06/16/22 • COVID › VIEWS

What FDA Advisors Got Wrong About COVID Vaccines for Young Kids

What members of the U.S. Food and Drug Administration's vaccine advisory committee saw and heard during Wednesday's meeting should have stopped them from recommending authorization of COVID-19 vaccines for children as young as 6 months — but it didn't.

By James Lyons-Weiler, Ph.D.

Editor's Note: *Advisors to the U.S. Food and Drug Administration on Wednesday recommended the agency grant Emergency Use Authorization of the Pfizer and Moderna COVID-19 vaccines for children under 5 years old, despite questions about safety and efficacy, and whether children, who are at low risk of serous illness from the virus, need the vaccines.*

Here are a few things members of the U.S. Food and Drug Administration's (FDA) Vaccines and Related Biological Products Advisory Committee (VRBPAC) saw and heard before they voted to recommend approval anyway:

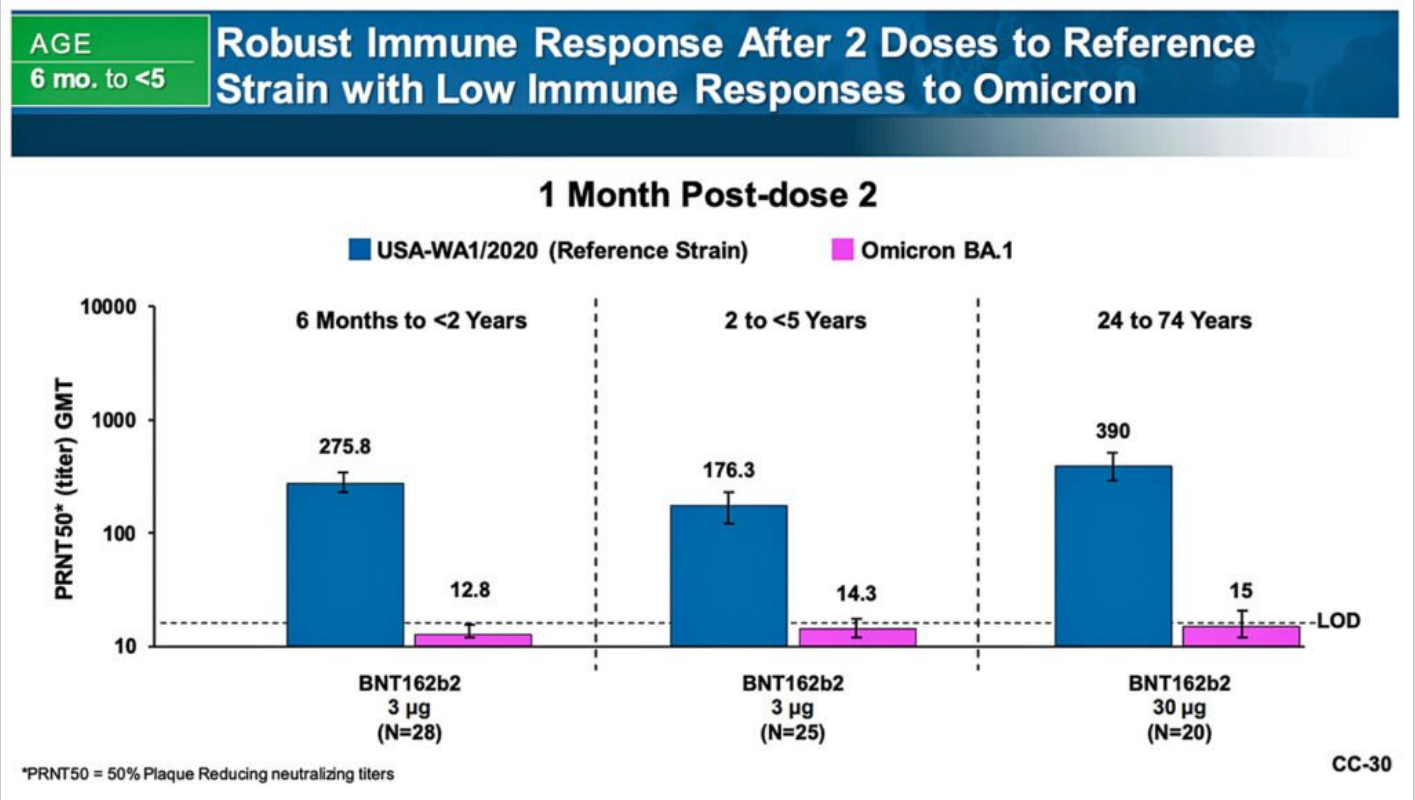
1. They proceeded for recommendation of approval based on a guess that three doses will correct negative efficacy.

Pfizer has a serious problem: Its two-dose data reflected the reality I've been reporting about (and predicted) since the Israeli and Barnstable County data came out: the confidence interval for their estimate of the number of cases prevented by three doses of their vaccine points, if anything, to negative efficacy (-369.1 to 99.6).

The confidence interval crosses zero. The problem is not just that the result is based on a ridiculously small number of data points. See Point 2.

2. The problem also is that this result confirms (validates) the result of the two-dose vaccine. Their measure of vaccine efficacy was only 14.5% seven days after the second dose the confidence intervals crossed zero, so they were not statistically significant.

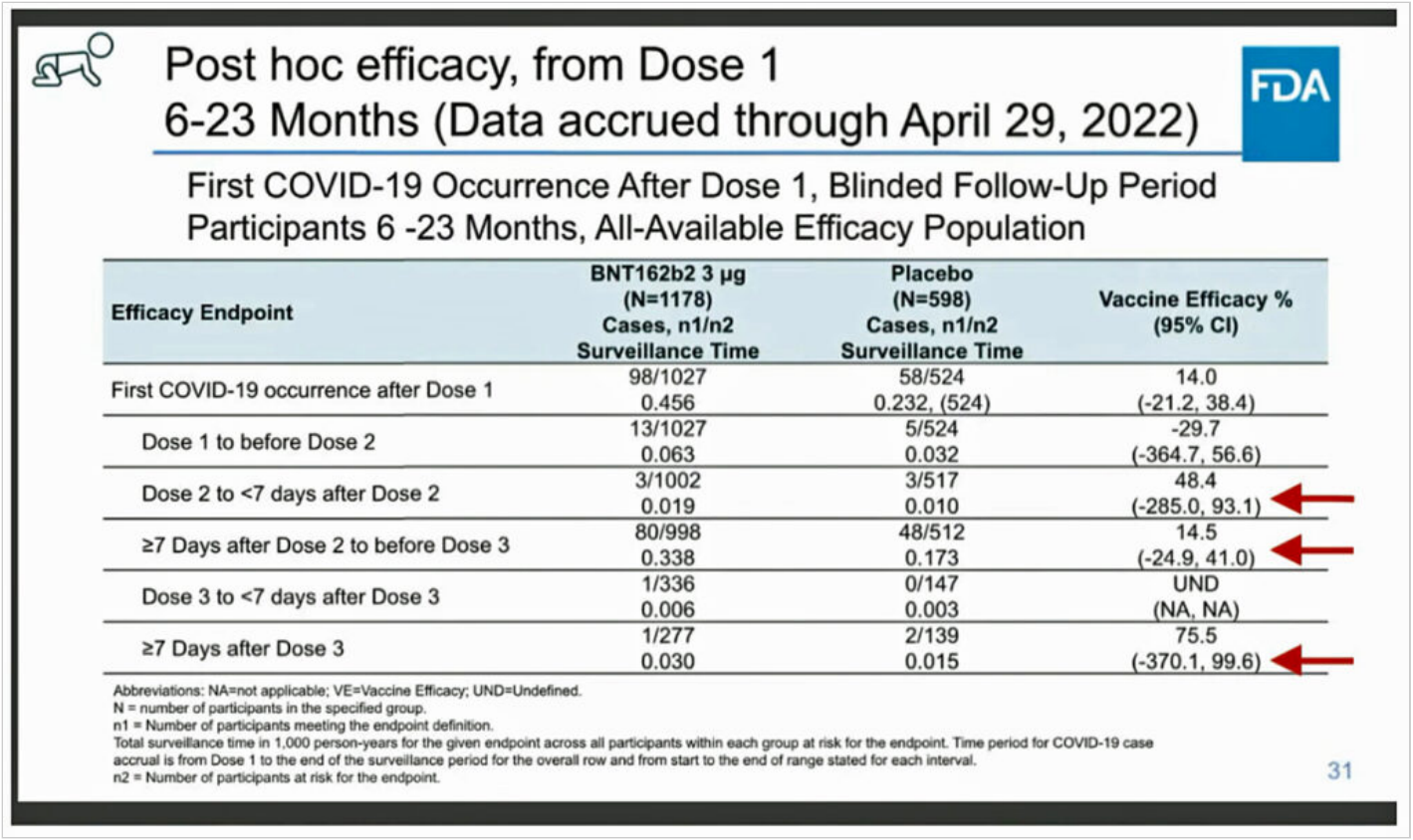
3. They relied on proxy outcome measures (neutralizing antibodies). Neutralizing antibodies sound good, but they are the wrong antibodies (the Wuhan-1 virus is extinct). Look at the antibody response to Omicron (Pfizer):



I predict the entire vaccination program is going to drive COVID-19 numbers up across the board routinely and on a regular, ongoing basis due to antibody-dependent enhancement, as predicted by Dr. Fantini's analysis.

4. Given these three points alone, FDA might just as well be staring at a blank sheet of paper and rubberstamp the approval.

Look at the confidence interest after Dose 2 and Dose 3.



Post hoc efficacy, from Dose 1
6-23 Months (Data accrued through April 29, 2022)

FDA

First COVID-19 Occurrence After Dose 1, Blinded Follow-Up Period
Participants 6 -23 Months, All-Available Efficacy Population

Efficacy Endpoint	BNT162b2 3 µg (N=1178) Cases, n1/n2 Surveillance Time	Placebo (N=598) Cases, n1/n2 Surveillance Time	Vaccine Efficacy % (95% CI)
First COVID-19 occurrence after Dose 1	98/1027 0.456	58/524 0.232, (524)	14.0 (-21.2, 38.4)
Dose 1 to before Dose 2	13/1027 0.063	5/524 0.032	-29.7 (-364.7, 56.6)
Dose 2 to <7 days after Dose 2	3/1002 0.019	3/517 0.010	48.4 (-285.0, 93.1)
≥7 Days after Dose 2 to before Dose 3	80/998 0.338	48/512 0.173	14.5 (-24.9, 41.0)
Dose 3 to <7 days after Dose 3	1/336 0.006	0/147 0.003	UND (NA, NA)
≥7 Days after Dose 3	1/277 0.030	2/139 0.015	75.5 (-370.1, 99.6)

Abbreviations: NA=not applicable; VE=Vaccine Efficacy; UND=Undefined.
N = number of participants in the specified group.
n1 = Number of participants meeting the endpoint definition.
Total surveillance time in 1,000 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 Dose 1 to the end of the surveillance period for the overall row and from start to the end of range stated for each interval.
n2 = Number of participants at risk for the endpoint.

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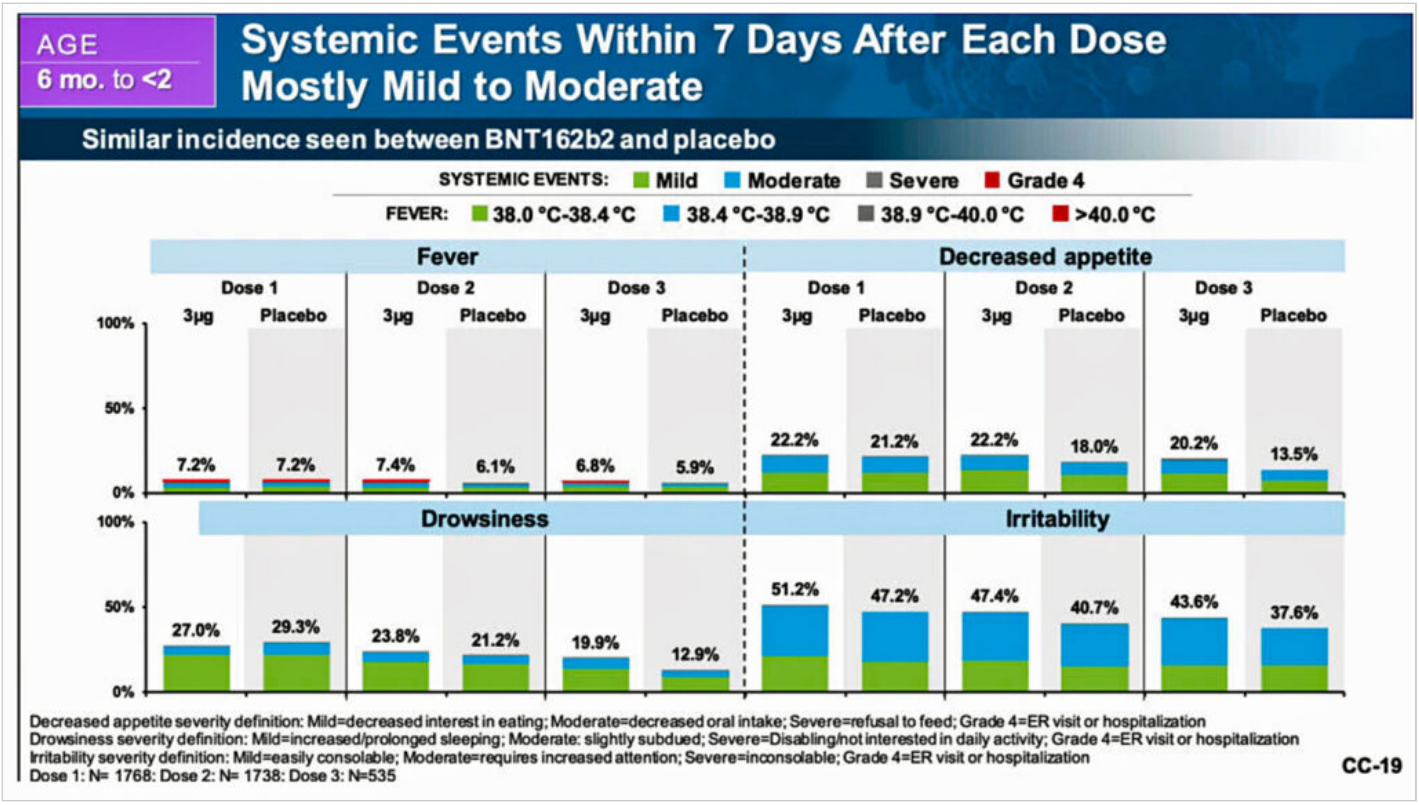
5. No one raised the issue of failure to meet FDA's required 50% efficacy.

Moderna and Pfizer's own endpoint data fall short of the 50% mark. Pfizer decreased its dose and this seems to have decreased the reported adverse events. But we'll get to the real problem with adverse events shortly.



AGE
6 mo. to <2

Systemic Events Within 7 Days After Each Dose
Mostly Mild to Moderate

Similar incidence seen between BNT162b2 and placebo

SYSTEMIC EVENTS: Mild Moderate Severe Grade 4
FEVER: 38.0 °C-38.4 °C 38.4 °C-38.9 °C 38.9 °C-40.0 °C >40.0 °C

Fever

Dose 1		Dose 2		Dose 3	
3µg	Placebo	3µg	Placebo	3µg	Placebo
7.2%	7.2%	7.4%	6.1%	6.8%	5.9%

Decreased appetite

Dose 1		Dose 2		Dose 3	
3µg	Placebo	3µg	Placebo	3µg	Placebo
22.2%	21.2%	22.2%	18.0%	20.2%	13.5%

Drowsiness

Dose 1		Dose 2		Dose 3	
3µg	Placebo	3µg	Placebo	3µg	Placebo
27.0%	29.3%	23.8%	21.2%	19.9%	12.9%

Irritability

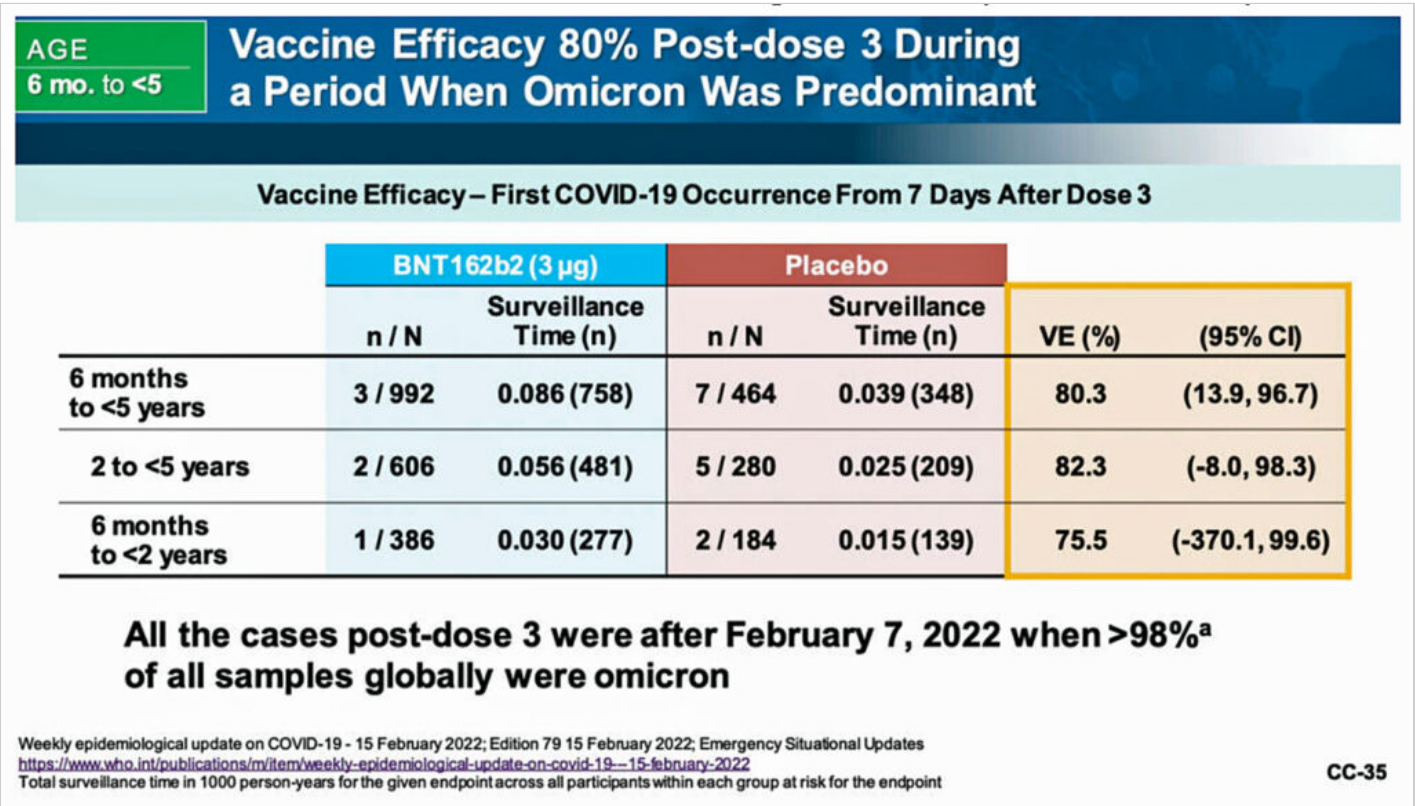
Dose 1		Dose 2		Dose 3	
3µg	Placebo	3µg	Placebo	3µg	Placebo
51.2%	47.2%	47.4%	40.7%	43.6%	37.6%

Decreased appetite severity definition: Mild=decreased interest in eating; Moderate=decreased oral intake; Severe=refusal to feed; Grade 4=ER visit or hospitalization
Drowsiness severity definition: Mild=increased/prolonged sleeping; Moderate: slightly subdued; Severe=Disabling/not interested in daily activity; Grade 4=ER visit or hospitalization
Irritability severity definition: Mild=easily consolable; Moderate=requires increased attention; Severe=inconsolable; Grade 4=ER visit or hospitalization
Dose 1: N= 1768: Dose 2: N= 1738: Dose 3: N=535

CC-19

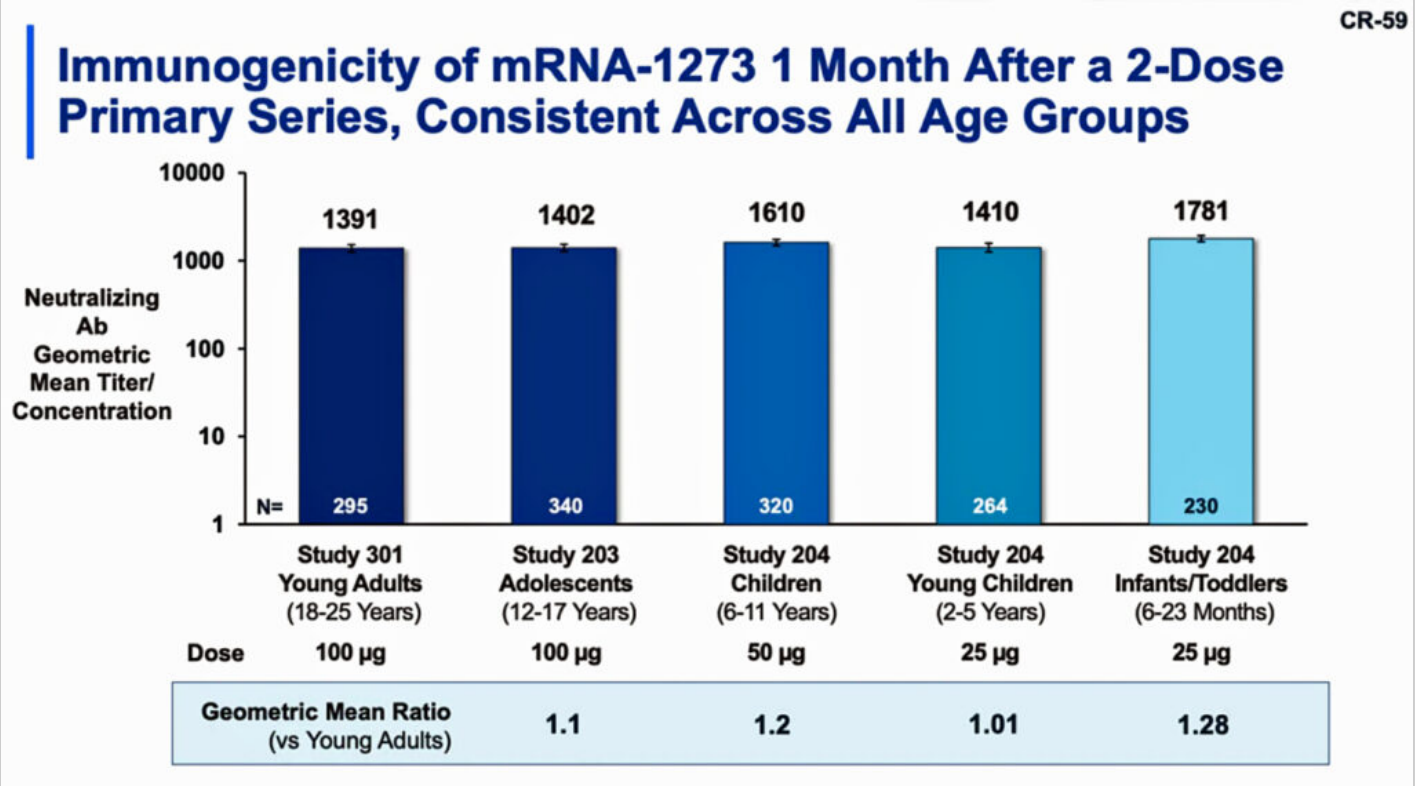
6. Their numbers are ridiculously small. Pfizer showed an estimate of 80.3% vaccine efficacy is based on – get this – 7 cases in the placebo group and 3 in the vaccine group.

Notice the emblazoned 80% — as if that data point has any basis in reality.



7. They are ignoring the risk of altered neurodevelopment. The Moderna vaccine especially had high numbers of high fevers (>104°). Many studies exist that show that high fever following vaccination is associated with autism, especially if the kids are given acetaminophen.

8. Moderna presented antibody data against the reference strain (Wuhan-1). But We don't only care about how good a vaccine is at generating antibodies. Moderna knows this. VRBPAC knows this. Now you know this, too.



9. Inconsistent case definition. Moderna ran only PCR tests if patients in the vaccinated group had two symptoms.

In other words, they made up their own clinical designation of "COVID-19." Under CDC's case definition (which is also not correct), Moderna's data show that in kids 2 to 5, "vaccine efficacy" was 36.8% but under Moderna's new definition, 46.4%.

Moderna also used antigen tests, making any measure of efficacy incomparable to other studies.

10. Risk of hospitalization cited out of context.

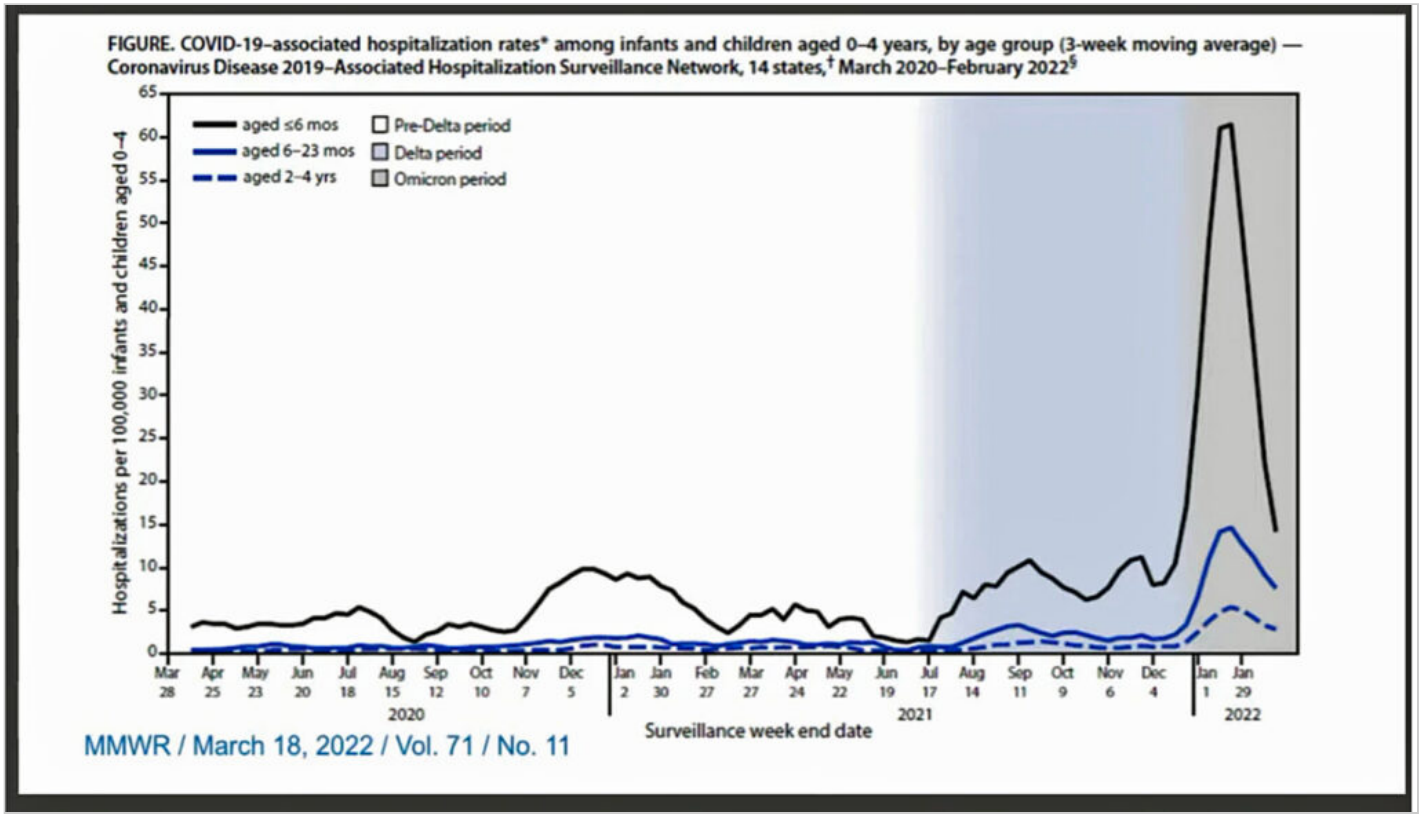
One committee member compared the risk of a child dying from COVID-19 to a person being struck by lightning (see my calculations here).

They showed the Omicron hospitalization rate "surge."

Yet it's much lower than that for influenza, per CDC:

	Illness rate	Hospitalization rate
Age group	**Estimate**	**Estimate**
0-4 yrs	11,027.50	76.9
5-17 yrs	7,704.60	21.1
18-49 yrs	6,667.50	37.4

2015-2016 Hospitalization Rate (Per 100,000 cases) from Influenza Image credit: CDC



11. They may have broken the rules of engagement for open meetings

Any reasonable person would expect that public open meetings held by organizations such as VRBPAC would know and follow administrative rules for open meetings.

How is it then that only VPBPAC members managed to ask questions and voice their opinions on how necessary (or not) COVID-19 vaccination in children might be AFTER the votes were made to approve the vaccine for children under 5?

Dr. Meryl Nass was denied an opportunity to speak in the public comment period, yet the same pro-vaccine mother was able to speak two days in a row. Thus, the public may have been denied the opportunity to contribute their comments.

This is being looked at by lawyers. If it is true the FDA broke the rules of open meetings, then any ethical judge would rule this vote to recommend is null and void ab initio.

Originally published on James Lyons-Weiler's Popular Rationalism Substack page.

The views and opinions expressed in this article are those of the authors and do not necessarily reflect the views of Children's Health Defense.

SUGGEST A CORRECTION

James Lyons-Weiler, Ph.D.

James Lyons-Weiler is the president and CEO of the Institute for Pure and Applied Knowledge, an advocacy group that pushes for accuracy and integrity in science and for biomedical researchers to put people's health before profits.