On behalf of the Adult Vaccine Access Coalition (AVAC), we appreciate the opportunity to comment on the September 19 Executive Order (EO) on Modernizing Influenza Vaccines in the United States to Promote National Security and Public Health.

AVAC consists of over 55 organizational leaders in health and public health that are committed to addressing the range of barriers to adult immunization and to raising awareness of the importance of adult immunization. AVAC works towards common legislative and regulatory solutions that will strengthen and enhance access to adult immunization across the health care system. Our priorities and objectives are driven by a consensus process with the goal of enabling the range of stakeholders to have a voice in the effort to improve access and utilization of adult immunizations.

Seasonal influenza is a major driver of vaccine preventable disease cases, resulting in hospitalizations, provider visits, prescriptions and other direct and indirect health care costs each year. As the EO points out, an influenza pandemic presents a significant threat to our population and our nation’s health security.

We appreciate HHS’ commitment to keeping Americans healthy and safe both from seasonal influenza and from the potential of pandemic influenza. The EO comes at a critical time, as there is an urgent need to raise awareness of the burden of flu across the life course. The flu is a contagious and potentially deadly virus that causes up to 79,000 deaths a year and costs more than $10 billion in direct medical expenses and more than $16 billion in lost earnings.

Adults seeking access to and coverage for vaccines encounter a confusing health care system that presents multiple barriers, including misinformation or a lack of reliable information about recommended vaccines, financial hurdles, as well as technological and logistical obstacles. Vaccine confidence and hesitancy also remain a challenge across all sectors of the health care system and our government.

Sec. 2 Policy
The Executive Order includes a five-year national plan to improve the flu vaccine by encouraging advanced technology. The value of research and innovation is especially important, having led to the eradication and elimination of several serious infectious diseases. Continued research and development—including research that advances our understanding of the immune system—is necessary to improve the effectiveness of existing vaccines and to develop new vaccines against emerging threats. The vaccine development process is unique from other pharmaceuticals products. Higher production post-approval costs, increasing quality standards and product complexity makes the investment in new vaccine products challenging. A policy environment that supports the value of innovation, both for breakthrough discoveries and incremental innovation, leads to the research and development of vaccines for new diseases, improvements and advancements in new and innovative vaccine platforms and technologies and other discoveries that support the vaccine ecosystem to reduce vaccine-preventable diseases across the life-course. While we commend the EOs long term plan, we also would propose that the EO include a short-term plan for seasonal flu vaccine while technological advancements are being worked on to improve the seasonal and pandemic vaccines over the longer term.

Section 3. National Influenza Vaccine Task Force
Section 3 of the EO establishes a Task Force to enact the policy laid out in Section 2. As a diverse stakeholder coalition, we appreciate that the Task Force “may consult” with outside stakeholders. We recommend that outside stakeholders, including members of AVAC, have an opportunity to be actively engage with the Task Force. There are numerous public health and provider organizations, private industry, trade associations, patient groups, academia and others that have missions dedicated to the improvement of vaccines and education of the public as it relates to vaccine confidence. These organizations would add expertise and insight that could prove vital to the mission of the Executive Order. For a full list of the AVAC membership visit www.adultvaccinesnow.org.

Sec. 4. Agency Implementation
AVAC applauds that Sec. 4(a)(iv) seeks to expand flu vaccine development activities conducted by CDC. The CDC flu line has remained steady at $187 million since FY2015, despite 2017-2018 being one of the worst flu seasons in 40 years. The influenza program supports flu surveillance and diagnostic capacity, public awareness and provider education, enhancing international, federal, state and local flu response. It also provides essential support for seasonal and pandemic flu vaccine development.
by sequencing, testing and preparing viruses for vaccine production.\textsuperscript{1,2} We applaud the President for including a request for a $10 million increase in his FY20 Budget request for CDC’s work to improve the effectiveness of the seasonal flu vaccine and address high priority activities and reduce barriers to seasonal influenza vaccination.

AVAC urges support for increased funding for the CDC immunization program which serves as the backbone for surveillance, reporting, and response activities for a wide variety of stakeholders across the health care system. Funding for the immunization program line at CDC has remained around $610 million since FY15. These dollars provide a critical source of funding for state and local public health to invest in vaccine purchase and delivery for people not covered under other programs, immunization information systems (IIS), effectiveness monitoring, educating the public and supporting providers.

In particular, IIS should serve as an integral part of pandemic response plans. These confidential, population-based, computerized systems can record immunization doses administered by participating providers to persons residing within a given jurisdiction. They provide state and local public health agencies aggregate data on immunization coverage rates for disease surveillance and program operations. This includes timely monitoring of vaccine uptake of federally purchased vaccines, capability of tracking multi-dose vaccines, access to population-based vaccination coverage data and estimates, and reporting mechanisms that include provider verified data. These systems are typically operated and managed by state and local health departments. IIS’ serve as a vital component for emergency preparedness and response activities and are an optimal tool for use during a flu pandemic or other emerging infectious disease event by enabling communication with providers, identifying variations in access and utilization of immunization, and enabling implementation of targeted strategies during emergency preparedness and response activities.

We would also like to call attention to Sec. 4 (iv), which references that the Director of CDC “increase influenza vaccine use through enhanced communication and by removing barriers to vaccination; and (E) enhance communication to healthcare providers about the performance of influenza vaccines, in order to assist them in promoting the most effective vaccines for their patient populations. Meaningful improvements in flu vaccine utilization will only be achieved with a strong foundation that incorporates the latest research and communication strategies. Tools to disseminate vaccine information—including publication of evidence-based recommendations, use of mass and social media, provider education and training, and support of non-federal stakeholder partners—are proven ways to educate and

drive adult immunization demand. Communication and engagement should be strategic, evidence-based, culturally appropriate and reflect the health literacy, language proficiency, and functional and access needs of specific target populations. Special attention should be paid to communicating the risk and cost of vaccine preventable diseases with the goal of establishing vaccination as a routine part of preventive care and building confidence in flu vaccination as a societal norm.

Lastly, Section 4 (v) advises the Administrator of CMS to examine the current legal, regulatory, and policy framework surrounding payment for influenza vaccines and assess adoption of domestically manufactured vaccines that have positive attributes for pandemic response (such as scalability and speed of manufacturing). We would appreciate more clarity on this section. Individuals of Medicare age are especially susceptible to the risks and complications of vaccine preventable diseases, including influenza.

Individuals with heart disease, lung disease, and diabetes and are at increased risk of flu-related complications and exacerbation of underlying disease, even when the conditions are well-managed. It is estimated that 31% of US adults age 50-64 years and 47% of those age 65 years and older have at least one chronic health condition that puts them at high risk for flu-related complications, including hospitalization, catastrophic disability, and even death. In fact, 90% of flu-related deaths and the majority of flu-related hospitalizations occur in older adults—the individuals most likely to be living with chronic health conditions. Recent research shows a direct correlation between influenza vaccination and lowered risk for cardiovascular events such as heart attack and stroke.³ We hope that CMS will be directed to promote the use of influenza vaccination among the Medicare population.

Thank you again for the opportunity to comment. Should you have questions, please feel free to reach out to AVAC Managers Abby Bownas (abownas@nvglc.com) or Lisa Foster (lfoster@nvglc.com).

Sincerely,

Alliance for Aging Research
American Public Health Association
Association for Professionals in Infection Control and Epidemiology
Families Fighting Flu
IDSA
National Association of County and City Health Officials
National Association of Nutrition and Aging Services Programs (NANASP)
National Hispanic Medical Association
Novavax

³ https://www.nfid.org/toolkits/sample-newsletter-website-content/