February 15, 2012

The Honorable Tom Harkin
Chairman, Senate HELP Committee
731 Hart Senate Office Building
Washington, DC 20510

The Honorable Richard Burr
217 Russell Senate Office Building
Washington, DC 20510

The Honorable Gene Green
2470 Rayburn House Office Building
Washington, DC 20515

The Honorable Mike Enzi
Ranking Member, Senate HELP Committee
379A Russell Senate Office Building
Washington, DC 20510

The Honorable Robert Casey
393 Russell Senate Office Building
Washington, DC 20510

The Honorable Mike Rogers
133 Cannon House Office Building
Washington, DC 20515

Dear Senators and Representatives:

The Infectious Diseases Society of America (IDSA) represents nearly 10,000 physicians and scientists devoted to patient care, prevention, public health, education, and research in infectious diseases. IDSA members will help lead our nation’s response to any future pandemic or bioterror attack at the federal, state and local levels. On behalf of IDSA, I write to commend your leadership in developing legislation to reauthorize the Pandemic and All Hazards Preparedness Act (PAHPA). Programs included in PAHPA reauthorization play an important role in equipping the nation to respond to public health emergencies, including bioterror attacks, influenza pandemics, and emerging infection outbreaks. As you craft final PAHPA reauthorization legislation, IDSA urges you to include the following provisions from each chamber’s bill:

Senate Provisions:

- Establishing an independent non-profit Strategic Investor to foster and accelerate the development of needed medical countermeasures (MCMs). IDSA supports this provision and particularly language referencing the Strategic Investor’s role in facilitating the development of novel antimicrobials for multi-drug-resistant organisms as well as related point-of-care diagnostic tests and vaccines. Antimicrobial research and development (R&D) has declined dramatically in the U.S., even as rising numbers of patients contract and succumb to resistant pathogens against which existing antibiotics have failed. New diagnostic tools are needed to help physicians use antimicrobials appropriately and to identify patients eligible for antimicrobial clinical trials.
• Requiring the Food and Drug Administration (FDA) and product sponsors to develop regulatory management plans for all MCMs, including security, pandemic and epidemic products. It is very important to provide product sponsors a clear and predictable pathway for product review and evaluation. IDSA prefers the Senate language over the House’s provision which refers solely to security MCMs. The House may have intended its language to include pandemic and epidemic products as well, but the Senate language makes this point clear.

• Requesting that the National Biodefense Science Board (NBSB) provide advice and guidance to ASPR regarding the Public Health Emergency Medical Countermeasures Enterprise on improving biosurveillance and requiring a GAO report on situational awareness programs. Strong biosurveillance and situational awareness programs are necessary for obtaining timely and accurate insight on current and emerging threats — both manmade and naturally occurring.

• Directing the Secretary to update criteria for states’ pandemic influenza plans. IDSA supports this provision recognizing that state influenza plans are critical to help ensure a rapid and appropriate response to a pandemic. Criteria for these plans should be updated to take into account lessons learned from the 2009 H1N1 influenza pandemic as well as any new scientific evidence regarding influenza prevention, treatment, surveillance and containment.

• Enhancing preparedness efforts for children, particularly prioritizing pediatric MCM development. Children have different medical needs than adults and respond to medications and vaccines differently. IDSA supports these provisions, including: (1) establishing a federal pediatric disaster preparedness advisory board; (2) directing the Assistant Secretary for Preparedness and Response (ASPR) and the Biomedical Advanced Research and Development Authority (BARDA) to conduct pediatric studies on MCMs; (3) allowing the Secretary to consider the availability of pediatric MCMs when developing the list of priority drugs for pediatric research; (4) requiring that FDA and product sponsor regulatory management plans include a plan for demonstrating safety and effectiveness (whenever possible) in pediatric populations and for developing pediatric dosing, formulation and administration; and (5) requiring that the NBSB have at least one member with pediatric expertise.

House Provisions:

• Strengthening pediatric preparedness, including: (1) requiring the ASPR to report on the state of pediatric preparedness, where gaps exist and how HHS plans to address those gaps; and (2) requiring hospitals receiving federal preparedness funds to include pediatrics in preparedness planning. IDSA supports these provisions as complementary to the Senate’s more detailed pediatric preparedness provisions.

• Permitting mass dispensing of MCMs without a prescription during an emergency. IDSA supports this provision, recognizing that in large scale scenarios it would be extremely difficult and potentially impossible to provide timely prescriptions for MCM to all eligible persons. Like the other provisions related to emergency use of products, the mass dispensing contains appropriate safeguards.
Finally, while we understand the nation’s current fiscal pressures, we believe that greater investment in key areas is crucial to protect the American people and others from biothreats, pandemics and emerging infections. While PAHPA reauthorization can strengthen our nation’s public health preparedness, additional funding for these efforts would have an even greater impact.

For further information, please contact Amanda Jezek, IDSA’s Government Relations Director at ajezek@idsociety.org or 703-740-4790. We look forward to working with you to advance the nation’s ability to prepare for and respond to public health emergencies.

Sincerely,

Thomas G. Slama, MD, FIDSA
President