

Crossing the Valley of Death: Bringing Promising Medical Countermeasures to Bioshield
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Witness:

Mr. David P. Wright

PharmAthene

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Testimony

Mr. Chairman, Members of the Committee: I commend this committee for its focus on the vital legislation which brings us together today.

I am David Wright, President and CEO of PharmAthene.

PharmAthene was founded to develop countermeasures for bioterrorism and has made significant progress in developing products which prevent and treat anthrax and agents of chemical warfare. In two short years, we have brought two products forward to a stage where they could soon be acquired for the Strategic National Stockpile.

In bringing these two products forward, PharmAthene has had experience with BioShield I, NIH, DARPA, and other DOD agencies.

There are many critical issues that need to be resolved for Project Bioshield to be as effective as possible.

Today, I am here to address the issue commonly referred to as the Valley of Death. This abrupt funding gap – after proof of concept and before procurement poses three serious problems:

- 1) It prevents promising technologies from being developed.
- 2) It keeps large pharmaceutical and biotech companies from entering this field; and
- 3) It slows the development of products our Nation urgently needs.

Our firm has had experience with this issue as I will illustrate from two products in PharmAthene's portfolio. The contrast between our experience with BioShield and the DOD process, I submit, could be helpful to this Committee in drafting legislation for BioShield II.

PharmAthene's lead product, Valortim™ has demonstrated significant efficacy in preventing and treating anthrax and will become an important part of the U.S. arsenal to combat this devastating terrorist threat. Some background regarding Valortim™ should be helpful here: Valortim™ was originally discovered in Medarex's laboratories and despite its promising potential, it languished unfunded in their labs due to the funding gap known as the Valley of Death. Despite Bioshield, products such as this do not receive adequate funding because there are no clear cut coordinated provisions for the funding gap – the Valley of Death – between proof of concept and the Strategic National

Stockpile.

While PharmAthene, in this instance, was able to step in with the necessary funding to pull Valortim™ out of Valley of Death, there was invaluable time lost. This product could have been in the Stockpile TODAY. However, even with all of our best efforts it will take us nearly 18 more months to deliver Valortim™ to the Strategic National Stockpile.

In contrast to our experience with Valortim™, we at PharmAthene have developed a product called Protexia™, an effective countermeasure to chemical and nerve gas threats which has gained critical support from the DOD. The DOD had been looking for a better way to protect its warfighters from chemical threats on the battlefield. They announced their interest through what is referred to as a Broad Area Announcement. The DOD process includes a step called Milestone A whereby qualified companies are provided financing through proof of concept. This is similar to the Bioshield mechanism as provided by the NIH.

The critical difference, that I am here to highlight, is that the DOD has a Milestone B process that kicks in upon successful completion of Milestone A. The DOD through this Milestone B provides funding to fill the gap. This facilitates the development of a company's product through manufacturing, human safety and further animal efficacy studies. Therefore, it totally precludes the Valley of Death from entering into their process. As a consequence of Milestone B, Protexia™ will experience an uninterrupted flow in development and funding from proof of concept all the way to procurement.

I strongly recommend that as the Committee considers legislation for BioShield II, that you support programs to provide funding for promising products from proof of concept through procurement - thereby eliminating the Valley of Death. I am Confident that your doing so will both provide incentives to companies to focus their resources on the critical needs spawned by bioterrorism as well as increase the likelihood that those who do will be successful in serving our Nation's interest.

Thank you