Despite Incomplete Safety Trials, the FDA Grants Full Approval to Pfizer-BioNTech's COMIRNATY® for Adolescents 12-15 Years of Age

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Without a completed safety study or expert committee review, the FDA issued a supplemental Biologics License Application ("sBLA") approval letter granting full FDA approval to Pfizer-BioNTech's COMIRNATY® COVID-19 mRNA vaccine for use in children ages 12-15. This was done even though safety study completion, on which approval should be based, will not be completed until May 31, 2023. [see this and this] Additionally, the approval was issued even though COMIRNATY is still not available in the United States. [DeMasi, Maryanne. "Is Pfizer's FDA-approved COMIRNATY Vaccine Available in the US?" Brownstone Institute, May 22, 2022] Thus, the FDA has approved a commercial drug for children without appropriate evidence of safety.

There was no emergency to approve this vaccine without a full safety evaluation. The only vaccine currently available for American children is Pfizer's Emergency Use Authorization (EUA) drug, a drug that is legally distinct from COMIRNATY® per the FDA. [Johnson, Ron. "Sen. Johnson Continues to Press the FDA, Pfizer, BioNTech on Transparency and Politicization of Vaccine Approval Process." *Ron Johnson Senator from Wisconsin*, Senate.gov, 8 Oct. 2021] The FDA has approved COMIRNATY® over a year *before* the results of the safety data will be known. In short, the FDA approved a drug for children without complete safety data and without the participation of an expert panel. Moreover, it approved a drug for children that is not currently available in the U.S. and has no known date when it will be available. [DeMasi, Maryanne. "Is Pfizer's FDA-approved COMIRNATY Vaccine Available in the US?" *Brownstone Institute*, May 22, 2022] Therefore, children are still receiving an experimental vaccine with the original Wuhan Alpha spike protein mRNA, which is outdated and known to have serious adverse side effects.

The FDA's mission statement purports to protect residents of the United States from harms, including those from medications, from the products that it regulates. [See this] So why did the FDA skip the standard safety steps to approve COMIRNATY® for adolescents before its

level of safety was fully understood? To answer this, one must look at what has happened and what has been omitted.

Background

In a new low for the agency charged with keeping Americans safe and ensuring the drugs it regulates are effective, the FDA gave full approval on August 23, 2021, to Pfizer-BioNTech for its BLA STN 125742/0 mRNA vaccine, also known as COMIRNATY®, to be used in adolescents 16 years of age and older. The FDA issued a post-marketing requirement related to this approval. The associated Pediatric Study C4591001 to evaluate the safety and effectiveness of COMIRNATY® in children 12-15 years of age is due to be completed in May 2023, with final report submission due in October 2023. [p. 5.] It is noteworthy that the initial approval letter from August 2021 approved the use of COMIRNATY in children 16 years and older, despite increasing evidence of serious side effects, including myocarditis. [p. 5.]

Can we trust the data from this trial?

There has been extensive criticism of this trial since November 2021, and of the FDA's reliance on it for granting Emergency Use Authorizations (EUAs) for vaccinating young children. [Shir-Raz, Yaffa, M.D. "Serious violations and manipulations of trial protocol: How Pfizer obtained FDA emergency authorization for children." *AFLDS Frontline News*, November 23, 2021] The efficacy claims, for instance, are based on data from before Delta and before Omicron. Children's Health Defense also sent a letter to the FDA Vaccines and Related Biological Products Advisory Committee (VRBPAC) explaining the problems with the children's trials. [See this]

Are there not pre-existing protections for children with higher standards than protections for adult medications?

Yes. The Pediatric Research Equity Act (PREA) "requires the conduct of pediatric studies for certain drug and biological products." [See this] It requires biologics licensing applications (BLAs), or supplements to applications, for any new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration to contain a "pediatric assessment" showing that it is safe for children, unless the applicant has obtained a waiver or deferral (reference section 505B(a) of PREA).

What does the deferred language mean in the FDA approval letter?

The FDA approval allowed for "deferral" of the usual testing process. "If a deferral has been granted, the pediatric assessment will be due on or before the date specified by the Agency (section 505B(a)(3) of PREA)." [See this]

Although the trial purportedly showed 100% effectiveness and that the drug was tolerated well, the safety of patients in the trial was not fully established prior to the FDA's approval of this injection for minors. All participants in the trial needed to be monitored for long-term protection and safety for an *additional two years* after their second dose. That is why data will continue to be collected until May 2023, and a final report will be submitted to the FDA by October 31, 2023. [p. 5.] So the approval for the Pfizer mRNA injection for minors short-circuited this process.

Under those circumstances, how can we ensure this vaccine's long-term safety to our children?

We cannot ensure long-term safety under this truncated process. The trial that was used only follows the candidates within the trial itself, and the FDA's only requirement of Pfizer, in this case, was that they present their own data. Thus, there is no reference to any adverse events that are subsequently reported in the Vaccine Adverse Events Reporting System (VAERS), which has been shown to only report 1% of vaccine injuries, a gross level of underreporting. [AHRQ's Lazarus Report, 2011] Under these circumstances, there is no mechanism by which the FDA can look at the totality of the data in terms of harms to children over time.

What could the FDA do to provide safety during medical interventions, especially in pediatric patients?

The safety of a product should be paramount in infants and children, with proper observation and reporting of serious adverse events, and a longer time should be allocated for this to happen prior to any drug approval, as is usually the case.

The Pfizer pediatric trial does not end for nearly another year, and yet the FDA committee decided that completion of such longer-term follow-up did not need to be a prerequisite to licensure unless warranted by a specific safety concern. [See this and this]. By truncating the timeline of the trials and restricting the data observed, they did not look for and, thus, chose not to find safety concerns.

Call to Action

Americans must demand that the VAERS database be improved, and people should be strongly encouraged to report adverse events directly into its online portal. The database findings should be reviewed by the VRBPAC, alongside any trial data from a pharmaceutical company. Additionally, no drug should be approved for use in children without fully completed, submitted, and evaluated safety studies over the appropriate length of time.

Potentially ALL American children aged 12-15 are affected, as this is a full commercial approval. The stakes could not be higher for the health and wellbeing of our next generation of Americans.

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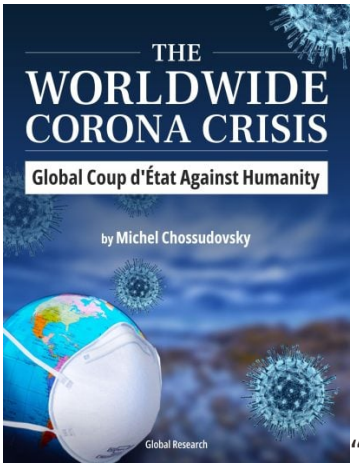

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