

# CRS Report for Congress

## Oversight of Dual-Use Biological Research: The National Science Advisory Board for Biosecurity

Updated April 27, 2007

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Prepared for Members and  
Committees of Congress

# Oversight of Dual-Use Biological Research: The National Science Advisory Board for Biosecurity

## Summary

Policymakers have addressed the threat of biological weapons and biosecurity issues for many years. An issue garnering increased attention is the potential for life sciences research intended to enhance scientific understanding and public health to generate results that could be misused to advance biological weapon effectiveness. Such research has been called “dual-use” research because of its applicability to both biological countermeasures and biological weapons.

The federal government is a major source of life sciences research funding. Tension over the need to maintain homeland security and support scientific endeavor has led to renewed consideration of federal scientific oversight policies. Balancing effective support of the research enterprise and security risks generated by such research is a complex challenge. Policies addressing science and security generate tensions between federal funding agencies and federal funding recipients. To minimize these tensions while maximizing effective oversight of research, insight and advice from disparate stakeholders is generally considered essential.

The National Science Advisory Board for Biosecurity (NSABB) was established as one tool to aid policymakers and researchers in assessing the risks of federally funded, life-sciences research. It aims to provide the Secretary of Health and Human Services and researchers a source for advice on dual-use research and other biosecurity issues. Advice rendered by the NSABB may shape research activities and standards practiced by researchers in life science research fields.

The NSABB is composed of experts in biological sciences, law, security, and other areas and federal officials representing agencies that fund life sciences research. Its responsibilities include identifying and defining dual-use research, advising the Secretary of Health and Human Services on biosecurity issues, and providing recommendations on an ethical code for life scientists. The issues the NSABB addresses are also being explored by professional societies, non-profit organizations, and other groups. Guidance and activities undertaken by the NSABB are likely to be closely scrutinized and challenged by stakeholder groups.

The success of the NSABB in addressing federal concerns related to biodefense and biosecurity may influence congressional action. Absent an existing, effective mechanism to address potentially controversial issues raised by federally funded dual-use research, policymakers could act to establish an oversight mechanism through legislation. Should the NSABB be successful in linking the scientific and security communities and developing guidelines for effective scientific self-oversight, the board could evolve into a forum that policymakers may use to consider the intersections of science and security. Whether the tools available to the federal government are adequate to assess and control security risks from federally funded research or if additional authorities may ultimately need to be developed is yet to be determined. This report will be updated as events warrant.

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# Oversight of Dual-Use Biological Research: The National Science Advisory Board for Biosecurity

Some scientific and technological advances that provide great benefits to society can also be used maliciously. For example, biological research on the origins of virulence, the development of vaccines, and the genetic manipulation of biological agents are simultaneously relevant to public health and to biological weapons. Some policymakers are concerned that publishing such dual-use research results in the open literature could aid or further the goals of adversaries of the United States. The National Science Advisory Board for Biosecurity (NSABB) was established to facilitate understanding and oversight of such potentially contentious research. Issues of potential congressional interest include the mechanism and appropriateness of NSABB review of scientific research; the scope of NSABB recommendations with respect to publication of scientific research; the domestic and international adoption of practices or codes developed by the NSABB; the implementation of NSABB guidelines at the local level; and applicability of NSABB recommendations to federal agencies other than HHS.

## Origins of the NSABB

Nonprofit organizations, professional associations, and other interested groups have been active in weighing the need for additional oversight of dual-use biological research.<sup>1</sup> These groups have made a wide range of recommendations, including the development of federal oversight schemes, self-regulation of research activities by scientists, and development of ethical codes.

One prominent effort was by the National Academies, which convened the Committee on Research Standards and Practices to Prevent the Destructive Application of Biotechnology. This committee, chaired by Dr. Gerald Fink of Massachusetts Institute of Technology, met between April 2002 and January 2003. The committee considered ways to minimize threats from biological warfare and bioterrorism without hindering the progress of life sciences research. The

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<sup>1</sup> Dual-use biological research, in this context, is defined as “biological research with legitimate scientific purpose that may be misused to pose a biologic threat to public health and/or national security.” Department of Health and Human Services, *National Science Advisory Board for Biosecurity Charter*, March 4, 2004. See also Department of Health and Human Services, *National Science Advisory Board for Biosecurity Charter — Revised*, March 16, 2006.

Committee's 2004 report, *Biotechnology Research in an Age of Terrorism*, is usually referred to as the Fink Report.<sup>2</sup>

The Fink Report contained seven recommendations to ensure responsible oversight for biotechnology research with potential bioterrorism applications. One of these recommendations was to create a National Science Advisory Board for Biodefense within the Department of Health and Human Services to provide advice, guidance, and leadership for a system of review and oversight of experiments of concern.<sup>3</sup>

## Formation of the NSABB

Following the publication of the Fink Report, the Secretary of the Department of Health and Human Services (HHS) created the National Science Advisory Board for Biosecurity and chartered it in March 2004. The NSABB responsibilities include many of the recommendations suggested by the National Academies. The NSABB charter outlines twelve responsibilities:<sup>4</sup>

- Develop criteria for identifying dual-use research and research results.
- Develop guidelines for the oversight of dual-use research, including guidelines for the risk/benefit analysis of dual-use biological research and research results.
- Provide recommendations on the development of a code of conduct for scientists and laboratory workers that can be adopted by professional organizations and institutions engaged in the performance of life science research.
- Provide recommendations on the development of mandatory programs for education and training in biosecurity issues for all scientists and laboratory workers at federally-funded institutions.
- Advise on national policies regarding the conduct of dual-use biological research. This includes strategies for addressing national security concerns while at the same time fostering continued rapid

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<sup>2</sup> National Research Council, *Biotechnology Research in an Age of Terrorism*, National Academies Press, 2004.

<sup>3</sup> Other recommendations from the Fink Report include educating the scientific community on dual-use aspects of biological research, augmenting the existing recombinant DNA oversight system to provide review of experiments of concern, relying on self-governance by scientists and publishers to control publication of dual-use research results, relying on current legislation and regulation for protection of biological materials, developing new channels of communication between life scientists and the national security and law enforcement communities, and creating an international biosecurity forum to harmonize measures across national boundaries. National Research Council, *Biotechnology Research in an Age of Terrorism*, National Academies Press, 2004.

<sup>4</sup> Department of Health and Human Services, *National Science Advisory Board for Biosecurity Charter*, March 4, 2004. General information regarding the NSABB can be found online at [<http://www.biosecurityboard.gov/>].

progress in public health research and food and agriculture research (e.g., new diagnostics, treatments, vaccines and other prophylactic measures, and detection methods).

- Advise on national policies governing publication, public communication, and dissemination of dual-use research methodologies and results.
- 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).<sup>5</sup>
- 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.
- Recommend strategies for coordinated international oversight of dual-use biological research.
- Address any other issues as directed by the Secretary of HHS.

The charter calls for both voting and non-voting NSABB members. The HHS Secretary, in consultation with the heads of other federal departments and agencies conducting life sciences research, appoints up to 25 voting members. Among these appointees are experts in the biological sciences, law, security, and other related areas. Voting members may not be federal government employees. Non-voting members are *ex officio* representatives of the Executive Office of the President, Department of Health and Human Services, Department of Energy, Department of Homeland Security, Department of Veterans Affairs, Department of Defense, Department of the Interior, Environmental Protection Agency, Department of Agriculture, National Science Foundation, Department of Justice, Department of State, Department of Commerce, Intelligence Community, National Aeronautics and Space Administration, and other agencies as appropriate. Thus, agencies and departments that conduct or support life sciences research are represented during deliberations of the NSABB.

To meet the charge laid out by its charter, the NSABB has established working groups, focused on development of criteria to identify dual-use research, communication of results of dual-use research, development of a life sciences code

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<sup>5</sup> Institutional Biosafety Committees provide local oversight of recombinant DNA research. They are established on the institutional level and are generally comprised of laboratory technical staff and persons with expertise in recombinant DNA technology, biological safety, and institutional policies. For more information on Institutional Biosafety Committees, see online at [<http://www4.od.nih.gov/oba/IBC/IBCindexp.htm>].

of conduct, development of international perspectives on dual-use research, and guidance on chemical synthesis of bacterial and viral genomes.<sup>6</sup> Subsequent to the formation of these initial working groups, an additional working group on development of an oversight framework was established.<sup>7</sup> These working groups discuss alternatives and develop proposals to be presented to the whole NSABB. The working groups have provided draft recommendations or reports to the NSABB.<sup>8</sup>

## Activities of the NSABB

The NSABB met for the first time on June 30 — July 1, 2005. Subsequent meetings of the full board occur on a quarterly basis, while individual working groups meet in closed session according to need. Each full board meeting contains reports from the various working groups on progress made towards meeting their chartered goals.

During its meetings, the NSABB has discussed different types of ethical codes, ways of identifying dual-use research, publication and dissemination tools, and mechanisms to assess research in emerging technology areas. Its working groups outlined and scoped activities related to their tasks and missions and generated draft reports and recommendations. The NSABB has also provided advice to the HHS Secretary regarding dual-use research and reviewed the publication of scientific research results related to the genome of the 1918 influenza virus.

In October 2005, a research article was published in *Science* magazine describing the reconstruction of an influenza virus bearing all of the identified gene sequences of the 1918 influenza virus.<sup>9</sup> The genetic sequences of the final three gene segments of the virus were published concurrently in the magazine *Nature*.<sup>10</sup> The decision to perform and publish these experiments was met with some public concern.<sup>11</sup> Prior to the publication of the research article, the HHS Secretary

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<sup>6</sup> Janet Coleman, “NSABB Working Groups Will Begin Discussions Soon,” *Research Policy ALERT*, July 5, 2005.

<sup>7</sup> This working group was established in July 2006. See National Science Advisory Board for Biosecurity, *Meeting Minutes*, July 13, 2006.

<sup>8</sup> Draft recommendations from the working groups can be found online at [<http://www.biosecurityboard.gov/>].

<sup>9</sup> Terrence M. Tumpey, Christopher F. Basler, Patricia V. Aguilar, et al., “Characterization of the Reconstructed 1918 Spanish Influenza Virus,” *Science*, vol. 310, October 7, 2005, pp. 77-80.

<sup>10</sup> Jeffery K. Taubenberger, Ann H. Reid, Raina M. Lourens, et al., “Characterization of the 1918 Influenza Virus Polymerase Genes,” *Nature*, vol. 437, October 6, 2005, pp. 889-893.

<sup>11</sup> For example, see Sabin Russell, “Deadliest Flu Bug Given New Life in U.S. Laboratory; Some Applaud Scientific Feat, but Others Decry Move as Reckless,” *San Francisco Chronicle*, October 6, 2005, p. A1.

consulted with the NSABB for guidance.<sup>12</sup> The NSABB met and unanimously agreed that the scientific benefit of the information outweighed the potential risk of misuse. It recommended that publication of the article be accompanied by an editorial discussing the potential biosecurity implications of the research.<sup>13</sup> This appears to be the first consultation by the HHS Secretary of the NSABB regarding the publication of a research result prior to its publication.

The NSABB working groups have presented draft reports and recommendations that have been adopted by the NSABB as a whole. These reports and recommendations include draft criteria for identifying dual-use research of concern, tools for the responsible communication of dual-use research, considerations for a dual-use research code of conduct, consideration of biosecurity concerns related to the synthesis of select agents, and a draft outline of an oversight framework.

While these draft reports and recommendations have been adopted by the board as a whole, they have not yet been formalized and submitted to HHS for consideration. Before the NSABB recommendations will be adopted by HHS, they will be submitted for public comment, possibly through notice in the *Federal Register*; and those comments weighed and addressed. Following such a process, HHS will consider whether and how to incorporate the recommendations into official policies or procedures.

## **Stakeholder Activities Related to NSABB Mandates**

Both before and since the establishment of the NSABB, many stakeholders participated in debates over the mechanisms for controlling or overseeing the products of dual-use research. In general, no consensus has been reached on the best approach. This section will briefly describe some of the stakeholder activities undertaken in areas related to the NSABB's mandate.

### **Investigating Pathogen Genomes**

Pathogen genomes are considered critical to understanding pathogen characteristics, such as virulence and antibiotic resistance. Genomic information could be key to developing effective countermeasures to those pathogens, as well as providing insight into basic science broadly applicable to other bacteria and viruses. On the other hand, it may be that such genomic information could also be put to malicious use to enhance the dangerous aspects of a particular pathogen or induce virulence in a nonvirulent species.<sup>14</sup>

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<sup>12</sup> Centers for Disease Control and Prevention, "Researchers Reconstruct 1918 Pandemic Influenza Virus; Effort Designed to Advance Preparedness," *Press Release*, October 5, 2005.

<sup>13</sup> This editorial was published in the same issue. Philip A. Sharp, "1918 Flu and Responsible Science," *Science*, vol. 310, October 7, 2005, p. 17.

<sup>14</sup> Claire M. Fraser and Malcolm R. Dando, "Genomics and Future Biological Weapons: the (continued...)"



In part because of the dual-use nature of pathogen genomes and continued federal research efforts towards identifying these genomes, the National Academies convened a panel and issued a report in 2004 addressing pathogen genome data restrictions.<sup>15</sup> The panel recommended that information on pathogen genomes not be restricted, but instead that scientists be allowed open access to genomic information.

The related area of synthetic genomics, by which existing or novel pathogens might be constructed from their constituent nucleic acids, has also drawn attention from the research and policy community. While generally viewed as a scientific field still under development, community members, scientists, and policy experts have all advocated a proactive stance with respect to ensuring safety, security, and scientific productivity.<sup>16</sup> Consensus regarding the manner that these goals can be achieved has not yet been reached.

## Defining Dual-Use Research

Defining dual-use research has been an area of much discussion, and several competing approaches have been put forth. One is based on identifying particular pathogens of concern. For example, some institutions identify dual-use research as research involving specific pathogens, often relying on the select agent list.<sup>17</sup> An alternate approach is to identify extrinsic factors that raise particular concern. Some biosecurity experts focus on whether such research could have immediate weapons implications, rather than focusing on specific pathogens.<sup>18</sup> Others suggest the use of uniform criteria for comparison of pathogen research to identify those experiments of concern.<sup>19</sup> The National Academies have suggested seven classes of experiments

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<sup>14</sup> (...continued)

Need for Preventive Action by the Biomedical Community,” *Nature Genetics*, vol. 29, 2001, p. 253.

<sup>15</sup> National Research Council, *Seeking Security: Pathogens, Open Access, and Genome Databases*, National Academies Press, 2004.

<sup>16</sup> For example, see ETC Group, *Extreme Genetic Engineering: An Introduction to Synthetic Biology*, January 2007; Stephen M. Maurer, Keith V. Lucas, and Starr Terrell, *From Understanding to Action: Community-Based Options for Improving Safety and Security in Synthetic Biology — Draft 1.1*, April 15, 2006; and Jonathan B. Tucker and Raymond A. Zilinskas, “The Promise and Perils of Synthetic Biology,” *The New Atlantis*, Spring, 2006.

<sup>17</sup> Select agents are those biological agents or toxins having the potential to pose a severe threat to public health and safety. Select agents are defined by regulation. See 42 CFR 73.

<sup>18</sup> Gerald L. Epstein, “Controlling Biological Warfare Threats: Resolving Potential Tensions Among the Research Community, Industry, and the National Security Community,” *Critical Reviews in Microbiology*, vol. 27, 2001, p. 321.

<sup>19</sup> For example, Steinbruner *et al.* have suggested that a conceptual framework using three criteria, transmissibility, infectivity, and pathogenicity, be used to identify the intrinsic danger of research activities. John Steinbruner, Elisa D. Harris, Nancy Gallagher, and Stacy Okutani, *Controlling Dangerous Pathogens: A Prototype Protective Oversight System*, Center for International and Security Studies at Maryland, University of Maryland, (continued...)

that might warrant extra discussion or review.<sup>20</sup> A joint approach might be possible, identifying specific pathogens but also establishing other criteria that could be applied more generally.

## Establishing a Code of Conduct

Professional groups in the life sciences have adopted or are exploring the potential for codes of conduct.<sup>21</sup> For instance, in 2005, the American Society for Microbiology revised and approved its code of ethics, which requires its members to report misuses of microbiology information to “appropriate authorities.”<sup>22</sup> The American Medical Association guidelines require physician researchers to “lend their expertise to the development of safeguards and oversight mechanisms.”<sup>23</sup>

Development of such codes has been an international, ongoing endeavor. For example, in 2005 the Meeting of States Parties to the Biological Weapons Convention held discussions on methods of developing and establishing ethical codes for scientists. The Interacademy Panel on International Issues, an organization of the national science academies, has identified key components to be considered in a code of conduct or ethics.<sup>24</sup> Other organizations have attempted to facilitate best practices development, including ethical codes, to increase biosecurity.

## Policy Concerns Relating to the NSABB

The establishment of the NSABB has raised several issues of potential congressional interest. These include the mechanism and appropriateness of NSABB review of scientific research, the scope of NSABB recommendations with respect to publication of scientific research, the domestic and international adoption of practices or codes developed by the NSABB, the implementation of NSABB guidelines at the

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<sup>19</sup> (...continued)  
December 2005.

<sup>20</sup> The seven classes of experiments include those that would demonstrate how to render a vaccine ineffective, would confer resistance to therapeutically useful antibiotics or antiviral agents, would enhance the virulence of a pathogen or render a nonpathogen virulent, would increase transmissibility of a pathogen, would alter the host range of a pathogen, would enable the evasion of diagnostic/detection modalities, or would enable the weaponization of a biological agent or toxin. National Research Council, *Biotechnology Research in an Age of Terrorism*, National Academies Press, 2004.

<sup>21</sup> For a representative list of codes of ethics developed by professional groups, see online at [[http://www.biosecuritycodes.org/codes\\_archive.htm](http://www.biosecuritycodes.org/codes_archive.htm)].

<sup>22</sup> American Society for Microbiology, *Code of Ethics*, 2005, available online at [<http://www.asm.org/ASM/files/ccLibraryFiles/FILENAME/000000001596/ASMCcodeofEthics05.pdf>].

<sup>23</sup> American Medical Association, *Guidelines to Prevent Malevolent Use of Biomedical Research*, June 2004.

<sup>24</sup> Interacademy Panel on International Issues, *Statement on Biosecurity*, December 1, 2005.

local level, and applicability of NSABB recommendations to federal agencies other than HHS.

## **Oversight of Federally Funded Dual-Use Biological Research**

The NSABB draft criteria for identifying dual-use research, guidelines for the local oversight of dual-use research, and advice on policies governing local review and approval processes are contentious among stakeholders. The scope and applicability of these definitions and guidelines are balanced against the practicality of oversight activities. A trade-off between the scope of research activities falling under the dual-use definition and the degree of scrutiny performed by local oversight may exist.

If dual-use research is broadly defined, so as to capture the maximum number of potentially dangerous research activities, a significant burden may be placed on local oversight when attempting to apply NSABB-recommended policies and guidelines. To minimize delaying research activities, local oversight on the conduct of each research proposal may become cursory in order to process the large proposal volume.

Conversely, if dual-use research is narrowly defined, so as to limit potential adverse effects from overseeing a large volume of research, contentious dual-use research may not be captured under this definition. This might lead to the conduct of research later deemed inappropriate.

The draft framework report attempts to bridge this gap by using a relatively broad definition, but placing the dual-use assessment at the local level, on the researcher performing the dual-use research and on the research institution. The NSABB draft report would have the federal government develop guidelines, based on the NSABB-recommended criteria, that would be used to frame dual-use research of concern. Using tools recommended by the NSABB, local entities may assess the dual-use implications of research results and judge whether further review is needed.

By taking this approach, the NSABB spreads an administrative burden, reviewing the research activities, among many persons, rather than creating a general burden localized at a particular agency. Thus, the potential for increased costs and delays in the review process are limited, as the strain on federal resources is minimized. Critics, on the other hand, doubt the efficacy of such a local review. They assert that researchers, and to some extent the research institutions, are vested in the success of their research programs. As such, they are less likely to perceive potential misuse or dangers of their research activities and may thus err on the side of permissiveness.

Local review of dual-use research under a guideline paradigm, rather than a regulatory paradigm, has been criticized by arms control advocates. These advocates state that compliance with existing guidelines has not been uniform, even among those entities receiving federal funds. Absent clear penalties from violating these guidelines, it is not apparent how successful voluntary local review will be in

capturing all dual-use research of concern. On the other hand, a regulatory framework may be considered unwieldy and burdensome to the research enterprise.<sup>25</sup>

The NSABB draft framework suggests several layers in the local review of dual-use research activities: to determine if dual-use research is of concern, to determine the risk it may pose, and to determine what risk management techniques might best mitigate this risk. As such, publication and dissemination of dual-use research of concern may be appropriate, when such publication and dissemination best manages the risk of such research results.<sup>26</sup>

The need for federal agencies to address and coordinate oversight of intramural, potentially dual-use research has been highlighted by reports from agency Inspectors General.<sup>27</sup> Some federal agencies taking part in the NSABB are developing interim guidelines to identify dual-use intramural research. Other agencies await output from the NSABB before attempting such analysis. Absent a clear recommendation from the NSABB regarding dual-use research, federal agencies will likely continue to establish independent, interim guidelines for their own use. Proliferation of different guidelines and standards between funding agencies may complicate future compliance with a uniform standard recommended by the NSABB.

## Mechanism and Appropriateness of NSABB Review

The use of the NSABB in vetting the publication of the 1918 flu research paper has been identified by some as a successful exercise of the NSABB advisory mission. The HHS Secretary sought input from the NSABB regarding the proposed publication of research results that have dual-use aspects. Once that recommendation was received, it was acted upon, and the research paper was published with an accompanying editorial.

Nevertheless, the timing and mechanism of this process have been questioned. The editor-in-chief of *Science*, Dr. Donald Kennedy, described the involvement of the NSABB as an “11<sup>th</sup>-hour intervention from the [S]ecretary’s office.”<sup>28</sup> He wrote that prior to the intercession of the HHS Secretary’s office, both the Director of the Centers for Disease Control and Prevention and the Director of the National Institute of Allergy and Infectious Disease had reviewed the research article before the

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<sup>25</sup> For example, the select agent rule is considered by many scientists to be burdensome and restrictive to research activities. See Sandia National Laboratories, *International Biosecurity Symposium: Securing High Consequence Pathogens and Toxins — Symposium Summary*, SAND2004-2109, June 2004.

<sup>26</sup> Such an example might be the case where the public health benefits greatly outweigh the risk of enhanced weapon potential. See the earlier discussion of the 1918 flu publication.

<sup>27</sup> Office of Inspector General, USDA, *Audit Report — Adequacy of Controls to Prevent the Improper Transfer of Sensitive Technology*, Report No. 02601-1-Ch, September 2005, and Office of Inspector General, Department of Energy, *Inspection Report — Coordination of Biological Select Agent Activities at Department of Energy Facilities*, DOE/IG-0695, July 2005.

<sup>28</sup> Donald Kennedy, “Better Never Than Late,” *Science*, vol. 310, October 14, 2005, p. 195.

NSABB was consulted, and both felt the public health benefits outweighed the public health risks. While the NSABB supported the decision to publish the 1918 flu research article, Dr. Kennedy wrote that even if the NSABB had not approved, he would have published the research article unless it had been classified.

The late inclusion of the NSABB review raises questions regarding the role the board plays in advising policymakers on publication of potentially contentious research results. The editor-in-chief of *Science* argued that the NSABB's role is not to provide advice on specific research papers, but instead to develop broader guiding principles.<sup>29</sup> However, the NSABB's charter explicitly requires the NSABB to

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.<sup>30</sup>

An apparent point of dissension is whether the 1918 flu publication qualifies under the NSABB charter as a specific experiment requiring additional guidance, and, if so, whether such review extends to publication. Depending on what threshold is used for such a determination, the NSABB may be placed in the position of providing additional guidance on many submitted publications or relatively few.

A further concern relates to the mechanism by which the federal government is informed of potential dual-use articles. If such notification occurs late in the publication process, then the business of publishing could be disrupted. It may be argued that in the case of the 1918 flu publication, since several of the authors were federal employees, the government should have been self-informed and involved the NSABB earlier so as to avoid possible private sector disruption. When federally funded research is performed outside the federal government, however, it seems less likely that the government will be informed before the results are submitted for publication. An area of potential congressional interest may be how federal research agencies are informed of federally funded research results before their publication and what mechanisms may exist to assess any dual-use nature.

Finally, the advice of the NSABB in the case of the 1918 flu publication was unanimous; all NSABB members recommended publication augmented by an accompanying editorial. In future cases, the NSABB voting members may not all agree. In that case, what is the appropriate mechanism and threshold for action? Should the advice given by the NSABB be based on a consensus approach, majority vote, or some other mechanism?

## **Restricting Publication**

Another concern is whether the federal government, or by extension the NSABB, which advises policymakers, has the authority to prevent the publication of

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<sup>29</sup> Donald Kennedy, *ibid.*

<sup>30</sup> Department of Health and Human Services, *National Science Advisory Board for Biosecurity Charter*, March 4, 2004.

federally funded life sciences research based on its potential dual-use implications, and if so, whether this power extends to non-federally funded research. There is at least one example of the publication of non-federally funded research raising dual-use concerns. Prior to the inaugural meeting of the NSABB, a research article describing the potential impact of contaminating the milk supply with botulinum toxin was to be published in *Proceedings of the National Academy of Sciences*.<sup>31</sup> The article's publication was delayed, but eventually published over the objections of HHS.<sup>32</sup> Unlike the 1918 flu publication, the authors of this article were not federal employees, and the research was not funded by the federal government.

Congress may be asked to provide oversight of government activities related to publication of dual-use research results to determine what statutory authorities, if any, may need to be enacted to meet homeland security requirements.

## International Cooperation

One of the recommendations of the Fink Report was to develop an international forum to develop and harmonize international approaches towards biosecurity issues. While the NSABB has been charged with developing policies for publication, communication, and dissemination of dual-use research results, it is a U.S. government body. The extent to which these policies will be adopted by or harmonized with other nations is yet to be determined.

The publication of the 1918 flu research may again serve as a case study for this potential difficulty. The article on reconstructing the influenza virus was published in *Science*, a U.S. journal, but the genetic sequence was published in *Nature*, a U.K. journal. Even if the NSABB had recommended that the research not be published and *Science* had followed this recommendation, the companion article might still have been published in *Nature*.

The extent to which the NSABB incorporates other countries' norms into its guidance may influence harmonization of norms with other nations. Development of guidance that is not adopted by other nations may cause U.S. journals to be at a competitive disadvantage with respect to foreign journals because of potential restrictions on publication. If publication in a foreign journal bypasses NSABB guidance procedures, the increase in biosecurity expected from the NSABB guidelines may not be realized.

On the other hand, adoption of other nations' norms and guidance in an attempt to maximize efforts at harmonization may have drawbacks. If harmonization makes U.S. policy less stringent, it may make the NSABB guidance less effective. Alternately, if other nations' have more stringent norms and guidances,

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<sup>31</sup> Lawrence M. Wein and Yifan Liu, "Analyzing a Bioterror Attack on the Food Supply: the Case of Botulinum Toxin in Milk," *Proceedings of the National Academy of Sciences of the United States of America*, vol. 102, July 12, 2005, p. 9984.

<sup>32</sup> J. Kaiser, "ScienceScope," *Science*, vol. 309, July 1, 2005, p. 31. Alison McCook, "PNAS Publishes Bioterror Paper, After All," *The Scientist*, June 29, 2005.

harmonization might lead to guidance that overly inhibits research efforts or research publication.

## Local Implementation of NSABB Guidelines

The advice and guidance developed and promulgated by the NSABB may be acted upon at the institutional level by Institutional Biosafety Committees (IBCs). IBCs were established under the *NIH Guidelines for Research Involving Recombinant DNA Molecules* to provide local review and oversight research with recombinant DNA.<sup>33</sup> The effectiveness of such oversight may vary among institutions, especially as IBCs are typically staffed by volunteers. While some institutions have expanded the oversight role of the IBC, this expansion of oversight is done on the institutional, rather than the federal, level.

Critics have claimed that the IBC system is highly flawed and in many cases does not provide rigorous oversight of current research activities.<sup>34</sup> In addition, no clear enforcement mechanism has been enunciated for the event that an IBC concludes that research should not be conducted or disseminated on biosecurity grounds, but the researcher disagrees. This raises questions regarding the actual impact of NSABB guidance. Currently, potential penalties for violating recombinant DNA guidelines, which are implemented by IBCs, include possible revocation of federal funding.<sup>35</sup>

An alternate mechanism for implementing NSABB guidelines might be through consulting researchers at NIH Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases Research.<sup>36</sup> Advocates of such a plan suggest that scientists at these Regional Centers of Excellence might draw on a large pool of participating institutions and institutional knowledge and may consider the broader biodefense implications of specific research experiments. Researchers may resist submitting research plans and results to another, potentially competing, institution, preferring their research to be reviewed either at their own institution or by the federal government.

Another possibility would be to establish another, new institutional review committee to solely address dual-use research concerns. Creating a parallel review committee for dual-use research may remove strain from existing review boards, but tax the resources of individual institution. Many review boards are staffed by persons who volunteer their time and effort. Finding additional appropriately qualified

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<sup>33</sup> *NIH Guidelines for Research Involving Recombinant DNA Molecules* is found online at [[http://www4.od.nih.gov/oba/rac/guidelines\\_02/NIH\\_Gdlnes\\_ink\\_2002z.pdf](http://www4.od.nih.gov/oba/rac/guidelines_02/NIH_Gdlnes_ink_2002z.pdf)].

<sup>34</sup> The Sunshine Project, *Mandate for Failure: The State of Institutional Biosafety Committees in an Age of Biological Weapons Research*, October 2004.

<sup>35</sup> See National Institutes of Health, *NIH Guidelines for Research Involving Recombinant DNA Molecules*, April 2002.

<sup>36</sup> For more information on the Regional Centers of Excellence, RCEs, for Biodefense and Emerging Infectious Diseases Research, see online at [<http://www.rcebiodefense.org>].

individuals to sit on a new review board may prove challenging to smaller institutions.

Since the adequacy of the IBC system has been challenged, it is unclear whether the NSABB will rely upon this system for implementation of its guidelines. The NSABB may recommend an alternate system or a composite system, where decisions by the IBCs are validated by a third party in the case of conflict. The potential cost of any such system has not yet been addressed.

## Ethical Codes of Scientific Conduct

Some researchers have suggested that a uniform code applicable to all life sciences, perhaps similar to the Hippocratic Oath for medical doctors, be developed to raise awareness of scientists' ethical obligations.<sup>37</sup> A federal advisory code of ethics or conduct for life scientists may have limited effect and application. An advisory code not placed in regulation would only apply to federally funded research and exist as a policy statement with respect to the conduct of that research. Sanctions for violating such policies usually are limited to withdrawal of federal financial support and the potential for barring violators from future federal support.

A code of conduct or ethics promulgated by a scientific body or community may reach more scientists, including those not engaged in federally funded research. Therefore, a greater number of scientist might take part, and the overall effectiveness of the code may be greater. The greater the number of scientists participating in such a code, the more likely scientists will be aware of the potential security risks posed by their dual-use research. A code promulgated by a scientific body though would generally lack substantive sanctions, except in those research areas where accreditation by the scientific body is necessary.

Some advocates for the establishment of codes recommend that code implementation be self-directed by the scientific community, rather than by government oversight. Some scientists claim that a code developed by the scientific community is more likely to be adopted and applied than one developed by an external body. They assert that a code developed by scientists through consensus may become incorporated into scientific practice, even if unanimous support is not initially found within the scientific community.<sup>38</sup>

The NSABB's proposal for a code of ethics or conduct for life scientists has drawn some criticism. Some experts question the value of such a code absent formal

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<sup>37</sup> Margaret A. Somerville and Ronald M. Atlas, "Ethics: A Weapon to Counter Bioterrorism," *Science*, Vol. 307, March 25, 2005, pp. 1881-1882.

<sup>38</sup> A similar approach was taken in the development of practices related to recombinant DNA research at the Asilomar conference. The consensus document established at Asilomar lacked unanimous support, but became standard practice among the life scientist community. For an overview of this process see Donald S. Fredrickson's "Asilomar and Recombinant DNA: The End of the Beginning," found in *Biomedical Politics* National Academy Press, 1991, pp. 258-298.



requirements and an enforcement framework to ensure its effectiveness.<sup>39</sup> They posit that developing and implementing ethical codes along with other efforts, such as intelligence activities and export controls, might better prevent misuse of biological information.<sup>40</sup>

Other scientists have challenged the external imposition of a code as restricting the role and independence of the scientific community. Asserting that scientific research is most productive when minimally fettered, these scientists express concern that restrictive codes of conduct will limit research activities. Such limitations may occur through active measures, such as determining a research area to be inappropriate for further research, or through passive measures, such as additional administrative burdens or increased peer pressure with respect to the scope of research activities.<sup>41</sup>

The practical impact of a code of ethics may be somewhat limited should the code be contingent on federal funding, rather than arising through an educational mechanism. For example, state and private universities and federal laboratories, both of which rely on federal funding, would likely implement ethical training if federal funding was contingent on ethics or conduct training. Private sector life science research, for example, that found in pharmaceutical companies, that lack federal research funding would not be required to develop equivalent training. This difference might lead to gaps in adherence of the code of conduct.

Because of the many different types of potential codes, the level of detail developed in any code for dual-use research, whether it from an outside body or from the scientific community, is yet undetermined. Some codes are quite detailed, while other codes are aspirational in nature, stating high-level aims and goals. In developing a code of ethics or conduct, a tension exists between describing overly specific behaviors or activities and stating sufficiently actionable items. A code that is too vague or generally stated may be viewed as unenforceable and lacking effect, while a code that enumerates many prohibited activities may be viewed as overly restrictive and unable to adapt to scientific progress.

## **Applicability to Other Research Fields**

While dual-use activities in the biological sciences have received much attention, other research fields may also yield research results that raise security concerns. Members of the NSABB have been appointed for their ability to advise on biosecurity issues, but not necessarily for their ability to advise on other research areas. One possible issue facing policymakers is the extent to which NSABB advice

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<sup>39</sup> See, for example, Brian Rappert, "Responsibility in the Life Sciences: Assessing the Role of Professional Codes," *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, July 2004, vol. 2, pp.164-174.

<sup>40</sup> Eugene Russo, "Biosecurity Advisory Board Considers Code of Ethics," *Research Policy ALERT*, July 6, 2005.

<sup>41</sup> For an example of research in an areas where ethical concerns have been raised, see CRS Report RL33554, *Stem Cell Research: Ethical Issues*, by Erin D. Williams and Judith A. Johnson.

will be applicable to interdisciplinary research results, where research from other disciplines intersects with life sciences research. For example, mechanical engineering and aerosol science research results that could increase the effectiveness of biological weapons through more effective delivery or dissemination might not be captured in NSABB advice regarding life sciences.

The NSABB, though established by the Secretary of HHS and managed by NIH, appears to be expected to advise and provide guidance to all federal agencies and departments performing life sciences research. As Rajiv Venkayya, Special Assistant to the President for Health and Biodefense, told the NSABB,

[E]very Cabinet secretary is going to be listening to what you have to say and they're going to be taking your recommendations seriously as they decide what to do about experiments that raise biosecurity concerns.<sup>42</sup>

Members of agencies performing life sciences research have been appointed to the NSABB in an *ex officio* capacity, but it is unclear if a more formal mechanism exists for these agencies to request the aid of the NSABB. Whether advice requested by an outside agency must flow through the HHS Secretary's office, or whether another agency can request advice directly from the NSABB, is not described in the NSABB charter.

The ability of other agencies to draw upon the NSABB may relate to how broadly NSABB guidance is applied outside of research funded by HHS. Each agency represented by *ex officio* members has agreed to consider any recommendations developed by the NSABB when establishing oversight for dual-use research. These federal funding agencies may be more inclined to directly use NSABB guidance if they have previously drawn on the advice of the NSABB. Conversely, if it is difficult for agencies other than HHS to use the advisory capability of the NSABB, other federal funding agencies may choose to independently generate dual-use guidelines for research results. Such proliferation of dual-use guidelines might complicate oversight and decrease compliance.

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<sup>42</sup> Andrew J. Hawkins, "National Biosecurity Advisory Board Members Stress Balance, International Implications," *Research Policy ALERT*, July 1, 2005.