

F. JAMES SENSENBRENNER, JR.

FIFTH DISTRICT, WISCONSIN

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The Honorable John P. Holdren
Office of Science and Technology Policy
Executive Office of the President
725 17th Street, NW Rm. 5228
Washington, DC 20502

Dear Dr. Holdren:

Since our previous correspondence, the National Science Advisory Board for Biosecurity (NSABB) reconvened and recommended publication of two controversial H5N1 research papers. Both papers were recently published.

Their publication ended an extended controversy over the individual research papers, but it marked the beginning of a larger debate on how our government should handle dual use research of concern (DURC).

While I continue to believe that the federal government should have been more prepared for these issues, I am glad that the government and scientific community have at last begun to engage in a debate about how best to balance the critical issues of scientific freedom and national security raised by DURC. I further believe that the debate should be a public one. It is the public who will benefit from advances in life sciences, and it is the public who could suffer if a newly-created virus is released outside of a laboratory.

Recent steps to address DURC have raised numerous questions. Please respond to the following by August 17, 2012.

1. In January, 2012, leading influenza researchers announced a voluntary moratorium on bird flu research. The moratorium was initially intended to last 60 days, but has already extended over 6 months.

Do you believe the moratorium should be lifted?

2. While the moratorium was voluntarily instituted, Adolfo Garcia-Sastre, a virologist at Mount Sinai School of Medicine and an organizer of the Centers of Excellence for Influenza Research and Surveillance's annual conference, said he doubted the moratorium would be lifted in the near future because flu researchers are still waiting for guidance from the federal government about lab safety requirements and risk-mitigation plans.

- What role does the federal government play in lifting the moratorium?
- When will the government provide the guidance necessary to allow flu researchers to lift the moratorium?

- What discussions has the federal government had with flu researchers regarding the moratorium?
3. On June 21, 2012, Dr. Francis Collins wrote that all departments and agencies that “fund or conduct life science research with certain high-consequence pathogens and toxins” must conduct inventories of the specified research and report the results to the Assistant to the President of Homeland Security and Counterterrorism within 60 days of March 29, 2012.

Dr. Collins further wrote that within 90 days of that date, the same departments and agencies were required to submit (1) the number of unclassified current and proposed projects of DURC, (2) the number of current projects identified as DURC through initial proposals versus progress reports, and (3) a summary of the risks associated with these projects, the mitigation measures already in place to address these risks, other measures that have been proposed or implemented, and the number of projects to which each of these measures would be applied.

Both deadlines have since passed.

- Have the inventories and data been delivered?
- How onerous was the assembly of data for covered agencies?
- Is the received data useful for the government’s oversight and monitoring of government-funded DURC?
- Is this monitoring an effective way to identify federally-funded DURC in early stages of research?

Please provide a summary of the data received with your response.

4. The World Health Organization (WHO) recently released guidelines for the adoption of appropriate risk control measures. WHO recommended that national authorities “identify, approve and oversee the laboratories which might work on this material.”¹ How are these guidelines being incorporated?
5. The National Institute of Health (NIH) recently announced a “Government Policy for Oversight of Life Sciences Dual Use Research of Concern.” I remain unconvinced that this policy will sufficiently balance the critical interests at stake. Rather than a system of review, the policy seems to be little more than a registration requirement for a limited number of projects dealing with specific pathogens. And while NIH has assured me that compliance with the policy is mandatory, it clearly states that federal departments and agencies “should implement” the enumerated actions—creating a risk that federal entities will interpret the policy as discretionary.

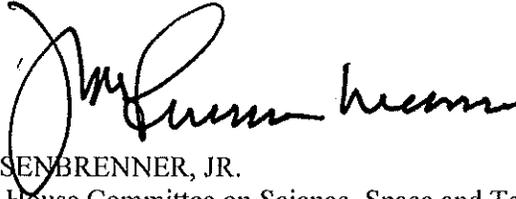
NIH announced that it plans to release a new policy for dealing with DURC and further plans to make it available for public comment.

- When is the new policy expected to be released?
- How will the new approach differ from the previously issued “Government Policy”?
- Will the initial policy remain in effect?
- What deficiencies in the original policy does the new policy hope to address?

¹ *Guidance for adoption of appropriate risk control measures to conduct safe research on H5N1 transmission*, World Health Organization (July 2012), available at http://www.who.int/influenza/human_animal_interface/biosafety_summary/en/index.html.

I appreciate your cooperation with my inquiry and your efforts to implement government-wide policies that appropriately balance scientific freedom and global security.

Sincerely,

A handwritten signature in black ink, appearing to read "F. James Sensenbrenner, Jr.", written in a cursive style.

F. JAMES SENSENBRENNER, JR.
Vice Chairman, House Committee on Science, Space and Technology

cc: The Honorable Ralph Hall
Chairman, House Committee on Science, Space and Technology

The Honorable Eddie Bernice Johnson
Ranking Member, House Committee on Science, Space, and Technology