

A Bridge Beyond the 'Valley of Death'

Op-Ed

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By Anna G. Eshoo

A MONTH after the 9/11 attacks on our country, we were attacked a second time when envelopes of anthrax spores were mailed to several media outlets and congressional offices. The attacks killed five people, crippled mail service and cost hundreds of millions of dollars to clean up.

More recently, a lethal new strain of avian influenza -- the so-called Asian bird flu -- has begun to spread around the world, causing nearly 150 deaths and threatening to become the next deadly pandemic.

Whether the threat is man-made bio-terrorism or a highly infectious disease, our country is at risk and losing precious time in the race to develop effective medical countermeasures that could save thousands -- or even millions -- of lives.

Since the passage of the Project Bioshield Act in July 2004, it has become apparent that few companies are willing to risk their limited resources to develop the vaccines and antidotes to respond to chemical, biological, radiological or nuclear attacks or to a fast-spreading contagion.

Their reluctance is understandable. New drugs can cost more than \$800 million and take more than a decade to develop. On average, only 1 in 5,000 potential new drugs is ever licensed. Given the risks and the costs involved, it's not surprising that companies and their investors would rather pursue the next blockbuster cancer or cholesterol medicine rather than take a chance on an uncertain market where the government is likely to be the primary, and possibly only, customer.

Project Bioshield often doesn't provide adequate incentives for companies to develop innovative bio-defense products. While the law authorized \$5.6 billion over 10 years to obtain drugs and vaccines for the Strategic National Stockpile, companies only receive payment at the end of the development process when they can deliver a minimum number of doses.

As a result, many potential drugs are languishing in the laboratory in what's known as the "Valley of Death." This 2-to-5-year window between basic research and eligibility for Project Bioshield funding represents some of the most difficult and costly advanced research in a drug's development. It involves developing pre-human testing, efficacy trials, production design and a range of other steps needed to determine whether a drug will be safe and effective.

One example is Cellerant Therapeutics in San Carlos. The "Valley of Death" funding gap has slowed development of a drug that could treat radiation victims after a "dirty bomb" explosion. Cellerant is trying to fill the gap with venture capital, but as CEO Bruce Cohen testified before the House Energy and Commerce Committee, which I'm a member of, "it takes an enormous amount of time and effort, and our investors are not prepared to have us use their capital for a program whose financing is beyond the control of the commercial pharmaceutical market."

Earlier this year, I joined with Rep. Mike Rogers, R-Mich., and introduced the Biodefense and Pandemic Drug Development Act (HR5533) to accelerate drug and vaccine development and bridge the "Valley of Death."

The centerpiece of the legislation is the Biomedical Advanced Research and Development Authority (BARDA), which will establish a single point within the Department of Health and Human Services to coordinate development of medical countermeasures. To encourage researchers and drug and vaccine makers to bring products to market more quickly, BARDA will provide milestone payments at key stages in the drug development process. This procurement method has already succeeded in developing innovative military technology under the guidance of the Defense Advanced Research Projects Agency. DARPA, established in response to the Soviet launch of Sputnik, was instrumental in developing the Internet, Stealth technology and the Predator unmanned aerial vehicle.

I'm hopeful we will be able to send this bipartisan legislation to the president. The sooner we eliminate the "Valley of Death," the faster we'll have access to life-saving medical countermeasures.

This is a race we can't afford to lose.

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