Public health and drug industry officials have been meeting this month about the U.S. production of medical countermeasures to biological threats, offering an early glimpse into the possible recommendations of the Obama administration's comprehensive biosecurity review.

The discussions indicate the recommendations could include hundreds of millions of dollars more for new medicines to counter bioterrorism, improved transparency and coordination of government contracting, stronger leadership and accountability, and even children's issues in formulating the medical response.

“We've learned a lot over the last several years as we've tried to move this whole enterprise forward,” said Nicole Lurie, the assistant secretary for preparedness and response at the Department of Health and Human Services, in a conference call with the National Biodefense Science Board on Feb. 10. “But it may be that not all the forces are aligned the way we want them to produce success.”

Part of that re-alignment process will require the removal of barriers to the involvement of capital markets in the production of medical countermeasures, she said.

“Because, as I think we all recognize, in large part, although certainly not entirely, some of the challenges are challenges related to the markets.”

Lurie, who is tasked with heading the administration's review, asked the biodefense board to play a lead role in the re-examination of U.S. biodefense efforts. At the meeting, the board voted to approve a report on factors constraining industry involvement in the development and production of new vaccines and drugs — a complex and long-standing problem for the government's troubled civilian biodefense effort.

Lurie also commissioned several other white papers on major components of the countermeasures enterprise. Those reports were scheduled to be discussed at an Institute of Medicine workshop, also scheduled Feb. 10, but that discussions was postponed until next week due to the winter storms.

Children's issues are another element that will factor into Lurie's recommendations. At a meeting of the National Commission on Children and Disasters on Feb. 2, the assistant secretary mentioned assigning senior staff to work on children's issues and take pediatric needs into consideration in disaster response, which includes medical countermeasures development.

Early Recommendations

Biopharmaceutical industry officials have long complained of an anemic federal funding stream for medical countermeasures, arguing market forces do not support the government's requests for a broad range of drugs and vaccines to counter bioterrorism threats.

The biodefense board's report supports these criticisms. The advisory panel said Congress and the administration provide adequate and consistent funding to the medical development and procurement efforts for several years, accelerate the pace of development, centralize program leadership, coordinate closely with state and local governments and first-response agencies,
prepare in advance for pediatric care, and demonstrate a long-term commitment to private-sector partners.

The recommendations address long-held industry fears that a lack of immediate results in the complex, failure prone business of drug and vaccine development will cause a risk-averse federal government to lose faith in the effort and cut off funding, making industry unable to recoup development costs.

"The inherent complexity of drug and vaccine development requires time and persistence," the report says. "Drug discovery and development cannot be ‘surged’ in any meaningful way, especially for CBRN [chemical, biological, radiological and nuclear] incidents that could happen without notice."

In contrast to the development of drugs and vaccines for influenza, market forces and other incentives cannot sustain a vibrant, responsive and flexible industrial base to produce medical countermeasures against a broad range of threats without a substantial government investment, the report continued. The failure to fund the program over the last several decades, it noted, is "incompatible with the potential consequences of these threats."

Limited Success

The government has taken a number of important steps to strengthen U.S. biodefense over the last eight years, the authors noted. These include the creation of the Biomedical Advanced Research and Development Authority, or BARDA, (PL 109-276) in 2006 to fund late-stage drug and vaccine development; a law (PL 108-276) allowing the Food and Drug Administration to approve unlicensed medicines for use in emergencies when other treatments are unavailable; rules allowing the use of animal studies to prove the effectiveness of drugs that would be unethical or unfeasible to test on people; an agreement between HHS and the Defense Department to take an integrated approach to medical countermeasure development; and stepped up meetings and workshops with public and private stakeholders.

Despite these efforts, there is a long list of threats for which medical countermeasures are lacking. While most of the expertise for the production of medical countermeasures resides in the private sector, a raft of complications has prevented its full engagement in biodefense efforts. Among industry’s criticisms, according to the report: Contracting with the federal government is slow, unwieldy and expensive, and the efforts of the numerous agencies and offices involved, from basic research to distribution, are uncoordinated.

As a result, there is a lack of clarity on a number of issues, the authors noted, including federal requirements for the countermeasures, the desired size of procurements, the manufacturing capacity companies will need to have on standby — a major and continuing expense — and the length of the regulatory review process, among other things, the report said.

Because the development of a single drug of vaccine can take more than 10 years and require a sustained investment, a critical question from industry is whether Congress has the stomach to provide adequate funding for the development of the entire portfolio of desired medical countermeasures, from basic research through procurement.

In years past, Congress diverted money from a 10-year, $5.6 billion reserve fund for procuring new countermeasures under Project Bioshield (PL 108-276) to pay for other needs; lawmakers shifted $412 million out of the Bioshield fund through the 2009 omnibus spending law (PL 111-8) for use in pandemic preparedness and another $700 million this fiscal year for the activities of BARDA and the National Institute for Allergy and Infectious Diseases. Such moves signal a lack
of government commitment and destroy industry confidence that the substantial risk and investment required to develop new drugs will be rewarded, industry officials say.

Industry Perspective

PharmAthene Inc., of Annapolis, Md., is a biodefense company that worked unsuccessfully with HHS on an anthrax vaccine. President and CEO David Wright said the civilian biodefense program suffers from a conceptual problem among government agencies because it is funded through the public health budget, where it must compete with popular entitlement programs and other health care needs.

“So when you talk about increasing the HHS budget, which is already large, by $3 billion a year for medical countermeasures, it sounds like an awful lot of money,” Wright said.

“However, if you look at this as a defense item, which it really is — this is part of our national defense requirements in order to protect the American people and the American economy — this is less than the cost of a couple of [long-range] bombers.”

In addition, the government has to be willing to accept inevitable failures in funding the complex activity of drug and vaccine development and manufacturing.

“The development of biotech or pharmaceutical products is full of risk,” Wright said. “If you look at the studies that have been done the chance of a product that comes off the bench . . . making it to the market is less than 10 percent.”

Even during late-stage clinical trials, drugs suffer about a 30 percent rate of failure, he said, and that’s after about eight years of development and several hundred million dollars of expense.

“So the concept that we could do this risk free, the concept that BARDA is not going to have failures,” Wright said. “And if BARDA gets punished for having those failures, then they’re not going to take the risks they need so that America can have the products they need when they need them.”

*Matt Korade can be reached at mkorade@cq.com.*