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After 8 Years, HHS Countermeasure Program Still a Work in Progress

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Supplies for the U.S. Strategic National Stockpile of medical countermeasures. An eight-year-old federal initiative has equipped the nation with a variety of new drugs for use following a possible strike incorporating biological armaments or other weapons of mass destruction, the Obama administration said in an assessment issued this month (Centers for Disease Control and Prevention photo).

WASHINGTON -- A leading federal WMD defense program can cite significant successes in eight years of operations, but continues to face major complications and threats to its pool of funding.

[Project Bioshield](#) was established in July 2004 with a \$5.6 billion war chest intended to spur private production of medical countermeasures that would be used to treat victims of an act of bioterrorism or other unconventional weapons event. It has added a host of new drugs to the Strategic National Stockpile of protective drugs, the Health and Human Services Department said in a September [report](#) on program activities in 2011.

"The medical countermeasures pipeline has never held more promise than it does today," HHS Assistant Secretary Nicole Lurie, who heads the department's preparedness and response activities, wrote in the report. "Innovation, enhanced partnerships and collaboration, and sustained investments throughout the last decade have resulted in the addition of eight new countermeasures in the Strategic National Stockpile (SNS), able to treat the effects of anthrax, botulism, smallpox, and radiological and nuclear agents."

By the end of 2011, the Bioshield Special Reserve Fund had allocated more than \$2.6 billion for massive stocks of vaccines and other medicines, the report indicates. Among the acquisitions: 28.75 million doses of BioThrax, the only anthrax vaccine certified by the Food and Drug Administration; 4.8 million doses of a drug for treating people exposed to radiation; and 107,560 doses of a botulism antitoxin.

The procurement process, though, has been given to hiccups since its inception. Bioshield's first planned big acquisition -- 75 million doses of a new anthrax vaccine -- collapsed in late 2006 and California-based producer [VaxGen](#) never recovered.

More recently, the program awarded a single-bid contract for [SIGA Technologies](#) to produce 1.7 million doses of the smallpox drug ST-246. The firm's top shareholder is a wealthy backer of the Democratic Party, while a member of its board of directors also reportedly has ties to the White House. Those connections have provoked concern on Capitol Hill about whether the company received preferential treatment. There also have been questions about the efficacy of the drug and the \$225 price tag for each dose, which is seen as high.

Danish pharmaceutical firm Bavarian Nordic by December 2011 had shipped 5.9 million doses of a 20 million-dose order of its Imvanune smallpox vaccine. However, the company said last month it faced a dire financial situation as it had not received a new order for the product that provides 95 percent of its revenue, [Bloomberg](#) reported.

"They've definitely achieved things by making purchases and there are more products available than there were in 2004. There's still room for improvement in the operations of the program and in the countermeasure development," said Amesh Adalja, a senior associate with the Center for Biosecurity at the University of Pittsburgh Medical Center.

Others have been less measured. Health and Human Services Secretary [Kathleen Sebelius](#) in 2011 said the countermeasure program was "full of leaks, choke points and dead ends." Others have said the original \$5.6 billion tranche was simply not enough to attract interest from major drug makers in turning their work toward the anti-WMD goal.

The "No. 1 priority," Adalja told *Global Security Newswire*, should be providing more Food and Drug Administration-licensed drugs and diagnostic tools for Category A bioterrorism agents -- materials such as anthrax, plague, smallpox and tularemia that are considered to pose a high threat to national security. "There are still some gaps that need to be filled," he added, citing the lack of rapid diagnostic system for any of the Category A materials.

These gaps can be attributed to both Washington and the pharmaceutical companies that would have no other customer for some countermeasures except the government, according to Adalja. He noted as an example that there have been only a handful of naturally occurring anthrax cases in the United States since 2001 -- not enough to create a private market for a bacteria-defeating drug.

Health and Human Services officials did not respond by press time to multiple requests for comment on the procurement process and other aspects of Project Bioshield.

Departmental priorities for the current and next fiscal years include swapping in replacement drugs for stockpiled anthrax and smallpox treatments that are nearing the end of their shelf lives and to procure new countermeasures for chemical, radiological and nuclear materials, according to a June Congressional Research Service [report](#). "Future targets for Project Bioshield procurement include new

broad spectrum antibiotics and countermeasures against anthrax, smallpox, viral hemorrhagic fevers and radiation."

Adalja said he believes there is ongoing development of countermeasures and diagnostics on all Category A agents, but some have not reached the point at which they can be procured by Bioshield. Supporting the private sector in getting their products to that point is a key aim of the Biomedical Advanced Research and Development Authority, the 6-year-old HHS branch charged with overseeing Bioshield and other medical countermeasures development and acquisition activities.

The authority has been a key recipient of the nearly \$2 billion in Bioshield funds that have been shifted into this fiscal year to separate HHS programs for work on anti-WMD drugs and other disease projects. A [2012 analysis](#) by two issue experts indicated about \$1 billion had by then gone to BARDA coffers through the prior budget year.

It could not be immediately determined how much money remains in the Bioshield Special Reserve Fund, as not all funds that are allocated have necessarily been spent. The program's mandate ends in the fiscal year that begins on Oct. 1, but two bills submitted this year in Congress would maintain the project.

While the Obama administration asserted the funding shifts would bolster "future successful acquisitions of medical countermeasures under Project Bioshield," the Congressional Research Service warned last year that "continued transfers would reduce the amount of money available for countermeasure procurement, could affect the willingness of developers to participate in Project Bioshield and might change the respective roles of the federal government and private developers in countermeasure development."

Continuous withdrawals of money from the program are "concerning," Adalja said. "I think Bioshield was signed into law with this specific purpose. I think that any diminution in the amount of the Special Reserve Fund hampers its ability to do what it was designed to do."

Health and Human Services made the case for maintaining the program and ensuring it has needed funding in its new report. "Without an ongoing Special Reserve Fund we risk losing the base of industrial partners we depend on for the development and manufacture of biodefense products," Lurie wrote.

This month's HHS document makes clear that the department sees implementation of Project Bioshield and its broader countermeasure program as a developing process.

The department this year issued a strategic plan for its Public Health Emergency Medical Countermeasures Enterprise and has enacted measures suggested in a [2010 countermeasures review](#), among other work noted by Lurie.

One key HHS aim is to provide funding and business direction to developing biotechnology firms that could deliver medical countermeasures that would have applications against multiple threats.

“Despite our progress since 2004, we continue to face serious threats that could have catastrophic consequences to our public and medical health,” Lurie wrote. “With the continued dedication of our partners and support for investment in novel technologies and productions, our national health security will continue to improve and our communities will become more resilient in the face of public health and medical incidents.”