06/15/22 • COVID › NEWS

FDA Advisors Unanimously Endorse Pfizer, Moderna COVID Shots for Infants and Young Kids, Ignore Pleas to 'First Do No Harm'

"All the risks are to the innocent children and all of the billion-dollar rewards go to the government-protected pharmaceuticals," said Rep. Louie Gohmert (R-Texas), after advisors to the U.S. Food and Drug Administration today voted 21-0 to recommend Pfizer's and Moderna's COVID-19 vaccines for infants and young children.

The U.S. Food and Drug Administration's (FDA) vaccine advisory panel today unanimously voted 21-0 to recommend Pfizer and Moderna's COVID-19 vaccines for infants and young children, stating the totality of the evidence available shows the benefits of the vaccines outweigh the risks of use.

Pfizer's three-dose vaccine would cover children 6 months to 5 years old, while Moderna's two-dose vaccine covers children 6 months to 6 years old.

States have already ordered millions of doses made available prior to FDA authorization by the Biden administration.

Depending on whether the FDA and Centers for Disease Control and Prevention (CDC) accept the recommendations of their advisory panels, White House officials have said the administration of vaccines for these age groups could start as early as June 21.

The Vaccines and Related Biological Products Advisory Committee (VRBPAC) ignored pleas from experts, the vaccine injured and a congressman representing 17 other lawmakers to halt authorization until questions about the safety and efficacy of COVID-19 vaccines for the nation's youngest children could be properly addressed.

Many of the committee members, including pediatrician Dr. Ofer Levy, said the decision to authorize the shots was about providing a choice to parents who wanted access to COVID-19 vaccines, despite concerns by public commenters the panel was not adhering to the requirements for Emergency Use Authorization (EUA) and that authorization would eventually lead to mandates — as it did with adult vaccines.

"I know that the death rate from COVID and young children may not be extremely high," said Dr. Jay Portnoy, professor of pediatrics at Children's Mercy Hospital in Kansas City, Missouri. "It's absolutely terrifying to parents to have their child be sick."

Portnoy said there are "so many parents who are absolutely desperate to get this vaccine" and he thinks the committee "owes it to them to give them the choice."

Several committee members, including Dr. Paul Offit, director of the Vaccine Education Center at Children's Hospital of Philadelphia, raised concerns about Pfizer's COVID-19 vaccine for kids and the minimal protection it provided after two doses.

Offit said he still supports authorizing a three-dose regimen for the youngest age groups but expects four doses may be needed.

Moderna's vaccine for infants and toddlers consists of two 25-microgram shots, while Pfizer's vaccine is a triple-dose regimen of 3-microgram shots each.

Combining all ages together, Pfizer said its three-dose regimen for children 6 months to 5 years old was 80% effective at preventing illness from the Omicron variant based on preliminary data from its clinical trial.

The 80% number was calculated 30 days after the third dose. As noted by committee members, the efficacy number is likely to go down after 30 days and post-approval monitoring was suggested.

Moderna said its two-shot vaccine was about 51% effective against infection from Omicron in children under 2, and about 37% among kids 2 to 5 years old, citing different efficacy numbers than what was reported by the company in March.

In a March 23 press release, Moderna said its vaccine in the 6-month to 2-year age group was only 43.7% effective. In the older age group, the company said its vaccine was 37.5% effective.

A top official at Moderna has already said a booster will be necessary.

All previously authorized COVID-19 vaccines and boosters for all age groups were required to meet the FDA's 50% requirement prior to obtaining EUA.

But Dr. Peter Marks, director of the Center for Biologics Evaluation and Research at the FDA, last month told the House Select Subcommittee on the Coronavirus Crisis the agency would not withhold authorization of a pediatric vaccine if it fails to meet the agency's 50% efficacy threshold for blocking symptomatic infections.

Congressman calls out FDA for failing to answer lawmakers' questions

During the public hearing portion of the meeting, Rep. Louie Gohmert (R-Texas) said there are many unanswered questions regarding the safety and efficacy of COVID-19 vaccines, especially for babies and young children.

"I'm deeply concerned that the push to vaccinate these children is nothing more than a dystopian experiment with unknown consequences," Gohmert told the committee. "Some of us have outlined these questions in a letter to VRBPAC but have not received any answers, and I pose some of them here."

Gohmert said:

> "Number 1, why has the FDA refused to release the hundreds of thousands of pages of data from preapproval manufacturer studies, post-approval adverse events data and other post-approval manufacturer data?
>
> "Number 2, what is the cardiac risk factor in administrating these COVID vaccines to children?
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> "Number 3, world-renowned immunologists have raised concerns about potential antibody-dependent enhancement, or ADE, resulting from COVID vaccines, and since ADE was a problem in prior unrelated respiratory vaccine trials, we need to know what studies, if any, the FDA has that it's used regarding ADE from COVID vaccines in children 5 and under or any age group. Can the FDA affirm there's no risk of ADE for vaccinated children?

> "Number 4, if widely approved among children 5 and under, how many lives, if any, does FDA estimate will be saved next year? Given the injuries reported in the FDA's VAERS [Vaccine Adverse Event Reporting System] system, how will FDA evaluate serious vaccine injuries versus serious COVID outcomes?
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> "Number 5, is it possible the proposed COVID vaccines in young children could create increased risk in future novel COVID variants?
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> "Number 6, why has the FDA recently lowered the efficacy bar for COVID vaccines for youngest children? This change significantly lowers the expected benefits from any COVID vaccination for young children and it's of particular concern given that over 70% of that age cohort already is seropositive."

Gohmert said these questions and 13 other questions posed by lawmakers are critical and deserve answers from the FDA and VRBPAC prior to any EUA with the "accompanied protection for liability for all harm done."

Gohmert added:

> "In conclusion, some of us have grave concerns that in balancing the risk to rewards here, all the risks are to the innocent children and all of the billion-dollar rewards go to the government-protected pharmaceuticals, leaving me to wonder if Republicans get a majority I may need to have a bill [...] to allow civil and criminal liability to vaccine providers and accessories despite an EUA which would force more sensitivity towards vaccine harm to our young children."

Vaccine-injured speak out

During the public hearing session of the meeting, numerous individuals discussed the injuries they experienced after being vaccinated with Moderna and Pfizer's COVID-19 vaccines, pleading with officials to look at what's occurring with the adult population before they authorize vaccines for kids.

Jasmine King, a 38-year-old lawyer whose law license lapsed after she was injured by her first dose of Moderna, said she has been to more than 50 doctor appointments and has spent more than $20,000 in co-pays, treatments and supplements to heal from her injuries.

King said she is being monitored for Lou Gherig's disease and developed sensory nerve symptoms, motor nerve problems, heart palpitations and autonomic nervous system issues after being vaccinated.

King asked the advisory panel to look at what's happening in the adult population to see what could happen in the pediatric population — if authorization is given — and consider vaccine injuries when discussing the risks of COVID-19.

Kathlyn Hinesley pointed out that the FDA is legally prohibited from approving any biological product for emergency use unless there's an emergency that poses a risk of death to the target group, the product is effective in preventing the disease, it is safe and the benefits must outweigh the risk.

Hinesley stated:

> "With regard to the first point, children without comorbidities who acquire COVID-19 have a 99.98% survival rate. There is no emergency. Moving forward to effectiveness, a study [...] which includes data analysis of 145 countries found that COVID-19 vaccines were in fact associated with a 38% increase in COVID cases and a 31% increase in deaths. Could these vaccines be negatively affecting immunity?

> "The number of severe adverse events affecting children ages 5 to 17 reported to VAERS as of June 3 was 8,811, including 114 deaths and 1,346 cases of myocarditis — a condition that can be fatal.
>
> "We can assume if these vaccines are authorized, some babies will die. The benefits of these vaccines are questionable and the risks are clear."

Hinesley told the committee if they authorized injections for this age group, they would be participating in the killing of children.

Sam Dodson, an intellectual engineer, called out the FDA for doing "nothing" with the "massive safety signals," colluding with pharmaceutical companies to suppress trial data for 75 years, ignoring fraudulent data, ignoring adverse events like myocarditis and prion diseases and ignoring issues with infertility.

Dodson also expressed concerns about biodistribution data he accused the agency of "doing nothing" about.

"You turned a once-respected agency into a corrupt vessel for the very corporations you swore to protect the American public from," Dodson said. "If you have one shred of humanity left you will call for an immediate halt to the shots […]."

Before his time ended, Dodson said the panel might want to figure out how they're "going to diagnose myocarditis in very young babies who can't talk."

Dr. Katarina Lindley, a physician and member of the steering committee for the World Council for Health, said data from the CDC from February showed 74.2% of children have already acquired COVID-19 and expressed concerns over Moderna and Pfizer's data presented to the FDA.

Lindley stated:

> "Over 150 studies show that natural immunity is superior. The infection fatality rate under 5 years of age is 0.1 in 100,000 or 1 in a million. The risk of the shot in the already immune is higher than 1 in a million.
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> "Both Pfizer and Moderna expressly eliminated those that were naturally immune from their study. They did this to avoid the hyperimmune response and possibly death.
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> "Vaccinating the already immune puts them at risk of having a hyperimmune response. This means you'll be voting for some children to have a severe adverse reaction and possibly death if you vaccinate the immune. This is bad medicine."

FDA advisors fail to discuss vaccine imprinting among infants and toddlers

Immune imprinting was not on the agenda at the VRBPAC meeting, nor was it discussed among experts.

However, the authors of an op-ed published this week in STAT, a pharmaceutical industry publication, raised the issue as justification for calling on the FDA panel to reject Pfizer and Moderna's EUA for young children.

Steve Brozak, founder of the WBB Research Institute, and Dr. Richard Marfuggi, surgeon and medical director of the WBB Research Institute and member of the New Jersey State Biomedical Ethics Committee, wrote:

> "The vote on this vaccine for this vulnerable sector of the population is not inexorable. The availability of a therapy is not a justification for its use when benefits of such use are so poorly

> justified and no data on future consequences for this population to specifically include imprinting even exists.
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> "The VRBPAC should say 'no' to vaccinating infants and toddlers with the Moderna or Pfizer/BioNTech vaccines. 'First do no harm' has never been a more important dictum."

Immune imprinting, or original antigenic sin (OAS), results from exposure to proteins or other biological structures of viruses, like the SARS-CoV-2 spike protein, that allow a virus to penetrate host cells and cause infection.

OAS refers to the preference of the immune system to recall existing memory cells — that recall the same pathogen for antibody production — rather than stimulating a new response when encountering a novel but closely related antigen.

According to Brozak and Marfuggi, imprinting can come directly from an acute infection acquired naturally or indirectly through vaccination.

"It can result in reduced — or enhanced — responses to future variants with unknown clinical consequences," they wrote. "The former is beneficial, the latter is not."

Immune system imprinting and the negative effects of imprinting are not new concepts. A team of researchers in a 2013 paper described how infants who survived the 1889 Russian pandemic were more likely to experience excess mortality as adults during the Spanish flu pandemic of 1918.

Infants who survived the 1918 Spanish flu were more likely to experience excess mortality as adults during the Hong Kong flu of 1968 and infants exposed to the swine flu pandemic of 1957 were more likely to experience excess mortality as adults during the 2009 H1N1 pandemic in Mexico.

According to the Doctrine of Original Antigenic Sin by Dr. Thomas Francis, the initial priming of the immune system (initial exposure to the virus, either in the wild or via a vaccine) gets "fixed" for life.

If the initial priming of the immune system is sub-optimal and biased, then that sub-optimal initial priming can effectively derange and bias the immune response long-term, which would guide all future immunological responses, said Dr. Paul Elias Alexander, a global expert on COVID-19.

According to Brozak and Marfuggi, the immune systems of infants and toddlers — the latest targets of COVID-19 vaccine manufacturers and health agencies — are immature and developing.

They wrote:

> "If an immature immune system is immunologically imprinted, either by acute infection from the currently circulating viral variant or by a COVID-19 vaccine based on the original, wild-type variant that is no longer in circulation, it may fail to develop appropriate defenses when confronted — even years later — by a Covid variant or another totally different pathogen."

According to Alexander, "The COVID-19 vaccines being administered in the U.S. only reduce symptoms, thus allowing the host to stay alive (an evolutionary future it did not have) while remaining capable of transmitting. Evidence shows vaccinated persons are indeed susceptible to infection, and as alarmingly, carry as high a viral load as the unvaccinated."

In addition, vaccinated persons are likely to spread the virus to other members of their household, Alexander said.

"Imperfect, leaky and harmful COVID-19 vaccines could rob children of robust, durable and potent natural innate immunity that has always protected them and helps reduce the infectious pressure while contributing to population herd immunity."

Some vaccines could drive the evolution of more virulent pathogens, and "Marek's disease effect and vaccination may well be at play here with COVID vaccines — moderating symptoms while not stopping infection or transmission, thus posing a danger to the unvaccinated and vaccinated," Alexander added.

As The Defender reported Tuesday, Robert F. Kennedy, Jr., Children's Health Defense chairman and chief legal counsel, sent a letter to VRBPAC members last week warning that the organization is poised to take legal action should the EUAs be granted.

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