FDA Violated Own Safety and Efficacy Standards in Approving COVID Vaccines for Children

The FDA recently authorized Pfizer's and Moderna's COVID-19 vaccines for children as young as six months. Troublingly, the evidence the FDA used for those decisions violates at least three safety and efficacy standards from earlier FDA publications about COVID-19 vaccines:

- In 2021, the FDA warned that "antibody tests should not be used to evaluate a person's level of immunity or protection from COVID-19 at any time, and especially after the person received a COVID-19 vaccination." Yet, antibody tests are the main evidence the FDA cited when approving these vaccines for young children.
- In 2021, the FDA declared, "We know from our vast experience with other pediatric vaccines that children are not small adults," and thus, a "comprehensive evaluation of clinical trial data" is necessary to "support of the safety and effectiveness" of vaccines before they are "used in a younger pediatric population." Yet, the FDA used small studies with narrow data and claimed these vaccines are effective and safe for children by extrapolating from studies done on adults.
- In 2021, the FDA wrote that "the primary study objective" is that the vaccines are at least 30 percent effective with 95 percent confidence in preventing COVID-19. Yet, none of the studies on young children met this threshold, and some were negative, meaning that the vaccine could increase the chances of catching COVID-19.

Amplifying those problems, the FDA approved the vaccines for young children even though the clinical trials:

- used antibody tests that are not targeted to the Omicron variant, which accounts for 100 percent of current COVID-19 cases.
- excluded children apt to have serious adverse reactions to the vaccines.
- found adverse reactions to the vaccines, including fevers up to 105.4 ºF, eye-rolling seizures, convulsions, limping, and a "severe" decline in white blood cells that creates the "risk of overwhelming infection."
- did not enroll enough children to show any clinically meaningful benefits like preventing severe COVID-19, hospitalization, or death.
- would need to be 400,000 times larger/longer to determine if the vaccines save more toddlers and preschoolers than they kill.
- fail to report the absolute efficacy rates of the vaccines, which a medical journal explains can "mislead and distort the public's interpretation of COVID-19 mRNA vaccine efficacy and violate the ethical and legal obligations of informed consent."
- largely excluded children with evidence of a prior COVID infection, which exaggerates the efficacy of the vaccines and may downplay their risks.
- had 1–3 months of blinded follow up for safety and efficacy, while the FDA and other health agencies said that one year should be the bare minimum.

The bulk of these facts come directly from the FDA, often buried on webpages in long lists of documents with vague recurring names like "Decision Memorandum."

For thorough documentation of these facts, including extensive quotes of the FDA documents with hyperlinks to them, continue reading by clicking here.

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