

AAAS American Association for the Advancement of Science
AAMC Association of American Medical Colleges
AAU Association of American Universities
COGR Council on Governmental Relations
FASEB Federation of American Societies for Experimental Biology
NASULGC National Association of State Universities and Land-Grant Colleges

July 15, 2008

Dennis L. Kasper, M.D.
Chair, National Science Advisory Board for Biosecurity
Director of the Channing Laboratory
Department of Medicine
Harvard Medical School
1801 Longwood Avenue
Boston, MA 02115

Dear Dr. Kasper:

The undersigned organizations are grateful to the NSABB and its staff for its exceptional and thoughtful leadership on the question of dual-use biological research and dual use research of concern. These organizations include: the Federation of American Societies for Experimental Biology (FASEB); the American Association for the Advancement of Science (AAAS); the Association of American Universities (AAU); the Association of American Medical Colleges (AAMC); Council on Governmental Relations, (COGR); and the National Association of State Universities and Land-Grant Colleges (NASULGC). All of our organizations reaffirm the commitment to safeguarding the nation's security while supporting the open inquiry and the conduct of biological research upon which future innovation in medicine, health, and agriculture depends.

With respect to the NSABB Draft Oversight Framework Development released for Federal comment in 2007, we submit the following statement that recapitulates several comments made by our organizations individually, following transmission of the draft to the federal government. In particular, we endorse FASEB's earlier comments, which were developed through the Federation's Science Policy Committee in close cooperation with the investigator community.

Communication of dual use research: Our organizations agree with the NSABB's principles for communication of dual use research (pages 24-25 of the draft Framework), which are balanced and thoughtfully articulated to encompass the needs of science and security. We further agree, as FASEB noted earlier, with the Board's statement that "any restriction on scientific communication should be the rare exception rather than the rule." The tools developed by NSABB and incorporated in the Framework will be of great use to publishers of scholarly journals and to scientists themselves.

Education and awareness: Our organizations see a strong need for NSABB and federal agencies to do far greater outreach to the scientific community *before* implementing any oversight system. The Board's commendable outreach activities to date need to be dramatically expanded, as suggested on page 30 of the draft Framework document. Our own surveys of our respective memberships indicate that awareness of dual-use issues is particularly high among investigators closest to particular kinds of research, such as that involving select agents or requiring specialized facilities, but falls off dramatically in the scientific community broadly. Working with scientific societies and universities to raise awareness within the scientific community about the work of the NSABB and the issue of dual use research will be critical to successful adoption of any effective regulatory or self-regulatory scheme. Moreover, all outreach to the scientific community should be mindful of the perception by the lay public. Any communication done in the name of outreach and education should follow the principles of responsible communication outlined in the NSABB proposal. Furthermore, we agree that the research community bears and accepts the responsibility to be aware of the risks associated with potential misuse of biomedical research, and to conduct research in accordance with the interests of the public good.

Institutional Responsibility, Liability and Regulatory Burden: The draft Framework document enumerates more than a dozen general categories of institutional responsibilities, such as establishing and implementing internal policies and practices for oversight of Dual Use Research of Concern (DURC) "that minimize any negative impact on the conduct of life sciences research," establishing mechanisms for assisting investigators in complying with dual use research policies, providing "appropriate" education on dual use research, establishing internal mechanisms for appeal, etc. Our central concern with the document is that it does not provide institutional officials with any direction for meeting such responsibilities. More significantly, the draft Framework recommends specific sanctions for "noncompliance" without providing commensurate criteria or framework by which institutional officials can understand how to meet compliance or even what constitutes compliance.

Because the NSABB document is unclear regarding liability issues surrounding dual use research, investigators or institutions may choose to forgo certain research rather than risk liability. Alternatively, they may over-interpret the potential for misuse, thus over-report DURC and create a tremendous burden on institutions in addition to delaying important research. In this respect, the current Framework could have a chilling effect on research.

Our organizations are concerned about the feasibility of implementing the oversight system, as proposed, as well as the potential burden it could place on both investigators and institutions. In particular, the criteria for identifying DURC is vulnerable to subjective interpretation and could result in a vast underreporting or over-reporting of such research. Either scenario diminishes the goal of increasing security.

Review of Dual Use Research: The greatest potential problem with oversight of dual use research is the ambiguity inherent in assessing whether or not it is of concern and therefore in need of further review. Although the NSABB has modeled its proposed oversight system on existing systems that work fairly well, such as the Institutional Animal Care and Use Committees (IACUCs), Institutional Review Boards (IRBs), and the Recombinant DNA Advisory Committee (RAC), there is a crucial difference between these mechanisms and the proposal for review of dual use research: identifying the need for review. A researcher is either using animal models, human subjects or recombinant DNA, therefore triggering the need for review, or he/she is not,

precluding the need for further review. This is in contrast to dual use research, in which the need for review is subject to a great deal of interpretation. This uncertainty calls into question the feasibility of an effective oversight system, as well as raising serious questions relating to liability and burden on institutions and investigators.

Control of Information: The draft NSABB Framework could appear to promote a federal requirement for control of information that is retroactively deemed sensitive to security. Such retrospective determination of the sensitivity of research programs or findings has been from the outset at the core of the concerns of the academic research community, and the draft language thus raises many troubling implications for policy that we believe can be better addressed simply through revisions to the framework.

We applaud the Administration's recent reaffirmation of National Security Decision Directive 189 (NSDD 189), which sets forth classification as the *unique* mechanism for control of information that is considered vital to national security, and affirms clearly that other products of federally supported fundamental research remain unrestricted.

International Harmonization: Given the nature of today's research enterprise, our organizations believe strongly that in order for any system of oversight for dual use research to be successful, it needs to be adopted internationally. While we support the United States' leadership in this area, we think it is critically important that any effort to regulate dual use research be global in its reach and uniform in its application.

Given the concerns raised by both the higher education and scientific communities regarding the draft NSABB Framework, we strongly encourage the Administration to employ the federal rulemaking process before implementing the recommendations laid-out in the draft Framework.

Thank you for this opportunity to respond to the proposed NSABB Framework.

Sincerely,

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