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If the FDA is serious about vaccine hesitancy, it should fully approve vaccines now

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July 28, 2021

As the Delta inferno spreads across the country, epidemiologists worry that, although its victims are overwhelmingly the unvaccinated, continued viral replication will produce a new mutant strain that can evade natural or vaccine-induced immunity, affecting everyone.

We can wind up back where we were in March 2020, with hospital ICUs overflowing and politicians re-issuing emergency orders that would place a good number of us back under house arrest. To snuff out the fire before it is too late requires getting as many people vaccinated as possible.

But a recent Kaiser Family Foundation survey suggests 30 percent of the vaccine hesitant, concerned they are taking an "experimental" drug, are waiting for the Food and Drug Administration (FDA) to formally approve the vaccine.

What is the FDA waiting for?

Under ordinary circumstances, it can take up to 10 to 15 years for the FDA to approve a new vaccine. However, the FDA can grant Emergency Use Authorization (EUA) to a new vaccine during public health emergencies, when time is of the essence.

To receive an EUA the vaccine still must meet rigorous safety and efficacy benchmarks. The FDA uses data from tens of thousands of patients who participated in phase 1 and phase 2 trials, along with any partial data from the yet-to-be completed phase 3 trials, to determine that "the known and potential benefits outweigh the known and potential risks of the vaccine."

It continues to collect efficacy data and monitor the vaccine for side effects after it grants emergency authorization. After the vaccine makers collect enough "real world" data from a vaccine's emergency use, they apply for full, formal approval. But that can take at least 10 months.

Pfizer submitted a request for full approval to the FDA in May. The other mRNA vaccine manufacturer, Moderna, tendered its request in early June. Johnson and Johnson, which makes a one-dose vaccine using a completely different platform—a DNA adenovirus as a vector—is expected to submit its request soon. The FDA agreed to give priority review of Pfizer's data, meaning it has until January 2022 to get back with an answer. It hasn't yet agreed to review Moderna's data because the company has not turned it all in yet.

With an annual budget of $5.9 billion, the FDA should be able to assemble enough experts to check over Pfizer's data and render an opinion before next year. They should also start looking over the data Moderna provided thus far to get the ball rolling on that company's request. The U.K. Medicines and Health Care Regulatory Agency employs "rolling reviews" of vaccine data, collecting it from the manufacturer and reviewing it in real time.

This way, when enough information has been gathered, they can quickly decide on approval.

The EU's European Medicines Agency does so as well. But the FDA doesn't even begin to review the data until the drug maker turns in the completed report. Even then, reviews are often scheduled to take place weeks later. It is difficult to imagine a private sector organization adopting such a clunky process.

Responding to calls to speed up the process, the FDA announced in mid-July that an answer to Pfizer's request is "likely to come much sooner" than the January 2022 deadline. Some think it might come in two months.

But the Delta fire still rages. How many months before a vaccine-resistant variant evolves? The FDA is taking too long. It already has data from what amounts to real world clinical trials in the U.S. of roughly 350 million doses given.

The evidence shows there are minimal major side effects or unusual adverse events associated with the mRNA vaccines. In fact, their safety profile is extraordinarily good.

It is rare that the FDA has an opportunity to view the real-world effects of a vaccine or drug on such a large population group in such a compressed time frame. Ordinarily, it takes several years to get data on these many millions of vaccine recipients.

The FDA should give full approval posthaste. Hopefully, this will remove the stigma of "experimental drug" that is keeping many people from getting themselves vaccinated—an action that could, quite literally, save their lives and prevent a more deadly variant from emerging.

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