National Institutes of Health (NIH)
Office of the Director
Office of Science Policy
Office of Biotechnology Activities
NATIONAL SCIENCE ADVISORY BOARD FOR BIOSECURITY (NSABB**)**

November 25, 2014
Conference Call Meeting
11:00A.M. – 1:00P.M. (EST)

MEETING MINUTES

VOTING MEMBERS
Samuel L. Stanley, Jr., M.D., Chair
Kenneth I. Berns, M.D., Ph.D.
Craig E. Cameron, Ph.D.
Andrew Endy, Ph.D.
J. Patrick Fitch, Ph.D.
Christine M. Grant, J.D., M.B.A.
Marie-Louise Hammarskjold, M.D., Ph.D.
Clifford W. Houston, Ph.D.
Joseph Kanabrocki, Ph.D., C.B.S.P.
Gardiner Lapham, R.N., M.P.H.
Jan Leach, Ph.D.
James W. LeDuc, Ph.D.
Margie D. Lee, D.V.M., Ph.D.
Francis L. Macrina, Ph.D.
Joseph E. McDade, Ph.D.
Jeffrey F. Miller, Ph.D.
Rebecca T. Parkin, Ph.D.
Jean L. Patterson, Ph.D.
I. Gary Resnick, Ph.D.
Susan M. Wolf, J.D.
David L. Woodland, Ph.D.

***AD HOC* VOTING MEMBERS1**
Theresa M. Koehler, Ph.D.
Marcelle C. Layton, M.D.
Stephen S. Morse, Ph.D.

ABSENT

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[1] Ad hoc voting members are incoming members who will participate in a non-voting capacity until their appointments to the Board are finalized.

***EX OFFICIOS* / FEDERAL AGENCY REPRESENTATIVES**
Brenda Cuccherini, Ph.D., M.P.H., U.S. Department of Veterans Affairs
Susan Coller-Monarez, Ph.D., Department of Homeland Security
Diane DiEuliis, Ph.D., U.S. Department of Health and Human Services
Dennis M. Dixon, Ph.D., National Institutes of Health
Brendan Doyle, Ph.D., U.S. Environmental Protection Agency
Meg L. Flanagan, Ph.D., U.S. Department of State
Gerald Epstein, Ph.D., U.S. Department of Homeland Security
Andrew Hebbeler, Ph.D., Office of Science and Technology Policy
Wesley Johnson, Ph.D., U.S. Department of Commerce
Franca R. Jones, Ph.D., U.S. Department of Defense
David Liskowski, Ph.D., National Aeronautics and Space Administration
CAPT. Carmen Maher, R.N., U.S. Food and Drug Administration
Michael W. Shaw, Ph.D., Centers for Disease Control and Prevention
Eileen Thacker, D.V.M., Ph.D., U.S. Department of Agriculture

Welcome
Samuel L. Stanley, M.D., NSABB Chair; President, Stony Brook University

Dr. Stanley opened the meeting at 11:03 a.m. by welcoming NSABB members, U.S. Government (USG) representatives, and members of the public. He followed with a brief review of the USG pause on certain types of gain-of-function (GOF) research involving influenza, severe acute respiratory syndrome (SARS), and Middle East respiratory syndrome (MERS) viruses announced by the White House Office of Science and Technology Policy (OSTP) and the U.S. Department of Health and Human Services (HHS) on October 17, 2014.

Dr. Stanley briefly reviewed the meeting agenda and noted that two primary objectives of the meeting would be provision of an update on the implementation of the USG funding pause and a discussion of a draft NSABB statement intended to convey questions and concerns about the funding pause raised at the October 22 NSABB meeting.

Review of Conflict of Interest Rules
Mary E. Groesch, Ph.D., Executive Director, NSABB;
Senior Policy Advisor, Program on Biosecurity and Biosafety Policy, Office of the Director, National Institutes of Health

Dr. Groesch performed a roll call and explained that members of the NSABB are considered special government employees and as such are subject to federal rules of ethical conduct and reviewed the rules of ethics, codes of conduct, and the process for assessing and managing potential conflicts of interest.

Implementation of USG Funding Pause on GOF Research involving Influenza, MERS, and SARS Viruses

Dennis M. Dixon, Ph.D., Chief, Bacteriology and Mycology Branch, Division of Microbiology and Infectious Diseases, National Institute of Allergy and Infectious Diseases, National Institutes of Health

Dr. Dixon thanked the NSABB for the opportunity to provide an update on the implementation of the USG funding pause. He focused on the implementation of the pause by NIH/NIAID, the feedback and questions NIAID received from the scientific community, and the steps taken to address any confusion about the pause. He said that NIAID first identified the projects in their portfolio with relevance to the USG finding pause. He next outlined the steps in the process for review, which starts with the program officer, goes to an internal committee, through the NIAID Office of the Director, and onto the Director of the NIH for final determinations.

Dr. Dixon highlighted key areas in the funding pause announcement that could generate confusion as currently worded related to the scope, criteria for inclusion, and scale of impact of the pause. He noted that the pause covers all influenza viruses, not just highly pathogenic avian influenza strains or reconstructed 1918 H1N1 influenza. Pertinent to concerns discussed at the October 22, 2014 NSABB meeting, he clarified that surveillance and routine characterization of naturally occurring isolates were not intended to be captured by the pause and indicated that letters of clarification were sent to all of the original researchers who received letters identifying their work as being within the scope of the pause.

Dr. Dixon said that case-by-case assessments of relevant factors were being undertaken to evaluate what research was reasonably anticipated to result in increased transmissibility or increased pathogenicity of influenza, SARS or MERS viruses. He emphasized that within NIH/NIAID the criteria being used were evidence-driven and based on the results of previous studies.

With respect to the impact of the pause on ongoing research, he indicated that only a very small number of biomedical research projects (~18) were anticipated to be affected, however he noted that with the evaluation and implementation process still ongoing, the actual numbers were in flux at this point. Dr. Dixon said that grantees should be in contact with their program officers with any questions or concerns and reiterated that the pause has a provision for granting exceptions when it is determined there is public health urgency.

Discussion

Dr. Susan Wolf inquired about the balance of considerations being given to public health urgency and national security concerns. Her question was addressed by Dr. Andrew Hebbeler from the White House OSTP who said that NIH would be mainly focused on public health implications of specific research, but other USG agencies and departments that have more of a national security focus may be considering the national security implications in more detail.

In response to a question from Dr. Gary Resnik on how the NIH involves the national security community in deliberations about granting exceptions, Dr. Dixon indicated that the only examples of exceptions that he was aware of at the moment were considered to be related to public health, such as work on MERS and SARS animal models for the purpose of countermeasure development.

Dr. Marie-Louise Hammarskjöld asked how long the case-by-case approach being undertaken by NIAID would take. Dr. Dixon responded that NIAID was moving as fast as they could and hoped to complete the implementation process within a month. He explained that grantees had been given approximately 90 days to submit material for consideration and that this period had not yet expired. Dr. Hebbeler added that the approximately 18 projects being evaluated by NIAID were the only USG-funded projects that they were aware of that could potentially be subject to the funding pause.

Dr. Ken Berns followed Dr. Hebbeler's comment with a question about whether there were internal projects ongoing at the Centers for Disease Control and Prevention (CDC) that were subject to the pause. Dr. Michael Shaw, Senior Advisor for Laboratory Science in the Office of Infectious Diseases at the CDC, responded that a review conducted by an internal biosecurity board determined that the internal projects did not fall under the pause. He added the projects in question were related to vaccine development and understanding antiviral resistance.

Dr. Eileen Thacker, of the U.S. Department of Agriculture (USDA) Agricultural Research Service, indicated that avian influenza projects at the USDA are evaluated using both dual use research of concern (DURC) and GOF considerations but were not considered to be subject to the pause since the work is conducted in poultry and typically does not involve putting the natural avian viruses into mammals. She added that, at the time of this meeting, USDA research projects involving highly pathogenic avian influenza were deemed not to be subject to the moratorium.

Review and Discussion of the NSABB Draft Statement on Gain-of-Function Research

Dr. Stanley gave a brief overview of the NSABB statement, beginning by commending the U.S. government for undertaking this deliberative process. He said the intent of the Board's statement was to convey the concerns expressed by the scientific community that research projects viewed as critical to public health could be potentially halted by the pause. Dr. Stanley added that the statement urges the U.S government to engage with the research community, educate them about the pause, and make any clarifications about the scope. He also said that the Board wanted the U.S. government to ensure that there is an expedited process for granting exceptions.

Board Comments on the Draft NSABB Statement

Dr. Stanley opened the session to comments from NSABB members. Dr. Susan Wolf suggested significant edits to the draft document by recommending the removal of text

that expressed the Board's concern that the concepts surrounding biosafety, biosecurity, DURC and GOF were being confused. Dr. Wolf said that, given the purpose of the statement, she thought the text was unnecessary. She also recommended that language in the Board's statement describing the criteria for granting exceptions be altered to exactly mirror the language in the pause in order to minimize any confusion. Both Dr. Joe Kanabrocki and Dr. Frank Macrina expressed their agreement with the suggested changes.

Dr. Christine Grant asked who the intended recipients of the NSABB statement were. Dr. Groesch responded that normally NSABB documents are submitted to the U.S. government through the Secretary of Health and Human Services, who then disseminates them among the relevant government departments and agencies. Dr. Grant followed with a second question about how concurrence among different levels of the government was being achieved on the subject of granting exceptions to the pause, citing a concern that one level may disagree with another. Dr. Groesch again responded, saying that when the NIH is considering the request for an exception, the Department of Health and Human Services as well as other relevant Offices of the Secretary are consulted. The Executive Office of the President is also notified, she said.

Public Comments on the Draft NSABB Statement

Dr. Stanley opened the session to comments from members of the public. Prior to the first public comment, Dr. Hebbeler noted that the government has been working to put together a frequently asked questions (FAQ) document, which was recently published publicly on the S3 (science, safety, and security) website: (http://www.phe.gov/s3/Pages/default.aspx). Dr. Groesch said that she would distribute the FAQ to the NSABB members.

Dr. Mark Denison, a professor and coronavirus researcher at Vanderbilt University Medical Center, pointed out that while the number of labs anticipated to be affected by the pause was small, the impact to these labs was significant. He encouraged rapid communication with the affected laboratories.

Dr. Mark Lipsitch, Professor of Epidemiology at Harvard University, questioned whether the examples of projects at the CDC mentioned earlier by Dr. Shaw truly fell under the current pause or under the HHS framework on research involving highly pathogenic avian influenza. Dr. Lipsitch inquired of Dr. Shaw whether any work similar to the synthesis of 1918 H1N1 influenza virus was ongoing. He additionally expressed his concern that merits of GOF research were possibly being overstated. Dr. Shaw responded by saying that the experiments referred to by Dr. Lipsitch have ceased and were no longer being done at the CDC. He added that there were no plans to do anything similar to the 1918 H1N1 influenza virus reconstruction. Dr. Denison responded to Dr. Lipsitch's concern about the merits of GOF being overstated by speaking about the importance of GOF experiments to the creation of animal models of diseases, specifically highlighting the lack of an animal model for infection with MERS virus, which is currently responsible for significant outbreaks in a number of Middle Eastern countries.

Robert Verger, a journalist, asked if any disease surveillance work was being placed on hold as a result of the pause. Dr. Dixon responded that more information on particular projects would be needed, and said that the public call was not the proper venue to discuss unpublished, ongoing research.

John Steel, Assistant Professor at Emory University, urged that the focus be restricted to only "gain of function of concern", and not all GOF research.

Journalist David Malakoff asked about the anticipated timeline for the release of the NSABB statement, and questioned whether entire deliberative process, would be completed in the estimated one year time frame originally stated by the USG. Dr. Stanley conferred with Dr. Groesch and they estimated the process to edit, finalize, and release the NSABB statement would take one to two weeks. On the question of the timeline for releasing a new U.S. government policy on gain of function research, Dr. Stanley said that right now the Board was on schedule.

Continued Discussion and finalization of the Draft Statement

Dr. Berns motioned for approval of the NSABB statement with the modifications discussed earlier in the meeting. Dr. Macrina seconded the motion. Twenty NSABB members voted to approve the statement with the modifications discussed; Dr. McDade voted not to approve. The motion was passed.

Adjournment

Prior to adjourning the meeting, Dr. Stanley gave a brief update on the Board's progress saying that a 13-member working group, co-chaired by Dr. Berns and Dr. Kanabrocki, had been formed to manage the Board's first task of advising on the design, development, and conduct of risk and benefit assessment studies of GOF research. He adjourned the meeting at 12:51 p.m.