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Fast track vaccines and drugs, not only during pandemics

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Earlier this month, world markets soared on the news that Pfizer/BioNTech reported its new COVID-19 vaccine was 90% effective in creating immunity to the deadly coronavirus. Pfizer teamed up with the German company BioNTech to develop and test the vaccine and used their own capital resources to do it. One week later, the biotech company Moderna announced its COVID-19 vaccine was more than 94% effective in clinical trials. Other companies are hard at work testing their own vaccines, which also show great promise.

Vaccinations may soon become available to frontline health workers and the most vulnerable within a matter of weeks. This is an unusually fast turnaround; according to a report from the World Economic Forum, it takes an average of 10 years and $500 million for a vaccine to be developed and approved. While COVID-19 is highly contagious and rapidly spreads, providing a continuous pool of subjects for clinical trials, the speed at which these vaccines are coming online is still nothing short of astounding.

That's because the Food and Drug Administration (FDA) has been fast-tracking approval of COVID-19 vaccines as well as therapeutics under the Coronavirus Treatment Acceleration Program (CTAP). Under CTAP, the FDA grants emergency use authorization to vaccines that have already completed Phase One trials that demonstrate safety, and Phase Two trials that demonstrate safety and efficacy, but have not yet completed Phase Three (long-term protection) trials, if the benefits outweigh the risks.

The FDA granted Fast Track designation to the Pfizer/BioNTech mRNA-based vaccine in July. It granted the same designation to the mRNA-based vaccine being developed by Moderna last May. Earlier this month, the FDA fast-tracked a "subunit" vaccine made by Novavax that uses the S protein portion of the coronavirus "spike" to generate antibodies. Therapeutics such as the antiviral drug remdesivir have similarly been fast-tracked. This shows us how quickly drugs and vaccines can get from the research lab to the patients if the FDA lets them.

As Michael F. Cannon and I explain in a recent Cato Institute paper, the high cost of the FDA's approval process necessarily leads to higher drug and vaccine prices.

Rather than save lives, the usually lengthy FDA approval process may cost them. While keeping new drugs off the market until manufacturers conduct more and larger clinical trials no doubt

saves lives by preventing unsafe drugs from coming to market, it also causes patients to suffer and even die while waiting for treatments and vaccines to clear the FDA's approval process — a phenomenon called "drug lag."

Dissatisfaction with the length of the FDA's approval process led to a national "Right to Try" movement that spurred legislation at the state level and a federal "Right to Try" law in 2018.

A 2004 study by Mary K. Olson concluded the health improvements that result from shortening the FDA's approval process exceed the health losses by a factor of 12 in the first two years the drugs are on the market. Olson notes several caveats, including that consumers may underreport adverse reactions or that adverse reactions could occur beyond two years. She estimates, however, that even if consumers and physicians fail to report 30% of adverse drug reactions, the health gains would still be nine times greater than the health losses.

A 2006 study, using reasonably conservative assumptions, estimated that the health benefits that resulted from federal legislation that accelerated FDA reviews of new drug applications were between three and six times greater than the health losses.

This pandemic taught us how quickly and efficiently the private sector can meet the needs of a public health emergency. From repurposing factories to make personal protective equipment, hand sanitizer, or ventilators — to developing new therapeutics and vaccines — the efficient market-based private sector keeps coming to the rescue.

Lawmakers should learn from this. Fast-tracking drug and vaccine approvals should become the rule, not the exception. Better yet, lawmakers should allow patients to choose between drugs and vaccines that are FDA-approved and those approved by other "trusted" countries' regulatory agencies — a proposal called "reciprocity." Patients might even be allowed access to therapeutics approved by independent third-party certifiers if the label clearly states how and from whom the drug received certified approval.

The people shouldn't have to wait until the next public health emergency for the FDA to permit them faster access to treatments and cures.

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