



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

April 9, 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 March 1, 2012, inquiring about research on H5N1 avian influenza, the National Science Advisory Board for Biosecurity's (NSABB) process for weighing the risks and benefits of dual use research, and the National Institutes of Health's (NIH) review system for dual use life sciences research.

Research on changes in the genetic sequence and other factors that can affect the transmissibility of the H5N1 virus is critically important to international efforts to promptly detect the emergence of such strains and to develop vaccines that could protect against them. Currently, in the rare instances when the H5N1 virus is known to infect humans, it has a very high mortality rate but does not spread easily from person to person. Many scientists and public health officials are concerned, however, that the virus could evolve in nature into a form that is similarly deadly and also easily transmitted among humans—a development that could make this virus an extremely serious global public health threat.

The NSABB uses a risk-assessment tool to determine whether a given project may constitute dual-use research of concern (DURC)—research with the highest potential for yielding knowledge, products, or technology that could be misapplied to threaten public health or other aspects of national security—and to consider various risk-mitigation strategies, including communication strategies. The NSABB's default position is that the results of life sciences research should be communicated fully, whenever possible, in keeping with the principles of academic freedom and open scientific exchange that are core tenets of the US scientific enterprise. The NSABB's risk-assessment and communications tools can be found in the NSABB's report, "Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information" available at [http://oba.od.nih.gov/biosecurity/pdf/Framework%20for%20transmittal%200807\\_Sept07.pdf](http://oba.od.nih.gov/biosecurity/pdf/Framework%20for%20transmittal%200807_Sept07.pdf).

Through a Federal interagency policy process, the United States Government (USG) reviewed existing oversight mechanisms that address DURC. To enhance current guidelines and to facilitate a uniform approach to identifying and managing risks, the USG recently implemented a "Policy for Oversight of Life Sciences Dual Use Research of Concern" (Policy), available at [http://oba.od.nih.gov/oba/biosecurity/PDF/United States Government Policy for Oversight of DURC FINAL version 032812.pdf](http://oba.od.nih.gov/oba/biosecurity/PDF/United%20States%20Government%20Policy%20for%20Oversight%20of%20DURC%20FINAL%20version%20032812.pdf), to review, systematically and regularly, agency research portfolios across the government. This Policy complements existing USG regulations and

policies governing the possession and handling of pathogens and toxins such as the Select Agent Regulations, which ensure appropriate biosafety- and biosecurity-related oversight of the possession and handling of pathogens and toxins that have the potential to pose a severe threat to human, animal, or plant health, or to animal and plant products. The Policy will be updated, as needed, following domestic dialogue, engagement with our international partners, and input from interested communities including scientists, national-security officials, and global health specialists.

The USG, in partnership with the life-sciences community, has also been working to raise awareness about dual-use research, in part through the development of informational brochures, an educational video for investigators, and the conduct of workshops, presentations, and international symposia. Representative examples can be found at [http://oba.od.nih.gov/biosecurity/biosecurity\\_educational.html](http://oba.od.nih.gov/biosecurity/biosecurity_educational.html). These materials and activities are informed by earlier reports on the dual-use issue, including the 2004 National Research Council report on Biotechnology in an Age of Bioterrorism, as well as a series of reports developed by the NSABB ([http://oba.od.nih.gov/biosecurity/biosecurity\\_documents.html](http://oba.od.nih.gov/biosecurity/biosecurity_documents.html)). All of these reports and products emphasize individual-investigator awareness and local institutional responsibility, which are key to fostering responsible science, and many institutions have created dual-use research review programs to help achieve these goals.

The circumstances surrounding the recent review of H5N1 manuscripts are unprecedented. While the NSABB and other groups have examined the issue of DURC for years, this is the first instance in which there has been an NSABB recommendation to refrain from publishing information from a research paper. Thus, the USG until now had not needed to have a system in place specifically for restricting dissemination of the results of DURC. The NSABB's original recommendation that the H5N1 research publications it reviewed be published in a redacted form was provisionally accepted by the authors and the editors of *Science* and *Nature*, as you note, on the condition that the USG develop a mechanism by which the full versions of those papers would be circulated on a restricted basis to those who could use the information for public health and research purposes. Unfortunately, while the Export Administration Regulations ([http://www.gpo.gov/bis/ear/ear\\_data.html](http://www.gpo.gov/bis/ear/ear_data.html)) and International Traffic in Arms Regulations ([http://pmddtc.state.gov/regulations\\_laws/itar\\_official.html](http://pmddtc.state.gov/regulations_laws/itar_official.html)) can restrict the transfers of certain dual-use materials, equipment and technology, including intangible technology, outside the United States or to foreign nationals, the USG identified serious legal and procedural hurdles to the establishment of such a dissemination system that could not be overcome on a timescale that would be relevant to the publication of these papers. Additionally, for longer-term solutions to DURC, several Federal departments and agencies identified potential challenges with using export controls to communicate important public-health results.

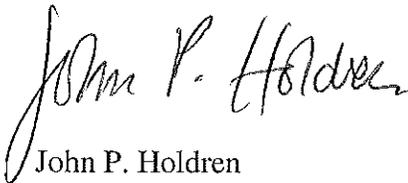
While the NSABB originally recommended that the editors of *Science* and *Nature* refrain from publishing the full manuscripts, additional data and clarification of the work by the authors prompted the USG to request the NSABB to review revised manuscripts. The NSABB reviewed those manuscripts on March 29 and 30 and recommended that the revised manuscripts be published in full because, in their estimation, the data described in the revised manuscripts do not appear to provide information that would immediately enable misuse of the research in ways that

would endanger public health or national security. The NSABB recommendations are currently under the review and consideration of the USG.

The NIH has a system in place for identifying and managing DURC in its intramural research program. At the time that the H5N1 research now in question was proposed, the NIH extramural research review system did not contain a review component specific for DURC. Nonetheless, the proposed research did, prior to the award, undergo review at multiple stages by non-governmental peer reviewers and National Institute of Allergy and Infectious Diseases advisory council members, as well as repeated reviews during the course of the research—including reviews that involved site visits by the Centers for Disease Control and Prevention Select Agent Program to ensure appropriate biosafety and biosecurity oversight. All reviews affirmed the value and importance of these studies. When results from these studies were recognized as raising potential DURC issues, NIH staff referred the draft manuscripts to the NIH/Office of Biotechnology Activities, which manages the NSABB, and referred the investigators to the NSABB framework document that describes options for managing manuscripts describing the results of DURC.

Thank you for your interest in this important issue. The USG maintains its support for scientific research that underpins improvements in global health and safety of the public and animal and plant health, while addressing 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 initial "J".

John P. Holdren  
Director