Statement for the Record Submitted by the
Association of American Medical Colleges (AAMC) to the
U.S. Senate Committee on Appropriations
"U.S. Government Response: Fighting Ebola and Protecting America"
submitted November 7, 2014

The Association of American Medical Colleges (AAMC) is pleased to submit this statement for the record for the Senate Appropriations Committee's November 12 hearing, "U.S. Government Response: Fighting Ebola and Protecting America." The AAMC is a not-for-profit association representing all 141 accredited U.S. medical schools; nearly 400 major teaching hospitals and health systems, including 51 Department of Veterans Affairs medical centers; and nearly 90 academic and scientific societies. Through these institutions and organizations, the AAMC represents 148,000 faculty members, 83,000 medical students, and 110,000 resident physicians.

As academic medical centers that are guided by a tripartite mission of leadership in medical education, medical research, and patient care, AAMC-member medical schools and teaching hospitals offer unique services and expertise typically unavailable elsewhere in the region, and they provide leading-edge care informed by the latest advances in medical and clinical research. AAMC-member institutions including the University of Nebraska Medical Center (UNMC), Emory University, and nearly all of the state-designated Ebola centers in New York, Texas, Maryland, Chicago, Cleveland, and elsewhere are already on the forefront of caring for Ebola patients in the United States and Africa. Others also are conducting vaccine trials and medical research targeting Ebola.

In a recent letter to White House Ebola Response Coordinator Ron Klain, more than 120 medical schools and teaching hospitals from 35 states and the District of Columbia expressed their readiness to work with state and federal officials in preparing for and responding to possible Ebola cases. The letter also expresses support for a robust, sustained federal investment in preparing and equipping institutions to screen, refer, and care for Ebola patients in the United States. Addressing Ebola – as well as other existing and future health care threats – will require an unwavering commitment to the nation's health care infrastructure, including hospital preparedness and medical research.

Scientists at AAMC-member medical schools and teaching hospitals are engaged in a spectrum of Ebola-related projects ranging from basic studies to understand better how the virus works to clinical trials to test candidate vaccines.

The National Institute of Allergy and Infectious Diseases (NIAID) at NIH is funding a collaborative Center of Excellence for Translational Research grant to support research at the University of Texas Medical Branch (UTMB) at Galveston, the Vanderbilt University Medical Center, and industry to develop and test new vaccines and broad spectrum treatments against the Ebola and Marburg viruses. The award combines three of the most promising post-exposure treatments that have shown the ability to completely protect animals against these viruses. The center will conduct three interdependent research

projects, supported by the Galveston National Laboratory at UTMB, a facility with the highest level containment required to safely work with deadly viruses, biosafety level four. UTMB has the only operational BSL-4 laboratory on a university campus in the United States.

At Vanderbilt University, researchers are using a high-efficiency method to isolate and generate large quantities of human antibodies from the blood of people who have survived Ebola and Marburg infections and who are now healthy. The goal of the collaboration is to develop safe and effective antibody therapies that can provide short-term protection to health care workers and others at risk of exposure to the Ebola and Marburg viruses.

Researchers at the University of North Carolina at Chapel Hill and colleagues have developed the first genetic strain of mice that can be infected with Ebola and display symptoms similar to those that humans experience. The team, including researchers from the University of Washington and the NIH Rocky Mountain National Laboratory, where the research took place, were able to breed together eight genetic mouse variants and successfully test a strain of mice to permit active research on potential Ebola vaccines and treatments. This model system more accurately reflected the human experience when infected with the virus and will significantly improve basic research on Ebola treatments and vaccines.

Researchers at NIH and Oregon Health & Science University (OHSU) have found that an experimental vaccine elicits antibodies that can protect nonhuman primates from Ebola virus infection. In this study, scientists at NIAID and OHSU's Vaccine & Gene Therapy Institute built on earlier work with an experimental vaccine composed of an attenuated virus carrying a gene that codes for an Ebola virus protein. Their results showed that important immune cells—CD4+ T cells and CD8+ T cells—had a minimal role in providing protection, while antibodies induced by the vaccine appeared to be critical to protecting the animals. The scientists say this finding will help improve future Ebola virus vaccine development. They plan to focus their studies on what level of antibody production is needed to establish protection from Ebola virus infection in humans.

NIAID intramural scientists are collaborating with Thomas Jefferson University investigators to produce a candidate Ebola based on an existing rabies vaccine. The researchers aim to generate immunity to Ebola, Marburg, and rabies viruses. The investigators plan to pursue a version of the vaccine for human and veterinary use as well as a version for use in African wildlife. The wildlife vaccine could help prevent transmission of Ebola virus from animals to humans. The vaccine candidate for use in humans is undergoing preclinical testing and has demonstrated protection against infection by rabies and Ebola viruses in animal models. NIAID is currently partnering with the Department of Defense to produce sufficient quantities of the vaccine candidate to begin clinical testing in early 2015.

In early October, the Center for Vaccine Development at the University of Maryland School of Medicine, working with the Center for Vaccine Development - Mali (a joint

enterprise of the University of Maryland School of Medicine and the Ministry of Health of Mali), began a clinical trial in Mali in health care workers (and other front-line workers) to evaluate a promising experimental Ebola. The vaccine, which prior to September had been tested only in animals but not in humans, was developed by investigators at NIAID's Vaccine Research Center (VRC) and manufactured by GlaxoSmithKline (GSK) Biologicals. The clinical trial in Mali brings to fruition two months of work by a consortium, assembled in mid-August at the behest of the World Health Organization, dedicated to move the candidate Ebola vaccine into clinical studies in West Africa.

These projects demonstrate that our ability to respond to the current Ebola outbreak as well as future emerging and reemerging diseases depends on a sustained federal investment in both the research personnel and infrastructure to undertake basic and clinical research.

Medical schools and teaching hospitals also offer experience in caring for the most complex patients, an asset in coordinating care for confirmed Ebola cases. For example, by staffing and maintaining costly biocontainment units, routinely training and drilling employees, and engaging in vaccine and related infectious disease research, Emory University and UNMC were prepared to step up immediately and play an essential role in the nation's response.

Likewise, several AAMC-member institutions are working with their state hospital associations and state governments to ramp up their capacity in case the nation must take additional and rapid action to care for more patients with Ebola. Well-established referral patterns exist in caring for the most complex patients at these institutions (burn, trauma, etc.), and building off this existing infrastructure can help strengthen the ability of the system to respond expeditiously to this novel situation.

Reaching this goal, however, will require a substantial federal and state commitment and a partnership that is sensitive to the unique operational challenges these institutions likely will encounter. This includes significant public relations challenges within the communities they serve. In addition to the unique costs associated with employee training, facility expansions/modifications, systems for safely transporting patients, and other requirements, these institutions also are likely to face lost clinical revenues because of fear within the community and the possible shift of resources away from other services. Similarly, the federal and state governments must help these centers secure adequate reimbursement from private and public payers for potentially costly and lengthy hospitalizations. These investments will require a steady, reliable, and long-term financial commitment to ensure continued support for readiness activities even as threats appear to diminish.

Ongoing readiness training alone costs hundreds of thousands of dollars annually, and one institution estimates just the direct costs of increased staffing can exceed $25,000 per patient per day. Costs will be even higher for institutions that may not have the existing

infrastructure for such efforts. Sample expenses to prepare for and respond to confirmed and anticipated Ebola cases include:

Domestic Preparedness

- Training health professionals, transportation teams, and others
    - Training to identify, isolate, and arrange transportation for infected patients
    - Training in proper use and donning/doffing of personal protective equipment
- Identifying, assessing, and readying treatment facilities to handle cases transported from community/other facilities
- Research to accelerate diagnostics, treatments, and vaccines

On-the-Ground Response

- Providing additional resources (e.g., personal protective equipment, hazmat suits, etc.)
- Covering the expense of transportation to designated treatment centers (including decontamination of transport vehicles as appropriate)
- Covering the expense of biohazard disposal
- Personnel costs, including potential housing for hospital staff
- Covering the expense (and possibly foregone revenue) of caring for an Ebola patient

Emergency supplemental funding will be critical to enable institutions to gear up for a rapid Ebola response, without undermining their ability to address daily health care challenges, such as hospitalizations as a result of influenza, heart attacks, injuries from car accidents, and the myriad of other health care needs.

Further, the budget caps imposed by the Budget Control Act have hindered the federal government's ability to invest in NIH and public health and hospital preparedness programs that are critical to successfully responding to Ebola and other emergencies. Ongoing support is necessary to strengthen preparedness not only to address the current epidemic, but also future emergencies as they arise.

The AAMC appreciates the opportunity to submit this statement, and looks forward to working with the Committee to advance emergency supplemental funding to address these needs and to reinvest in the nation's research and public health infrastructure.