

Testimony of Donald S. Burke, M.D.

Dean, University of Pittsburgh Graduate School of Public Health,
Director, Center for Vaccine Research at the University of Pittsburgh

U.S. Senate Appropriations Subcommittee on Labor, Health & Human Services, and Education and Related Agencies

August 21st, 2009

Mr. Chairman, Ranking Member, Senator Specter, and other esteemed committee members and staff, thank you for the opportunity to discuss the pressing need for the U.S. Government to find a better way to develop and produce biologic medical countermeasures for our country's health security. This endeavor represents a key component in the larger biodefense and public health framework and will certainly help ensure a safer and more resilient America. And on behalf of health scientists here in Pittsburgh and around the nation, I also thank you for your extraordinary efforts to provide increased funding for biomedical research through the National Institutes of Health.

I am a physician, an infectious disease expert, an epidemiologist, and vaccine researcher. I have worked on prevention and control of epidemic infectious diseases for my entire career. Previously, I served 23 years on active duty in the US Army, including service as the Associate Director for Emerging Threats and Biotechnology at Walter Reed Institute of Research (WRAIR). I currently serve as the Director of the University of Pittsburgh's Center for Vaccine Research. In every research setting, I have witnessed the difficulty in translation of advances in basic scientific research into medical products to protect people from serious health threats. I am here today to discuss the exciting idea of a new facility to solve this pressing national problem.

As you are aware, the first step in producing any effective drug to counter a bioweapon or epidemic begins in the research lab. Initial research and testing, if successful, then requires the crucial step of applied research. Translational research is a term used to describe the process by which a drug or vaccine candidate moves from early basic research, through the various stages of development, and eventually into a licensed product.

Both the NIH and DoD have made tremendous investments in basic research, with significant progress achieved in understanding disease threats, and identifying potential drugs and vaccines to mitigate their impact. Although there have been remarkable advances in the diagnosis and treatment of many medical conditions, infectious diseases remain the leading cause of deaths worldwide. Few discoveries in biomedical research are as important as those that revolve around vaccines for infectious agents that pose risks to global public health and global security.

The University of Pittsburgh is committed to joining with UPMC and other partners in developing a flexible multi-product vaccine facility, and indeed the University brings exceptional strengths to that partnership. Out of more than 3000 institutions nationwide, Pitt now ranks fifth in NIH funding and fifth in the number of individual grants received. Last year the University and its affiliates received more than \$450 million in NIH support.

The Center for Vaccine Research that I direct is evidence of the University's growing excellence in the field of vaccines. The Center is housed on two floors of the new, state-of-the-art biomedical science tower. The CVR consists of the research teams of 31 full time and affiliate doctoral level researchers, and

occupies 32,000 square feet of laboratory space. A key component is the Pittsburgh Regional Biocontainment Lab, a high containment facility that was constructed with NIH support. This lab is designed to permit research on vaccine development for avian influenza and swine influenza, tuberculosis, dengue, tularemia, and other highly infectious disease threats.

The Pittsburgh Regional Biocontainment Lab also serves as a core laboratory for the NIH-supported Regional Centers of Excellence for Biodefense. The RBL houses the nonhuman primate core of Mid-Atlantic RCE and Biosafety Level 3 (BSL3) research labs on a single floor, thus supporting a full spectrum of investigations from basic microbiological and immunological manipulations to animal challenge studies.

We have also gained national recognition for our exceptional collaborations between the School of Medicine and the School of Engineering, especially as related to the design and production of medical devices and more recently to the development of novel bio-manufacturing processes. These internal collaborations have been further enhanced by inclusion of engineering faculty from Carnegie Mellon University. We have NIH training grants for the Medical Scientist Training Program (MD/PhD) and for biotechnology, the latter focused on vaccine development with the Center for Vaccine Research (CVR). These interdisciplinary medical-engineering programs create a unique environment for academic consultations and training of biotechnology personnel related to vaccine design and manufacturing.

Those performing early clinical stage research such as is done in the CVR are typically not able to bring a product candidate all the way to licensure on their own. Discovery and development require different expertise. Product development expertise resides primarily with large biopharmaceutical companies whose business it is to bring drugs and vaccines all the way from lab to the consumer market. However, because most biodefense products are non-commercial by nature, there is no market-based incentive for biopharmaceutical companies to pursue their development and they have accordingly been reluctant to engage.

As products are developed and brought into early human clinical testing by the NIH or DoD there currently is not a clear path to licensure and procurement for the U.S. Government. Despite attempts by the U.S. Government to attract experienced biopharmaceutical companies to the process, few have entered.

For this reason, commercial partnering with the U.S. Government is essential to bringing biologic medical countermeasure candidates to full licensure. Without such a partnership, only the biopharmaceutical industry retains the ability and know-how for scaling production levels of biologics up to required levels. Larger biopharmaceutical companies possessing this experience and expertise in advanced development must be incentivized to engage if the U.S. Government wants to fulfill its biodefense requirements.

It is clear that given the lack of commercial incentives for these products, we cannot expect industry to enter alone. The formation of a public-private partnership between industry and the USG is the only alternative that has the real possibility of success in fixing a challenges that has been at the DoD and HHS for many years, one that I have personally encountered. I encourage the committee and the government to continue to develop this concept, and ultimately compete its implementation to ensure the best and most current ideas are incorporated.