Moderna 'safety' document - quick make one so we can pretend that we need to inject babies with obsolete injectables!

And it won't injure them. Except for 1/200.


Jessica Rose
Jun 11

As most of you probably know, in a few days, the VRBPAC meeting will happen again. This time around, they have decided, ahem, will decide, on whether infants (6 months-4 years) should be injected with the COVID-19 injectable products. Yes, the same products with proven lamentable efficacy by their own admission (36.8% in 2-5 year olds), and horrific safety profiles and you will see.

Please go to this document entitled: "Vaccines and Related Biological Products Advisory Committee June 14-15, 2022 Meeting Presentation". Released just in time is the document entitled: "mRNA-1273 PRIMARY SERIES 6 MONTHS TO 17 YEARS SPONSOR BRIEFING DOCUMENT VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE MEETING DATES: JUNE 14–15, 2022".

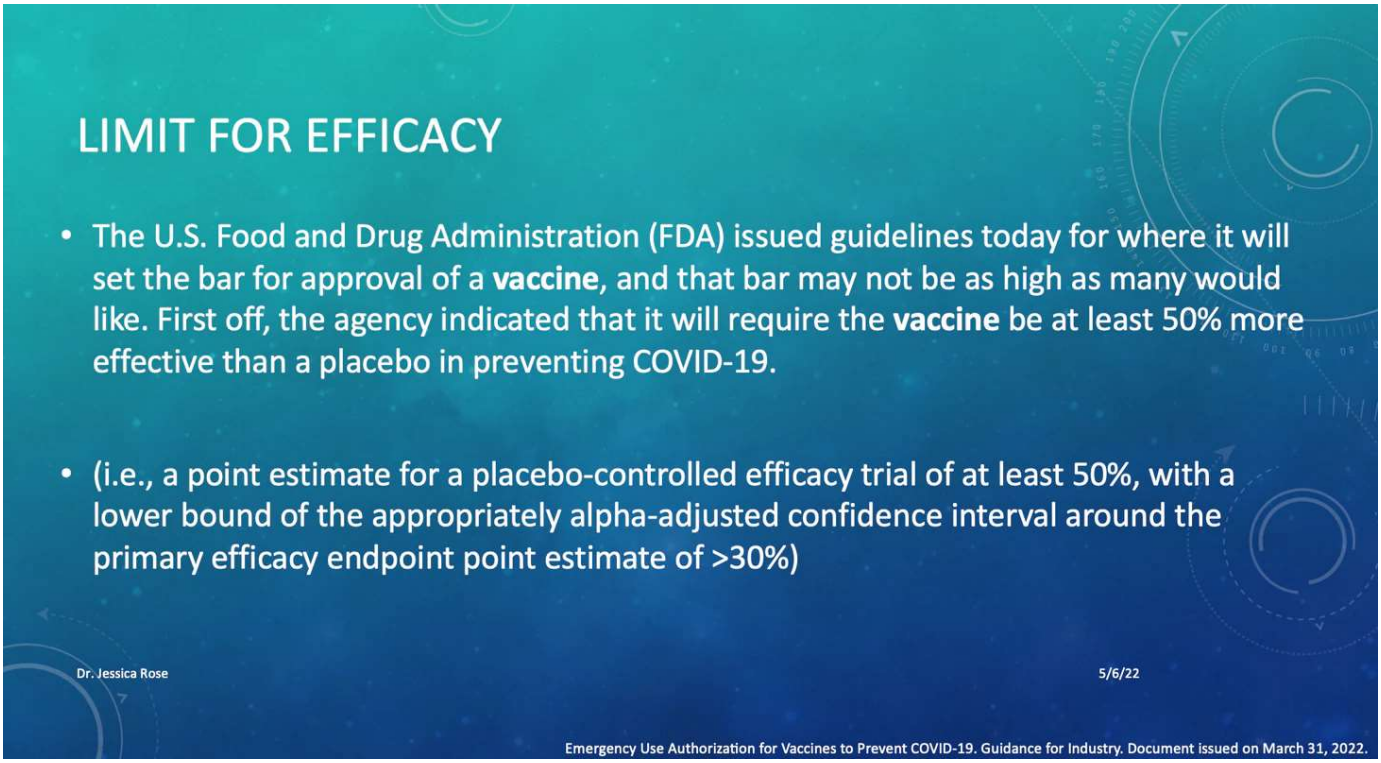
Alright I want to be succinct here. Please head to Page 43 of the Moderna document (the second link) for the OVERVIEW OF IMMUNOGENICITY AND EFFICACY. This will be all I have to say about efficacy and then I will pick on safety. It's not that I think the Vaccine Efficacy measurement holds much weight anyway, but let's assume that their measurement is adequate, for argument's sake/ Even though we're not allowed to argue. How in the world can they publish a 36.8% efficacy rate in 2-5 year olds and claim to have any justification whatsoever to inject children in this age group? The FDA Limit of Efficacy maintains that efficacy must be 50% over placebo to be approved for use.

4 OVERVIEW OF IMMUNOGENICITY AND EFFICACY

Summary

- Immunogenicity was a primary objective of the pediatric studies, with effectiveness to be inferred in infants, children, and adolescents by immunobridging to young adults in Study 301, where efficacy was demonstrated.
- Immunobridging was successfully demonstrated (by meeting the pre-specified co-primary non-inferiority criteria for GMR and seroresponse rate) for a 2-dose primary series of mRNA-1273 administered over 1 month in all age groups:
  - 12 to 17 years – GMR: 1.1 (95% CI: 0.9, 1.2); SRR difference: 0.2% (95% CI: -1.8, 2.4)
  - 6 to 11 years – GMR: 1.2 (95% CI: 1.1, 1.4), SRR difference: 0.1% (95% CI: -1.9, 2.1)
  - 2 to 5 years – GMR: 1.0 (95% CI: 0.9, 1.2), SRR difference: -0.4% (95% CI: -2.7, 1.5)
  - 6 to 23 months – GMR: 1.3 (95% CI: 1.1, 1.5), SRR difference: 0.7% (95% CI: -1.0, 2.5)
- Efficacy was a secondary objective of the pediatric studies. VE assessment was dependent on the circulation of SARS-CoV-2 and the amount of time available for follow-up blinded follow-up.
- Efficacy was demonstrated in all age groups, regardless of the SARS-CoV-2 variant circulating.
  - 12 to 17 years, VE 93.3 (95% CI: 47.9, 99.9), Original and Alpha
  - 6 to 11 years, VE (measured starting 14 days post-dose 1) 88.0% (95% CI: 70.0, 95.8), Delta
  - 2 to 5 years, VE 36.8% (95% CI: 12.5, 54.0), Omicron
  - 6 to 23 months, VE 50.6% (95% CI: 21.4, 68.6), Omicron
- Efficacy in pediatric groups also was consistent with efficacy (original strain)/effectiveness (Delta and Omicron) in adults against those variants in clinical trials and observational studies.
- Immune responses against multiple variants also were demonstrated using both binding and neutralizing antibodies.

https://www.fda.gov/media/159157/download. Page 43.



Now let's head to Table 26 on page 63. This was the first Table that caught my eye. It caught my eye because 20.5% of all 12-17 year olds in the drug arm (mRNA-1273) experienced and reported an adverse event (AE) within 28 days of injection. Of these, they even admit to 12.6% being 'related to vaccination'. This is compared with 15.9% of 12-17 year olds on 'placebo' experiencing and reporting an AE.

Table 26: Study 203 Proportion of Participants with Unsolicited AEs within 28 Days after Any Dose (Safety Set, 12 to 17 Years)

	mRNA-1273 N=2486		Placebo N=1240	
Category, n (%)	Any AE	Related to Vaccination	Any AE	Related to Vaccination
All	510 (20.5)	312 (12.6)	197 (15.9)	72 (5.8)
SAE	2 (< 0.1)	0	1 (< 0.1)	0
Fatal	0	0	0	0
Medically Attended AEs	156 (6.3)	19 (0.8)	81 (6.5)	5 (0.4)
Leading to Discontinuation - Vaccine	0	0	0	0
Leading to Discontinuation - Study	1 (< 0.1)	0	0	0
Severe	4 (0.2)	0	1 (< 0.1)	0
AESI of MIS-C	0	0	0	0

Abbreviations: AE=adverse event; AESI=adverse event of special interest; MIS-C=Multisystem Inflammatory Syndrome in Children; SAE=serious adverse event
Datacut: 08 May 2021
Source: Study P203, Table 3.2.1.1

https://www.fda.gov/media/159157/download. Page 63.

Now let's head to Table 29 on page 72. Here we see 29.6% of all 6-11 year olds in the drug arm (mRNA-1273) experienced and reported an adverse event (AE) within 28 days of injection. Of these, they even admit to 10.6% being 'related to vaccination'. This is compared with 25.1% of 6-11 year olds on 'placebo' experiencing and reporting an AE. I find this very strange. I still have a very strong suspicion that these 'placebos' are not saline and rather empty LNPs. Even if we take their 5% rate of AEs related to vaccination, how do they explain that?

Table 29: Study 204 Participants Reporting ≥ 1 Unsolicited Adverse Event within 28 Days after Any Dose (Safety Set, 6 to 11 Years)

Category, n (%)	mRNA-1273 N=3,007		Placebo N=995	
	Any AE	Related to Vaccination	Any AE	Related to Vaccination
All	891 (29.6)	319 (10.6)	250 (25.1)	50 (5.0)
SAE	3 (< 0.1)	0	2 (0.2)	0
Fatal	0	0	0	0
Medically Attended AEs	404 (13.4)	34 (1.1)	141 (14)	4 (0.4)
Leading to Discontinuation – Vaccine	2 (< 0.1)	0	0	0
Leading to Discontinuation – Study	1 (< 0.1)	0	0	0
Severe	12 (0.4)	9 (0.3)	2 (0.2)	1 (0.1)
AESI – Any	3 (< 0.1)	0	2 (0.2)	0
AESI of MIS-C	0	0	0	0
AESI of Myocarditis/Pericarditis	0	0	0	0

Abbreviations: AE=adverse event; AESI=adverse event of special interest; SAE=serious adverse event.
Note: Percentages are based on the number of safety participants. Solicited adverse reactions with toxicity Grade=0 that lasted beyond Day 7 or started after Day 7 are not included in this table.
Datacut: 10 Nov 2021
Source: Study P204 Table 14.3.1.7.1.2

https://www.fda.gov/media/159157/download. Page 72.

Now let's head to Table 33 on page 82. Here we see 40% of all 2-5 year olds in the drug arm (mRNA-1273) experienced and reported an adverse event (AE) within 28 days of injection. Of these, they even admit to 9.4% being 'related to vaccination'. This is compared with 37.5% of 2-5 year olds on 'placebo' experiencing and reporting an AE. Again, I find this high rate very strange. By the way, have you guys noticed that the cohort balance is ~2:1, ~3:1, ~3:1 in age groups 12-17, 6-11 and 2-5, respectively, with regard to mRNA-1273 and placebo. Again, why? Is this about your 'ethics' and how you justify injecting the unblinded clinical trial participants because 'they deserve the vaccine'?

Table 33: Study 204 Participants Reporting ≥ 1 Unsolicited Adverse Event within 28 Days after Any Dose (Safety Set, 2 to 5 Years)

Category, n (%)	mRNA-1273 25 µg N=3031		Placebo N=1007	
	Any AE	Related to Vaccination	Any AE	Related to Vaccination
All	1212 (40.0)	286 (9.4)	378 (37.5)	80 (7.9)
SAE	4 (0.1)	0	1 (< 0.1)	0
Fatal	0	0	0	0
Medically Attended AEs	662 (21.8)	30 (1.0)	221 (21.9)	3 (0.3)
Leading to Discontinuation - Vaccine	0*	0*	0	0
Leading to Discontinuation - Study	0*	0*	0	0
Severe	21 (0.7)	18 (0.6)	9 (0.9)	8 (0.8)
AESI – Any	5 (0.2)	2 (< 0.1)	1 (< 0.1)	1 (< 0.1)
AESI of MIS-C	0	0	0	0
AESI of Myocarditis/Pericarditis	0	0	0	0

Abbreviations: AE=adverse event; AESI=adverse event of special interest; MIS-C=Multisystem Inflammatory Syndrome in Children; SAE=serious adverse event

Note: Percentages are based on the number of safety participants. Solicited adverse reactions with toxicity Grade=0 that lasted beyond Day 7 or started after Day 7 are not included in this table.

*One participant in the mRNA-1273 group had a case report form entry of "AE" as a basis for vaccine discontinuation, but "dose not changed" was recorded on the AE case report form. After the data cut, the entry was updated to indicate that investigational product was withdrawn.

Datacut: 21 Feb 2022

Source: Module 2.5 (< 6 yrs), Table 45

https://www.fda.gov/media/159157/download. Page 82.

Now let's go back to Table 27. 55.8% of the 12-17 year old children experienced and unsolicited AE of which 15% was claimed to be caused by the injection. So for an absolutely obsolete product (93.3% 'VE' in the context of Original and Alpha?), parents are expected to inject their children with something with an undisclosed ingredient list that, in 55.8% of children, is associated with an AE?

Table 27: Study 203 Proportion of Participants Reporting Unsolicited AEs in the Entire Study after Any Dose (Safety Set, 12 to 17 Years)

	mRNA-1273 N=2,486	
Category, n (%)	**Any AE**	**Related to Vaccination**
Any AE	1386 (55.8)	372 (15.0)
SAE	21 (0.8)	0
Fatal	0	0
Medically Attended AEs	980 (39.4)	25 (1.0)
Leading to Discontinuation - Vaccine	3 (0.1)	1 (< 0.01)
Leading to Discontinuation - Study	0	0
AESI – Any	13 (0.5)	1 (< 0.01)
AESI of MIS-C	0	0
AESI of Other	13 (0.5)	1 (< 0.01)

Abbreviations: AE=adverse event; AESI=adverse event of special interest; MIS-C=Multisystem Inflammatory Syndrome in Children; SAE=serious adverse event
Datacut: 31 Jan 2022
Source: Study P203 Table 14.3.1.7.4.1

https://www.fda.gov/media/159157/download. Page 63.

Now let's go back to Table 38. 49.3% of the 6-23 months year old children experienced and unsolicited AE *within 28 days of injection*, of which 16.6% was claimed to be caused by the injection. So let's look at that 0.5% of all AEs being serious thing. That doesn't sound like much, right? I mean Walensky and Fauci would look at that and say, 'woohoo!'. 0.5% = 5/1000. Maybe they should start expressing the rate in this way so that people remember that we're talking about helpless infants. So if the public was informed that Moderna found that 1/200 children ages 6 to 23 months experienced a severe adverse event within 28 days of injection, I mean, like, at the injection site door, how many people would still go through with injecting their baby?

And by the way, what exactly is the difference between Severe and Serious? Because 1.2% of all 6-23 month olds experienced a severe AE. That's a 1/83 chance of experiencing a severe AE.

I chose this table because it refers to babies but the rate is even worse for 12-17 year olds with 1/125 suffering a serious adverse event. No time frame reported. Maybe some of you lovelies could make some posters and pin them to injection site doors.

Table 38: Participants Reporting ≥ 1 Unsolicited Adverse Event within 28 Days after Any Dose (Safety Set, 6 to 23 Months)

Category, n (%)	mRNA-1273 25 µg (N=1761)		Placebo (N=589)	
	Any AE	Related to Vaccination	Any AE	Related to Vaccination
All	869 (49.3)	292 (16.6)	284 (48.2)	71 (12.1)
Nonserious	868 (49.3)	292 (16.6)	284 (48.2)	71 (12.1)
Serious	8 (0.5)	1 (< 0.1)	0	0
Fatal	0	0	0	0
Medically attended	486 (27.6)	23 (1.3)	161 (27.3)	3 (0.5)
Leading to discontinuation from study vaccine	1 (< 0.1)	1 (< 0.1)	1 (0.2)	0
Leading to discontinuation from participation in the study	0	0	1 (0.2)	0
Severe	21 (1.2)	12 (0.7)	4 (0.7)	3 (0.5)
Special Interest (AESI)	3 (0.2)	2 (0.1)	0	0

Abbreviations: AE=adverse event; AESI=adverse event of special s of age
Note: Percentages are based on the number of safety participants. Solicited adverse reactions with toxicity Grade=0 that lasted beyond Day 7 or started after Day 7 are not included in this table.
Datacut: 21 Feb 2022
Source: Module 2.5 (< 6 yrs), Table 67 Study P204 Table 14.3.1.7.1.2

https://www.fda.gov/media/159157/download. Page 92.

So these are just a select few Tables that stuck out for me. By the way, do any of you find it appalling that the highest number of trial participants was 2,486, 3,007, 3,031 and 1,761, for age groups 12-17, 6-11, 2-5 and 6 to 23 months, respectively.

There is still time to file a comment but you guys should know that of the 126,947 public comments made in just 6 days, they are hiding them from the public. Make your comments anyway. You can do that here until June 14th, 2022 to do so. Use Docket No. FDA-2022-N-0904.



NOTICE

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

Posted by the **Food and Drug Administration** on May 31, 2022

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Document Details

Document ID
FDA-2022-N-0904-0001

Comments Received
128,947

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Less Details

Content

Action

Notice; establishment of a public docket; request for comments.

Summary

The Food and Drug Administration (FDA or Agency) announces a forthcoming public advisory committee meeting of the Vaccines and Related Biological Products Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. Members will participate via teleconference. This 2-day virtual meeting will be held to discuss recent requests to amend the Emergency Use Authorization (EUA) of the Moderna COVID-19 mRNA vaccine to include the administration of a primary series to infants, children, and adolescents 6 months through 17 years of age and to amend the EUA of the Pfizer-BioNTech COVID-19 mRNA vaccine to include the administration of a primary series to infants and children 6 months through 4 years of age. The meeting will be open to the public on both days. FDA is establishing a docket for public comment on this document.

Dates

https://www.regulations.gov/document/FDA-2022-N-0904-0001

Here. I made this. Please print and post everywhere. Schools. Parks. Clinics. Give to MDs. Make them read the bloody document. INFORM THEM AND HOLD THEM ACCOUNTABLE in case of injury.



1/200 infants 6 - 23 months experienced a SERIOUS ADVERSE EVENT

1/83 infants 6 - 23 months experienced a SEVERE ADVERSE EVENT

Table 38: Participants Reporting ≥ 1 Unsolicited Adverse Event within 28 Days after Any Dose (Safety Set, 6 to 23 Months)

	mRNA-1273 25 µg (N=1761)		Placebo (N=589)	
Category, n (%)	Any AE	Related to Vaccination	Any AE	Related to Vaccination
All	869 (49.3)	292 (16.6)	284 (48.2)	71 (12.1)
Nonserious	868 (49.3)	292 (16.6)	284 (48.2)	71 (12.1)
Serious	8 (0.5)	1 (< 0.1)	0	0
Fatal	0	0	0	0
Medically attended	486 (27.6)	23 (1.3)	161 (27.3)	3 (0.5)
Leading to discontinuation from study vaccine	1 (< 0.1)	1 (< 0.1)	1 (0.2)	0
Leading to discontinuation from participation in the study	0	0	1 (0.2)	0
Severe	21 (1.2)	12 (0.7)	4 (0.7)	3 (0.5)
Special Interest (AESI)	3 (0.2)	2 (0.1)	0	0

Abbreviations: AE=adverse event; AESI=adverse event of special s of age
Note: Percentages are based on the number of safety participants. Solicited adverse reactions with toxicity Grade=0 that lasted beyond Day 7 or started after Day 7 are not included in this table.
Datacut: 21 Feb 2022
Source: Module 2.5 (< 6 yrs), Table 67 Study P204 Table 14.3.1.7.1.2

from 25ug injection of Moderna mRNA-1273 product
Moderna: mRNA-1273 PRIMARY SERIES 6 MONTHS TO 17 YEARS SPONSOR BRIEFING DOCUMENT
Vaccines and Related Biological Products Advisory Committee June 14-15, 2022 Meeting Presentation

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jksmom01 Jun 11 Liked by Jessica Rose

You're a warrior for truth and exposing all the lies and corruption perpetuated on the public! Thank you for all you're doing! 👏👏👏

54 Reply Collapse

Mark Much Jun 11 Liked by Jessica Rose

1/200 is only short term. It will be much worse as time goes by. As Mike Yeadon says, it looks like the only reason for jabbing kids is depopulation, to kill them or make them sterile.

50 Reply Collapse

7 replies by Jessica Rose and others

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