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President

August 15, 2007

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Chair, National Science Advisory Board for Biosecurity
William Ellery Channing Professor of Medicine and
Professor of Microbiology and Molecular Genetics
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Dear Dr. Kasper:

The Association of American Medical Colleges (AAMC) has closely followed the establishment and deliberations of the National Science Advisory Board on Biosecurity (NSABB) and commends the level of expertise, thoughtfulness, and inclusiveness that characterizes the Board's discussions. The purpose of this letter is to convey our preliminary concerns with the Draft Report of the NSABB Working Group on Oversight Framework Development that was discussed and approved by the Board at its meeting on April 19, 2007.

The AAMC represents all 125 allopathic medical schools in the United States, some 400 teaching hospitals, and 94 academic societies representing more than 109,000 faculty. These institutions perform nearly 60 percent of the extramural research sponsored by the National Institutes of Health. Given that much of experimentation potentially subject to review as "dual use research of concern" (DURC) takes place within our member institutions, the Association has a profound interest in NSABB's recommended oversight framework.

The draft framework document enumerates more than a dozen general categories of institutional responsibilities, e.g., establishing and implementing internal policies and practices for DURC oversight "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 criticism of the document is that it offers *no* framework to guide institutional officials in 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.

This lack of exposition contrasts to the report's commendable elaboration of other aspects of the dual use issue, including a working definition of DURC (drawing from the earlier National Academies' Fink Report) and investigators' responsibilities in understanding and for reporting DURC. Given the lack of discussion or detail about an institutional framework, we are troubled that Federal Agencies reviewing the draft may not understand the need for further elaboration of a vision and system for local oversight, including the mechanisms for training and adaptation of personnel, adjudicating reported instances of DURC, etc. For some agencies, the draft report may create the expectation that there are readily available pathways or procedures for meeting the institutional responsibilities listed in the document; there are not. The final document must include a more detailed discussion of the institutional component before the NSABB moves on to develop an implementation strategy.

The NSABB has already demonstrated a willingness to communicate with institutions for collecting information and expertise on biosecurity topics. We strongly recommend that the NSABB convene one or more focus groups with other institutional officials (several such officials already serve on the Board) to revise the current draft and discuss scenarios for developing the institutional component of the framework. A focus group could also address issues of implementation. For example, question 1 in Appendix 5 focuses on options for adapting Institutional Biosafety Committees (IBCs) to oversight and administration of DURC. The AAMC expects that there would be formidable difficulties in tasking IBCs at many institutions for this role and believes that other alternatives or options must be better defined, if they exist. A simple survey, even if completed by a majority of research organizations, will not provide sufficient information on possible alternatives. The Association has several professional development groups comprised of institutional officials with sufficient experience and appreciation that could be marshalled for constituting these focus groups. Other university associations have similar networks.

Finally, the AAMC fully supports other recent comments of the Federation of American Societies for Experimental Biology (FASEB) and the Council on Government Relations (COGR). FASEB correctly notes that identification of DURC remains a fundamentally subjective and ambiguous judgment, such that regulatory oversight for dual use research is not at all parallel to existing structures for, say, oversight of recombinant-DNA research or research with animal models. There is, after all, little ambiguity about when investigators use recombinant-DNA or animal models, and thus about whether or not this research falls under the appropriate oversight procedures. AAMC, FASEB, and COGR applaud the Administration's earlier reaffirmation of National Security Directive 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. 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.

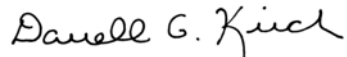
Dr. Dennis L. Kasper

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We urge the NSABB and the NIH to revise the draft oversight framework to elaborate the institutional responsibilities for prescribed oversight, and to consider conducting one or more focus groups with responsible institutional officials to gain informed community input to guide such a revision.

Sincerely,

A handwritten signature in cursive script that reads "Darrell G. Kirch".

Darrell G. Kirch, M.D.

cc: Dr. Amy Patterson, NIH