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Oversight Hearing on Biological Security: The Risk of Dual-Use Research April 26, 2012

Chairman Lieberman, Ranking Member Collins, and distinguished members of the Committee, thank you for holding this hearing on "Biological Security: The Risk of Dual-Use Research." I am Dr. Paul Keim, Acting Chair of the National Science Advisory Board on Biosecurity (NSABB). I appreciate the opportunity to speak to you about Dual Use Research, and in particular, the Board's activities and of our recent evaluation of two scientific papers concerning the avian H5N1 influenza virus

It has been recognized for many years that science and technology can be used for both good and bad purposes. It is this "two-sided coin" that we refer to as dual use research. The problem is that that all biological research can be construed as having potential bad applications as well as their good ones. NSABB created a new term – dual use research of concern or DURC – to distinguish normal research from that with an exceptionally high potential to be misused. Parameters defining DURC would include the magnitude of any danger and the immediacy of any threat, as balanced against the overall benefits of the work. Over the last 8 years, the Board has advised the U. S. government on best practices and policy approaches for research communication, personnel reliability standards, codes of conduct and international engagement for the issues associated with DURC. The Board has recognized that good policy needs to protect us from scientific misuse <u>and</u> protect the scientific enterprise from being overburdened with unnecessary regulation. Both are essential for our country to be safe, productive and to remain a global leader.

The National Science Advisory Board for Biosecurity is comprised of wellrespected scientists, lawyers, infectious disease experts, scientific editors and public health experts. We have an 8-year track record of protecting academic freedom while seeking policy recommendations that will minimize the misuse of biological sciences research. With that in mind, recognize the significance for the Board to unanimously recommend against the full publication of two scientific papers in November 2011 due to their potential to be misused. The U. S. government asked the Board to review two NIH funded studies reporting mutations that allowed a highly dangerous bird flu virus to transmit from one ferret to another. By a split vote, the Board instead recommended to the government that key elements of the studies not be published and that only redacted papers were acceptable for general distribution.

These recommendations were based upon the Board's findings that if this avian influenza virus acquires the capacity for human-to-human spread and retained its current virulence, the world could face a pandemic of significant proportions. We found the potential risk of public harm to be of unusually high magnitude.

The Board published its recommendations to the U. S. government along with its rationale. Importantly, we pointed out that an international discussion was needed amongst multiple societal components to develop policy in this arena of high consequence DURC. I would further note that in the few months since our

recommendations were released, there has been a flurry of U.S. and international meetings to discuss the risks and benefits of these experiments. The research, issues and policy consequences are now commonly known and being debated. This continuing global conversation is good for the scientific endeavor and for our biosecurity.

In late March 2012, the U. S. government tasked NSABB with reviewing revised versions of the two original manuscripts. This was coupled with a face-to-face meeting such that the Board could hear directly from the investigators about their research.

In this meeting, the Board received nonpublic information about the risks and benefits of the research from the international public health and research community, as well as from the United States intelligence community. In a classified briefing from National Intelligence Council and National Counterterrorism Center representatives, the Board heard an assessment of the risk for misuse and of the global political ramifications associated with these papers. The details of this briefing are classified, but I can tell you that many of the Board were left with the impression that the risk of misuse did not appreciably increase with full publication and there is a high likelihood of undesirable political consequences to not publishing.

In addition, the U. S. government issued new policy guidelines targeting high consequence DURC. This is based upon NSABB's definition of DURC and seven categories of experiments that warrant special consideration, and targeting particular high-consequence pathogens.

It was in this context that the Board arrived at different recommendations for the revised manuscripts. One paper was unanimously recommended for full

publication, while the other was recommended by a split 12 to 6 vote. In balancing the risks against the benefits of the revised manuscripts in the context of additional information and new U. S. government policy, the Board shifted its position.

In my opinion, the split vote is highly significant and signals that the Board still believes there is great potential for misuse of information generated by these types of experiments. The majority of Board members voted for publication, but they were clearly still troubled by this research and its potential to be misused. It is fair to say that the Board believes that these types of experiments will arise again and that these issues are not fully settled. As one Board member noted, "We have only kicked this can down the road and we'll be dealing with it again in the future."

It is critical that we establish policy that intensely monitors high potential DURC research from "cradle to grave" in order to protect us from misuse, but also to free low-potential DURC research from onerous regulations. We must be careful that we don't destroy the scientific enterprise as we try to protect against the misuse of some research.

Thank you for your attention.