From Bad to Worse

FDA advisors just voted 21-0 to authorize vaccines for children 6 months old to 5 years old[1].

Germany, France, Denmark, Norway, Sweden, and Finland all suspended Moderna for people under 30 due to safety concerns.

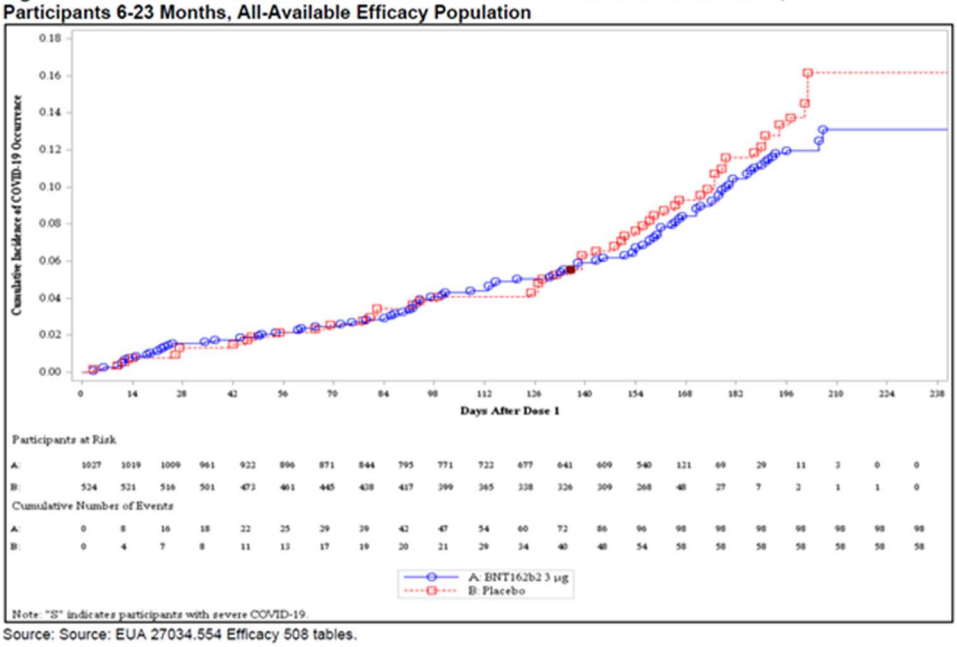
But in the U.S., we'll now be giving this product to infants.

Stating that much gets one banned on Twitter. Every statement a fact. TRUTH.

It's beyond idiotic. Try to spot the difference in Covid cases between the vaccine and placebo groups in the Pfizer supplied graph below. The lines don't even start to split until 140 days (almost 5 months) has passed, and then both groups still climb at similar rates.

[1] See: https://abcnews.go.com/Health/process-begins-vaccines-kids-remaining-group/story?id=85414734

Figure 1. Cumulative Incidence Curves for the First COVID-19 Occurrence After Dose 1, Participants 6-23 Months, All-Available Efficacy Population



Source: Source: EUA 27034.554 Efficacy 508 tables.

Here is a look at the vaccine efficacy throughout the inoculation process:

VRBPAC Briefing Document: Pfizer-BioNTech COVID-19 Vaccine EUA Amendment for Use in Children 6 Months Through 4 Years of Age

Table 19. First COVID-19 Occurrence Any Time After Dose 1, Blinded Follow-Up Period, Participants 6-23 Months of Age, All-Available Efficacy Population, Study C4591007

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

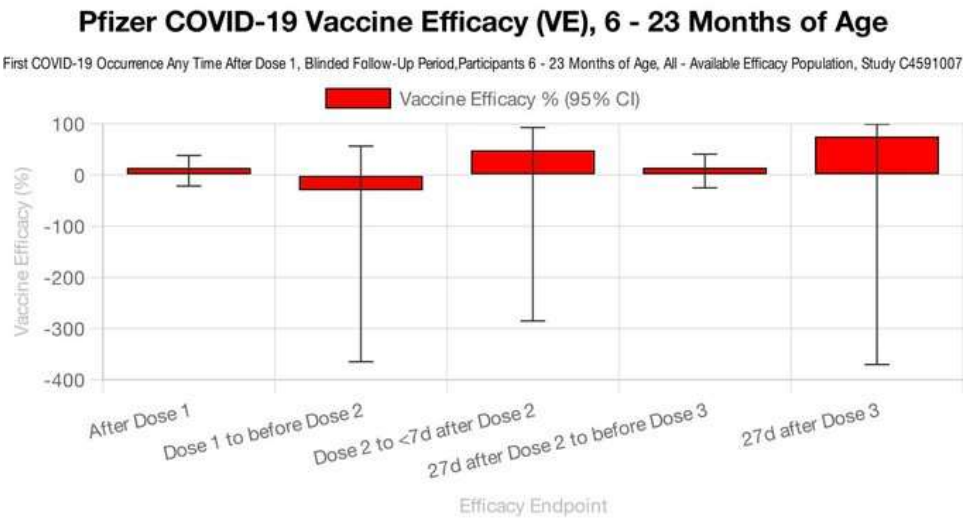
Source: EUA 27034.554 Efficacy 508 tables. Table E.D.1.
Abbreviations: NA=not applicable; VE=Vaccine Efficacy; UND=Undefined.
a. N=number of participants in the specified group.
b. n1=Number of participants meeting the endpoint definition.
c. Total surveillance time in 1,000 person-years for the given 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.
d. n2=Number of participants at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted to the surveillance time.

Table 20. First COVID-19 Occurrence Any Time After Dose 1, Participants 2 to <5 Years of Age, All-Available Efficacy Population, Study C4591007

Efficacy Endpoint	BNT162b2 3 µg (N[a]=1835) Cases, n1[b] Surveillance Time[c], (n2[d])	Placebo (N[a]=915) Cases, n1[b] Surveillance Time[c], (n2[d])	Vaccine Efficacy % (95% CI[e])
First COVID-19 occurrence after Dose 1	127 0.661, (1673)	92 0.323, (834)	32.6 (10.8, 48.8)
Dose 1 to before Dose 2	21 0.100, (1673)	8 0.050, (834)	-32.1 (-244.8, 43.8)
Dose 2 to <7 days after Dose 2	4 0.031, (1639)	5 0.016, (819)	60.1 (-85.6, 92.1)
≥7 Days after Dose 2 to before Dose 3	100 0.464, (1630)	74 0.228, (814)	33.6 (9.1, 51.3)
Dose 3 to <7 days after Dose 3	0 0.010, (553)	0 0.004, (222)	NE
≥7 Days after Dose 3	2 0.056, (481)	5 0.025, (209)	82.3 (-8.0, 98.3)

Between the first and second doses, the vaccine has a NEGATIVE VE, meaning it increases one's chance of getting Covid (by 30%). Then our children need to wait until 7 days after the booster shot (about 6 months from the start of the process) when the vaccine finally reaches a 75-82% effectiveness (and that is based upon 10 total cases that occurred in the study). Summing this for both sets of kids and normalizing for person years of exposure nets a 23.9% VE from day one through 7 days after the booster.

And look at the confidence intervals for the trial results. They're off-the-chart crazy! Almost 400% efficacy on the lower end of the 95% CI. This means that in all likelihood the vaccinated children have an almost 4-times greater chance of getting sick with Covid.



To say the vaccine has a VE of 75-82% requires one to ignore 97% of the Covid cases that occurred during the trial. Recommending this inoculation is akin to saying in the middle of a hurricane storm, "you'll be safer if you leave your house and drive through the hurricane."

This is criminal. We're way past incompetence and accidents here.

All of this comes from the FDA VRBPAC 6/14-15/2022 Meeting Briefing Document[2].

But wait, there's more.

Foremost was that the trial started with 4526 participants, of which 3000 didn't make it to the end of the trial. Two-thirds didn't make it! All that was said about those was, "participants may have been excluded for more than one reason."

From Dose 1 through the data cutoff, 2 placebo recipients and 6 vaccine recipients met the criteria for severe COVID-19. Only one hospitalization for severe COVID-19 disease and it was a

[2] https://www.fda.gov/media/159195/download

vaccinated child (fever and seizure). Not only doesn't the vaccine NOT prevent Covid, it doesn't prevent severe outcomes either.

Study withdrawals due to adverse events in participants were reported in 6 BNT162b2 recipients and 1 placebo recipient.

The uncertainties associated with benefits of the Pfizer-BioNTech COVID-19 vaccine when used in children include the following:

1. Duration of vaccine effectiveness, the blinded, placebo-controlled evaluation period for descriptive efficacy analyses was limited, and waning of protection following a primary series has been observed in older age groups.
2. Need for a booster dose based on experience with adults, it is likely that a booster dose will be needed in addition to the three-dose primary series to increase robustness, breadth, and duration of protection.
3. Effectiveness in certain populations at high risk of severe COVID-19, including immunocompromised individuals.
4. Benefits in individuals previously infected with SARS-CoV-2: descriptive post-Dose 3 efficacy analyses do not include cases in previously infected participants. However, observational data with other COVID-19 vaccines have demonstrated an added benefit of vaccination to protection conferred by natural immunity.53 Additionally, for individuals previously infected with the Omicron variant of SARS-CoV-2, a vaccine based on the ancestral strain S protein could provide a greater breadth of protection against SARS-CoV-2 variants.
5. Effectiveness in preventing post-acute sequelae of COVID-19: available data are not conclusive on the effectiveness of COVID-19 vaccines currently in use against long-term sequelae of COVID-19 among individuals who are infected despite vaccination. Additional evaluation is needed to assess the effect of this vaccine in preventing long-term effects of COVID-19, including data from clinical trials and from the vaccine's use post-authorization.
6. Future vaccine effectiveness as influenced by characteristics of the pandemic, including emergence of new variants: the continued evolution of the pandemic, including changes in the

virus infectivity, antigenically significant mutations to the S protein, and changes in practice of nonpharmacologic interventions to mitigate against transmission, will likely influence vaccine effectiveness over time. Continued evaluation of vaccine effectiveness following issuance of an EUA and/or licensure will be critical.

7. Vaccine effectiveness against asymptomatic infection and transmission of SARS-CoV-2: Available data for COVID-19 vaccines currently in use has demonstrated that effectiveness against asymptomatic infection is lower and less durable than effectiveness against symptomatic COVID-19. Available data also do not indicate high-level or durable effectiveness against transmission of SARS-CoV-2 from vaccinated individuals with breakthrough infections.