

October 19, 2014

MEMORANDUM TO: NSABB

FROM: RADM Kenneth W. Bernard, MD, USPHS (ret.)  
Former Special Assistant to the President  
for Biodefense (2002-2005)

SUBJECT: NSABB: A bit of historical context

In 2003, after reading the Institute of Medicine (IOM) Fink Committee report on dual use research of concern (DURC), I wrote the first NSABB Charter (with significant input from Bob Kadlec, Rajeev Venkayya, Curt Mann, Larry Kerr and John LaMontagne, among others). The White House Homeland Security Council created the NSABB in 2004 to ensure that the Fink Report's recommendations were addressed by USG policy to encourage and improve security without hobbling good science. In fact, we used the successful 1974-75 NIH Recombinant DNA Advisory Committee (RAC) as a model. The White House wanted to avoid having the Fink Report recommendations used, *de facto*, as hard "red-lines" that restricted whole categories of research out of fear, without adequate debate or discussion.

Our original intent for the NSABB was to set up a process for *institutional* level discussion of proposed projects that might be considered DURC (such as "gain of function") before starting the research, not after it was completed. The NSABB was also to be a national resource for DURC related issues, and, as such, act in an expert advisory role not only to the USG, but also to IBC-like committees at research institutions that would be reviewing specific research proposals for potential DURC (now called "institutional review entities" (IREs)). The NSABB was to have been asked for expert advice as needed — not provide primary research approval.

Of interest, the following is (a partial) list of the NSABB functional activities approved on January 21, 2004 by the White House Homeland Security Council in the original Charter.

"The NSABB will perform the following activities (*inter alia*):

- Advise on national policies governing local review and approval processes for dual-use biological research, including the development of guidelines for the case-by-case review and approval by Institutional Biosafety Committees (IBCs).
- Advise on criteria and processes for referral of classes of research or specific experiments by IBCs to the NSABB for guidance.
- Review and provide guidance on specific experiments insofar as they exemplify a significant or particularly complex permutation of an existing category of dual-use research, or represent a novel category of dual-use research that requires additional guidance from the NSABB.
- Respond to requests submitted by research institutions for the interpretation and application of the guidelines to specific research proposals in instances where a proposal has been denied by an IBC and the institution seeks additional advice."

Over time, many of these explicit activities were “delayed,” and the current 2014 charter only includes a very vague and general list of NSABB duties, and no specific reference local institutional oversight.

Two years after its first meetings in 2005, the NSABB did publish a plan for institutional review for DURC, the excellent 2007 “Proposed Framework for the Oversight of Dual Use Life Sciences Research.” Unfortunately, the framework remained “under review” for 5 more years.

Initial guidelines for government DURC oversight were finally adopted in 2012 – but only after the well-known influenza publication fiasco. Just last month —7 years after they were proposed, “*The United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern*” was finally announced, but won’t be implemented for yet another year.

Every stakeholder has a different reason for this unconscionable delay, mostly related to research community fears and questions, institutional and agency intransigence, and government process fouls. International science and security communities were ill served as a result.

Unfortunately, no one prioritized the institutional-level DURC oversight originally intended for NSABB until research on increased transmissibility of H5N1 influenza was done, and papers were accepted for publication at two prestigious journals. Then – far too late -- the NSABB was asked to opine. It was saddled with the impossible job of trying to adjudicate publication, rather than doing its intended job of advising IREs on whether, or how the research should be done in the first place. Predictably, and for obvious reasons, the NSABB failed in its newly assigned mission. Finally acknowledging a need for early institutional review research, the USG Institutional Oversight Policy for DURC was put on a fast track to approval.

I applaud your engaging in a discussion of “gain of function” research pressured, I presume, by the ongoing work on increased transmissibility of pandemic flu viruses. But while this discussion is a necessary component of the NSABB’s work, it is not an end in itself. The NSABB’s conclusions on this thorny subject can and should be framed so they can be applied by local IREs (and the Director of NIH and Secretary of HHS) *before* proposals are approved, funded, and undertaken — not after results are available and ready to publish.

The NSABB would best meet the DURC research and security needs of the United States (and internationally) if it adopted a “concept of operations” (CONOPS) that reasserts its original IRE advisory activities. The new Program on Biosecurity and Biosafety in the office of the Director at NIH should, therefore, implement and quickly operationalize a CONOPS for the new 2014 Institutional Oversight Policy as its single highest priority in the coming months.



CENTER FOR ARMS CONTROL AND  
NON-PROLIFERATION  
BIOLOGICAL AND CHEMICAL WEAPONS CONTROL PROGRAM

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Written comments in advance of the NSABB meeting on October 22, 2014

To: Contact Person: Carolyn Mosby, The National Science Advisory Board for Biosecurity Program Assistant (e-mail: [carolyn.mosby@nih.gov](mailto:carolyn.mosby@nih.gov))

From: The Scientists Working Group on Biological and Chemical Weapons, Center for Arms Control and Non-proliferation, 322 4th St., NE | Washington, D.C. 20002 | 202.546.0795

Date: October 20, 2014

Dear NSABB Committee,

I am writing on behalf of The Scientists Working Group on Biological and Chemical Weapons at the Center for Arms Control and Non-proliferation. We fully support the *Cambridge Working Group Consensus Statement on the Creation of Potential Pandemic Pathogens (PPPs)* [<http://www.cambridgeworkinggroup.org/>].

Our grave concern is the risk of a pandemic from release (escape) of a potential pandemic pathogen (PPP) from a laboratory. Risk has two components, the likelihood of release and the consequences of release. While the likelihood of release from a single laboratory in a single year is small, likelihood of release from one of several laboratories over several years is intolerably high. A potential consequence of a release is a pandemic with millions of deaths. As it stands, there is no proactive oversight nor regulations for this PPP research, so any and all of the world's nations can carry out this dangerous work without regard to consequences. But consequences would be shared by all of us.

The Center's Scientists Working Group has published or issued several papers on the risk of PPP research and documented escapes of deadly pathogens in the past, which have led to considerable fatalities. As an integral part of this comment, the titles of our key papers are listed below along with web addresses to access the papers.

*The Human Fatality and Economic Burden of a Man-made Influenza Pandemic: A Risk Assessment*  
[[http://armscontrolcenter.org/The\\_Human\\_Fatality\\_Burden\\_of\\_Gain\\_of\\_Function\\_Flu\\_Research\\_v1-5-14.pdf](http://armscontrolcenter.org/The_Human_Fatality_Burden_of_Gain_of_Function_Flu_Research_v1-5-14.pdf)]

*Laboratory Escapes and "Self-fulfilling prophecy" Epidemics*  
[[http://armscontrolcenter.org/Escaped\\_Viruses-final\\_2-17-14.pdf](http://armscontrolcenter.org/Escaped_Viruses-final_2-17-14.pdf)]

*The consequences of a lab escape of a potential pandemic pathogen*  
[<http://journal.frontiersin.org/Journal/10.3389/fpubh.2014.00116/full>]

*Biological threats: A matter of balance* [<http://thebulletin.org/biological-threats-matter-balance>]

*The unacceptable risks of a man-made pandemic* [<http://www.thebulletin.org/unacceptable-risks-man-made-pandemic>]



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*Threatened pandemics and laboratory escapes: Self-fulfilling prophecies*

[<http://thebulletin.org/threatened-pandemics-and-laboratory-escapes-self-fulfilling-prophecies7016>]

*Biological threats: A matter of balance*

BY SCIENTISTS WORKING GROUP ON BIOLOGICAL AND CHEMICAL WEAPONS | 2 FEBRUARY 2010

Sincerely yours,

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Center for Arms Control and Non-proliferation, and

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