

The Honorable James Langevin
Hearing: “Can BioShield Effectively Procure
Medical Countermeasures that Protect the Nation?”
Opening Statement – April 18, 2007

Good Afternoon.

Today the subcommittee will receive testimony regarding the BioShield program, focusing specifically on some recent difficulties within the program. Biological threats – both manmade and naturally occurring – present a real danger to the security of the United States. We must therefore do everything in our power to create and maintain robust tools to protect against these threats.

Project BioShield can and should be an important component of our nation’s defenses against such threats. This critical program is far too important to fail. Unfortunately, since its creation, BioShield has enjoyed varying levels of success, and in recent months, there have been some fairly significant setbacks this committee is particularly concerned with.

The cancellation of the \$877 million anthrax vaccine contract, the largest under BioShield, after VaxGen invested \$175 million of its own funds, does not bode well for the future of the program. Problems must be identified and fixed, and we must learn from any mistakes that have been made. Also of concern was the decision in March to close the Request for Proposals for a medical countermeasure to treat acute radiation syndrome.

As this subcommittee is responsible for preparation and response for both nuclear and biological attacks, we are especially concerned about these two cancellations. However, our witnesses on both panels should not assume that this subcommittee has pre-judged these matters. The BioShield process is a complicated one, and we are here today to hear from our witnesses about their experiences navigating the process.

Our private sector witnesses have had different experiences working with the program, and this subcommittee asked them to be here for precisely that reason. Our witnesses from the Departments of Homeland Security and Health and Human Services hold additional pieces of the BioShield puzzle. Dr. Runge from DHS and Dr. Parker from HHS represent the lead offices for BioShield activities in the two Departments.

Although not officially part of the BioShield program, the NIH and the FDA have played important roles in the process, including the VaxGen contract cancellation, and we have to better understand and define their roles if we want the program to succeed in the future.

The new Biodefense Advance Research and Development Authority – BARDA – may also have a role to play by supporting transitional research and development and

bridging the so-called “valley of death” between early basic research supported by NIH and final development and production.

However, that will not happen by itself. I believe we need to provide a more definite roadmap on how all these moving pieces fit together. That is the proper role of oversight, and that is our responsibility on this subcommittee.

I am hopeful that today’s hearing will shed light on some of the difficulties of implementing Project BioShield. I am also hopeful that after hearing from our two panels, we will gain insight on how best to move forward and fix some of these problems. We must work together to ensure that Project BioShield remains an effective line of defense. I believe that today’s hearing is a good first step towards that goal, but I also understand that the solutions will not be simple – they will take time, cooperation and diligence on all of our parts.

I thank both of our panels of witnesses for taking time to appear before our subcommittee today, and I look forward to their testimony.

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