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Press Statement on the NSABB Review of H5N1 Research

The U.S. government remains concerned about the threat of influenza, for the risks it poses seasonally, as well as its potential to cause a pandemic. Our domestic and global influenza surveillance efforts have become increasingly capable, along with expanded vaccine manufacturing capacity and assistance to other countries in their efforts to detect and respond to a pandemic. To enhance the detection of and response to influenza outbreaks, the U.S. government supports a broad range of domestic and global preparedness and response efforts that include research on better diagnostics, vaccines, and therapeutics.

Currently, H5N1 avian influenza virus — the strain commonly referred to as "bird flu" — rarely infects humans and does not spread easily from person to person. However, many scientists and public health officials are concerned that the virus could evolve in nature into a form that is transmissible among humans — an event that could potentially make this deadly virus an extremely serious global public health threat. Thus research on factors that can affect the transmissibility of the H5N1 virus is critically important to international efforts to prepare and prevent threats to public health.

While the public health benefits of such research can be important, certain information obtained through such studies has the potential to be misused for harmful purposes. The National Science Advisory Board for Biosecurity (NSABB) — an independent expert committee that advises the Department of Health and Human Services (HHS) and other Federal departments and agencies on matters of biosecurity — completed a review of two unpublished manuscripts describing NIH-funded research on the transmissibility of H5N1. These manuscripts — which describe laboratory experiments that resulted in viruses with enhanced transmissibility in mammals — concluded that the H5N1 virus has greater potential than previously believed to gain a dangerous capacity to be transmitted among mammals, including perhaps humans, and describe some of the genetic changes that appear to correlate with this potential.

Following its review, the NSABB decided to recommend that HHS ask the authors of the reports and the editors of the journals that were considering publishing the reports to make changes in the manuscripts. Due to the importance of the findings to the public health and research communities, the NSABB recommended that the general conclusions highlighting the novel outcome be published, but that the manuscripts not include the methodological and other details that could enable replication of the experiments by those who would seek to do harm.

The NSABB also recommended that language be added to the manuscripts to explain better the goals and potential public health benefits of the research, and to detail the extensive safety and security measures taken to protect laboratory workers and the public.

HHS agreed with this assessment and provided these non-binding recommendations to the authors and journal editors.

Recognizing the significant potential benefit of the information about the experimental details to the global influenza surveillance and research communities, the U.S. government is working to establish a mechanism to allow secure access to the information to those with a legitimate need in order to achieve important public health goals. The U.S. government is also developing a proposed oversight policy that would augment existing approaches to evaluating research that has the potential to be misused for harmful purposes.

The NSABB supports the overall goals of the National Institutes of Health, in conducting safe, ethical and informative
research to enhance health, lengthen life, and reduce the burdens of illness and disability. To learn more about the NSABB, visit www.biosecurityboard.gov.

About the National Institutes of Health (NIH): NIH, the nation's medical research agency, includes 27 Institutes and Centers and is a component of the U.S. Department of Health and Human Services. NIH is the primary federal agency conducting and supporting basic, clinical, and translational medical research, and is investigating the causes, treatments, and cures for both common and rare diseases. For more information about NIH and its programs, visit www.nih.gov.