



November 21, 2019

Office of the Assistant Secretary for Preparedness and Response
200 Independence Ave., SW
Washington, DC 20201

Submitted by:

Trust for America's Health
1730 M Street, NW
Washington, D.C. 20036

RE: COMMENTS ON EXECUTIVE ORDER ON MODERNIZING INFLUENZA VACCINES IN THE UNITED STATES TO PROMOTE NATIONAL SECURITY AND PUBLIC HEALTH

On behalf of Trust for America's Health (TFAH), I am pleased to offer the following comments on the implementation of the Executive Order on Modernizing Influenza Vaccines in the United States to Promote National Security and Public Health (Executive Order). TFAH is a nonprofit, nonpartisan public health policy, research and advocacy organization that promotes optimal health for every person and community and makes the prevention of illness and injury a national priority. Our commitment to prevention underlies our support of the Influenza Executive Order and our comments for its implementation moving forward.

Short Term Improvements to the Seasonal Flu Vaccine

Section 2 outlines the U.S. policy of modernizing domestic influenza vaccines as a public health and national security priority. While TFAH is in full agreement about the harms of the flu on our nation and appreciate the effort made by the Executive Order to modernize and improve the flu vaccine, we believe additional changes should be made in the short term while technological advancements are being worked on to improve the seasonal and pandemic vaccines. Based on the severity of the strain, the flu can cause 12,000-79,000 deaths a year, more than \$10 billion in direct medical expenses and more than \$16 billion in lost earnings. There needs to be a short term plan to improve both the effectiveness of the seasonal flu vaccine as well as the effectiveness of messaging to the general public in order to prevent further death and cost in medical expenses. This Executive Order states that there will be a five-year national plan in order to improve the flu vaccine with improved technology. While we approve of this plan, there should be a plan that will improve the flu vaccine in the short term to make even marginal improvements on the vaccine's effectiveness.

Centers for Medicare and Medicaid Services

As noted in the EO, flu vaccination rates remain far below CDC targets. These rates vary by age, with lowest coverage rates among adults 18-49 year old (34.9 percent in

2018-2019) and among children 13-17 years old (52.2 percent in 2018-2019).¹ Yet, financial barriers among Medicaid patients can discourage access. Not all state Medicaid agencies cover the seasonal influenza vaccine, and some cover it with a cost-sharing requirement. CMS should encourage state Medicaid plans to cover all ACIP-recommended vaccines without cost sharing. CMS should also encourage Medicare Advantage and stand-alone prescription drug plans to include immunizations in the zero-cost sharing vaccine tier.

Stakeholder Engagement

Section 3 (e) states that the Task Force “may consult” with outside stakeholders. While we believe that the government agencies that will sit on the Task Force have the expertise needed to achieve the goals of the Executive Order, TFAH suggests that stakeholders be regularly consulted and be an active part of 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. The vast majority of these stakeholders are membership organizations that work with the general public and provide insight that would perhaps be missing with only government agencies at the table. TFAH would be pleased to work with the Administration to provide a list of relevant stakeholders that could provide beneficial feedback.

Improving uptake of seasonal influenza vaccines

TFAH supports the expansion of the seasonal surveillance network to increase the number of sites and the number of samples collected in order to provide a more accurate and detailed estimation of vaccine effectiveness. In this process, the use of interim seasonal estimates should be evaluated to determine the positive and negative impacts these estimates provide. Given past instances when interim estimates have been significantly different than full season measures, the negative impact to vaccine confidence and the negative influence inaccurate estimates have on people continuing to seek late seasonal vacation must be considered. Additionally, any seasonal surveillance data gathered should rapidly be made publicly available and published versus only being presented in order to aid research and improve flu vaccine uptake. This will aid in creating more transparency around the flu vaccine which could then increase the public’s overall confidence. TFAH recommends that a more detailed assessment be conducted by HHS of the current seasonal flu communications, reasons for lower vaccine acceptance in some communities, and message testing to better explain the importance of the flu and other vaccination. This information could then be used by agencies and stakeholders to better educate the public on the flu and the importance of the receiving the flu vaccine annually.

¹ Flu Vaccination Coverage, United States, 2018–19 Influenza Season. Centers for Disease Control and Prevention, Sept 26, 2019. <https://www.cdc.gov/flu/fluvaxview/coverage-1819estimates.htm>

Funding for Centers for Disease Control and Prevention

TFAH applauds the goals outlined in Sec. 4(a)(iv) for expanding and accelerating flu vaccine development activities conducted by CDC. However, TFAH believes that in order to obtain the goals of the Executive Order, there should be increased funding for the Centers for Disease Control and Prevention. Funding for public health's vaccine and flu infrastructure has not kept up with the threats. 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, and supporting the seasonal and pandemic flu vaccine development by sequencing, testing and preparing viruses for vaccine production.^{2,3} We applaud the President's requested a \$10 million in FY20 for CDC's work to improve the effectiveness and reduce barriers to seasonal influenza vaccination, although we believe much more is needed for the ambitious activities outlined in the Executive Order. In addition, funding for the immunization program line at CDC has remained around \$610 million since FY15. This funding line is the 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, effectiveness monitoring, educating the public and supporting providers. They also use this funding line for outbreak investigation and control, so when there is an outbreak, it takes a lot of money away from the day-to-day activities supported by the funding line.^{4, 5, 6} The Executive Order should direct a spending plan for CDC influenza and immunization activities that reflect the goals set forth in the order, and the FY2021 President's Budget Request should include robust funding recommendations for these programs.

Conclusion

Thank you very much for the opportunity to provide comments on the Executive Order. We are very much committed to the use of vaccines for individuals of all ages domestically and globally, and look forward to working with your office on improvements to the flu vaccine in the future. If you have any questions, please contact Senior Government Relations Manager Cecelia Thomas at cthomas@tfah.org

² Fiscal Year 2020 Congressional Justification: Centers for Disease Control and Prevention. HHS, 2018. <https://www.cdc.gov/budget/documents/fy2020/fy-2020-cdc-congressional-justification.pdf>

³ U.S. Influenza Surveillance System: Purpose and Methods. Centers for Disease Control and Prevention, 2019. <https://www.cdc.gov/flu/weekly/overview.htm>

⁴ Marx GE, Chase J, Jasperse J, et al. Public Health Economic Burden Associated with Two Single Measles Case Investigations — Colorado, 2016–2017. *MMWR Morb Mortal Wkly Rep* 2017;66:1272–1275. DOI: <http://dx.doi.org/10.15585/mmwr.mm6646a3>

⁵ Ortega-Sanchez IR, Vijayaraghavan M, Barskey AE, Wallace GS. The economic burden of sixteen measles outbreaks on United States public health departments in 2011. *Vaccine*. 2014 Mar 5;32(11):1311-7. doi: 10.1016/j.vaccine.2013.10.012. Epub 2013 Oct 14.

⁶ Andrada C. Cost of Outbreak Response. *Outbreak Observatory*, Jul 12 2018. <https://www.outbreakobservatory.org/outbreakthursday-1/7/12/2018/cost-of-outbreak-response>