University of Maryland, Baltimore
Testimony to U.S. Senate Committee on Appropriations
"U.S. Government Response: Fighting Ebola and Protecting America"
Wednesday, November 12, 2014

The University of Maryland, Baltimore (UMB) is pleased to have the opportunity to submit testimony for the U.S. Senate Committee on Appropriations' hearing titled "U.S. Government Response: Fighting Ebola and Protecting America." Founded in 1807, the University of Maryland, Baltimore is a multidisciplinary campus of seven professional schools internationally recognized for professional and graduate education in medicine, dentistry, nursing, pharmacy, social work, and law. It is the University's goal to excel in educating professionals and engaging in research that addresses real-world issues affecting the human condition.

The University of Maryland, Baltimore has many strong partnerships in the affected countries that provide an opportunity to respond in a meaningful way to this crisis. In fact, our response is well underway: the University of Maryland School of Medicine's Center for Vaccine Development has mobilized their in-country resources and networks at the Malian border and is also actively engaged in the process of vaccine testing and deployment. Additionally, a School of Medicine physician recently returned from Sierra Leone where he treated Ebola patients; and nursing faculty from the Office of Global Health are responding to requests from their nursing partners in Liberia to help aide nurses on the frontlines of the Ebola response who lack basic personal protective equipment.

The University of Maryland School of Medicine Center for Vaccine Development

In August, the National Institutes of Health announced the first clinical trial of a vaccine to protect healthy people from infection by the Ebola virus. Professor Myron Levine, director of the University of Maryland School of Medicine's Center for Vaccine Development (CVD), is leading the trial in Mali.

The trial began on Wednesday, October 8, 2014, with the vaccination of the first subject, followed by two additional participants on October 9, all three being Malian health care workers. In the coming weeks, 37 more health care workers will receive the vaccine. "This research will give us crucial information about whether the vaccine is safe, well tolerated and capable of stimulating adequate immune responses in the highest priority target population, health care workers in West Africa," said Levine. "If it works, in the foreseeable future it could help alter the dynamic of this epidemic by interrupting transmission to health care and other exposed front-line workers."

The vaccine consists of an adenovirus (cold virus) that does not cause illness in humans and has been modified so that it cannot multiply in humans but produces a single attachment protein of Ebola virus. Immune responses directed against this single Ebola protein have been shown to be highly protective in animal model challenge studies which were carried out under the highest level of physical containment. Researchers hope this response will be robust enough to protect humans from the disease.

The vaccine was developed by investigators at the Vaccine Research Center (VRC) of the National Institute of Allergy and Infectious Diseases (NIAID) in Bethesda, MD. The clinical trial in Mali brings to fruition two months of work by a consortium dedicated to move the candidate Ebola vaccine into clinical studies in West Africa. Prior to September, testing had been only done in animals. The consortium, assembled in mid-August at the behest of the World Health Organization (WHO), includes the VRC, the Jenner Institute at the University of Oxford (which carried out clinical trials in UK adults paving the way for the African trial), the CVD and CVD-Mali (carrying out the first clinical trial of the vaccine in West Africa), GlaxoSmithKline (GSK) Biologicals (manufacturer of the vaccine) and the Wellcome Trust, UK (funder of the clinical trials in UK and Mali). Additional funding was provided by the Medical Research Council (MRC), UK and the UK Department for International Development (DFID). In addition, an MRC unit in The Gambia is expected soon to initiate a second, parallel clinical trial in that country. Ordinarily it would take between six to 11 months to obtain all necessary ethical, regulatory agency, technical, and administrative approvals needed to transition a vaccine from research in animal models to a clinical trial in a developing country where subjects are at risk of the natural disease. In this instance, with all consortium members working in unison, it took two months.

Pre-clinical research in primates by the VRC and Okairos, a biotechnology company acquired last year by GSK, indicates that the vaccine provides protection in non-human primates exposed to Ebola without significant side effects. The recent increase in funding for Ebola vaccine research is also enabling GSK to begin manufacturing at least 10,000 additional doses of the vaccine, even as the first clinical trials are occurring.

The CVD has earned an international reputation as an academic vaccine development enterprise for creating and testing vaccines against cholera, typhoid fever, paratyphoid fever, non-typhoidal Salmonella disease, shigellosis (bacillary dysentery), Escherichia coli diarrhea, malaria, and other infectious diseases, including influenza. In addition to its research and outpatient facilities in Baltimore, Maryland, the CVD has fixed facilities to conduct clinical studies in Mali, West Africa, Malawi, Southern Africa and Santiago, Chile, and undertakes time-limited field studies in many other countries in Africa, Asia and Latin America. The Center's international staff includes molecular biologists, microbiologists, immunologists, internists, pediatricians, epidemiologists, malariologists, biostatisticians and informaticians.

The University of Maryland, Baltimore's Interprofessional Ebola Information Network

The University of Maryland School of Nursing Office of Global Health (OGH) was established in 2009 to develop local and global partnerships to support the capacity of nurses to improve and strengthen health systems in resource limited settings. OGH also builds global nursing capacity through increasing access to advanced knowledge and practice, and contributes to the global effort for expanding nursing's leadership role in changing health policies and improving health systems.

Aligned with its goals, OGH has taken the lead on campus with the newly-created Ebola Information Network (EIN). The EIN will serve as a vehicle to share information with all

groups and individuals throughout the University who are actively engaged in or supportive of the Ebola response.

On August 12th, 2014, OGH facilitated a meeting of UMB faculty and staff who were actively engaged in some capacity in the response to the Ebola outbreak. Participants included representatives from several schools on campus, as well as the School of Medicine's Institute of Human Virology, the University of Maryland Medical Center Environmental Health Services, and the World Health Organization Collaborating Center for Occupational Health. During this meeting, it became evident that UMB had an enormous capacity that was currently being leveraged and was beneficial to our campus community, our university system, our international partners, and key global health organizations that were addressing the Ebola outbreak.

The concluding question discussed at the August meeting was how to best continue timely communication of activities, share best practices and resources, and collaborate with each other on requests from global health organizations, receive timely updates, and avoid duplication of efforts. As a result, EIN will be hosting a symposium on Ebola on November 18, 2014. At this symposium, UMB leaders and national Ebola experts will provide information on the disease, strategies for prevention and preparedness and response efforts being implemented by UMB interprofessional teams.

Conclusion

According to the Centers for Disease Control and Prevention, the 2014 Ebola outbreak is the largest outbreak in history. With research being one of the cornerstones of UMB's mission, it is our hope that our stellar researchers and health-care professionals can have a valuable and effectual impact on this devastating crisis.

The University of Maryland, Baltimore is happy to provide additional information, answer questions, or introduce the Committee to our researchers on campus. Thank you again for the opportunity to submit testimony on this vital subject.