

Breaking: FDA Panel Recommends Moderna Two-Dose COVID Vaccine for Kids Ages 6 to 17 Despite Serious Safety Concerns

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The U.S. Food and Drug Administration’s vaccine advisory panel on Tuesday voted 22 – 0 to authorize Moderna’s COVID-19 vaccines for children ages 6 to 11 and 12 to 17 despite the lack of short- and long-term safety data and no evidence children are at risk of serious illness.

The U.S. Food and Drug Administration’s (FDA) vaccine advisory panel today [voted](#) unanimously to recommend Moderna’s COVID-19 vaccine for children ages 6 to 17 after determining the benefits of the vaccine outweigh the risks for use.

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 advisors](#) 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.”

The committee tomorrow also will discuss amending EUA of 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.

During the [public comment session](#) of the meeting, individuals expressed concern over recommending a vaccine for an age group that has an almost [zero risk](#) of experiencing

severe illness or death from COVID-19 and has already acquired a high level of [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and rocket scientist said he is appalled at the FDA's arrogance in even "thinking of vaccinating healthy children with outdated, highly toxic COVID vaccines."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 don't outweigh the benefits as children from birth up to age 18 have a survival rate of 99.9% and virtually [zero 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](#), by Kathy Dopp and Stephanie Seneff, Ph.D., 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 an email to [The Defender](#), 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 confirms 635 cases of myocarditis in 18- to 30-year-olds

During the meeting, Dr. Tom Shimabukuro, a vaccine safety official at the Centers for Disease Control and Prevention (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, [Reuters reported](#).

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.

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.

Moderna’s vaccine data for kids riddled with problems

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](#)," Rogers said.

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. "There are no long-term safety studies on these genetic technologies."

Research [shows](#) any efficacy acquired by a vaccine [quickly wanes](#) to zero by 6 months and then turns negative after that, and that antibodies do not necessarily correlate with protection.

18 members of Congress 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.

Robert F. Kennedy, Jr., CHD chairman and chief legal counsel, also sent a [letter](#) to VRBPAC members last week warning that CHD is poised to take legal action should the EUAs be granted.

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.

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