**Office of the Assistant Secretary for Preparedness and Response**
**Biomedical Advanced Research and Development Authority**

**Distribution of Medical Countermeasures under Investigation**

The distribution and allocation of therapeutics approved by the Food and Drug Administration (FDA) under an Emergency Use Authorization (EUA) has been overseen by the Assistant Secretary for Preparedness and Response (ASPR). Following an initial opaque distribution of remdesivir directly to hospitals, the office has developed a more transparent process for allocating and distributing these scarce therapeutics. Currently, the weekly distributions of all EUA products are allocated to states, with states then determining allocations to hospitals or other facilities within their states. ASPR maintains a webpage with important information including updates on state allocations and other supportive documents. ASPR also holds weekly stakeholder calls and office hours to respond to questions from provider organizations, states and others. We encourage the continuation of these practices and offer recommendations to improve transparency in the distribution process.

**We recommend:**

- **Publicly disclosing the data used to make allocation decisions;**
- **Predicting allocation decisions further in advance than the current 1-week time frame to allow health care facilities to plan their own distribution to patients. For instance, recently authorized monoclonal antibody products are administered by infusion and require more intensive facility and staffing preparation and protocols.**

**Antibiotic R&D**

Antimicrobial resistance threatens our preparedness for any pandemic or mass casualty event, as secondary infections complicate treatment, lengthen hospital stays and increase the number of lives lost. Under the *National Action Plan for Combating Antibiotic Resistant Bacteria*, originally conceived and prioritized by the Obama-Biden administration, the BARDA Broad Spectrum Antimicrobials program and CARB-X initiative have been essential to leveraging public private partnerships to develop new FDA approved antibiotics. However, these activities alone are insufficient to deliver the robust and renewable antibiotic pipeline needed to address current and future threats.

The antibiotic market is uniquely broken. Nearly all large pharmaceutical companies have abandoned antibiotic research and development (R&D) and the small companies responsible for the vast majority of recent innovation are struggling to stay in business. In 2019, two small antibiotics companies filed for bankruptcy, despite launching important new antibiotics. New antibiotics must be used judiciously to preserve their effectiveness, but limited use makes it

extremely difficult for antibiotic developers to earn a return on their investments. Innovative approaches are needed to sustain the antibiotic market. BARDA's Project Bioshield contract awarded to Paratek in December 2019 is an important first step to provide support to antibiotic innovators post-approval, a time when small companies in particular struggle to raise sufficient funds to support manufacturing and post-approval studies and other requirements.

**We recommend:**

- **Working with Congress to enact new bipartisan legislation to reform the way the federal government pays for critically needed new antibiotics. The Pioneering Antibiotic Subscriptions To End Upsurging Resistance (PASTEUR) Act, S. 4760 would create a subscription model to provide set federal payments for critically needed new antibiotics that are delinked from the sales and use of those antibiotics, instead of paying per prescription through federal health programs;**
- **Increasing funding for existing ASPR and BARDA approaches to support antibiotic R&D.**

**Strategic National Stockpile**

States and hospitals need increased federal support to maintain a reserve of supplies, including personal protective equipment (PPE) and testing supplies (including swabs, reagents and test kit components). Inadequate supplies have been a persistent challenge throughout the pandemic, and better access to PPE is still needed by hospitals, clinics, testing sites and long-term care facilities. The federal stockpile has been insufficient, and a much stronger system is necessary to ensure production and distribution of PPE and testing supplies, including more fully leveraging the Defense Production Act.

In addition to supplies necessary to care for patients with COVID-19, health care facilities and providers also need supplies to provide routine, essential health care during a pandemic. For example, necessary efforts to expand COVID-19 testing capacity have diverted resources from other infectious diseases microbiologic testing capacity. Physicians and laboratories report serious shortages of testing supplies and trained medical technologists to perform tests necessary to treat other infectious diseases and guide appropriate antibiotic therapy.

**We recommend:**

- **Developing Federal guidelines in consultation with health care providers, health care facilities and public health departments on the amount and types of supplies that are appropriate to stockpile. State health departments' budgets were stretched prior to COVID-19 and hospitals are suffering serious financial consequences due to the pandemic, further increasing reliance on the strategic national stockpile during this and future pandemics.**

**Influenza Preparedness and Response**

The executive order (EO) "Modernizing Influenza Vaccines in the United States to Promote National Security and Public Health," appropriately prioritizes domestic efforts to modernize and improve the production and effectiveness of influenza vaccines and promotes increased

immunization rates. This includes research into better flu vaccines, including better adjuvants and new vaccine platforms to reduce reliance on egg-based vaccines; the ultimate goal being to improve current technologies and the development of a universal flu vaccine.

**We recommend:**

- **Implementing (including funding) a five-year national plan (as established by the National Influenza Vaccine Task Force) as well as a short-term plan for seasonal influenza vaccination. Significant investments in the implementation of the EO are needed for continued research, including sustained funding increases for BARDA (in addition to the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health [NIH]).**

*For questions regarding our recommendations, please contact Amanda Jezek, IDSA Senior Vice President for Public Policy and Government Relations at ajezek@idsociety.org or Andrea Weddle, HIVMA Executive Director at aweddle@hivma.org.*