

# How to upgrade Ebola fight: Column

Andrew von Eschenbach and Paul Howard 10:08 a.m. EST November 19, 2014

**A public-private partnership would increase our chances of developing a vaccine.**



Doctors Without Borders in Conakry, Guinea.(Photo: Patrick Fort, AFP/Getty Images)

2 CONNECT [1 TWEET](#)[LINKEDIN](#)COMMENTEMAILMORE

Nearly 40 years have passed since Ebola was [identified](#) in 1976, but today the United States seems to be caught flat-footed in fighting it. This is despite billions of dollars spent by the federal government after 9/11 preparing for pandemic outbreaks and bioterror attacks.

Why are there are no FDA-approved drugs or vaccines for Ebola? What happened? And going forward, how do we not only win the fight against this virus, but also better prepare for other natural or bioterror outbreaks that could be far more lethal?

We certainly have the technology to beat Ebola. Today, we can [map](#) the virus' DNA in days, if not hours, to identify vulnerabilities. Sophisticated diagnostics can measure whether patients are

responding to innovative drugs and vaccines in real time. Industry can churn out promising drugs by genetically modifying plants or animal cells to produce them in bulk. One such promising treatment for Ebola is a trio of monoclonal antibodies called [ZMapp](#), grown in genetically modified tobacco plants.

Vaccines against Ebola have been [tested in monkeys](#) since the 1990s, and the U.S., fearful of its potential as a weapon of terrorism, began investing heavily in Ebola research [after 9/11](#). Congress passed [Project BioShield](#) in 2004 and reauthorized it in 2013 to finance the development and stockpiling of drugs against the likely agents of bioterrorism – including Ebola.

Congress also created the [Biomedical Advanced Research and Development Authority](#) (BARDA) within the Department of Health and Human Services to coordinate multiple agencies, such as the NIH, FDA and CDC, and to streamline government's ability to buy promising drugs and vaccines. Congress even gave the FDA streamlined approval authority for countermeasures based only on animal tests, along with the authority to quickly authorize their use during public health emergencies. Ebola is on BARDA's shortlist.

Why, if we began preparing a decade ago, are we still struggling to catch up?

First, developing a treatment for Ebola is expensive. Small patient populations (often in poor countries) mean limited economic incentives for companies to develop drugs or vaccines. And BARDA's funding is far too small for the many challenges it faces. Drug development is extremely costly – it can easily cost hundreds of millions of dollars to develop a single FDA-approved drug.

Other government agencies, like the [Defense Threat Reduction Agency](#) (DTRA), that invested in developing countermeasures for the Pentagon are trapped in government red tape that can slow the process of funding qualified developers. As a recent, and damning, Bloomberg article on America's Ebola efforts [noted](#), "BARDA needs money [and] DTRA can't move quickly."

Putting all of our biodefense chips into the government basket just isn't a winning formula. Government doesn't have the profit-driven culture of rapid testing and innovation, common in the biotech and venture capital sectors, needed to select the best candidates, discard unpromising ones and develop the "winners" quickly.

But if government can't do it alone, what's the alternative?

Congress should authorize a [public-private partnership](#) (PPP) designed specifically to mutually fund and develop the most promising drugs and medicines to combat outbreaks like Ebola and bioterrorism.

The partnership, working in close collaboration with the NIH and Department of Defense, would have the authority to invest in a wide portfolio of promising projects, screened by impartial expert advisors. Many would perhaps fail, but with an effective oversight process, the "winners" would be quickly accelerated from discovery, through development, and on to delivery.

BARDA would maintain its role as government purchaser, but would be able to focus on picking from proven products. Our battle against pandemics can also pay dividends in the battle against much more common diseases. Technologies with both defense and civilian applications – like broad-spectrum antibiotics, or antiviral drugs that could be used to treat the flu – could be licensed to biotech or pharma companies at market rates. (Companies participating in the partnership could be given the first opportunity to bid on these products, with licensing revenues ploughed back into development.)

The advantage of a partnership would be that it would be based on a more viable business model, reassuring industry that there would be a predictable market for countermeasures well in advance of public health emergencies. For instance, the Bill and Melinda Gates Foundation's Global Alliance for Vaccines and Immunization (GAVI) helped [research, develop, and distribute](#) the first meningitis vaccine specifically for Africa, vaccinating 100 million people and [preventing](#) up to 150,000 deaths. In Europe, the [Innovative Medicines Initiative](#) brought industry, regulators and researchers together to design better ways of testing treatments for schizophrenia and Alzheimer's; [showed that](#) some brain changes associated with autism may be reversible and [helped develop](#) a new device for identifying patients at imminent risk of having heart attacks and strokes.

Our battle against pandemics can also pay dividends in the battle against much more common diseases. The partnership should be charged with finding new ways to reduce the time and cost it takes to move innovative new medicines to patients. According to researchers at Tufts University, it can cost more than \$1 billion and take 10-15 years to [produce](#) a single FDA-approved medicine.

The FDA has made great strides over the past 10 years to become a facilitator of medical product development, but much more can be done, and the partnership would be a great place for FDA to experiment with innovative new approaches like "[adaptive licensing](#)" and technologies such as early biomarker qualification that would rapidly accelerate access to life-saving innovative therapies.

The net effect of a nimble partnership is that we could afford to invest in more products and technologies with a much greater likelihood of success, protecting us from biologic threats while also developing better standards for drug development that could benefit patients everywhere.

Thankfully, there's already a bipartisan initiative in Congress – the [21<sup>st</sup> Century Cures Initiative](#), led by Michigan Republican Rep. Fred Upton and Colorado Democrat Rep. Diana DeGette -- looking at ways to bring America's drug discovery, development, and delivery framework into the 21<sup>st</sup> century. Their efforts could pay huge dividends for the fight not only against Ebola, but also for cancer, Alzheimer's and other diseases that threaten us. We have the tools, the technology, the knowhow and the political will to win this fight.

Millions of lives hinge on our success.

*Dr. Andrew von Eschenbach is [chairman](#) of the Manhattan Institute's Project FDA, and former commissioner of the FDA from 2006 to 2009. [Paul Howard](#) is director of the institute's Center for Medical Progress.*