

Director Expects 'Banner Year' at BARDA

By Matt Korade, CQ Staff

The threat of a bioterrorist attack has received renewed focus around the nation's capital with the release of the recent report of the congressionally mandated Commission on the Prevention of WMD Proliferation and Terrorism.

While the [commission's report](#) mentioned the proliferation of high-containment biodefense research labs as a source of the threat, it gave the research, development and acquisition of medical countermeasures to lethal pathogens less attention. CQ Homeland Security sat down with one of the key government officials involved in that effort, Robin Robinson, the first director of the Biomedical Advanced Research and Development Authority ([BARDA](#)), to discuss the government's progress in this key area of biodefense.

"We're dedicated to the mission and we've brought in a total of 230 folks to work at BARDA, many of whom are scientists that are from industry, and they have become dedicated to the mission," Robinson said.

Q: BARDA has been ramping up and you've been director since spring. What have been your top priorities?

A: My top priorities have been to realign the CBRN [chemical biological, radiological, and nuclear] medical countermeasure program to be similar to the pandemic influenza program we have at BARDA, with a heavy emphasis on advance development of medical countermeasures, so that we have real products that we are able to acquire in a relatively short period of time, because we didn't have the products that were far enough along in development to be able to use the special reserve fund for [Project Bioshield](#), to acquire products for the Strategic National Stockpile.

Q: On the pace of the process in general, [Project Bioshield](#) (PL 108-276) was passed in 2004 and the Pandemic and All-Hazards Preparedness Act (PL 109-417), which created BARDA, was enacted in 2006. How would you characterize the countermeasure development process so far?

A: Thus far for CBRN medical countermeasures, I think that we, as a young organization, were trying to understand how to approach this and to rethink it. With the PAHPA [Pandemic and All-Hazards Preparedness Act legislation in 2006, it gave us the authority to do advance development. I think what was realized at that time was we did not have enough products in the pipeline to move forward with Bioshield funding. Saying that, in 2008 we have really moved quite aggressively forward with our advance development, and I think a good example of that was the seven contracts that were awarded by BARDA in Sept. 2008 on acute radiation syndrome illnesses, looking at seven different types of products that could be used to treat people that were exposed to heavy loads of radiation, specifically for neutropenia illness . . . and that momentum has carried forward. You'll see in the early part of 2009 . . . more solicitations for advance development, and we're now seeing some products making it forward for consideration for Bioshield funding in early 2009. So I think we're now aligned the way we should be . . . and are really minimizing our risk for using the Bioshield funding.

2009 should be a banner year. We can already see that things are going to happen going forward, because we track these products, companies that are making them, where they are in development. On the pandemic influenza side . . . what you'll see very, very shortly is one of

the hallmarks of our program, cell-based influenza vaccine manufacture, which will be the actual facilities in the United States . . . The other part of that is we have a solicitation out on the street, [for] which we've already received proposals, and I'm very happy to say a large number of proposals, for new influenza antiviral drugs, to develop these forward toward licensure. And I think this is key in light of the fact that we're seeing the human H1N1 virus . . . becoming resistant to one of the neuraminidase antiviral drugs that we have, the Tamiflu drug. So I think the timing is very good, where we knew this could happen, and we're already there, trying to develop these new drugs. We will have these not only for seasonal purposes but also in case of a pandemic, where we may have a virus that is resistant to what we have in the [national] stockpile. . . . Fortunately we saw this occurring last year in northern part of Europe and it moved to South America, in their flu season that just ended, and now we're already seeing it in our flu season in the U.S.

Q: The Center for Biosecurity at the University of Pittsburgh Medical Center put out an analysis of how much it would cost to fund all of the countermeasures to a high degree of success, and it turned out to be a lot of money. One of the questions that arises, particularly around budget time, is can we convince the administration and Congress that the risk-taking kind of environment, if we want to make rapid progress, may really cost quite a bit? In tough economic times, that information is not always welcome. Do you think there's a low risk-tolerance among members of Congress, and how can you overcome it, if so?

A: First I must say that the leadership in Congress, both from the Senate and the House side have been very supportive of the bio-threat development of new products, and . . . that they continue to be in the administration. And indications from the new administration also is that this will be a prime initiative to continue forward, as these are really insurance policies that will have to be deployed, because the bio-threats are not a situation or theoretical . . . they did happen in 2001 and 2002, and the level of threat has not waned, it's still there. And they're more sophisticated than they ever were, so we have to complete the original mission and then also enhance that effort to stay ahead of the game, so to speak.

Q: So the funding for countermeasures development in 2009 and into the future, has that been discussed, do you expect it to increase dramatically? I know in 2009 it is expected to go up by at least \$2.2 billion based on the <Project> <Bioshield> authorization, and I also think BARDA is getting a good amount of money this year.

A: We see that we have very good signs from Congress that the FY09 appropriations will be what we asked for, and in FY10 we will be going back for the amount of money that we know that we can execute and move forward with. I think part of it was two-fold: One is, how much money do we actually have? And two is, I think they've been watching us to see how well we've been doing, you know, can we manage this. They don't want to throw money away, and I believe that at this point, what they have told me is they have confidence in BARDA, they have confidence in me and HHS, to execute the mission, and that we have a good path forward, and just stay on that path and they will provide the appropriate funding as we go forward.

Q: And the Obama transition team, have you been in discussion with them about these various issues?

A: The leaders at HHS . . . met with the transition team, some of the people were some of the pioneers in bio-threat analysis and policy, and they understood what we were doing, they were very complimentary in fact, and it will be a high priority for the new administration, and Secretary [Tom] Daschle and President-elect Obama.

Q: I saw some information on your Web site that dealt with the number of countermeasures that are under development or have been contracted out, etc., and I'm wondering for which threats countermeasures had been successfully developed or are under development. The one that springs to mind immediately is <anthrax>. I know there were plans under the PHEMCE [Public Health Emergency Medical Countermeasures Enterprise] strategic plan to have a second-generation rPA [recombinant protective antigen] <anthrax> vaccine. How is that moving forward?

A: Specifically with the rPA next-generation <anthrax> vaccine, we are in contract negotiations, and we hope to be able to award contracts when the protest which is public knowledge, is lifted, which will be sometime in January.

Q: The rPA vaccine has had some difficulties in the past. Have those difficulties been overcome?

A: We have studied this quite in depth, in fact, because of the stability problems with the rPA product from VaxGen, and we feel very confident now that those problems that were experienced in the past have been overcome; it was a formulation problem . . . and we feel confident that there are several different candidates out there that will move very quickly forward, and we'll be able to provide a really good set of vaccines. Our approach again is not to have one vaccine but several, so that we can have an infrastructure there and not just depend on one company.

Q: In addition, in the BARDA roundtable there was talk about the RFI-RFP [request for information and request for proposals] process, and this was something that some industry folks talked about last year. They had mentioned that they thought the process was taking too long, it wasn't specific enough, and that there wasn't enough transparency.

A: One of my main goals in 2009, going forward, is that it should not take any procurement more than nine months, from the time we send the RFP out to the time we award contracts. And our ultimate goal is to do it in six months, and we've been able to accomplish some of those at the end of 2008. Nothing should go past nine months and we're going to really work hard to do that, and we've already made some changes to do that. RFIs signal to the industry and to the public where we're looking for capabilities. But I assure you, we have our annual stakeholders' meeting, but we will have meetings on specific medical countermeasure products for specific threats, say for <anthrax>, for <anthrax> antitoxins, [and] we will be holding workshops specific about that, inviting manufacturers, and industry players, and other stakeholders to come to those meetings, smaller meetings, and to talk in very specific terms as to what our requirements are, what our timelines are to go forward, so that you get input as to what they have in development and how that relates to our requirements. And you'll see much more . . . satellite meetings . . . all across the country, so that we can communicate more effectively with our stakeholders and partners to let them know where we are. Again the strategic plan will be the roadmap going forward as we do these workshops on a regular basis.

Moving the process forward is just one aspect; smaller, very specific workshops is the second [thing]; and then the third one is that I go out to industry all the time. I probably see as many as 20 companies a month, and I go out to probably two or three to talk to them about where they are and so forth. The last [thing] is that we want to make these products better. We want to have greater stability, greater effectiveness, so they have broader reach. And so we will have, starting in 2009, an innovation piece: How can we make products or the manufacturing process for these products better? Not to invent them, not to come up with new ones – there's funding for that at the NIH and other places, DARPA for example -- but [to] make these products better. For

example, if you have medication that's provided by injection, can you provide it orally? Can you make the product instead of a stability/shelf life of two years, maybe make it four, or six, or eight years? Instead of having three doses, three injections, how about one injection? Those are very meaningful things that not only drive down the cost but also make the product much better all the way around. So we're going to be driving hard on that, the innovation, in 2009.

Q: I know there's the big project going on at Fort Detrick to build the biomedical research center there, which should foment a lot of interagency discussion about what countermeasures are needed and bring a lot of different stakeholders into the process. How is that expected to help this countermeasures process?

A: The administration, the Homeland Security Council led by Dr. Bob Kadlec, introduced and we adopted and have implemented an initiative called the one-portfolio approach, primarily with the Department of Defense and HHS, but there are other players, including the Veterans Administration, Homeland Security Department, and Department of Agriculture. That initiative specifically coordinates the development of medical countermeasures for bio-threats, and chemical, radiation and nuclear threats, for the U.S. governmentwide, and also the stockpiling of those products, which we were doing already, but it was not on a very formal basis. . . . This now formalizes that, that we work together, coordinating our research and development so that we are synergistic as opposed to overlapping when it's not really necessary [to do so], and then building on what we're doing, so that many of the products they have – [for example] a DARPA [product] coming up through the pipeline can maybe make it through BARDA, in fact, for the civilian population, or through other parts of the Department of Defense for the military population. So we coordinate that, and then, again, [the process allows us] to increase the list of products that we share in our stockpiles. That way we get a better price and have more leverage with the manufacturers in our requirements. So I think we're seeing a very big change, instead of stovepipe silos everywhere.

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