

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF SCIENCE AND TECHNOLOGY POLICY
WASHINGTON, D.C. 20502

November 14, 2012

The Honorable F. James Sensenbrenner, Jr.
Vice-Chairman, House Committee on Science, Space and Technology
Room 2449
Rayburn House Office Building
Washington, DC 20515-4905

Dear Vice Chairman Sensenbrenner:

Thank you for your letter dated August 1, 2012, inquiring about the voluntary moratorium on bird flu research and how the United States Government (USG) should handle dual use research of concern (DURC).

As you note, a voluntary moratorium on certain kinds of bird flu research was announced by influenza experts, including the authors of the two H5N1 papers, in January 2012. The moratorium applies only to research involving highly pathogenic avian influenza H5N1 viruses that is anticipated to lead to the generation of viruses that have enhanced transmissibility among mammals. This includes research involving ferret-transmissible H5N1 viruses that were generated as part of the research communicated in the two recently published H5N1 papers. Influenza research outside the specific subset outlined above has continued without interruption and supports our national-security interest in influenza preparedness.

It is important to underscore that the moratorium was adopted voluntarily by researchers, and the USG has no authority to lift the moratorium or direct that it remain in force. The research community will determine whether and when to lift the moratorium. In doing so, researchers should consider laboratory-safety recommendations, risks and benefits of the research, measures for mitigating risk, and mechanisms for communicating results of the research. The USG can facilitate the research community's consideration of these factors by engaging in a broad, open, and transparent discussion both within the USG and the influenza research community, in consultation with the broader scientific community and the public, both domestically and internationally. The USG has already engaged the influenza community at the annual meeting of the Centers of Excellence for Influenza Research and Surveillance (CEIRS) and will continue to discuss relevant safety and security issues with other stakeholders at upcoming meetings that are being planned by the USG and World Health Organization (WHO).

Regarding your question on implementation of the March 29, 2012, "United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern," all Federal departments and agencies (D/A) that fund or conduct life-sciences research within the scope of the Policy (i.e., research that involves one or more of 15 agents or toxins and produces, aims to produce, or is reasonably anticipated to produce one or more of seven effects) have submitted reports to the Assistant to the President for Homeland Security and Counterterrorism. The burden for D/A varied depending on how much research each funds or conducts within the scope of the Policy. The March 29 Policy is proving useful for gaining a broad understanding of current DURC and ensuring that appropriate mitigation measures are developed that recognize the importance of the

research and address potential security risks. This monitoring is critical to identifying DURC in the initial stages of research so that mitigation measures are implemented early, when necessary. Identification of research by the USG that is potentially DURC is not the only way that research should be monitored, however; institutions and researchers also have a role in the identification of DURC and implementation of risk-mitigation measures, where appropriate.

To this end, the USG has been working on a complementary policy that addresses the institutional oversight of DURC and would operate in tandem with the March 29 Policy. Institutional oversight of DURC is a critical component of a comprehensive oversight system because institutions are most familiar with the life-sciences research conducted in their facilities and are in a good position to identify DURC, develop appropriate mitigation measures, and promote and strengthen the responsible conduct and communication of DURC. We note that your letter discusses these policies with specific reference to the National Institutes of Health; however, the March 29 Policy is a Federal-wide policy implemented by all Federal D/As that fund and conduct life-sciences research. The companion institutional-oversight policy is being similarly developed and will also be a Federal-wide policy once completed.

As you note, in July 2012, the WHO released its “Guidance for Adoption of Appropriate Risk Control Measures to Conduct Safe Research on H5N1 Transmission” (*Guidance*). Through the U.S. Department of Agriculture’s (USDA) Select Agent Program, administered by the Animal and Plant Health Inspection Service (APHIS), the USG already has regulations in place that address those components of the *Guidance* that are directed at national authorities and laboratories.

As noted in our April 9, 2012, letter, highly pathogenic H5N1 is a select agent and, as such, the Select Agent Program already oversees laboratories that work with highly pathogenic H5N1, including ferret-transmissible H5N1 viruses that were generated from highly pathogenic H5N1. The Select Agent Program conducted reviews of the laboratories in the Netherlands and Wisconsin where the initial research studies to generate the ferret-transmissible H5N1 viruses were conducted. Further, the Select Agent Program also regulates which laboratories in the United States can receive any select agent, including ferret-transmissible H5N1 viruses, because it approves the transfer of select agents from both international and domestic laboratories to registered laboratories within the United States.

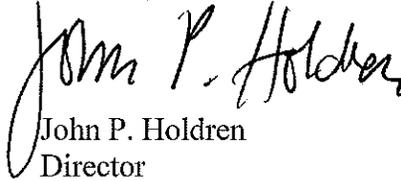
In the *Guidance*, WHO notes that its “staff informally consulted a number of relevant scientific bodies and experts from the human health and animal health communities to seek their perspectives related to biosafety and laboratory biosecurity guidance on conditions under which further research should be conducted on the laboratory-modified H5N1 viruses.” This is an important first step; however, it is clear that a more formal approach is needed to develop specific recommendations in this domain.

To this end, the Centers for Disease Control and Prevention (CDC), in consultation with the USDA Select Agent Program, published a formal request for information in the Federal Register on October 17, 2012 (<https://www.federalregister.gov/articles/2012/10/17/2012-25377/influenza-viruses-containing-the-hemagglutinin-from-the-gooseguangdong196-lineage>), which seeks comments, research data, or other information from the public related to the risk posed to public

health and safety by specific strains of highly pathogenic avian influenza H5N1 viruses. CDC also is working on the development of biosafety guidelines for research with ferret-transmissible H5N1 viruses.

Thank you for your continued interest in this important issue. This Administration is committed to supporting scientific research that promises improvements in global public health as well as animal and plant health, while addressing safety and national-security concerns and acting as responsible stewards of USG-funded research.

Sincerely,

A handwritten signature in black ink that reads "John P. Holdren". The signature is written in a cursive style with a large, looping initial "J".

John P. Holdren
Director