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Days after the FDA approved J&J's COVID vaccine for emergency use, the company announced plans to test the vaccine on newborns, despite the vaccine's risks and strong evidence that COVID poses virtually no risk to healthy children.

by [Megan Redshaw, J.D.](#) , [The Defender](#)

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On Friday, the U.S. Food and Drug Administration (FDA) [granted](#) Emergency Use Authorization for Johnson & Johnson's (J&J) [COVID vaccine](#), paving the way for the one-shot vaccine to be administered beginning this week.

The Centers for Disease Control and Prevention (CDC) also [recommended](#) the vaccine for people 18 and older. On Sunday, J&J [revealed plans](#) to test its one-shot vaccine on infants, including newborns, pregnant women and the immunocompromised. The expanded clinical trials were laid out in the company's application for emergency use approval and in [briefing materials](#) provided to the FDA and discussed briefly during the meeting.

According to the [New York Times](#), the plan for expanded clinical trials met the approval of Dr. Ofer Levy, director of the [Precision Vaccines Program](#) at Harvard's Boston Children's Hospital and a member of the FDA's advisory committee that

reviewed the company's vaccine data.

When Levy saw the outlines of the planned trials, he [said](#): "They did not get into a lot of detail about it but did make it clear they will be pursuing pediatric and maternal [coronavirus](#) immunization studies."

A spokesperson for Janssen Biotech, a J&J subsidiary, [confirmed](#) the company plans to extend clinical trials to children — first to children between the ages of 12 and 18, and immediately after to newborns and adolescents, then to pregnant women and immunocompromised individuals.

Levy [noted](#) vaccinating children will help the country reach [herd immunity](#), echoing comments made by Dr. Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases, during [Sunday's Meet the Press](#):

"Vaccinating young people will be necessary to approach herd immunity and significantly slow the spread of COVID-19 in the United States. While they typically have fewer symptoms than adults with COVID-19, children can still spread the disease."

[Children's Health Defense](#) President and General Counsel Mary Holland disagreed, stating that decades of intensive effort "[have not attained herd immunity](#) for any childhood disease." Holland has conducted [extensive research](#) on the history of vaccine policies.

Immunologist Tetyana Obukhanych, Ph.D., and others [agree](#) that officials use the [concept of herd immunity](#) as a "trump card to justify any measures, often at odds with personal freedom of choice, aiming to increase vaccination compliance," [The Defender reported](#).

Most of the world's vaccine market is pediatric vaccines, [according](#) to the Times, so it's not surprising that J&J would be looking to capitalize on a relatively untapped market for its coronavirus vaccine. As [The Defender reported](#) in

February, Bill Gates [set the stage](#) for a pediatric push last year, declaring his desire to make COVID-19 vaccines “part of the routine newborn immunization schedule” despite the fact that 99.997% of young people ages 0-19 survive COVID-19 with [most experiencing](#) either mild or no symptoms at all.

A study published in the [European Journal of Pediatrics](#) showed only a rare subset of children – mostly children with serious underlying medical conditions – experienced hospitalization or worse from COVID.

The [CDC](#) states: “COVID-19 is uncommon in newborns born to mothers who had COVID-19 during pregnancy. Some newborns have tested positive for COVID-19 shortly after birth, but it is unknown when they may have been exposed to the virus. Most infants and newborns who tested positive for COVID-19 had mild or no symptoms and recovered.”

According to the [Mayo Clinic](#), “While all children are capable of getting the virus that causes COVID-19, they don’t become sick as often as adults. Most children have mild symptoms or no symptoms.”

The potential adverse effects of J&J’s experimental vaccine remain relatively unknown. Unlike [Moderna](#) and [Pfizer’s](#) COVID-19 vaccines that rely on new [mRNA technology](#), J&J [utilized](#) a disabled [adenovirus](#) in their vaccine. Existing adenovirus vaccines [include](#) the controversial Ebola vaccine and respiratory syncytial virus.

“Do we really want to enlist our children in the war against an infectious disease when they are at little or no risk of getting COVID,” asked Lyn Redwood, RN, MSN, director and past president of Children’s Health Defense.

“After all, these vaccines are medical interventions that the U.S. Supreme Court [has recognized](#) as being unavoidably unsafe. We have to ask ourselves this difficult question: Is the potential risk to infants or children worth the potential

benefit for society?”

The FDA [found](#) J&J’s COVID vaccine to be only 67% effective in preventing moderate to severe symptoms at least 14 days after vaccination, and 66% effective in preventing moderate to severe symptoms at least 28 days after vaccination.

Although Moderna and Pfizer-BioNTech COVID vaccines are [purportedly](#) 95% and 94% [effective](#), these vaccine-makers have less aggressive plans to test their vaccines in younger age groups, [reported](#) the Times.

Two more COVID vaccines from [AstraZeneca](#) and [Novavax](#) are completing phase 3 clinical trials and are [expected to apply](#) for FDA authorization in the spring.

Biden’s administration announced today that J&J has partnered with pharmaceutical giant [Merck](#) to produce its COVID-19 vaccine, a senior administration official [confirmed](#) to CNBC News.

The [announcement](#) comes as the administration works to ramp up production of J&J ’s vaccine. In January, Merck [scrapped plans](#) to develop its own COVID vaccine after a clinical trial showed its shot was ineffective.

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