FDA approves Pfizer's COVID-19 vaccines for children aged 5–11

Benjamin Mateus 1 November 2021

On Friday, the Food and Drug Administration almost unanimously, 17–0 with one abstention, authorized the Pfizer COVID-19 vaccine under emergency use for children aged 5–11.

The Advisory Committee on Immunization Practices (ACIP) is scheduled to convene today to recommend who might receive the vaccines. The Centers for Disease Control and Prevention (CDC) director must then endorse these recommendations, meaning that the soonest that children can begin receiving vaccinations will be on Wednesday.

In anticipation of the regulatory approval, the Biden administration is relying on hospitals, clinics and pharmacies to inoculate children rather than public vaccination centers. "Kids have different needs than adults, and our operational planning is geared to meet those specific needs, including by offering vaccinations in settings that parents and kids are familiar with and trust," said Jeffrey D. Zients, the White House coronavirus response coordinator, to reporters.

Sonya Bernstein, a senior policy advisor on the COVID-19 response for the White House, explaining the hazards at play in trying to get children vaccinated, told the *New York Times*, "We know that access is going to be critical here. The administration has in recent weeks explored ways to provide a kid-friendly experience that makes sure that we're getting shots in arms with trusted providers in ways that make parents feel comfortable."

Approximately 28 million children in this age grouping would be approved to receive the Pfizer vaccine. The formulation contains only a third of the adult dosing, or 10 micrograms. The vaccines can be stored at standard refrigeration temperatures for up to 10 weeks. As with adults, the vaccine is given as a two-dose regimen 21 days apart.

The reduced dosing was selected based on the outcomes in the phase one trial for its safety, tolerability and immune response. The phase two and phase three trials that included 2,268 participants who were 5-11 years of age received the two-dose regimen.

A month after completing the series, antibody titers against the SARS-CoV-2 virus were comparable to the levels for those participants aged 16 to 25 who received the full adult-sized 30 microgram vaccines. Shots for those six months to four years of age remain under investigation.

With the FDA's announcement has come an about-face in the mainstream media's attitude on the dangers of the pandemic to children and schools as vectors for community transmission. Previously they had downplayed these concerns in order to push for a complete reopening of schools for in-person instruction.

Even as late as October 4, 2021, the *Washington Post* published an op-ed column by Jeffrey Vergales and Monica Gandhi, in which the authors claimed "in many cases, quarantines are probably doing more harm than good—given the well-documented costs, intellectual and social, of keeping children out of schools closed for inperson learning longer than many of its peer nations, despite evidence that schools could open safely."

The evidence has been contrary to these assertions. According to the American Academy of Pediatrics (AAP), one of the few reliable sources of information on the impact of the COVID-19 pandemic on children, at least 6.3 million children have tested positive for COVID-19. They account for 16.5 percent of all coronavirus infections in the country. More recently, they have accounted for 25.1 percent of weekly reported cases. For 11 straight weeks, more than 100,000 children have become infected each week. Almost 600 children have died from COVID-19 during the pandemic, 42.6 percent of them in the last four months.

With the FDA announcement, the *Post* now suddenly discovers the dangers to children from the coronavirus,

which can be overcome through the new vaccine, which will now overcome all resistance by parents to sending their children into social settings rather than protecting them at home.

The article notes: "A pediatric vaccine has been eagerly anticipated by many parents who want to ensure their children's safety and holiday gatherings. Experts say the immunizations [of children] will represent a milestone in a pandemic that has killed more than 737,000 people in the United States."

The *Post* cites critical expert testimony. Patrick S. Moore, a University of Pittsburgh microbiologist and committee member, declared, "To me, it seems that it is a hard decision but a clear one. Ninety-four children between five and 11 have died of COVID-19, and all have names. All of them had mothers."

These tragedies could have been avoided had the government taken the appropriate cautionary note and pursued an elimination strategy that had proven effective in many countries when resources and political will were committed to ensuring the virus was kept at bay.

The *New York Times* wasted no time with an opinion piece that followed the FDA announcement, calling for the end to mask mandates. In their usual attempt to offer a "balanced" portrayal of the issue, Jessica Grose, who is the parenting columnist at the *Times*, as if it was a foregone conclusion, said, "But it's time to start a serious discussion about taking off masks since it will take time to institute policies after communities—hopefully—come to some degree of consensus. Maybe the carrot of mask-free schools will inspire some more hesitant families to get their children vaccinated."

Not surprisingly, in a follow-up Tweet to the Grose opinion piece, Professor Emily Oster, one of the main propagandists for reopening schools, wrote, "Masking offramps are necessary. I will admit I have been reluctant to talk about this, in part due to fear of being yelled at. This wasn't brave. I will try to be braver."

Clearly, behind the shifting winds in the bourgeois press is a consistent social interest: to vaccinate children is to once and for all put an end to all mitigation strategies and open the country to all commerce and travel and ensure schools remain open regardless of infection rates in classrooms. And with vaccines now available for children, the doors will be flung open.

New evidence, however, pours cold water over such rosy appraisals. In a recent study published in *The Lancet: Infectious Diseases*, the authors investigated the "transmission and viral load kinetics in vaccinated and unvaccinated individuals with mild Delta variant infection in the community." Though vaccines have shown high efficacy against severe disease and death, their ability to protect against asymptomatic transmission and mild disease has been far less effective, and the level of protection appears to decline more rapidly over a short time.

When they calculated the Secondary Attack Rates (SARs) [when an infected person spreads the disease in a family home or dwelling unit] in household contacts, they found that the SARs in "household contacts exposed to the Delta variant was 25 percent in vaccinated and 38 percent in unvaccinated contacts," according to a comment in *The Lancet* by Dr. Annelies Wilder-Smith, underscoring the fact that though better protected against serious infections and death, breakthrough infections continue to occur among the vaccinated. They also found that though vaccinated individuals cleared the virus sooner, peak viral loads were similar between vaccinated and unvaccinated.

According to the CDC, there have been 10,857 deaths and more than 30,000 non-fatal hospitalizations among the vaccinated population. A recent Twitter thread provided these glaring statistics. Out of 119,752,227 fully vaccinated people in 41 US jurisdictions that publicly report COVID-19 breakthrough cases and deaths, 1,338,315, or 1.12 percent, have experienced a confirmed breakthrough case, and 12,339, or 0.01 percent, have died following a breakthrough case.

Vaccines alone will not end the pandemic. Allowing the virus to persist in the human population will only lead to more deaths and disease as it becomes endemic, to say nothing of the danger of further and more deadly mutations. It has been estimated that COVID-19 would kill up to 100,000 people per year in the US if allowed to exist in the population, a toll almost four times above that of the flu.

Although immunization of children is critical, it is more important to eliminate the coronavirus from human populations rapidly. The notion of allowing the virus to become endemic is a dangerous policy. Yet, every time daily cases of new infections begin to decline, there is repeated push to lift more restrictions.



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