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IDSAs

Infectious Diseases Society of America

December 2, 2019

The Honorable Alex Azar II
Secretary of Health and Human Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Azar,

The Infectious Diseases Society of America (IDSAs) greatly appreciates the opportunity to provide support and comments on President Trump's Executive Order "Modernizing Influenza Vaccines in the United States to Promote National Security and Public Health." IDSAs would welcome the opportunity to partner with the administration to advance this important effort to strengthen our influenza preparedness and response. We emphasize that significant new federal resources will be needed to realize the goals set forth in the Executive Order, and we encourage the administration to request these funds from Congress swiftly. We also strongly encourage the administration to pair this initiative with rapid action to strengthen our federal response to antibiotic resistance, and specifically to stabilize the crumbling antibiotic market. Every year, many influenza cases are complicated by secondary bacterial infections like pneumonia which increase risk of hospitalization and death. Such bacterial infections are increasingly difficult to treat to due antibiotic resistance.

IDSAs represents over 12,000 infectious diseases physicians, other health care professionals, and scientists. Our members work across all sectors in health care including public health departments, hospitals, academic medical centers, publicly-funded clinics, and private practice to achieve optimal patient and population health through direct patient care, community-based programs, research, and other interventions.

IDSAs appreciates the acknowledgements in the Executive Order regarding the shifting nature of both seasonal and potentially pandemic influenza, the need for more nimble technologies and production methods, and the limitations of influenza vaccines which contribute to suboptimal vaccination levels despite the critical role of vaccination as the most effective way to prevent disease.

The Executive Order objectives would take significant steps to address these challenges. Both seasonal and pandemic influenza vaccine production would be strengthened by transitioning from egg-based to cell-based platforms. This transition would decrease production time and reduce shifts in the virus as it goes through several generations of mutations during egg passage. Decreased production

time would allow for pandemic vaccines to be deployed more quickly and allow seasonal vaccine decisionmakers to gather more data and wait longer before deciding which strains to utilize in the next year's vaccine, hopefully leading to more broadly protective seasonal vaccines that would increase confidence and uptake. Improving on current vaccine technologies while continuing to search for a universal flu vaccine strikes an ideal balance between both short and long-term flu vaccine research priorities. Both during seasonal and potentially pandemic influenza seasons, the strain on health care systems dealing with large increases in patient numbers affects all of the facilities' services and capabilities, spreading the impact far beyond those who contract influenza.

IDSA supports the development of a National Influenza Vaccine Task Force to oversee the creation of a plan and report that includes all relevant agencies, though we believe input from non-governmental stakeholders will be vital in this process and should not be optional since this would bring together all key stakeholders and the best expertise in the United States. It may be helpful to include in the initial report an audit of current influenza vaccine efforts within the government, as there are multiple governmental and semi-governmental bodies engaged in different aspects of influenza and vaccines. This would help to ensure that work is not being duplicated and ongoing initiatives can be leveraged to achieve the Task Force's goals in a more efficient manner. Adequate funding will be an important part of the success of this initiative, as the goals stated are admirable but lofty, and the research, development, workforce, and public health infrastructure required to reach them will require significant investment.

Efforts to treat bacterial complications of influenza are compromised by growing antibiotic resistance and an inadequate antibiotic arsenal. Comprehensive influenza preparedness and response efforts should include investments to address antibiotic resistance and support the research, development and continued availability of urgently needed new antibiotics. Influenza cases can be significantly complicated by secondary bacterial infections, which are becoming increasingly difficult to treat due to antibiotic resistance.

The antibiotic pipeline is in a state of crisis for which urgent action is essential. We greatly appreciate numerous recent actions from the administration highlighting this problem—most recently the Centers for Disease Control and Prevention Antibiotic Threats in the United States report, released in November 2019. CDC highlighted 5 pathogens as urgent threats, up from 3 pathogens in 2013. CDC underscored great concern about the increase in antibiotic-resistant infections in the community, which can transform infections that could once have been treated in an outpatient setting into infections requiring hospitalization. CDC estimates that, on average, someone in the United States gets an antibiotic-resistant infection every 11 seconds and every 15 minutes someone dies. Many infectious diseases clinicians believe the actual burden is even higher.

The April 2019 bankruptcy of the small antibiotics biotech firm Achaogen following its launch of a new antibiotic shook the antibiotic marketplace and further depressed the already minimal investment interest in supporting antibiotic research and development. Additional companies are likely to face the same fate in the next few months unless the federal government acts now to stabilize the antibiotic marketplace and drive new investment in this area. Additional bankruptcies would jeopardize patient access to existing antibiotics, further weaken the already

collapsing pipeline of new antibiotics in development and cause a significant loss of scientific experts that can take many years to recover. IDSA strongly encourages you to request swift new funding from Congress to provide support for new antimicrobial market stabilization and strengthening initiatives by HHS, including potentially a novel pull incentive, to allow for antibiotic innovation.

It is equally essential that we protect the effectiveness of antimicrobials through stewardship. We applaud the September 2019 action by the Centers for Medicare and Medicaid Services (CMS) to require all hospitals to implement antimicrobial stewardship programs as a Condition of Participation in Medicare. Stewardship programs provide clinicians with the necessary tools and information to optimize antimicrobial prescribing, including education, the use of diagnostic tests, penicillin allergy testing, and surveillance to measure and improve appropriate use. IDSA is eager to work with you to help ensure the success of this important initiative. As you know, the Centers for Disease Control and Prevention (CDC) currently leads activities to promote optimal antimicrobial use. Given the new CMS requirement, this is an important time to provide an infusion of funding—particularly to help hospitals (including rural and critical access hospitals) initiate their stewardship programs and begin reporting antibiotic use and resistance data to the CDC National Healthcare Safety Network (NHSN). It is important to collect these data in order to evaluate the impact of stewardship efforts. Both of these activities can require initial funding to launch whereas continued operation is far less costly. We strongly encourage you to couple an emergency supplemental funding request to support the antibiotic pipeline with a request for new funding to support antimicrobial stewardship and NHSN reporting.

IDSA greatly appreciates your commitment to comprehensive efforts to prepare for and respond to the threats of influenza and antibiotic resistance and we look forward to working with you on behalf of patients and public health.

Sincerely,

A handwritten signature in cursive script that reads "Thomas J. File".

Thomas J. File, MD, FIDSA
President, IDSA