June 6, 2018

The Honorable Michael Burgess, M.D.
Chairman
Subcommittee on Health
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Gene Green
Ranking Member
Subcommittee on Health
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Burgess and Ranking Member Green:

The Healthcare Leadership Council (HLC) is writing to urge you to consider the second reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA), which is set to expire at the end of the 2018 fiscal year. Passed into law in 2006, PAHPA aims to "improve public health, medical preparedness, and response capabilities for emergencies, whether deliberate, accidental or natural." This act established the office of Assistant Secretary for Preparedness and Response (ASPR), whose mission is to strengthen our national health security and protect the public from 21st century health security threats, such as naturally occurring disease outbreaks, emerging infectious diseases, extreme weather events, and cybersecurity attacks on our healthcare delivery system. ASPR plays a crucial role in mobilizing a "coordinated national response" in emergencies to protect the public's health and our national security.

HLC is a coalition of chief executives from all disciplines within American healthcare. It is the exclusive forum for the nation's healthcare leaders to jointly develop policies, plans, and programs to achieve their vision of a 21st century health system that makes affordable, high-quality care accessible to all Americans. Members of HLC – hospitals, academic health centers, health plans, pharmaceutical companies, medical device manufacturers, laboratories, biotech firms, health product distributors, post-acute care providers, and information technology companies – advocate for measures to increase the quality and efficiency of healthcare through a patient-centered approach. Through this diversity, HLC develops a coordinated perspective on the impact of any legislation or regulation affecting the nation's medical infrastructure and the public's health.

PAHPA provides funding for coordination across the Department of Health and Human Services (HHS) federal agencies, such as the Centers for Disease Control and Prevention (CDC), the Centers for Medicare and Medicaid Services (CMS), Food and Drug Administration (FDA), and Substance Abuse and Mental Health Services Administration (SAMHSA), as well as local, state and territorial health entities, to prepare and respond to emergencies and disasters. Under PAHPA, ASPR works to organize, train, equip and mobilize "federal public health and medical personnel" in public health emergencies at state and local levels.

The Hospital Preparedness Program (HPP), a key initiative under the umbrella of ASPR, consists of cooperative agreements between states, and local entities, and focuses on funding coordinated hospital coalitions collaborating in an area with emergency medical systems and public health departments. Funding for this program has decreased significantly from $515 million in 2004 to $254 million in 2017. According to a 2017 Trust for America's Health report, "over half of states scored five or lower out of ten on emergency preparedness." We cannot expect states to combat the healthcare threats of our time with half of them ill-prepared to handle a public health emergency. To meet the challenges of 21st century threats to our nation's health security, increased funding is needed to develop and implement regional disaster programs, such as HPP, to improve our healthcare infrastructure and national readiness. 21st century infrastructure includes more sophisticated informatic approaches to identifying diseases, greater sharing of information to supply more sophisticated analytics, a greater understanding of the genetic components of disease, and a willingness to consider more expansive models of disease detection.

HLC strongly supports the authorization and an increase in funding to implement a "Regional Disaster Health Response System," a key priority for Assistant Secretary Kadlec, M.D. In addition to the current challenge of responding to disasters, this new tiered regional approach will enable cross-jurisdictional preparedness for 21st century threats that may cause mass casualties, including building specialized regional capabilities and coordinating capacity to care for a large influx in patients. We recommend that Congress authorize ASPR to fund demonstration projects to implement this new model using increases in HPP funds. ASPR is also required to address the complex needs of patients with chronic conditions during a disaster, many of whom rely on healthcare technologies for treatment. The Regional Disaster Health Response System would direct grants to state and local governments (without requiring a request from the federal government) to distribute to healthcare coalitions, academic medical centers and other entities. This approach will help address the unique needs of patients with chronic conditions during a disaster, accelerate response, increase physician capacity and access to medical specialists in emergencies. Additionally, the supply chain will be able to redirect needed medical products to the providers treating the population affected by the public health event.

ASPR oversees research, development and acquisition of medical countermeasures, such as vaccines, medicines, and other pertinent medical supplies. ASPR carries out and manages these functions through three key programs: The Biomedical Advanced Research and Development Authority (BARDA), Project Bioshield, and the Public Health Emergency Medical Countermeasures Enterprise. BARDA, a critical medical countermeasure enterprise, has partnered with the National Institutes of Health (NIH), HHS, and biotechnology and pharmaceutical companies to develop 34 medical countermeasures approved or licensed by the FDA. BARDA has also assisted with the development of 27 medical countermeasures to combat national health security threats identified by the Department of Defense (DoD) and Department of Homeland Security (DOH), such as smallpox, anthrax, botulinum, and radiologic and chemical events, through Project Bioshield. BARDA has aided in the development of 23 influenza vaccines, antiviral drugs, devices and diagnostics to confront the risk of pandemic influenza. While this progress is laudable, there is still a lack of progress in the development of critical new and novel antibacterial therapies to tackle the threat of Antimicrobial Resistance (AMR). As such, it is important that new incentives, including post-market incentives, are put in place to help provide the economic certainty needed to bring these vital medicines to market.

The 21st Century Cures Act also provides a Medical Countermeasures Innovation provision (section 3084), to allow BARDA to enter an arrangement with a nonprofit entity to catalyze medical countermeasure (MCM) development and implementation. These public-private partnerships are vital to creating MCMs and highlight the importance of providing consistent public funding to ensure these partnerships can continue in the future to protect public health.

Public-private partnerships are likewise important to the healthcare supply chain in order to ensure the availability of medical products critical to any emergency, pandemic response, or following a natural disaster or public health emergency. A major "lesson learned" from the previous hurricane season that will benefit from a public-private partnership is re-entry for healthcare supply chain personnel after a disaster. Medical product distributors play a unique role in emergency preparedness, working diligently to ensure access to needed healthcare commodities for patients and providing key support to first responders during natural disasters, biological events, and other adverse emergencies. Unfortunately, during this past hurricane season, issues arose that prohibited distributors from adequately responding, thus creating barriers to accessing essential goods.

For these reasons, we would recommend ASPR establish a process to facilitate the transportation and distribution of essential healthcare goods during a presidentially declared emergency or major disaster declaration. This process should allow collaboration and input from both industry stakeholders and other federal agencies to best coordinate an appropriate process to allow these essential businesses and associated personnel to transport and distribute life sustaining medical products to a disaster area. This process should also improve communication related to fuel prioritization, hospital vacancies, law enforcement, access, and federal agency coordination.

Another example includes clinical laboratories, who are a crucial in providing information to connect healthcare stakeholders during an emergency. Clinical laboratories are the first line of detection and response to pandemic disease. The longstanding cooperation between public health, commercial laboratories, and academic research centers has been weakened by rate cuts from the Protecting Access to Medicare Act (PAMA). PAHPA provides the opportunity to strengthen diagnostic infrastructure by ensuring funding for laboratory testing and access to informatics that will allow rapid analysis of lab results across large patient datasets. PAHPA can answer the critical need to aggregate patient records across multiple institutions, providers, and states that will allow for rapid analysis of diverse lab providers.

As a multistakeholder coalition across all disciplines within healthcare, HLC strongly endorses the second reauthorization of PAHPA and the expansion of HPP funding to implement regional disaster programs. The protection of our nation's health security requires coordination and collaboration between the public and private sectors, and across multiple departments and agencies at the federal, state, and local level. Given the number of entities involved, this only underscores the complexities of current and emerging healthcare threats. Our healthcare system cannot afford to be siloed, rather, it must be integrated to successfully confront these challenges.

Thank you for your attention to this important matter. Should you have any questions, please contact Tina Grande at 202.449.3433 or tgrande@hlc.org.

Sincerely,

Mary R. Grealy
President
Healthcare Leadership Council