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Title 3—

The President

Executive Order 13887 of September 19, 2019

Modernizing Influenza Vaccines in the United States to Promote National Security and Public Health

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 301 of title 3, United States Code, it is hereby ordered as follows:

Section 1. *Findings.* (a) Influenza viruses are constantly changing as they circulate globally in humans and animals. Relatively minor changes in these viruses cause annual seasonal influenza outbreaks, which result in millions of illnesses, hundreds of thousands of hospitalizations, and tens of thousands of deaths each year in the United States. Periodically, new influenza A viruses emerge from animals, including birds and pigs, that can spread efficiently and have sustained transmission among humans. This situation is called an influenza pandemic (pandemic). Unlike seasonal influenza, a pandemic has the potential to spread rapidly around the globe, infect higher numbers of people, and cause high rates of illness and death in populations that lack prior immunity. While it is not possible to predict when or how frequently a pandemic may occur, there have been 4 pandemics in the last 100 years. The most devastating pandemic occurred in 1918–1919 and is estimated to have killed more than 50 million people worldwide, including 675,000 Americans.

(b) Vaccination is the most effective defense against influenza. Despite recommendations by the Centers for Disease Control and Prevention (CDC) that nearly every American should receive the influenza vaccine annually, however, seasonal influenza vaccination levels in the United States have currently reached only about 45 percent of CDC goals.

(c) All influenza vaccines presently in use have been developed for circulating or anticipated influenza viruses. These vaccines must be reformulated for each influenza season as well as in the event of a pandemic. Additional research is needed to develop influenza vaccines that provide more effective and longer-lasting protection against many or all influenza viruses.

(d) The current domestic enterprise for manufacturing influenza vaccines has critical shortcomings. Most influenza vaccines are made in chicken eggs, using a 70-year-old process that requires months-long production timelines, limiting their utility for pandemic control; rely on a potentially vulnerable supply chain of eggs; require the use of vaccine viruses adapted for growth in eggs, which could introduce mutations of the influenza vaccine virus that may render the final product less effective; and are unsuitable for efficient and scalable continuous manufacturing platforms.

(e) The seasonal influenza vaccine market rewards manufacturers that deliver vaccines in time for the influenza season, without consideration of the speed or scale of these manufacturers' production processes. This approach is insufficient to meet the response needs in the event of a pandemic, which can emerge rapidly and with little warning. Because the market does not sufficiently reward speed, and because a pandemic has the potential to overwhelm or compromise essential government functions, including defense and homeland security, the Government must take action to promote faster and more scalable manufacturing platforms.

Sec. 2. *Policy.* It is the policy of the United States to modernize the domestic influenza vaccine enterprise to be highly responsive, flexible, scalable, and more effective at preventing the spread of influenza viruses. This is a public

health and national security priority, as influenza has the potential to significantly harm the United States and our interests, including through large-scale illness and death, disruption to military operations, and damage to the economy. This order directs actions to reduce the United States' reliance on egg-based influenza vaccine production; to expand domestic capacity of alternative methods that allow more agile and rapid responses to emerging influenza viruses; to advance the development of new, broadly protective vaccine candidates that provide more effective and longer lasting immunities; and to support the promotion of increased influenza vaccine immunization across recommended populations.

Sec. 3. *National Influenza Vaccine Task Force.* (a) There is hereby established a National Influenza Vaccine Task Force (Task Force). The Task Force shall identify actions to achieve the objectives identified in section 2 of this order and monitor and report on the implementation and results of those actions. The Task Force shall be co-chaired by the Secretary of Defense and the Secretary of Health and Human Services, or their designees.

(b) In addition to the Co-Chairs, the Task Force shall consist of a senior official from the following executive branch departments, agencies, and offices:

(i) the Department of Defense (DOD);

(ii) the Department of Justice;

(iii) the Department of Agriculture;

(iv) the Department of Veterans Affairs (VA);

(v) the Department of Homeland Security;

(vi) the United States Food and Drug Administration;

(vii) the Centers for Disease Control and Prevention;

(viii) the National Institutes of Health (NIH);

(ix) the Centers for Medicare and Medicaid Services (CMS); and

(x) the Biomedical Advanced Research and Development Authority (BARDA).

(c) The Co-Chairs may jointly invite additional Federal Government representatives, with the consent of the applicable executive department, agency, or office head, to attend meetings of the Task Force or to become members of the Task Force, as appropriate.

(d) The staffs of the Department of State, the Office of Management and Budget (OMB), the National Security Council, the Council of Economic Advisers, the Domestic Policy Council, the National Economic Council, and the Office of Science and Technology Policy (OSTP) may attend and participate in any Task Force meetings or discussions.

(e) The Task Force may consult with State, local, tribal, and territorial government officials and private sector representatives, as appropriate and consistent with applicable law.

(f) Within 120 days of the date of this order, the Task Force shall submit a report to the President, through the Assistant to the President for National Security Affairs, the Assistant to the President for Domestic Policy, the Director of the Office of Management and Budget, and the Director of the Office of Science and Technology Policy. The report shall include:

(i) a 5-year national plan (Plan) to promote the use of more agile and scalable vaccine manufacturing technologies and to accelerate development of vaccines that protect against many or all influenza viruses;

(ii) recommendations for encouraging non-profit, academic, and private-sector influenza vaccine innovation; and

(iii) recommendations for increasing influenza vaccination among the populations recommended by the CDC and for improving public understanding of influenza risk and informed influenza vaccine decision-making.

(g) Not later than June 1 of each of the 5 years following submission of the report described in subsection (f) of this section, the Task Force shall submit an update on implementation of the Plan and, as appropriate, new recommendations for achieving the policy objectives set forth in section 2 of this order.

Sec. 4. *Agency Implementation.* The heads of executive departments and agencies shall also implement the policy objectives defined in section 2 of this order, consistent with existing authorities and appropriations, as follows:

(a) The Secretary of HHS shall:

(i) through the Assistant Secretary for Preparedness and Response and BARDA:

(A) estimate the cost of expanding and diversifying domestic vaccine-manufacturing capacity to use innovative, faster, and more scalable technologies, including cell-based and recombinant vaccine manufacturing, through cost-sharing agreements with the private sector, which shall include an agreed-upon pricing strategy during a pandemic;

(B) estimate the cost of expanding domestic production capacity of adjuvants in order to combine such adjuvants with both seasonal and pandemic influenza vaccines;

(C) estimate the cost of expanding domestic fill-and-finish capacity to rapidly fulfill antigen and adjuvant needs for pandemic response;

(D) estimate the cost of developing, evaluating, and implementing delivery systems to augment limited supplies of needles and syringes and to enable the rapid and large-scale administration of pandemic influenza vaccines;

(E) evaluate incentives for the development and production of vaccines by private manufacturers and public-private partnerships, including, in emergency situations, the transfer of technology to public-private partnerships—such as the HHS Centers for Innovation and Advanced Development and Manufacturing or other domestic manufacturing facilities—in advance of a pandemic, in order to be able to ensure adequate domestic pandemic manufacturing capacity and capability;

(F) support, in coordination with the DOD, NIH, and VA, a suite of clinical studies featuring different adjuvants to support development of improved vaccines and further expand vaccine supply by reducing the dose of antigen required; and

(G) update, in coordination with other relevant public health agencies, the research agenda to dramatically improve the effectiveness, efficiency, and reliability of influenza vaccine production;

(ii) through the Director of NIH, provide to the Task Force estimated timelines for implementing NIH's strategic plan and research agenda for developing influenza vaccines that can protect individuals over many years against multiple types of influenza viruses;

(iii) through the Commissioner of Food and Drugs:

(A) further implement vaccine production process improvements to reduce the time required for vaccine production (*e.g.,* through the use of novel technologies for vaccine seed virus development and through implementation of improved potency and sterility assays);

(B) develop, in conjunction with the CDC, proposed alternatives for the timing of vaccine virus selection to account for potentially shorter timeframes associated with non-egg based manufacturing and to facilitate vaccines optimally matched to the circulating strains;

(C) further support the conduct, in collaboration with the DOD, BARDA, and CDC, of applied scientific research regarding developing cell lines and expression systems that markedly increase the yield of cell-based and recombinant influenza vaccine manufacturing processes; and

(D) assess, in coordination with BARDA and relevant vaccine manufacturers, the use and potential effects of using advanced manufacturing platforms for influenza vaccines;

(iv) through the Director of the CDC:

(A) expand vaccine effectiveness studies to more rapidly evaluate the effectiveness of cell-based and recombinant influenza vaccines relative to egg-based vaccines;

(B) explore options to expand the production capacity of cell-based vaccine candidates used by industry;

(C) develop a plan to expand domestic capacity for whole genome characterization of influenza viruses;

(D) 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; and

(v) through the Administrator of CMS, 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).

(b) The Secretary of Defense shall:

(i) provide OMB with a cost estimate for transitioning DOD's annual procurement of influenza vaccines to vaccines manufactured both domestically and through faster, more scalable, and innovative technologies;

(ii) direct, in coordination with the VA, CDC, and other components of HHS, the conduct of epidemiological studies of vaccine effectiveness to improve knowledge of the clinical effect of the currently licensed influenza vaccines;

(iii) use DOD's network of clinical research sites to evaluate the effectiveness of licensed influenza vaccines, including methods of boosting their effectiveness;

(iv) identify opportunities to use DOD's vaccine research and development enterprise, in collaboration with HHS, to include both early discovery and design of influenza vaccines as well as later-stage evaluation of candidate influenza vaccines;

(v) investigate, in collaboration with HHS, alternative correlates of immune protection that could facilitate development of next-generation influenza vaccines;

(vi) direct the conduct of a study to assess the feasibility of using DOD's advanced manufacturing facility for manufacturing cell-based or recombinant influenza vaccines during a pandemic; and

(vii) accelerate, in collaboration with HHS, research regarding rapidly scalable prophylactic influenza antibody approaches to complement a universal vaccine initiative and address gaps in current vaccine coverage.

(c) The Secretary of VA shall provide OMB with a cost estimate for transitioning its annual procurement of influenza vaccines to vaccines manufactured both domestically and with faster, more scalable, and innovative technologies.

Sec. 5. *Termination.* The Task Force shall terminate upon direction from the President or, with the approval of the President, upon direction from the Task Force Co-Chairs.

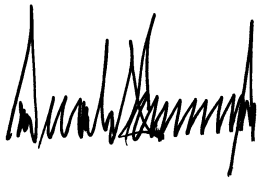
Sec. 6. *General Provisions.* (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.



THE WHITE HOUSE,
September 19, 2019.

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