Wonkblog

The little-known federal program that could speed up an Ebola cure

By Jason Millman October 27 Follow @jasonmillman

A vial of experimental Ebola vaccine being tested at the University of Maryland. (AP Photo/University of Maryland School of Medicine)

Drugmakers are now pouring hundreds of millions of dollars into developing Ebola vaccines and cures with a clear and immediate need for these products, as an Associated Press story outlines today. But there's even more that the federal government could be doing to nudge more drugmakers into funding such treatments, according to a health economist behind a recent federal initiative encouraging drugmakers to fight rare diseases.

The New York Times recently reported that a potential Ebola vaccine sat on the shelf for nearly a decade, which hints at the problem in funding for such treatments. Many drug companies are hesitant to pay vast sums of money for developing products where the likely payoff is limited — think small disease populations in particularly poor countries. That's not to say that these investments aren't happening. There are just a lot of these rare diseases out there, so resources are naturally limited. And Ebola had fallen off the radar until this year's outbreak.

One of the carrots the federal government uses to encourage drugmakers to fund rare disease research is a relatively new one, awarding manufacturers with a voucher that speeds up the regulatory review process. For drugmakers, shaving off anywhere between four months and a year in review time could be worth up to hundreds of millions of dollars, according to the Duke University economists who thought up the program almost a decade ago.

The voucher system generally works like this: Drug companies qualify for quicker FDA review of a drug application that treats a certain rare disease. If the application ultimately gets approved, the drugmaker is then rewarded with an FDA voucher letting the company seek faster regulatory review of another product that wouldn't otherwise qualify for it.

Companies choose when to use the voucher, or they could also sell it off to another company.

The voucher program, which became law in 2007, covers 16 rare and tropical diseases that particularly affect the developing world, including malaria and tuberculosis. Not on that list: Ebola.

But one of the intellectual fathers of the voucher program thinks that Ebola should qualify, given the current crisis in West Africa.

When the program was originally enacted, Ebola "wasn't a concern at the time," said Duke professor David Ridley, who proposed the system in a 2006 article in the policy journal Health Affairs. A year later, it was put into law.

Even though private sector money is now flowing toward Ebola cures and vaccines, Ridley said the voucher program would still provide a boost to efforts to fight the disease. Given the failure rate of clinical trials, he said, it's better to encourage more options in the rush to eradicate the deadliest outbreak in the virus's history.

"We want a lot of activity in this space because the odds of any one drug making it to market are very low," Ridley said. "We need multiple drugs because of drug resistance, and some might be better than others."

The Health and Human Services secretary has the authority from the legislation to add Ebola to the list of diseases covered by the voucher program, Ridley said. Congress can also approve a law updating the list.

Ridley sees two possible arguments against extending the program to Ebola. First, there's now the private sector money pouring into the disease. And second, broadening the program could devalue the worth of the vouchers, making them less attractive to drugmakers.

The FDA has so far rewarded four vouchers in the program's history, including two this year — one of those was sold off to another company for $67.5 million. Going forward, Ridley said he expects two voucher awards per year.

Ridley said he thinks the voucher program still needs some changes. Right now, companies have to give notice to the FDA a year in advance that they intend to cash in their voucher, while Ridley would like to see that time reduced to three months. Also, the FDA allows a voucher to be sold only once, but Ridley said there shouldn't be any limits on resales. Finally, he said, companies that win a voucher should have to report whether enough people can afford the rare disease drug.

Ridley and his colleagues originally proposed that voucher winners immediately give up patent rights to that drug, but that didn't make it into the law. Ridley said he understands that the drugmakers would want to retain those rights if their products could be used toward other diseases, for example. Also, they already have the experience of manufacturing the drug at scale.

"I'm comfortable with the way the law turned out," he said.

Jason Millman covers all things health policy, with a focus on Obamacare implementation. He previously covered health policy for Politico.
