Johnson & Johnson and Bavarian Nordic

Testimony before the U.S. Senate Committee on Appropriations

Hearing on "U.S. Government Response: Fighting Ebola and Protecting America"

November 12, 2014

Chairwoman Mikulski, Ranking Member Shelby and members of the Committee, thank you for the opportunity to submit written testimony on behalf of Johnson & Johnson along with its subsidiary Crucell Holland B.V., and Bavarian Nordic A/S, regarding our joint efforts to respond to the current Ebola crisis by rapidly advancing the development and production of a promising vaccine candidate.

Johnson & Johnson, with its 270 operating companies and 126,000 employees around the world, is an international leader committed to bringing innovative ideas, products and services to advance the health and wellbeing of people everywhere. Crucell is one of the Janssen Pharmaceutical Companies of Johnson & Johnson dedicated to the research, development and production of vaccines, with a focus on supplying vaccines to UNICEF and the developing world. Bavarian Nordic is an international company developing and manufacturing novel cancer immunotherapies and vaccines for infectious diseases, including a smallpox vaccine that is stockpiled by the U.S. government.

As we are all acutely aware, the Ebola crisis is crippling affected West African countries and has spread to the United States and Europe. There have been over 13,042 confirmed, probable, and suspected cases of Ebola virus disease, with nearly 5,000 confirmed deaths as of November 2, according to the latest figures from World Health Organization (WHO). Actual figures are likely to be much higher. Presently, there is no licensed vaccine, treatment or cure that exists for Ebola. However, years of biomedical research, public-private partnerships and investments have brought to bear promising solutions that could meet the scope of the worldwide outbreak.

Specifically, Johnson & Johnson, through a collaboration between Crucell and Bavarian Nordic, has developed a promising Ebola vaccine regimen that has so far demonstrated 100 percent protection in stringent non-human primate challenge studies. This vaccine program is a two-component regimen targeting the Ebola Zaire virus, using the AdVac vector from Crucell, and a vector from Bavarian Nordic's MVA-BN technology. Crucell Filovirus vaccine development has received direct funding from, and is also using, preclinical services from the NIAID, part of NIH under Contract Numbers HHSN272200800056C, HHSN272201000006I and HHSN272201200003I. Preclinical experiments conducted with NIH of the combination vaccine regimen demonstrated that when both vaccines were administered two months apart, complete protection was achieved against the Kikwit variant of Ebola Zaire, which is highly similar to the virus that is the cause of the current outbreak in Western Africa.

The further development and manufacturing of this and other Ebola vaccines and therapeutics could be supported through the Biomedical Advanced Research and Development Authority (BARDA), the Special Reserve Fund (SRF) and the Joint Vaccine Acquisition Program (JVAP). Therefore, we strongly support robust funding of not only NIH, but also BARDA and the SRF at the Department of Health and Human Services, and the Department of Defense's (DoD) JVAP. These agencies and funding mechanisms lead the world in building successful public-private partnerships to research, develop, and manufacture needed vaccines and drugs that address domestic and global threats that the private sector simply could not pursue on its own.

While this Committee reviews and decides the appropriations needed to respond to the current Ebola outbreak, we strongly encourage Congress to also review the need for sufficient, sustainable funding for NIH, BARDA, SRF and JVAP to keep the pipeline of new drug and vaccine discovery supported at a level that ensures the successful development of the medical countermeasures needed to prepare for and respond to the next emerging infectious disease or terrorist threat.

As part of its responsibility to advance innovations that address urgent unmet medical needs worldwide, Johnson & Johnson is quickly mobilizing its extensive resources to collaborate with health authorities and governments and other experts to respond to the Ebola crisis. On October 22, Johnson & Johnson announced a commitment to accelerate and significantly expand production of an Ebola vaccine program in development at its Janssen Pharmaceutical Companies. This commitment is in addition to Johnson & Johnson's support of the Centers for Disease Control and Prevention Foundation's Global Disaster Response Fund and trusted international partners working in the hardest hit countries to help protect the brave health workers on the front lines of the crisis today.

In order to meet the demands of this critical international need, Johnson & Johnson is providing capital to Bavarian Nordic through an equity investment in order to support the development, testing and production of Bavarian Nordic's vaccine. The company's MVA-BN vaccine platform technology and large scale manufacturing capacity have been built through a successful decade-long partnership with BARDA, the SRF and NIH on the development, manufacturing, and stockpiling of the company's smallpox vaccine.

Working with Bavarian Nordic, the U.S. federal government, the World Health Organization (WHO) and an array of other public health stakeholders, Johnson & Johnson is targeting production of more than one million doses of the vaccine regimen by the end of 2015, 250,000 of which are expected to be released for broad application in clinical trials by May 2015. The vaccine regimen would be made available through various U.S. and international defense and aid programs. Johnson & Johnson's proactive commitment to devote initial capital to this endeavor reflects the company's response to the WHO's calls for urgent action to develop vaccines and therapeutics to treat patients and prevent the further spread of Ebola.

Crucell and Bavarian Nordic are preparing for Phase 1 clinical trials, with studies beginning in early January of 2015 in the United States, Europe and Africa to achieve a thorough body of evidence for the vaccine's success rates. This first stage of engagement will require in excess of $20 million. Phase 2 clinical trials will start shortly thereafter. Johnson & Johnson is seeking

funding from several government entities to support these efforts but is fully prepared to assure that both Crucell and Bavarian Nordic are financially resourced to ramp up advanced manufacturing and production capabilities to fill the initial deployment of 250,000 vaccine doses by May 2015. Non-stop acceleration of testing and scaling up over the next year is expected to yield one million vaccine courses by the end of 2015 and two to four million by the end of 2016.

This multi-faceted drive will require a robust scaling up of manufacturing assets, materials, platforms and human resources to produce the target dosages and bring the first large-scale inventory of an Ebola vaccine to market to fill the stated needs of the WHO, U.S. government and the nations of Liberia, Sierra Leone and Guinea, among others.

Overall, this endeavor is expected to cost in excess of $350 million for the full scope of Crucell and Bavarian Nordic's activities under this accelerated development pipeline. We seek to share some of the financial risk of the vaccine development and clinical trial costs with governmental and non-governmental funders, and will pursue funding opportunities that may be offered through U.S. federal agencies such as BARDA or DoD.

Johnson & Johnson and Bavarian Nordic are committed to working with governmental and non-governmental entities to eliminate Ebola as a global health threat as expeditiously as possible. We look forward to further discussions with Congress and the Administration as partners in this effort, and stand ready to respond to any inquiries from this Committee as you develop related appropriations legislation. We believe the battle against Ebola is a winnable one, but we also seek to work with Congress long-term to sustain the medical countermeasures enterprise with robust funding for the key HHS agencies and programs that undergird these activities.