclear answers to this question. A recent study in adults(13), funded by NIH found: *"people with prior COVID-19 had greater odds of adverse effects and more severe adverse effects after COVID-19 vaccination. Data from randomized clinical trials were not conclusive with regard to the association between prior COVID-19 and adverse effects after vaccination. Other smaller real-world reports have also reported increased adverse effects in people with prior COVID-19. In this study, which included 895 participants with prior COVID-19, there was a strong association between prior COVID-19 and vaccine adverse effects."*
- CDC continues to ignore AEs other than myocarditis. A recent paper from NIH has acknowledged that neurological events may occur after Covid-19 vaccination.(14)
- The contribution of a high rate to seroprevalence (77%) reported by CDC in 5–11-year-olds, to protection continues to be ignored.
- The gene therapy nature of these quasi vaccines is also ignored, as are questions as to the distribution of the mRNA and spike protein, and the product's long-term consequences.
- 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.(15)
- The data provided by Pfizer and CDC are largely irrelevant to future strains.

I refer to previous submissions made either to FDA (1,10,16-19) or CDC.(1,5,18,20-24) for further detail on a number of the above points.

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