Written by <u>Veronika Kyrylenko</u> on September 13, 2021



Trick-or-treat? FDA Expected to Approve Pfizer COVID Jab for Children Ages 5 to 11 by Halloween

Former Food and Drug Administration (FDA) Commissioner Dr. Scott Gottlieb, who is also a current Pfizer director, predicted Sunday that the FDA will grant Pfizer's COVID shot an approval for emergency use in children ages 5 to 11 by the end of October.

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In an interview with Face the Nation, Gottlieb said that the Big Pharma company is expecting to have clinical data on its vaccines in young children before the end of September, which will then be filed "within days" with the FDA. He went on to state that the FDA said it then will be a "matter of weeks, not months" to evaluate that data, and then, per his estimates, it would take from four to six weeks for the regulators to green-light the jab for use.



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"In a best-case scenario, given that timeline they've just laid out, you could potentially have a vaccine available to children aged 5 to 11 by Halloween," Gottlieb said. He added: "If everything goes well, the Pfizer data package is in order, and the FDA ultimately makes a positive determination, I have confidence in Pfizer in terms of the data that they've collected. But this is really up to the Food and Drug Administration to make an objective determination."

Further, Gottlieb explained that parents, who have "understandable concerns" regarding the use of this vaccine, would have to consult with their child's pediatrician to determine how to approach the issue of vaccination. Noting that there will be "not a binary approach — do I vaccinate my child or not," suggesting that he does not view refusal to inoculate little ones as an option. Gottlieb described some of the details on how a child may be given an upcoming shot: "You could go with one dose for now. You could potentially wait for the lower dose vaccine to be available.... If your child has had COVID, one dose may be sufficient. You could space the doses out more. So there's a lot of discretion that pediatricians can exercise" depending on the "child's needs," per Gottlieb.

Pfizer <u>started testing</u> its jabs on healthy 6-month to 11-year old children just in the end of March, which means that no mid- and long-term side effects of shots could possibly have been studied by now. Also, there is an almost <u>nonexistent</u> chance of young children dying of COVID. Yet, despite these facts, the FDA has seen an enormous amount of pressure from the politicians and a part of the medical community to swiftly approve a COVID shot for children younger than 12.

In the end of August, more than 100 House lawmakers on both sides of the aisle <u>wrote</u> to the FDA asking for an update on its timeline for vaccines for children, citing the current "alarming" situation.

Around the same time, the American Academy of Pediatrics (AAP), considered the world's largest and most influential professional association for pediatricians, and also the largest pediatric publisher, sent

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<u>a letter</u> to the FDA urging the agency to authorize the vaccine for children under 12 "as swiftly as possible." To those who believe in authority of expertise and science, it would be also be useful to know that the judgement of the seemingly respectable organization might be marred with a financial interest, since Pfizer is a major donor — a fact the AAP tried <u>unsuccessfully to hide</u>.

Last Friday, seemingly responding to the growing pressure, the FDA issued a <u>statement</u> that reflected that they are "eager" to see COVID jabs available for young children and "eager" to get them inoculated "as soon as possible." Still, while reassuring the public that "the FDA is working around the clock" to get it done, the body did not provide any timeline on when the approval may be issued.

Sure enough, the FDA also stressed that the evaluation of jabs "will not cut any corners." However, in the same statement, the regulators also said that the safety data on the possible side effects in children would be based on "at least two months" of follow-ups. Now, assuming that "at least two months" does not mean "a lot more than two months," that certainly does not sound like no "corners" are being cut. Given the already existing concerns in COVID jabs injuring and killing thousands of people, two months of jabs' safety data in children does not look sufficient enough to recommend it to some <u>28 million kids</u>.

Dr. Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases and President Joe Biden's top medical advisor, <u>said</u> that getting children vaccinated is an important step toward achieving herd immunity. Dr. Fauci is known as a big proponent of the vaccine mandates, so as soon as the shot gets an OK from the federal regulators, it is expected that he will advocate that the schools require their youngest students to get jabbed. Last week, the Los Angeles Unified School District, the second largest in the nation, made <u>such a decision</u> for their students older than 12, who are already eligible for the Pfizer shot.

In May, the FDA expanded the emergency use authorization for the Pfizer-BioNTech vaccine to include individuals from ages 12-15. And on August 23, the FDA granted <u>full approval</u> for Pfizer's Comirnaty vaccine, which is yet to make it to the American market, for use by people over the age of 16.



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