

F. JAMES SENSENBRENNER, JR.

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April 23, 2012

Dr. Francis Collins, M.D., Ph.D  
Director  
National Institute of Health  
9000 Rockville Pike  
Bethesda, Maryland 20892

Dear Dr. Collins:

Last summer, the National Institutes of Health (NIH) funded two research teams that genetically modified the H5N1 avian influenza virus making it capable of respiratory transmission between ferrets. The National Science Advisory Board on Biosecurity (NSABB) recommended that journals refrain from publishing the details of this research because it believed that the benefits were outweighed by the risk that terrorist groups could use it as a recipe to create a biological weapon. On February 28, NIH asked that the NSABB reconvene to reexamine new versions of the two studies.

On March 1, 2012 I wrote to Dr. John Holdren, Director of the Office of Science and Technology Policy, and requested information on the Administration's policies regarding Dual Use Research of Concern (DURC).<sup>1</sup> Subsequent events appear to confirm my initial suspicion that the Administration is woefully unprepared to identify and handle issues surrounding potentially dangerous research.

After my initial letter, but prior to Dr. Holdren's April 9 response, the Administration released its "Policy for Oversight of Life Sciences Dual Use Research of Concern."<sup>2</sup> This new policy does not address the United States Government's inability to control dissemination of sensitive information, but if properly implemented, could help identify sensitive issues. Dr. Holdren's letter did not identify the authors of the policy, but noted that it was a product of an "interagency policy process."

Dr. Holdren referred to the circumstances surrounding the H5N1 manuscripts as "unprecedented." He further wrote:

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<sup>1</sup> Letter, F. James Sensenbrenner, Vice-Chairman House Committee on Science, Space and Technology, to Dr. John Holdren, Director Office of Science and Technology Policy (March 1, 2012).

<sup>2</sup> Policy for Oversight of Life Sciences Dual Use Research of Concern (March 28, 2012), *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_States_Government_Policy_for_Oversight_of_DURC_FINAL_version_032812.pdf). Under this new policy, the research at issue would appear to be of great concern. Section 3(1) of the new policy lists the agents and toxins that the new policy pertains to. The avian flu virus, which the Policy describes as "highly pathogenic," is the first pathogen listed. Section 3(2) lists the categories of experiments that are covered. The first category is experiments that "enhanc[e] the harmful consequences of the agent or toxin." Because the experiments at issue increased the transmissibility of avian flu, it therefore involve the first pathogen and first category of research identified in the new policy.

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 [United States Government] until now had not needed to have a system in place specifically for restricting dissemination of the results of DURC.<sup>3</sup>

As Dr. Holdren observed, the NSABB has examined these issues for years. In fact, the NSABB was formed for the purpose of examining these issues.<sup>4</sup> While the NSABB had never recommended against dissemination before, the circumstances were foreseeable, maybe even inevitable, and the United States Government should have been better prepared.

The NSABB reconvened as directed on March 29-30 to examine two revised manuscripts regarding the H5N1 research. Upon reexamination, the board advised that journals publish both papers in full. A recent letter from an NSABB member, however, suggested that the process was biased. Dr. Michael Osterholm wrote:

I believe that the agenda and speakers for the March 29 and 30<sup>th</sup> NSABB meeting as determined by the OBA staff and other USG officials was designed to produce the outcome that occurred. It represented a very "one sided" picture of the risk-benefit of the dissemination of the information in these manuscripts. The agenda was not designed to promote a balanced reconsideration of the manuscripts.<sup>5</sup>

Taken together, it appears that the Administration was unprepared for the possibility that the NSABB might recommend against dissemination, and then, caught on its heels, sought to avoid the recommendation. If true, this response does little to prepare the United States Government to better handle similar issues in the future.

The value of open scientific research is undeniable, and the circumstances when the government may need to control access to DURC will be rare. The government needs, however, to be prepared to identify and handle these circumstances when they occur. As the NSABB recommended, "The U.S. Government should expeditiously develop a mechanism to provide controlled access to sensitive scientific information."<sup>6</sup>

The need for an effective, practical, and feasible mechanism for selectively sharing sensitive scientific information has never been more apparent. Please respond to the following questions by May 18, 2012:

1. Why did NIH request that the NSABB reconsider its previous decision?
2. What was done to ensure that the NSABB was briefed by disinterested subject matter experts?
3. What steps are you taking to investigate the recent allegations of bias?
4. Which agencies and officials participated in the inter-agency policy process that created the "Policy for Oversight of Life Sciences Dual Use Research of Concern?"

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<sup>3</sup> Letter, Dr. John Holdren, Director Office of Science and Technology Policy, to F. James Sensenbrenner, Vice-Chairman, House Committee on Science Space and Technology (April 9, 2012).

<sup>4</sup> The NSABB's charter lists one of its duties as to: "Advise on policies governing publication, public communication, and dissemination of dual use research methodologies and results." Charter, National Security Advisory Board for Biosecurity (revised March 10, 2010) *available at* [http://oba.od.nih.gov/biosecurity/about\\_nsabb.html](http://oba.od.nih.gov/biosecurity/about_nsabb.html).

<sup>5</sup> Letter, Dr. Michael Osterholm, Member NSABB, to Dr. Amy Patterson, Associate Director of Science Policy at the National Institute of Health (April 12, 2012).

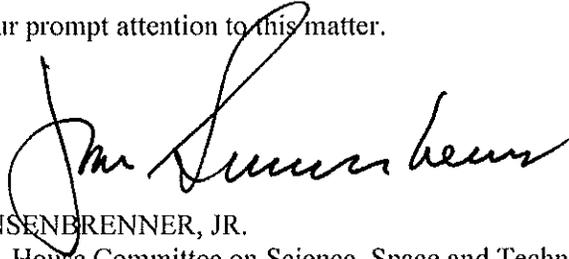
<sup>6</sup> Findings and Recommendations, National Science Advisory Board for Biosecurity (March 29-30, 2012).

5. What mechanisms does NIH have in place to ensure that agencies comply with the new oversight policy? Is compliance with the policy mandatory?

In addition, please provide all documents prepared by NIH in preparation for the March 29-30 NSABB meeting and all documents related to NIH's decision to recommend that the NSABB reconsider its initial recommendations.

I appreciate your prompt attention to this matter.

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