

Infectious Disease and Bioterrorism: A New Model for Protection

The Situation

As recent events have demonstrated, the emergence of an infectious disease creates cascading effects on a nation's

Anthrax letter attacks in the United States in 2001 killed five, caused panic across the nation, and decontamination efforts on Capitol Hill alone cost \$27 million

The SARS outbreak in 2002-2003 caused 772 deaths in Asia and Canada and contributed to \$19.5 billion in economic losses

Since the recent H1N1 outbreak, Congress has committed \$7.7 billion for pandemic influenza preparedness, and the Centers for Disease Control and Prevention estimate an additional \$8 billion would be required in the event of an outbreak to procure sufficient vaccine quantities for Americans (not including the expenses for syringes, needles, or distribution)

public health, national security, and economy. Cities immobilize, commerce slows, financial markets react in kind, and global economic stability is endangered. This does not have to be the reality. With proper preparedness, it is possible to greatly mitigate the impact of infectious disease, whether man-made or natural.

The Challenge

Today, there is universal agreement that the spread of infectious disease poses an ever-increasing threat to the United States. In addition, nearly every western government recognizes the need to strengthen its response against a bioterrorist attack. This is supported by the recent

Weapons of Mass Destruction Commission report and other studies and intelligence estimates.

Disaster preparedness is essential to reducing the impact of both naturally occurring infectious diseases and biological agents. For both strategic and economic reasons, President Obama repeatedly has made clear his commitment to accelerating the development of new medicines and vaccines for biodefense and public health.

Although American pharmaceutical (pharma) industry expertise in drug and vaccine development is unparalleled,

its business model does not intersect with the need because commercial demand for many of these products is low.

We as a nation have also looked to academia and small biotechnology companies (biotechs) for solutions. Though each is a vital component in responding to the challenge, neither has adequate resources or experience in developing and manufacturing vaccines and therapeutics.

Pharma, academia and small biotechs have committed to addressing this challenge and some progress has been made. In spite of this, the U.S. government's advanced development and manufacturing needs remain unmet and require an innovative approach.

The Solution

The good news is that technology exists to permit faster, more effective, and significantly less costly production of drugs and vaccines. Disposable manufacturing technologies can be deployed in a single facility that simultaneously produces multiple products. These technologies are perfectly suited for low-volume biodefense requirements and for providing surge production in a crisis. Incorporating flexible technologies maximizes facility utilization, thereby reducing cost and lowering the risks of drug development. UPMC proposes a flexible, multi-product facility that can reduce drug development and production costs to the U.S. government by 80 percent, compared to the current approach.

Essential to the success of this solution is its operating model. We propose a public-private partnership that allows the government to leverage the domain expertise of private industry in a not-for-profit environment. This model enables the government to partner with leading pharmaceutical companies, biotechnology companies, and academic institutions, and provides flexibility to

This partnership will fill a critical gap in infectious disease and biodefense preparedness.

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recruit top people through industry-standard wages and employment policies under terms that would ensure the facility's core public mission is not compromised.

At a time when concerns about the economy are high, this approach to drug and vaccine production is a means to create a new domestic biomanufacturing model built on the nation's expertise in translational science and our ability to link and mobilize public and commercial interests.

UPMC's Proposal: Costs, Jobs, and Timing

To advance this solution, UPMC has developed a proposal to create a public-private partnership based on a 2008 Department of Defense-sponsored study, the results of which have been widely briefed within federal departments, agencies, and White House offices.

Under this proposal, the government investment required would be \$580M to fully fund the commitment for facility design, construction, and startup. The not-for-profit entity would be selected through a competitive bidding process and responsible for an additional \$200M-\$300M (paid in cash or in-kind contributions) for facility build-up, business operations, and workforce education and training.

The facility would be overseen by the Department of Health and Human Services. The following is an estimated timeline:

- **Detailed facility design completion — 2009 (six to eight months; 250 new jobs)**
- **Construction — 2010 to 2012 (2,000 new jobs)**
- **Facility validated and operational — 2013 (1,000 direct employees; up to 6,000 indirect jobs)**

By pursuing this proposed initiative, the U.S. government will be taking the bold step needed to ensure the nation's preparedness, with an associated financial commitment that is far less than the potential economic impact that would result from a single event.

The proposed solution will:

Provide new drugs and vaccines at reduced risk and cost to the U.S. government

Ensure availability of both the stockpiling and surge production capability for medicines to protect the nation

Support and sustain the efforts of academia and the biotechnology companies currently engaged in biodefense drug development while providing technological benefits and a focal point for large biopharmaceutical firms to engage their expertise in this national security imperative

Allow for the leveraging of biodefense development technologies for global public health drug and vaccine development challenges

Train a new generation of scientists and engineers to build and sustain our biotechnology industry base