WASHINGTON Examiner

FDA should fast-track coronavirus vaccine

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March 13, 2020

With panic over the coronavirus rising by the day, many were heartened to hear that two possible vaccines have been developed and will be submitted to the Food and Drug Administration for approval. But don't get ahead of yourself: The federal government likely won't allow them to be widely available any time soon.

According to the National Institute for Health's Anthony Fauci, it could be 12 to 18 months before these drugs are widely available even if they are ready for human trials within just a few weeks. One of the manufacturers, Medicago, says it could quickly produce 10 million doses of the vaccine per month as soon as it gets the green light but that it didn't anticipate making it through all three phases of FDA approval until November 2021.

Fauci also pointed out that even this lengthy timeline would amount to one of the quickest approvals the bureaucratic agency has ever managed. Some experts question whether waiting this long really makes sense and whether a vaccine can't be released more quickly, assuming it doesn't cause severe harm in clinical tests.

I spoke to Dr. Jeffrey Singer, a practicing physician and fellow at the libertarian-leaning Cato Institute. He told me that the delay in widespread availability of coronavirus tests is largely due to the top-down control exercised by the Centers for Disease Control and Prevention, which had control over the test and needlessly limited private labs' ability to make them.

"By contrast, South Korea seems to have its outbreak under control.. … They've tested huge numbers of people and even offered drive-by testings. ... That's because the South Korean health authorities, right from the get-go, worked with the private sector," Singer said.

"That didn't happen here," he continued. "The government wanted to be the source of the test. Now, they're playing catch up."

Will the same thing happen with coronavirus vaccines? Unfortunately, it's possible.

Singer argued that the government shouldn't block the release of possible vaccines while it completes all three phases of testing as it would normally do.

Rather, he says, the FDA could release the vaccine as soon as it completes phase one and is shown to be safe for human use. Further phases test efficacy, but Singer believes that even if we don't know how well they work, vaccines should be made available as soon as possible to the most at-risk populations, such as the elderly and those with preexisting conditions. That could be a matter of months rather than years.

“It would be reasonable, particularly for high-risk populations, to be able to try it,” Singer told me. “Because if it does work, I’m better off, and if it doesn’t, I’m no worse off than now. I say go for it.”

Singer was alarmed at the thought that bureaucrats might keep a vaccine under lock even after it has been shown to be safe: “To deny me the right to try it is to deny me the right to life.”

The R Street Institute’s Chelsea Boyd, an epidemiologist who researches harm reduction, told me she wasn’t so keen on Singer’s idea of a “right to try” approach to the vaccine.

“I have mixed feelings about that,” Boyd said, “just because [the coronavirus] is not an assured death even for at-risk populations. And when you give vaccines to immunocompromised folks, who are often not eligible for standard clinical trials, well … that’s risky.”

She warned the same populations at risk for coronavirus are also at risk for taking risky medications.

However, Boyd explained that one option worth considering is the “emergency use authorization” process established under the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013. This process permits the FDA to allow “unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions ... when there are no adequate, approved, and available alternatives.”

Basically, the traditional three-phase approval process could be circumvented.

According to the FDA, in order to receive emergency authorization, it still must be shown that the product “may be effective” and that the “Known/potential benefits outweigh known/potential risks.”

The FDA has already utilized this process to allow the use of more coronavirus tests. But Boyd warns that even if they were to pursue this route for vaccines, 12 to 18 months is still an “optimistic” timeline. We may simply have to wait quite a while for a vaccine whether we like it or not.