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BEFORE THE SENATE COMMITTEE ON HEALTH, EDUCATION, LABOR AND
PENSIONS

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Senator Brown, Ranking Member Enzi, and other Committee members, thank you for this opportunity to appear before you to discuss the state of tuberculosis vaccine development and to describe the work of the Aeras Global TB Vaccine Foundation, a public-private partnership focused on product development. We appreciate your interest in this critical matter and we look forward to working with you and other Senators in the future. Your role is crucial to ensuring adequate resources and incentives to accelerate vaccine development.

We applaud your leadership in addressing the worldwide tuberculosis pandemic, which infects 8 million people and kills 1.6 million people each year. Of particular concern are the rising threats of drug-resistant tuberculosis and co-infection with HIV/AIDS. In fact, tuberculosis is the cause of death of half of the people with HIV/AIDS who die in Africa. New tools are urgently needed to diagnose, treat and prevent TB, including new and effective vaccines. Modeling studies show that without such vaccines, we cannot eliminate TB.

We thank Senator Brown and others for highlighting the needs for these new tools in the bipartisan Comprehensive Tuberculosis Elimination Act. As this bill

makes clear, more resources and strategic focus are needed to spur the creation of 21st century technologies to curb the pandemic. We also applaud Ranking Member Enzi and the full Committee for their support of Senator Brown and Senator Brownback's creative, balanced and forward-looking amendment to the FDA Revitalization Act. This measure holds the promise of speeding the development of products to combat neglected diseases like TB.

As recent experience shows, tuberculosis – like any infectious disease - is a problem that knows no borders, and the United States needs to strengthen efforts to halt its spread. The tools used in most places around the world are outdated and inadequate. Diagnostic tools currently in use were invented over 100 years ago; antibiotics used to fight TB are over 50 years old; and the vaccine currently in use in countries outside the United States was invented over 85 years ago and has limited effectiveness. Clearly, we need new solutions.

One important approach to developing these new tools is the Product Development Partnership (PDP) model, which bridges the gap between the public sector's urgent need for these interventions and the private sector's technological expertise. Three such PDPs are engaged in the search for new tools to combat TB: the Global Alliance for TB Drug Development; the Foundation for Innovative New Diagnostics; and my organization, the Aeras Global TB Vaccine Foundation. Aeras' mission is to accelerate the development and delivery of safe, effective, affordable vaccines to prevent TB infection around

the world. We are essentially a non-profit biotech company, guided by business principles and seeking to be as efficient and flexible as a for-profit entity.

I myself am a hybrid of public and private experience, having spent more than 20 years creating vaccines at the Walter Reed Army Institute of Research, followed by over seven years as Executive Director of Clinical Development of Vaccines at Merck, before becoming Aeras' CEO in 2003. During my career, I have had the opportunity to be involved in the development of nine vaccines that are on the market today. Based on that experience, we operate Aeras on an industrial model, making tough decisions weighing risks, resources and time. My staff, most of whom have biotech or pharma experience, have quarterly benchmarks they must reach, directly tied to their compensation.

However, unlike any individual drug company, we are testing a portfolio of the world's most advanced TB vaccine candidates from a variety of sources, including several we have invented ourselves. Aeras collaborates with the best scientists around the world, whether in South Africa or India; in Maryland or Tennessee; whether with a small biotech company, a large vaccine manufacturer, a leading academic researcher, or the outstanding scientists of our own government. This gives us an advantage over any single company, and provides our funders with a central focus for TB vaccine development.

Why don't drug companies do more of this research? The private sector, where most vaccine product development expertise resides, has generally stayed on the sidelines, because of the scientific challenges and an unpredictable market. Vaccines are among the most cost-effective and medically effective health interventions, but inventing them presents technical challenges that require significant investment. For profitable products, the public and private sectors have collaborated in a model where public sector agencies such as the National Institutes of Health finance basic research that industry translates into products via clinical trials, process development, manufacture, licensure and marketing. This model breaks down for neglected diseases such as TB. While the NIH continues to play a vital role in funding basic research and some early clinical development, its mandate does not include industrial-style product development. Biotech and pharmaceutical companies may have potential vaccine candidates or technologies that could help solve the TB problem, but feel constrained by the need to maximize shareholder value. By taking on the expense and effort of early to late stage product development, PDPs like Aeras minimize risk and offer the private sector an opportunity to develop products that would otherwise not be commercially viable. At the same time, our agreements with industry contain provisions to ensure that any vaccine that emerges will be affordable and produced in adequate quantities.

Aeras currently has six vaccine candidates in our pipeline, with clinical trials underway in the United States, Europe, Africa and Asia. The best of these

vaccines are scheduled to enter proof of concept efficacy trials in 2009, enabling us to rationally select vaccines for subsequent large scale trials in field sites we are developing in South Africa, India, Kenya, Uganda, and Cambodia. These trials will be conducted under the highest ethical standards with vaccines that meet all FDA quality and safety requirements.

I want to express appreciation for past financial support provided to Aeras by the Centers for Disease Control and Prevention to develop field sites in India, and the cooperation we have received from the National Institutes of Health. Aeras' programs have also attracted funding from the governments of the Netherlands and Denmark, as well as the Bill and Melinda Gates Foundation.

I ask for your sustained and increased leadership and commitment. Research into designing and testing new tools to fight TB needs more funding. Supporting NIH basic research and CDC programs and directing resources toward Product Development Partnerships is the most effective way to develop new tools to defeat this horrible disease. I thank you for this opportunity to highlight the need for a preventive TB vaccine and Aeras' efforts to develop such a vaccine, and I look forward to answering any questions you may have.