VIGOURTIMES



OPINION

# Why The Rush For Toddler Vaccines?

By Mike Schacter Last updated Jul 5, 2022

‘This is a very historic milestone, a monumental step forward,” President Biden declared last week after the Food and Drug Administration authorized

Pfizer

and

Moderna

vaccines for toddlers. “The United States is now the first country in the world to offer safe and effective Covid-19 vaccines for children as young as 6 months old.”

In fact, we don’t know if the vaccines are safe and effective. The rushed FDA action was based on extremely weak evidence. It’s one thing to show regulatory flexibility during an emergency. But for children, Covid isn’t an emergency. The FDA bent its standards to an unusual degree and brushed aside troubling evidence that warrants more investigation.

As it initially did for adults, the FDA granted the Pfizer and Moderna vaccines for toddlers an emergency-use authorization allowing the agency to expedite access for products that “prevent serious or life-threatening diseases or conditions.” While adult Covid vaccines clearly met this standard in late 2020, the toddler vaccines don’t.

Only 209 kids between 6 months and 4 years old have died from Covid—about 0.02% of all virus deaths in the U.S. About half as many toddlers were hospitalized with Covid between October 2020 and September 2021 as were hospitalized with the flu during the previous winter. More children were hospitalized during the Omicron wave last winter, but hospitalization rates were still roughly in line with the 2019-20 flu season. None of the 5,400 or so toddlers in Moderna’s trial were hospitalized for Covid. Yet at least 15 were hospitalized for non-Covid infections.

The two children in Pfizer’s trial who got sickest with Covid also tested positive for other viruses. It’s possible that many hospitalizations attributed to Covid this winter were actually instigated or exacerbated by other viruses. Doctors had warned that more “immunologically naive” children were likely to get sick once schools reopened and lockdowns were lifted.

Evidence supporting the efficacy of Moderna and Pfizer vaccines in adults, at least at the time they were approved, was also far stronger. Both trials were large and robust enough to demonstrate 95% efficacy against infection with a strong degree of certainty. By contrast, the FDA authorized the vaccines for toddlers based on a comparison of the antibodies they generated to the original Wuhan variant with those in young adults who

had received two doses. But two doses offer little if any protection against Omicron infection in adults, and even protection against hospitalization is only around 40% to 60%.

At least Moderna's trial showed modest efficacy against symptomatic Omicron infection —37% among 2- to 5-year-olds and 51% for those 6 months to 2 years old. Pfizer claimed its vaccine was 80% effective, but this is misleading. For one, Pfizer contravened numerous clinical-trial conventions. Its initial protocol involved only two doses, but this failed to generate the antibody levels required for FDA approval. So Pfizer added a third dose, which the FDA generously allowed. Usually the agency won't let drugmakers make a course correction when a trial ends in failure.

Pfizer then planned to track at least 21 cases to establish a bare-bones measure of efficacy. By comparison, Moderna tracked more than 250 cases. Yet Pfizer truncated its data collection on April 29—the day after Moderna announced it had submitted its application for emergency-use authorization—even though a mere 10 cases had been recorded after the third dose. It's hard not to conclude that Pfizer cut corners to avoid getting beaten by Moderna. But as a result too few cases were documented to measure with any degree of confidence Pfizer's vaccine efficacy. Pfizer nonetheless proclaimed its vaccine was 80% effective. Moderna scientists must be seething. A Pfizer spokesperson says the FDA was more interested in vaccine "immunogenicity" data than efficacy among toddlers and will do another efficacy analysis after more cases accrue.

More troubling, vaccinated toddlers in Pfizer's trial were more likely to get severely ill with Covid than those who received a placebo. Pfizer claimed most severe cases weren't "clinically significant," whatever that means, but this was all the more reason that the FDA should have required a longer follow-up before authorizing the vaccine.

Also worrisome: Most kids who developed multiple infections during the trial were vaccinated. This warranted more investigation, since experimental vaccines for other diseases sometimes increase susceptibility to infection.

Scientists are also discovering that triple-vaccinated adults who were previously infected with the Wuhan variant have a weaker immune response to Omicron, leaving them more susceptible to reinfection. This phenomenon, called “immunological imprinting,” could explain why children who received three Pfizer shots were more likely to get reinfected.

The FDA brushed aside the risk that inoculating infants against a variant no longer circulating could blunt their immune responses to Omicron and its offshoots. There’s a reason vaccine trials usually take a decade. Some steps can be accelerated, but an extended follow-up is often necessary to ensure potential side effects aren’t overlooked.

The FDA standard for approving vaccines in otherwise healthy people, especially children, is supposed to be higher than for drugs that treat the sick. But the FDA conspicuously lowered its standards to approve Covid vaccines for toddlers. Why? Perhaps it felt pressure from the White House as well as anxious parents. White House Covid response coordinator Ashish Jha repeatedly told parents that he expected vaccines for toddlers would be approved and available in June. Recall how Mr. Biden accused

Donald Trump

of pressuring the FDA to rush Covid vaccine approvals by suggesting they could be available before the November 2020 election.

Mr. Biden’s hypocrisy is hard to stomach. The FDA, to its credit, accelerated Covid treatments and vaccines when they were desperately needed. But children would have been better off had the FDA taken more time to ensure the vaccines really are safe and effective, even if this meant that America wouldn’t be first.

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