

Covid-19 Vaccine for Young Children: Red Flags Over Pfizer's Bid for EUA. No Justification for Terrifying Children and Placing Them at Risk

# **Description**

USA: Never before have Americans foisted the fear of sickness in adults onto children and traded the risk to adults for risk to children. Clearly, some in the US think it's okay to inject fear of harming others into the hearts and minds of children for the sake of adults. This, to me, reveals the selfishness inherent in individuals who have a self-aggrandized sense of entitlement. Adults who have not cared well for themselves have placed themselves at risk of severe COVID-19 are now expecting to use children as a buffer for their own health

Granted, some of them have not had the chance to learn of effective means of reducing their personal risk of contracting the SARS-CoV-2 virus, nor of means to reduce their risk of serious COVID-19 due to censorship and disinformation by LMOs (legacy media outlets). In projecting fear of COVID-19 onto children, adults have mandated futile public health measures, such as masking in school – a mistake based on a fallacy propagated by Fauci and CDC that many states are now waking up to as complete a waste of time as lockdowns.

On Tuesday, February 15, VRBPAC, the Vaccines and Related Biological Products Advisory Committee, will be meeting to consider an application from Pfizer for an EUA for kids 6-months to 4-years old.

The likelihood that the vaccine will prevent a single case of COVID-19 in adults is nearly zero.

The fact is, there is no emergency in this age group. Even NIAID Director Anthony Fauci doubts the number of hospitalizations attributed to COVID-19 in children is actually due to COVID-19.

From Newsweek (12/31/2021):

"Speaking to MSNBC's Ayman Mohyeldin, who was filling in for Rachel Maddow on Wednesday night, Fauci suggested that some of the children currently being treated at medical facilities were hospitalized with COVID as opposed to 'because of COVID.'

He added that some children who are currently listed as being in hospital with COVID may actually be

receiving treatment for 'a broken leg or appendicitis,' rather than for a severe reactions (sic) to the virus."

This means there are a number of important breaches of ethical and legal standards involved in the activities undertaken to render the data to be considered by FDA.

- (1) Under the US Code of Federal Regulations, it is illegal to conduct medical experiments on a person and enroll them in a clinical trial unless there is a direct potential personal benefit to them via their participation. Since there is no COVID-19 emergency in this age group, the studies conducted by Pfizer may well have been illegal and are certainly immoral.
- (2) Post-EDU Vaccine adverse event surveillance is a form of clinical research, and parents will not be provided, as required under the Common Rule and the rest of <u>US 45-CFR-46</u>, the opportunity to decline on the basis of refusal to participate in medical experimentation on their children.
- (3) The EUA sought will be based on data from a scant 2 months of follow-up on safety. If the EUA is sought, millions of children will be vaccinated based on 2 months' data for a biologic known to cause harm in adults; this is utterly unacceptable.
- (4) Post-EUA vaccine adverse event surveillance studies will involve reports of vaccine-related injuries and deaths to VAERS. Causality will be denied due to the design of the VAERS reporting system. These include that not all events must be reported; contract to testimony by CDC Director Rochelle Walensky, events following vaccines do not have to be reported. There are no penalties for doctors who fail to report, and many physicians will lie to the parents of their patients and state, without any scientific evidence, that the adverse event or death could not have been caused by the COVID-19 vaccine.
- (5) In the studies that led to the EUA for COVID-19 vaccines for adults, vaccine manufacturers skipped Phase 2 by conducting Phase 1 trials followed by combined Phase 2/3 trials. In this study leading up to their bid for EUA for children, Pfizer combined Phases 1, 2 and 3 into a Phase 1/2/3 trial. This prevents the generation of data confirming prior adverse events found in separate Phase 1 and 2 trials. This is utterly reprehensible.
- (6) The causality of injuries and deaths following COVID-19 vaccines in this age group will not be able to file for compensation via the National Vaccine Injury Compensation Program's "Vaccine Court,", in which the Health and Human Services (HHS) is both the defendant and the administrator. Parents who file vaccine injury claims for their children in the NVICP have to seek experts for testimony linking, at the cellular and molecular level, the constituent parts of COVID-19 vaccines and the specific physiological basis of injuries or deaths in specific patients. Arguing causality using a single patient is the status quo of the culture of the Vaccine Court, which any scientist worth their salt will tell you is next to impossible. HHS medical experts will provide testimony arguing against each and every single death or injury following COVID-19, and no participants in the National Vaccine Injury Compensation Program will be able to access the testimony from other cases including rulings, nor will they be able to cite precedent.

The rules in the NVICP abrogate a number of important fundamental precepts of Western Law. The HHS, which falls in the Executive Branch of US Government, is both the defendant and the administrator of the NVICP, which is (ostensibly) part of the US Judiciary branch of government, a

clear violation of the separation of powers doctrine of the US Constitution.

## From Cornell.Edu:

"Separation of powers is a doctrine of constitutional law under which the three branches of government (executive, legislative, and judicial) are kept separate. ... Each branch has separate powers, and generally each branch is not allowed to exercise the powers of the other branches."

How do we know all of this? We know this because these facts have been established for a long time as the status quo for all other pediatric vaccines on the CDC's recommended vaccine schedule.

However, for COVID-19 vaccine-related injuries and deaths, parents will have to file in a program called the <u>Countermeasures Injury Compensation Program (CICP)</u>. The CICP has been in play since 2013, long before COVID-19. Parents will have to file a "request for benefits" package. Unlike the NVICP, in which one can file up to three years following initial symptoms linked to the vaccine, CICP requires that parents file within one year.

Parents have twelve months to link their children's death or injury to COVID-19 vaccines based on 2 months of follow-up for safety. And, of course, Pfizer will not be liable for any damages.

### Some Predictions Based on Leaked Data

We've had a peek at the data that will be reviewed by VRBAC – and we need to insist that they consider absolute risk reduction, as opposed to relative risk reduction. From the New York Times:

"One person familiar with the data, who spoke on condition of anonymity, said children 2 to 4 years old who were given two shots were infected at a rate 57 percent lower than the children in the placebo group. Children 6 months to 2 years old who got shots were infected at a rate 50 percent lower than the placebo group. There were fewer than 100 cases of symptomatic infection — a small fraction of the participants overall."

Here, we see a *leak* from Pfizer, designed to inspire confidence in their stocks, offered without any caveat as a forward-looking statement (alert Security Exchange Commission). I can tell from the language, however, that the data are representing rates of diagnosis (not reductions in hospitalizations), and that they are prepared as relative risk reduction. That's the thing about percentages: a 57 percent reduction in diagnosis can involve a handful of children (1% is 50% of 2%, after all), and this practice of reporting only relative risk is par for the course for VRBPAC and other committees, such as the Advisory Committee on Immunization Practices (ACIP) committee.

The futile continued use of vaccines that target extinct variants, however, may make VRBPAC's job of cheerleading difficult: the data appear to not support protection against Omicron (Source: New York Times).

The results are also likely to be arbitrarily subdivided into subjective age groups ("6 mos-2 years" and "over 2 years old") because the results may not have been impressive using all of the data from all children in the study in a single analysis.

The evidence of "immunity" will also likely be restricted to antibody production, and we know that high antibody production is (1) not indicative of long-term immunity and (2) desirable given the possibility of

pathogenic priming.

The FDA Committee will not be told by Pfizer that the scientific evidence is mounting that the use of vaccines designed for extinct COVID-19 variants is linked to the easier spread of the virus from cell to cell in infected individuals. You can read my article on Dr. Fantini and colleagues' findings on this <a href="here">here</a>, published Dec 26, 2021.

## How to Contact VRBPAC and Urge Them to Deny the EUA

You can participate with the VRBPAC meeting, scheduled for Feb 15th, 2022, here

# FDA Docket FDA-2022-N-0082

- 1. Take some time and draft, in your own words, a message outlining your concerns.
- Be sure to reference that you are addressing the Pending FDA EUA Consideration of the Pfizer COVID-19 Vaccine Use in Children Ages 6 months through four years of age, Docket FDA-2022-N-0082.
- 3. Pfizer's Press release is here.
- 4. The New York Times Article with the evidence of the data leak is here(subscription required).
- 5. Also send your message as email to SEC Chair, Gary Gensler [email protected] and remind him that earlier press releases related to COVID-19 vaccines did not include the required "Forward-Looking Statements" and that you are concerned that the data leak violates SEC requirements.

The Roster for the VRBPAC Committee is here.

Address your message as follows:

### To: Hana El Sahly, M.D., Chair and the entire VRBPAC Committee

Subject: Pending EUA Meeting, Pfizer COVID-19 Vaccine in Young Children

Feel free to use any or all of the text of my articles as inspiration, but please try to make your message your own.

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By Dr. James Lyons-Weiler

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### **Date Created**

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