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President's Council of Advisors on Science and Technology Releases Plan to Improve Nation's Vaccine Response Against Pandemic Influenza and Other Outbreaks

Improvements Could Cut Several Weeks Off Vaccine Production, Save Thousands of Lives

Targeted Federal investments in five key areas could shorten by weeks or months the time needed to produce enough vaccine doses to protect the entire Nation in the event of another outbreak of pandemic flu—an advance that could save thousands of lives—according to a new report by the President's Council of Advisors on Science and Technology (PCAST).

Report to the President on Reengineering the Influenza Vaccine Production Enterprise to Meet the Challenges of Pandemic Influenza, released today, provides a roadmap that, within one to three years, could significantly increase the Nation's ability to produce vaccines in a timely fashion. The recommended improvements would speed production of not only vaccines for influenza but also an array of other medical countermeasures against infectious diseases that could erupt naturally or occur as a result of a biological attack.

"Delays involving traditional methods for making influenza vaccines slowed production of a protective vaccine during the 2009-2010 H1N1 influenza pandemic, leaving large numbers of Americans vulnerable to severe illness or death and raising new awareness of the limitations of the system by which influenza vaccines are produced today," said Harold Varmus, who was until recently a co-chair of PCAST and oversaw work on the report. "The good news is we now know how to reduce the likelihood of such delays with new and improved technologies. And in a serious pandemic, cutting even a few weeks off the vaccine production schedule can translate into saving thousands of lives."

PCAST, which advises the President on matters of science and technology, undertook its review at the request of the Executive Office of the President in the aftermath of the 2009-2010 H1N1 pandemic. During the course of that two-stage outbreak, the time between the declaration of a need for a vaccine and the start of the second U.S. wave of the pandemic was 18 weeks.

Yet initial doses were not available until 26 weeks after that declaration, by which time the second wave was already peaking. Ultimately, sufficient doses to cover half the population were not available until the 38-week mark. And even if production had continued apace, it would have taken an additional ten weeks to produce enough doses to protect the entire Nation. All told, the process was three to five months slower than ideal.

The new report analyzes current influenza vaccine production processes and identifies ways the Federal Government could support improvements in relevant technologies to reduce the time required to supply vaccine to the U.S. population when the next influenza pandemic occurs.

It identifies five key junctures where improvements over current practices could contribute to a faster overall response, and specifies those agencies that should receive targeted Federal support to accomplish the work of making those improvements:

- **Surveillance:** Accelerate identification of newly emerging pandemic viruses, so vaccine production can start sooner. (Centers for Disease Control and Prevention)

- **Seed viruses:** Develop a collection of stock viral "backbones" to allow faster production of specific vaccine strains. (National Institute of Allergy and Infecti**ous Diseases** and the Biomedical Advanced Research and Development Authority. (BARDA))

- **Sterility tests:** Develop better and faster tests to ensure sterility during vaccines production. (BARDA and the Food and Drug Administration (FDA))

- **Potency-test reagents:** Develop faster and more reliable tests to document vaccine potency. (BARDA and FDA)

- **Fill-and-finish:** Enlarge capacity and modernize machinery used in final stages of vaccine production, including vial-filling. (Federal agencies in collaboration with manufacturers)

With proper support, the report concludes, the improvements outlined above can be achieved in as little as one year and in some cases in two to three years. And with the exception of improved sterility testing (which is estimated to have the potential to trim only one week from production times), each of the above options has the potential to accelerate delivery of final product by a few weeks or more.

Looking further ahead, the report recommends that the Nation invest in a broader range of research that promises even greater benefits in the longer term, including:

- Moving away from the current practice of growing influenza viruses in fertilized chicken eggs, which is an inefficient method, and using modern cell-culture systems instead;

- Expanding the use of live, weakened (or "attenuated") viruses instead of killed viruses in vaccine production, which would produce a greater number of vaccine doses from an equivalent amount of live virus material;

- Developing recombinant vaccines using modern genetic engineering tools to allow more effective scale-up of vaccine production;

- Conducting research into the use of adjuvants, vaccine ingredients that can boost immunological potency and thus allow smaller amounts of virus material to be used per dose of vaccine, making vaccine available to more people.

The report also recommends that the Administration develop a new management structure that vests authority with the Assistant Secretary for Preparedness Response (ASPR) at the Department of Health and Human Services (HHS) to coordinate and task component agencies at HHS with supporting and implementing the above recommendations. In addition, it recommends that HHS create a small advisory committee comprised of representatives from the biotechnology, pharmaceutical and investment communities, to guide the Department's engagement with industry and that a component of the Executive Office of the President, such as the National Security Council, assume overall responsibility for conduct of the initiative.

The report concludes that an investment of $1 billion or more annually for several years can be justified on a cost-benefit basis, in part because Federal investments in influenza pandemic response would speed development of technical platforms and production facilities that would support medical countermeasures against a variety of other dangerous pathogens, and in part because large numbers of lives could be saved by relatively inexpensive improvements in current methodologies.

"While these recommendations are driven by the recent H1N1 pandemic, they have been crafted with the specific aim of simultaneously enhancing the Federal Government's broader medical countermeasure (MCM) enterprise," said PCAST co-chair Eric Lander, who, with Varmus, co-chaired PCAST's Influenza Vaccinology Working Group, which coordinated creation of the report. "We advocate development of new technological platforms for speedier vaccine production, improved collaboration with the private sector, regulatory science innovation to make the vaccine approval process smoother and more predictable, and a more sophisticated degree of project management—all of which are central to the government's efforts to protect against infectious diseases generally."

The full report is available here.

The President's Council of Advisors on Science and Technology (PCAST) is an advisory group of the nation's leading scientists and engineers who directly advise the President and the Executive Office of the President. PCAST makes policy recommendations in the many areas where understanding of science, technology, and innovation is key to strengthening our economy and forming policy that works for the American people. PCAST is administered by the Office of Science and Technology Policy (OSTP).

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