FDA Advisors Unanimously Recommend Moderna's COVID Vaccine for Kids 6 to 17, Completely Ignore Data

A vaccine committee advising the U.S. Food and Drug Administration (FDA) on Tuesday unanimously recommended Moderna's COVID-19 vaccine for children ages 6 to 17 after determining the benefits of the vaccine outweigh the risks.

The Vaccines and Related Biological Products Advisory Committee (VRBPAC) voted 22 to 0 to recommend Moderna's two-dose vaccine for 6- to 11-year-olds at half the strength of the adult version, and 22 to 0 in favor of authorizing the shot for 12- to 17-year-olds at the same strength as adults.

The FDA's vaccine panel will meet again on Wednesday to discuss amending Emergency Use Authorization (EUA) for Moderna's COVID-19 vaccine to include the "administration of the primary series to infants and children 6 months through 5

years of age" and the Pfizer-BioNTech vaccine to "include the administration of the primary series to infants and children 6 months through 4 years of age."

After VRBPAC makes its recommendations, the FDA will then decide whether to authorize Moderna and Pfizer's vaccines for the suggested age groups.

According to the Centers for Disease Control and Prevention (CDC), only 189 children aged 5 to 11 and 443 adolescents and teens have died of COVID-19 over the course of the pandemic — most of whom already had underlying conditions.

Roughly two-thirds of children aged 6 to 17 who were hospitalized with COVID-19 had underlying conditions.

According to data from the Vaccine Adverse Event Reporting System, between Dec. 14, 2020, and June 3, 2022, 1,295,329 adverse events have been reported, including 236,767 serious injuries and 28,714 deaths following COVID-19 vaccinations.

In children ages 5-17, there have been 49,283 adverse events reported, including 114 deaths.

As for the efficacy of Moderna's COVID-19 vaccine — there were so few cases of COVID-19 among pediatric trial participants that efficacy data fell far short of the data collected for adults. Company officials said they planned to examine real-world effectiveness if the shots are authorized in an "authorize it now and we'll tell you it doesn't work later" situation.

During the public comment session of the meeting, individuals expressed concern over recommending a vaccine for an age group that has almost no risk of experiencing severe illness or death from COVID-19. Others pointed out statistics that showed more than 75% of the pediatric population already had natural immunity.

Dr. Harvey Klein, orthopedic surgeon, mechanical engineer and rocket scientist said he is appalled at the FDA's arrogance in even "thinking of vaccinating healthy children with outdated, highly toxic COVID vaccines."

Klein said:

> *"Children have a "99.998% recovery rate with no sequelae if they get COVID. Vaccine Adverse Event Reporting System (VAERS) statistics show children ages birth to 18 who have been vaccinated with Pfizer-BioNTech and Moderna's so-called vaccines have had severe life-threatening adverse reactions, such as myocarditis, Guillain-Barré Syndrome and many more severe adverse reactions [including] death.*

"We know that VAERS is underreported by a factor of 100. The data cries out loudly to stop this insanity immediately before you kill or maim one more innocent child."

Klein said the risks do not outweigh the benefits as children from birth up to age 18 have a survival rate of 99.9% and virtually no risk of death.

"Why in the world would you want to try to improve on perfection by exposing them to significant chances of being permanently severely injured or dead?" Klein asked. "The risk is infinite, the benefits are non-existent and the efficacy is extremely negative."

Dr. David Gortler is a pharmacologist, pharmacist, FDA and healthcare policy oversight fellow and FDA reform advocate at the Ethics and Public Policy Center in Washington, D.C.

In a public comment published on the Ethics and Public Policy Center's website, Gortler said the FDA and its advisory panel have "maintained a highly non-scientific and casual attitude toward approving a vaccine whose short- and long-term effects on children are unclear."

Gortler said the FDA has failed to address genotoxicity, teratogenicity, oncogenicity of COVID-19 vaccines and cardiovascular risk following vaccination, potential fertility issues and clinical effects of spike proteins in donated or transfused blood.

"Before parents consent to vaccinate their children against COVID, basic medical ethics requires that they be informed of exactly how safe that vaccine is," Gortler said.

Four million doses must be administered to children 5 to 11 years of age to prevent a single ICU admission in the same age group, Gortler said.

"Assuming two doses per child, that means two million children must risk potentially serious side effects to prevent a single child from requiring intensive care due to COVID-19."

Another analysis shows COVID-19 vaccination increases a child's risk of dying from infection.

"Children under 18 are also 51 times more likely to die from the vaccine than they are to die from COVID infection if not vaccinated," Gortler said, citing the analysis. "In other words, there is no clinical or epidemiological justification for vaccination in this particular group."

In a press release, Mary Holland, Children's Health Defense (CHD) president and general counsel, said:

> *"Vaccinating young children against a virus that poses no harm to them is unethical and dangerous.*

> *"However, it does bring Pharma closer to its ultimate goal of getting COVID shots added to the recommended childhood vaccine schedule, which means Pfizer and other COVID vaccine manufacturers will have a captive market in perpetuity and likely never be held accountable for harm or even death to young children caused by their products."*

CDC says 635 cases of myocarditis in 18- to 30-year-olds not statistically significant

Moderna first requested authorization of its COVID-19 for the 12 through 17 age group a year ago, but health officials were concerned the shot could cause myocarditis and delayed the decision. Because of the concerns, Moderna held off on applying for authorization in 6- to 11-year-olds.

Moderna says concerns about myocarditis have now subsided after health officials presented data to the advisory committee on the risks of heart inflammation.

During the meeting, Dr. Tom Shimabukuro, a vaccine safety official at the CDC, said some data suggest a higher risk of myocarditis among people 18 to 39 years old after receiving Moderna's COVID-19 vaccine – which is administered at a higher dose than the Pfizer-BioNTech shot.

Shimabukuro said the findings were not consistent across various safety databases and were not statistically significant.

The CDC confirmed 635 cases of myocarditis, or heart inflammation in the 5 to 17 age group out of almost 55 million doses of the Pfizer-BioNTech vaccine administered. The agency said the condition occurred most often in adolescent boys after receiving their second dose.

"Based on health provider assessments, around 80% of those diagnosed appeared to have fully recovered. Another 18% had improved but not fully recovered," Shimabukuro said.

However, the CDC uses a narrowed case definition of "myocarditis," which excludes cases of cardiac arrest, ischemic strokes and deaths due to heart problems that

occur before one has the chance to go to the emergency department.

As The Vault Project previously reported, there have been numerous deaths in the 18 to 39 age group due to myocarditis, which pathologists have confirmed were caused by COVID-19 vaccines and are absent from the CDC's numbers.

Moderna's vaccine data for kids is concerning

The FDA last week released its risk-benefit assessment of Moderna's application for emergency use of its COVID-19 vaccine for children ages 6 months to 17 years old.

The single-spaced 190-page document was released just two days before the VRBPAC meeting.

Instead of providing four separate documents breaking down the data by adolescents ages 12 to 17, 6 to 11, 2 to 5 and 6 months to 23 months, the company lumped all age groups together to massage the data, said Toby Rogers, Ph.D.

Looking at each individual age group, the shot fails in each category, Rogers said. But lumping them together creates noise that makes it difficult to interpret the data. Moderna then subdivided these age groups into eight different subgroups resulting in 32 different tables.

Moderna also did this with its adverse event data by creating 20 adverse event tables allowing it to eliminate or hide data it didn't like.

Moderna's data showed its vaccine did not reduce severe outcomes because the risk of COVID-19 in this age group is infinitesimally small.

Another problem with Moderna's data is that it ignored actual

health outcomes by analyzing antibodies in the blood.

First, Moderna claims the sample size for each of the four subgroups of children is about 3,000. But when it came to looking at antibodies in the blood, the company only looked at the bloodwork of about 300 kids in each age group.

No explanation was given for the criteria they used to exclude 90% of the sample from their analysis.

The second issue is that "no placebo recipients were included in the Immunogenicity Subset" (p. 26). This means they did not include any blood work from anyone in the placebo group as required for a randomized controlled trial.

It is unknown whether the increase in antibody levels is from children who previously acquired natural immunity or from COVID-19 vaccines.

As part of its analysis, Moderna compared antibody levels in the blood of about 10% of children against antibody levels in a sample of roughly 300 adults ages 18 to 25 enrolled in a previous clinical trial.

Because antibody levels were similar, Moderna claimed its vaccine would prevent disease.

Yet, Moderna only measured antibody levels two months after the second dose – the time period when the antibody levels are at their peak.

"Data on safety are non-existent and woefully incomplete given the very short follow-up time post-vaccination, and the cohort sizes are too small to pick up any real adverse events," said CHD Chief Science Director Dr. Brian Hooker in a press release. "There are no long-term safety studies on these genetic technologies."

Research shows any efficacy acquired by a vaccine quickly wanes to zero within 6 months and then turns negative after

that, and that antibodies do not necessarily correlate with protection.

18 lawmakers demand answers from FDA

Eighteen members of Congress on June 8 wrote a letter demanding answers from the FDA regarding the safety and efficacy of COVID-19 shots for infants and young children prior to authorizing COVID-19 vaccines for young children.

They asked why the FDA has been slow to release "hundreds of thousands of pages of data pre-approval manufacturer studies, post-approval adverse events data and other post-approval manufacturer data submitted to the FDA as required by law; whether the FDA will release within 14 days the data that served the basis of the FDA's EUA approval should it be granted for children under 5, what the cardiac risk factor is in administering COVID vaccines to kids, why the FDA lowered its 50% efficacy threshold requirement for the nation's youngest children, whether COVID vaccines cause antibody-dependent enhancement, whether there's an increased risk of disease to future variants if vaccinated, how many lives will be saved through vaccination over the next year and how many children have died from COVID age 5 and under had pre-existing conditions.

The group also asked the agency for examples of medical emergencies for children ages 4 and under that would allow it to use its "emergency use authorization" and further questioned the data being used to justify EUA of COVID-19 vaccines for kids.

The advisory committee did not acknowledge the letter or answer their questions.