National Science Advisory Board for Biosecurity (NSABB)
Meeting Minutes

February 28, 2022
Virtual Meeting

Contents

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NSABB Members Present

Gerald W. Parker, Jr., D.V.M., Ph.D. (Chair)
Shannon Benjamin, M.S., M.B.A.
Kenneth Bernard, M.D.
Mark R. Denison, M.D.
Christina Egan, Ph.D.
Jacqueline Fletcher, Ph.D.
John D. Grabenstein, R.Ph., Ph.D.
Karmella Haynes, Ph.D.
Rachel Levinson, M.A.
Alex John London, Ph.D.
Nicolette Louissaint, Ph.D., M.B.A.
Syra Madad, D.H.Sc., M.Sc., MCP
Dennis Metzger, Ph.D.
Rozanne M. Sandri-Goldin, Ph.D.
Pamela A. Silver, Ph.D.
Ara Tahmassian, Ph.D.

NSABB Members Absent

None

Welcome, Call to Order, and Conflict-of-Interest Disclosures

Gerald W. Parker, Jr., D.V.M., Ph.D., NSABB Chair; Associate Dean for Global One Health, Texas A&M University

Jessica Tucker, Ph.D., Acting Deputy Director of the Office of Science Policy (OSP), National Institutes of Health (NIH)

Dr. Parker opened the meeting at 12:00 p.m. and invited Jessica Tucker, Ph.D., Designated Federal Official for the NSABB, to review the conflict-of-interest (COI) policy.

Dr. Tucker reviewed the COI statement, reminding NSABB members that they are Special Government Employees of the U.S. government and, as such, are subject to rules of conduct. Members are to disclose personal, professional, and financial COIs. Should an issue arise that could affect—or appear to affect—a member's interests, the member is requested to recuse himself or herself from the discussion.

Introductory Remarks

Gerald W. Parker, Jr., D.V.M., Ph.D., NSABB Chair; Associate Dean for Global One Health, Texas A&M University

Dr. Parker recognized former NSABB members who have completed their terms of service. He also welcomed incoming members. Dr. Parker described that as a federal advisory committee,

the NSABB provides advice, guidance, and recommendations on biosecurity oversight of dual use research (DUR). The members provide expert perspectives to help ensure that the federal government's oversight framework keeps up with rapid advances in science that could raise biosecurity concerns. Biosecurity policy considerations are essential to ongoing efforts to bolster U.S. biodefense and improve pandemic preparedness. The Board can help ensure that biosecurity frameworks strike the right balance of allowing the benefits of vital research to continue rapidly while managing biosecurity risk.

Dr. Parker stated that NSABB input has been key in discussions regarding biosecurity and DUR. During the January 2020 meeting, the NSABB was charged with providing recommendations to balance security and public transparency when sharing information about research with enhanced pandemic potential pathogens and with evaluating policies governing U.S. dual use research of concern (DURC). Dr. Parker recalled that this is the first meeting of the NSABB since its activities were paused because of the COVID-19 pandemic, which required members to prioritize COVID-19 research and response. He also thanked those members of the public who submitted written comments. The comments were posted on the NIH OSP website and shared with the Board before the meeting.

U.S. Government Perspectives: Research Oversight

Andrew M. Hebbeler, Ph.D., Assistant Director for Health and Life Sciences, White House Office of Science and Technology Policy (OSTP)

Daniel Z. Gastfriend, M.B.A., M.P.A., Director for Biodefense and Pandemic Preparedness, U.S. White House National Security Council (NSC)

Life sciences research has extraordinary benefits, including to areas beyond health and medicine. However, certain kinds of research can be inherently risky given the possibility for biosafety lapses or deliberate misuse. Dr. Hebbeler introduced several definitions adopted by the U.S. government that were precisely scoped and informed by extensive analysis, including by the NSABB:

- **DURC:** a subset of life sciences research (involving one of 15 defined pathogens or toxins and seven categories of experiments) that has the greatest potential for generating information that could be readily misused to threaten public health and national security
- **Potential pandemic pathogen (PPP):** a pathogen that is both (1) likely highly transmissible and likely capable of wide and uncontrollable spread among humans and (2) likely highly virulent and likely to cause significant morbidity and/or mortality in humans
- **Enhanced PPP (ePPP):** a PPP resulting from the enhancement of the transmissibility and/or virulence of a pathogen

Dr. Hebbeler described the policy frameworks governing DURC and research involving ePPPs. The DURC policies promote a collaborative approach between federal funders and research institutions to identify DURC research and mitigate any risks throughout the life cycle of the research. Following a series of laboratory incidents in 2014 and the subsequent pause on certain types of research, a process was initiated to evaluate risks and potential benefits of such research. With NSABB input, the OSTP Potential Pandemic Pathogen Care and Oversight (P3CO) Policy Guidance and, following that, the HHS P3CO Framework, were developed to mitigate risks

associated with a certain subset of life sciences research. The research subject to these policies is done with rigorous biosafety and biosecurity conditions and oversight in place to mitigate risks to public health, agriculture, and national security.

Mr. Gastfriend emphasized that this is a critical time for the U.S. government to evaluate policies on biosafety, biosecurity, and life sciences DURC. The COVID-19 pandemic has demonstrated the devastating consequences of a global biological event, and preventing, detecting, preparing for, and responding to biological incidents is a top priority for the Biden administration. On his first day in office, President Biden tasked government agencies with reviewing actions to mitigate emerging domestic and global biological risks. Working with departments and agencies across the government, the National Security Council is reviewing policies and developing options informed by input from external stakeholders, including the NSABB.

Charge to the NSABB

Lawrence A. Tabak, D.D.S., Ph.D., Acting Director, NIH

Lyric Jorgenson, Ph.D., Acting Associate Director for Science Policy, NIH

Dr. Tabak stated that the NIH, the U.S. Department of Health and Human Services (HHS), and the whole of the U.S. government remain committed to ensuring that research with infectious agents is conducted responsibly in terms of biosecurity and safety. The comprehensive biosecurity policy framework is grounded in the identification and assessment of risks and benefits and the effective mitigation of risks. Some of the same research that involves biosecurity concerns is also essential for protecting global health. A key challenge is enabling research that has potentially great benefits for human health while ensuring that safety and security risks are identified and managed effectively.

Dr. Tabak also noted that, as science and technologies advance, the government regularly reviews and, as needed, updates oversight systems to help identify novel risks to ensure that there is effective risk mitigation and that procedures are grounded in thoughtful risk assessments that reflect the current state of the science.

The NSABB plays a key role in biosecurity policy review and analysis by encouraging public discussion and providing expert input to inform U.S. government policy. Dr. Tabak announced that the charge given to the Board in January 2020 is now being expanded to enable a broader review and evaluation of the scope and effectiveness of the major U.S. biosecurity policy frameworks that govern research with DURC and ePPP:

- **United States Government Policy for Oversight of Life Sciences DURC (2012):** requires federal funding agencies to identify DURC in their research portfolios and work to mitigate risks as needed
- **United States Government Policy for Institutional Oversight of Life Sciences DURC (effective 2015):** requires federally funded research institutions to establish a system to identify DURC and work with funding agencies to mitigate risks as needed
- **OSTP Recommended Policy Guidance for Departmental Development of Review Mechanisms for Potential Pandemic Pathogen Care and Oversight (P3CO) (2017):**

directs federal departments and agencies to adopt a department-level, multidisciplinary, pre-funding ePPP review mechanism
- **Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens (HHS P3CO Framework) (2017):** ensures HHS department-level pre-funding review and evaluation of proposed ePPP research

The NSABB's amended charge is divided into two phases, with Phase 1 being the review and evaluation of P3CO policy:

- Evaluate and provide recommendations on the effectiveness of the current oversight framework (OSTP Policy Guidance and process adopted by HHS) for research involving ePPPs including:
    - Scope, in terms of preserving benefits of ePPP research while minimizing potential biosafety and biosecurity risks
    - Considerations for supporting ePPP research internationally
    - Balancing considerations regarding security and public transparency when sharing information about research involving ePPP
- Consider Policy Guidance impact on research programs and institutions

Dr. Tabak explained that Phase 2 of the NSABB's charge consists of two components. Phase 2A, the review and evaluation of DURC policies, is as follows:

- Evaluate and analyze U.S. government federal and institutional policies for the oversight of DURC to:
    - Evaluate effectiveness in achieving their intent
    - Evaluate the impact on research institutions and the U.S. government's ability to support research
    - Identify implementation challenges
    - Evaluate effectiveness with regard to publication, public communication, and dissemination of DURC methodologies and results
- Reevaluate the definition of DURC, considering advances in life sciences research and convergence with other scientific disciplines/sectors
- Evaluate the effectiveness of the DURC pathogen list and experimentation type construct to determine whether:
    - Approach sufficiently addresses future potential threats, across the spectrum of life science research
    - Approach is conducive to research risk-mitigation
    - Alternative approaches warrant consideration

Phase 2B of the NSABB's charge focuses on the *Recommended Policy Guidance for Departmental Development of Review Mechanisms for Potential Pandemic Pathogen Care and Oversight*:

- Evaluate Section 8 on future commitments and provide recommendations on possible incorporation of the *P3CO Policy Guidance* into policy frameworks associated with any recommended revisions of DURC policies

Throughout Phase 2, the NSABB should consider flexible and adaptive governance approaches that can:

- Keep pace with scientific advances and the evolving understanding of risks and benefits
- Coalesce and integrate with existing governance guidance or policy
- Be applied to mitigate risk not only from research of concern but also from other biosecurity and biosafety considerations

Dr. Jorgenson then outlined the anticipated timeline for the NSABB's work, with a goal to wrap up by the end of 2022. The Board will likely form working groups to address each of the two phases of the charge. Listening sessions will garner input from relevant stakeholders, researchers, institutions, federal funding agencies, and the public to inform the NSABB's deliberations.

NSABB Discussion and Next Steps

Gerald W. Parker, Jr., D.V.M., Ph.D., NSABB Chair; Associate Dean for Global One Health, Texas A&M University

Jessica M. Tucker, Ph.D., Acting Deputy Director, OSP, NIH

Given the NSABB's timeline, Dr. Parker said that the Board must begin work immediately. He supported the recommendation of setting up two working groups to support Phases 1 and 2.

Members of the NSABB discussed the charge and posed questions on the scope including how the policies and guidance would apply to research conducted internationally and researchers moving their work abroad if the U.S. government limited certain research activities. Dr. Parker pointed out that part of the charge is to understand some of the international implications. Dr. Tabak said that the U.S. government has certain levers at its disposal for any government-funded research. Funded scientists are expected to abide by any regulations and policies that are in place. Dr. Jorgenson also said that the charge to the NSABB includes evaluation of current oversight, both domestically and internationally.

Dr. Denison stated that he believes the current P3CO policy is inadequate in that it excludes vaccines and surveillance activities, but it does not address antivirals. He cautioned about proscriptive policies that do not provide sufficient capacity for responding quickly to public health crises and noted the tight timeline. Dr. Parker agreed about the importance of ensuring the NSABB can conduct thoughtful deliberations while understanding that there is some urgency, too.

Dr. Silver asked whether the amended charge will involve the NSABB conducting a review of how DUR grants had been approved for funding. Dr. Parker said that instead of focusing on individual grants, the NSABB is looking at policies writ large to assess their effectiveness. As an advisory body, the Board does not need to drill down to the level of individual grants, but it can weigh in on policies to frame grants management.

Dr. Bernard underscored the importance of ensuring that any recommendations from the NSABB not inhibit research that could result in a competitive disadvantage to the United States. Dr. Hebbeler agreed that in addition to balancing safety and security, there is the additional layer of competitiveness. He stated that a model to consider may be how we have approached global norms for new biotechnologies. Dr. Jorgenson pointed out the importance of the NSABB's first

task: to consider the scope and effectiveness of current definitions. She recommended considering whether a particular definition's scope remains appropriate.

Ms. Levinson pointed out that even before the pandemic, scientists had challenges getting particular reagents or toxins in the United States despite their availability elsewhere in the world. Some researchers moved their laboratories abroad. She cautioned about the risk of deterring students and postdoctoral fellows from going into certain fields that would be of great value but are considered too difficult to enter.

Dr. Haynes asked whether considering relationships with community scientists and the public to reestablish trust between nonscientists and the scientific community is within the Board's scope. Dr. Parker agreed that the NSABB's deliberations need to be informed by the public at large, since the public has a stake. The NSABB's timeline includes listening sessions designed to garner broader input to ensure public concerns are considered, and the NSABB's amended charge would support engagement with different groups outside the scientific community.

Dr. Fletcher asked whether the Board will discuss the agricultural and environmental types of biothreats. Dr. Parker noted that the scope of DURC includes the environment, animals, and plants.

Dr. London remarked on international standards and the importance of providing credible assurance to the public that research that is allowed has sufficient social value to justify the risks. He underscored the importance of relying on diplomatic and policy colleagues to ensure that there is a solid underpinning to policy guidelines. It is critical to avoid the "race to the bottom" where other places have a weaker policy environment that allows risks to be taken even if they are not justified by adequate social value.

Closing Remarks and Adjournment

Gerald W. Parker, Jr., D.V.M., Ph.D., NSABB Chair; Associate Dean for Global One Health, Texas A&M University

Dr. Parker and Dr. Tucker explained that NIH will reach out to NSABB members to ask which working group they would like to serve on. Members may also opt to participate in both groups.

Dr. Parker adjourned the meeting at 1:07 p.m.

Certification

I hereby acknowledge that, to the best of my knowledge, the foregoing Minutes and the following Attachments are accurate and complete.

This Minutes document will be considered formally by the NSABB; any corrections or notations will be incorporated into the Minutes.

Jessica M. Tucker -S

Digitally signed by Jessica M. Tucker -S
Date: 2022.05.25 17:22:13 -04'00'

Jessica Tucker, Ph.D.
Executive Secretary
National Science Advisory Board for Biosecurity

Date

Gerald W. Parker, Jr.

May 27, 2022

Gerald W. Parker, Jr., D.V.M., Ph.D.
Chair
National Science Advisory Board for Biosecurity

Date

Attachment I
NSABB Voting Member Roster

Chair

Gerald W. Parker, Jr., D.V.M., Ph.D.
Associate Dean for Global One Health
College of Veterinary Medicine & Biomedical Sciences
Texas A&M University

Voting Members

Shannon Benjamin, M.S., M.B.A.
Associate Director, Research Safety BSL-3
Environmental Health & Safety
National Emerging Infectious Diseases Laboratories
Boston University

Kenneth Bernard, M.D.
RADM, U.S. Public Health Service (Retired)
Former Special Assistant to the President for Biodefense, Homeland Security Council, White House
Former Special Adviser for Health and Security on the National Security Council

Mark R. Denison, M.D.
Edward Stahlman Professor of Pediatrics
Professor of Pathology, Microbiology and Immunology
Director of the Division of Pediatric Infectious Diseases
Vanderbilt University Medical Center

Christina Egan, Ph.D.
Deputy Director, Division of Infectious Disease, and Chief, Biodefense and Mycology Laboratories
Wadsworth Center
New York State Department of Health

Jacqueline Fletcher, Ph.D.
Regents Professor Emerita
National Institute for Microbial Forensics and Food and Agricultural Biosecurity
Oklahoma State University

John D. Grabenstein, R.Ph, Ph.D.
Executive Director (Retired)
Global Medical Affairs
Merck Vaccine Division
Merck & Co., Inc.

Karmella Haynes, Ph.D.
Associate Professor
Wallace H. Coulter Department of Biomedical Engineering
Georgia Institute of Technology and Emory University

Rachel Levinson, M.A.
Executive Director, National Research Initiatives
Knowledge Enterprise
Arizona State University

Alex John London, Ph.D.
Clara L. West Professor of Ethics and Philosophy
Department of Philosophy
Carnegie Mellon University

Nicolette Louissaint, Ph.D., M.B.A.
Senior Vice President of Policy and Strategic Planning
Healthcare Distribution Alliance

Syra Madad, D.H.Sc., M.Sc., MCP
Faculty, Boston University's Center for Emerging Infectious Diseases Policy & Research
Fellow, Harvard Kennedy School Belfer Center for Science and International Affairs
Senior Director, System-wide Special Pathogens Program, NYC Health + Hospitals

Dennis Metzger, Ph.D.
Professor and Chair
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Albany Medical College

Rozanne M. Sandri-Goldin, Ph.D.
Chancellor's Professor and Chair, Department of Microbiology and Molecular Genetics
University of California, Irvine School of Medicine

Pamela A. Silver, Ph.D.
Elliot T. and Onie H. Adams Professor of Biochemistry and Systems Biology
Member, Harvard University Wyss Institute of Biologically Inspired Engineering
Department of Systems Biology
Harvard Medical School

Ara Tahmassian, Ph.D.
Chief Research Compliance Officer
Richard A. and Susan F. Smith Campus Center
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