



Written by [Veronika Kyrylenko](#) on May 4, 2021

## Roll Up Your Sleeves, Kids: The FDA Is Poised to Approve Pfizer-BioNTech Vaccine for Adolescents

The U.S. Food and Drug Administration (FDA) is expected to authorize the Pfizer-BioNTech coronavirus vaccine for children ages 12 to 15 by early next week, a federal government official [told](#) CNN on Monday.

Pfizer had applied for an Emergency Use Authorization (EUA) for its coronavirus vaccine for 12-to-15-year-olds. The FDA will have to amend the current EUA for the vaccine to include this new age cohort, but the process should be straightforward, said the official who requested anonymity.

The FDA is currently reviewing data submitted by Pfizer to support the extended use. At the end of March, Pfizer-BioNTech [announced](#) that a clinical trial involving 2,260 12-to-15-year-olds showed an efficacy of 100 percent and that the vaccine is well tolerated. The vaccine is currently authorized in the United States for emergency use in people 16 and older.

Ugur Sahin, the CEO of BioNTech, tries to convince young people and their parents to get a shot as a prerequisite of returning to normal. "Across the globe, we are longing for a normal life. This is especially true for our children," he [said](#) in a statement in March. "It is very important to enable them to get back to everyday school life and to meet friends and family while protecting them and their loved ones."

The FDA appears to be in a rush to allow Pfizer jabs to hit the market as soon as possible, and is even likely to skip the discussion and vote on its use. Typically, before issuing an emergency use authorization (EUA) for a drug, the FDA holds meetings of its independent Vaccines and Related Biological Products Advisory Committee (VRBPAC) to review the data and vote on whether to recommend EUA. That will not happen in extending EUA to 12-to-15-year-olds, the official said. "While the FDA cannot predict how long its evaluation of the data and information will take, the agency will review the request as expeditiously as possible." This may sound alarming, but, rest assured, they promise to use a "science-based approach."

The former head of the U.S. Food and Drug Administration (FDA) [said](#) over the weekend that some 10 million U.S. children could receive the Pfizer-BioNTech coronavirus vaccine before fall should the jab receive EUA for the nation's younger population. Dr. Gottlieb estimated that some five million children between the ages of 12 and 15 would immediately receive the jab following approval, while another five to seven million would likely be vaccinated before the beginning of the fall 2021 school year.



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Dr. Sean O’Leary, a pediatric infectious diseases specialist at the University of Colorado [urges](#) the government to hasten the vaccine rollout for adolescents before the summer break begins. “We’re coming into the summertime when many adolescents come into the office to get their routine vaccines. And so if we missed those then, we may not be able to catch them up in the near future,” he believes.

Dr. Fauci said he hopes to see some kids starting to get vaccinated for COVID-19 in the next few months. He is certain that it would be a needed step to securing widespread immunity to the virus. Even though children and adolescents are spared the severe complications of COVID-19, they are still viewed as potential spreaders by Dr. Fauci.

If the ongoing trials are successful — and Pfizer has just presented the “brilliant” results — Dr. Fauci said they would be followed by another round of testing down to those nine years old. “Hopefully by the time we get to the late spring and early summer we will have children being able to be vaccinated,” Fauci [said](#) at a White House coronavirus briefing in January, and now it looks like his time estimates were correct. “As we get later into the year, towards the end of the year. I think by the time we get to the first quarter of 2022, we’ll be able to vaccinate children at virtually any age.... Hopefully before then. But I think that’s going to be the latest we’ll see it,” Fauci [predicted](#) recently.

The news come amid substantial concerns over the novel mRNA vaccines’ safety. Doctors and physicians argue that these so-called vaccines — or, more properly, unapproved experimental gene-therapy injections — may cause severe health implications that include death (*TNA* has covered it in detail [here](#), [here](#), and [here](#)), and [unpredictable long-term gene mutations](#).

Pfizer and Moderna both are testing their mRNA shots in children as young as six months old, and expect to ask the FDA for EUAs covering infants and children later this year.



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