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Association of Biomolecular Resource Facilities  
The American Society for Bone and Mineral Research  
American Society for Clinical Investigation  
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Teratology Society  
The Endocrine Society  
The American Society of Human Genetics  
Society for Gynecologic Investigation  
Environmental Mutagen Society  
International Society for Computational Biology  
American College of Sports Medicine

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# Federation of American Societies for Experimental Biology

----*Quality Life Through Research*----

August 8, 2007

Dennis L. Kasper, M.D.  
Chair, National Science Advisory Board on Biosecurity  
Director of the Channing Laboratory  
Department of Medicine  
Brigham and Women's Hospital  
Harvard Medical School

Dear Dr. Kasper:

The Federation of American Societies for Experimental Biology (FASEB) appreciates the opportunity to provide feedback to the National Science Advisory Board on Biosecurity (NSABB) on the draft report of the NSABB Working Group on Oversight Framework Development. FASEB comprises 21 scientific societies collectively representing more than 80,000 researchers engaged in basic and clinical biomedical research.

First and foremost, FASEB wishes to applaud NSABB for the thoughtful and thorough effort made in producing this report, as well as the Board's willingness to engage in dialogue with the scientific community. The misuse of biological research could potentially damage the public's support for the biomedical research enterprise, and FASEB strongly supports NSABB's work to maintain public trust and ensure the security of our nation. We could not agree more with your statement: "Information from life sciences research is clearly vital to improving public health, agriculture, and the environment and strengthening our national security and economy<sup>1</sup>." However, it is equally critical to mitigate the threat or perception of threat arising from the misuse of the results or processes of biological research. The NSABB document is an important step in trying to find the balance between science and security.

FASEB would like to make some general comments on this document as well as begin to address the specific questions raised by NSABB in Appendix 5 (specific responses attached). In particular, we have concerns related to: identifying the need for review; liability issues; regulatory burden; and security issues surrounding the control of information. As you well know, the issues surrounding the oversight, conduct and dissemination of dual use research are complex, subject to genuine differences of opinion, and may evolve over time based on the awareness or background of the discussants. Because of this, and because FASEB is attempting to consult as broadly with our societies and their members as possible, we may provide further or more detailed input at a later time as we receive feedback from our members. Nonetheless, we felt it was important to

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<sup>1</sup> NSABB. 2007. Draft report of the NSABB working group on oversight framework development, pp. 3.

begin a dialogue with NSABB on an oversight proposal that would have tremendous impact on the scientific community.

**Identifying the need for review:** 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) or 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. NSABB itself found that there were “significant differences in assessments made by individual NSABB members” and that there were “difficulties inherent in explicitly defining the point at which the magnitude and/or immediacy of the threat of misuse makes dual use research ‘of concern.’”<sup>2</sup> FASEB believes such 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, as detailed below.

**Feasibility, liability and regulatory burden:** Overall, FASEB is concerned about the feasibility of implementing the oversight system, as proposed, as well as the potential burden it could create on both investigators and institutions. In particular, the criteria for identifying dual use research of concern (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. While we agree with the idea that the principal investigator (PI) who is most intimately familiar with his or her own research program might be in the best position to determine if additional review is necessary, there is evidence that self-reporting of ill-defined activities, such as conflicts-of-interest, results in a less than desirable rate of compliance and potential underreporting<sup>3</sup>. Investigators may not see the dual use implication of their research or, when confronted with an experiment that is open to interpretation, may opt to err on the side of research progress rather than regulatory review. As the NSABB proposal concedes “any such evaluation is subjective, and will be influenced by the individual’s knowledge, experience, and judgment.”

Conversely, because the NSABB document is unclear regarding liability issues surrounding dual use research, investigators or institutions may choose to over-interpret the potential for misuse, thus over-reporting DURC and creating a tremendous burden on institutions in addition to delaying important research. One can envision a scenario in which an investigator or institutional official exercises his or her best judgment and finds that a research proposal is not subject to further review at a local or national level *vis-à-vis* its DURC potential. Or, as the NSABB document describes, the research is DURC but does not fall into the provided categories, thus making it difficult for the PI to assess<sup>4</sup>. It is possible that such research may be later identified by DURC by a biosecurity expert or, in a far worse scenario, is misused to cause harm. Who bears liability for this ‘slipping through the cracks’? What are the consequences of unintentionally categorizing research as not of concern and who would bear the brunt of those consequences? What would be the procedure for investigating such an incident or determining potential penalties and can conclusions be drawn given NSABB’s own admission that “[d]etermining the applicability of this [dual use research of concern] criterion is a subjective and sometimes challenging task<sup>5</sup>”? If institutions believe that they or their investigators are open to potential criminal or other penalties, they will likely adopt policies that will cause a far greater proportion of their research portfolios to be reviewed than is necessary.

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<sup>2</sup> NSABB. 2007. Draft report of the NSABB working group on oversight framework development, pp. 22.

<sup>3</sup> National Institutes of Health. 2007. Proactive compliance site visits FY2000-2004: A compendium of findings and observations. [http://grants1.nih.gov/grants/compliance/compendium\\_2002.htm#fcoi](http://grants1.nih.gov/grants/compliance/compendium_2002.htm#fcoi)

<sup>4</sup> NSABB. 2007. Draft report of the NSABB working group on oversight framework development, pp. 17

<sup>5</sup> *Ibid*

**Timing of identification and review:** As NSABB has stated, and previous cases of dual use research of concern have shown, research can be identified as DURC at many points during the research process. This again calls into question the feasibility of the review system. While PI's might be able to review research at the proposal stage and prior to publication, or at the time of their yearly attestations, to provide meaningful oversight and security, it would really be necessary to provide review at nearly every stage of the process, an untenable solution. One can imagine a scenario in which a graduate student or postdoctoral fellow performs an experiment that results in an unexpected result which constitutes DURC. Even if the best case scenario is assumed, in which the educated, aware trainee brings this result to the attention of his/her PI, what happens next? Is the trainee's research on hold until a regional or local review body next meets? Such a requirement could have severe career consequences on a young scientist. And while FASEB fully supports the NSABB's guidance, in principle, regarding the responsible communication of research, such a scenario would make retroactive control of such information very difficult. Open records laws in some states would make such data, if generated at a publicly funded institution, potentially subject to access by the public. Thus a formal review could increase risk of dissemination, rather than prevent it.

**Consistency of guidelines and interpretation:** We appreciate NSABB's reluctance to provide detailed guidance to federal agencies about developing guidelines to oversee dual use research. However, given the number of agencies represented on NSABB, as well as NSABB's recommendation that "the U.S. government consider the need to apply dual use research oversight measures beyond what is usually thought of as the traditional life sciences disciplines<sup>6</sup>," FASEB is greatly concerned that this lack of detail will result in differing interpretations and resultant guidelines from the federal agencies. While it is our strong hope that the agencies participating in NSABB will coordinate development of oversight mechanisms, and that such consensus will be adopted by other relevant agencies, previous experience with science and security related issues suggests this is unlikely to occur and compliance with a myriad of regulations from various agencies will be tremendously difficult for both researchers and institutions.

**Mandatory education and awareness:** FASEB agrees with NSABB that researchers have a professional responsibility to be cognizant of dual use research issues and should be aware of how to responsibly and ethically conduct and disseminate the results of dual use research. While we are supportive of raising awareness in the scientific community about dual use research issues, we do not believe the federal government should invest time or resources in developing educational materials. Such materials already exist and FASEB would recommend that such resources, including the case-study based education modules developed by the Federation of American Scientists<sup>7</sup> and the Southeast Regional Center for Excellence for Emerging Infections and Biodefense<sup>8</sup>, be considered for adoption by the federal government. FASEB would also suggest that this material be integrated into existent institutional scientific ethics or responsible conduct of science courses.

Moreover, we strongly feel there is a great need for NSABB or the federal agencies to do far greater outreach to the scientific community before implementing any oversight system. FASEB is greatly appreciative of members of NSABB's willingness to participate in scientific meetings or policy fora, as well as of the staff of the Office of Biotechnology Assessment's efforts to exhibit at such meetings. Such activities need to be dramatically expanded, as suggested on page 30 of the draft document. The broader biomedical research community, which may have limited awareness biosecurity issues, may perceive the proposed oversight system as one of censorship or government interference with science. Working with scientific societies and universities to raise awareness of the scientific community about the work of the NSABB and the issue of dual use research will be critical to successful adoption of any regulatory schema. In addition, FASEB thinks it is important that any such outreach activities be done with sensitivity towards the members of the public, the non-scientific audience, who may be in attendance. As

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<sup>6</sup> NSABB. 2007. Draft report of the NSABB working group on oversight framework development, pp. 12.

<sup>7</sup> Federation of American Scientists. 2007. Case studies in dual use biological research. <http://www.fas.org/biosecurity/education/dualuse/>

<sup>8</sup> Southeastern Regional Center of Excellence for Emerging Infections and Biodefense. The Dual Use Dilemma in Biological Research. [http://www.serceb.org/modules/serceb\\_cores/index.php?id=3](http://www.serceb.org/modules/serceb_cores/index.php?id=3)

NSABB itself states, there is great risk for “public misunderstanding of and concerns about dual use research<sup>9</sup>” and any communication done in the name of outreach and education should follow the principles of responsible communication outlined in the NSABB proposal.

**Responsible communication of dual use research:** FASEB fully endorses NSABB’s view of communicating research responsibly, “in a manner that addresses both security concerns and the need for open sharing of research results and technologies so that the research can be validated and used for further research.<sup>10</sup>” The articulated principles are balanced and thoughtfully articulated to encompass the needs of science and security and we wholeheartedly agree that “any restriction on scientific communication should be the rare exception rather than the rule.” We feel it is important to reemphasize that scientific societies and the journals which they publish have long been at the forefront of establishing policies for ethical review of research publications, from the use of animal models to human subjects, and this is certainly the case for dual use research. FASEB believes that the tools developed by NSABB will be of great use to publishers of scholarly journals and to scientists themselves. However, we have also found, in consulting with our membership, that this is the area which arouses the greatest suspicion in the scientific community. Although it is clear upon reviewing the NSABB materials that the goal is not one of censorship or restriction, there is great fear that such problems may arise in the future. FASEB strongly urges NSABB to increase its outreach to both the scientific and publishing communities, as well as packaging the communication section of its draft report in a more concise manner. One suggestion would be to open such a document with the principles for responsible communication, which will resonate with the scientific community, rather than immediately introducing tools, the use of which might be misperceived by the reader.

**Control of information:** FASEB has long supported the reaffirmation of National Security Decision Directive 189 which states, “It is the policy of this Administration that, to the maximum extent possible, the products of fundamental research remain unrestricted. It is also the policy of this Administration that, where national security requires control, the mechanism for control of information generated during federally funded fundamental research in science, technology and engineering at colleges, universities and laboratories is classification....” As detailed in points above and below, FASEB has grave misgivings that the proposed oversight and communications guidelines produced by NSABB could result in products, procedures or communications that could be interpreted by federal agencies or individuals as being security risks that need to be controlled outside of the federal classification system. The scientific and security communities have struggled, in a number of venues, with the concept of “sensitive but unclassified” information. FASEB strongly believes that fundamental research thrives in an environment of free exchange of ideas, spontaneous changes of research direction, and open collaboration among colleagues in different laboratories or disciplines. While we suspect NSABB will agree that the research being evaluated, or even having been identified, for DURC potential should not be classified, many questions are raised by a process that highlights research of security concern and then attempts to retroactively control information related to it. As an example, which is mentioned in further detail in our response to Appendix 5, if an IBC creates a form based on NSABB’s “Points to Consider” (Appendix 1), in order to guide their decision making process, and then, using this form, identifies research that may merit discontinuation or restrictions on publication, what happens to that form? Or the proceedings of the meeting? Whose responsibility is it to ensure its security: the IBC, the Biosafety Officer, the institution, the federal government? Until these questions are discussed and resolved, it seems premature to try to implement any sort of oversight system which may create more security concerns than it resolves, to the detriment of both public trust and science.

**International harmonization:** FASEB is following the activities of the NSABB Working Group on International Collaboration with great interest. Given the nature of today’s research enterprise, we feel strongly that in order for any system of oversight for dual use research to be successful, it needs to be adopted internationally, given the nature of today’s research enterprise. While we support the United

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<sup>9</sup> NSABB. 2007. Draft report of the NSABB working group on oversight framework development, pp. 25.

<sup>10</sup> NSABB. 2007. Draft report of the NSABB working group on oversight framework development, pp. 23

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.

In closing, FASEB would like to thank the NSABB for producing a thorough and balanced report. Furthermore, we are extremely grateful for NSABB's willingness to engage and work with the scientific community and other stakeholders in the course of their activities. FASEB, on behalf of our member societies and scientists, looks forward to continuing to discuss these issues with NSABB and working together to balance the needs of science and security. If we may be of further assistance, please do not hesitate to contact us at any time.

Sincerely,

A handwritten signature in black ink that reads "Robert T. Palazzo". The signature is written in a cursive style with a horizontal line underneath the name.

Robert T. Palazzo, Ph.D.  
FASEB President

Cc: Dr. Elias Zerhouni, Director, National Institutes of Health  
Dr. Norka Ruiz Bravo, Director, Office of Extramural Research, National Institutes of Health

## Responses to questions from Appendix 5

1. There is little consensus over whether Institutional Biosafety Committee would have the expertise or resources to perform a risk assessment of dual use research. This speaks to the variation among IBCs and the differences between large and small institutions. For example, institutions that have chosen to assign their IBC the responsibility for reviewing research involving select agents or other potentially hazardous agents might be in a better position to incorporate dual use research into the IBC portfolio in terms of expertise. IBCs lacking sufficient expertise could perhaps be overcome by pooling expertise in regional, rather than institutional, bodies, but the timing of review could become problematic if such committees are unable to meet regularly or if the identification of DURC occurs midstream in the research process. Another point to consider is the security concern created by discussing dual use research issues in a public forum. IBCs are encouraged to make their meetings open to the public. If they were discussing DURC conduct, dissemination or communication, would such meetings be closed to the public? What would be the consequences for public perception of their work or that of the researcher involved? In those extremely rare instances where research is determined to be of such concern that it is discontinued or communication is prohibited, what are the requirements of IBC members to keep such information secure? Would penalties exist for noncompliance or inappropriate dissemination of such information?
2. While FASEB has no objection to the detailed criterion, we feel that it is quite true that “determining the applicability of this criterion is a subjective and sometimes challenging task.” For example, we found that immunologists reading criteria b and c could easily find applicability to their own research, leaving them to wonder whether it would be subject to further review or even prohibition. In particular, FASEB is concerned with NSABB’s statements that: 1) “It is important to emphasize that not all research that fits the categories below is necessarily dual use research of concern; rather it is research for which the criterion needs to be especially carefully considered. Moreover, it is also the case that research that does *not* fall into the categories below might also meet the criterion for being dual use research of concern<sup>11</sup>” and 2) “In many cases, there may be no clearly right or wrong answer. During the NSABB discussions of the oversight process and how the criterion would be applied in the initial evaluation for dual use of concern potential, the Board found significant differences among NSABB members.<sup>12</sup>” Taken together, these indicate that all research could be DURC and there’s no simple and accurate way to identify such research. While FASEB does not disagree with these statements, we do question whether, given that this is true, it is possible to establish a regulatory oversight system that can ensure security while not inhibiting research progress. The entire oversight process proposed by NSABB is dependent on: 1) reliably identifying DURC and 2) once identified, making risk-based assessments as to further action. If the first step is not possible, can or should the second be implemented?
3. The “Points to Consider” document is very useful in clarifying the information gathering process which might be used to identify potential DURC. Such a document could be very useful to committees or individuals charged with reviewing research for DURC potential. However, the use of the Appendix 1 document raises two issues of concern: the subjective nature of the answers and the security of the document itself. As detailed in our points above, the answers to the questions posed are going to be subject to differences in expertise, knowledge, and judgment. Even if there were consensus on identifying research as DURC, reaching consensus on risks versus benefits or appropriate risk management strategies is again going to depend on the person or persons making those decisions. One could envision a biosecurity official making a very

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<sup>11</sup> NSABB. 2007. Draft report of the NSABB working group on oversight framework development, pp. 17.

<sup>12</sup> NSABB. 2007. Draft report of the NSABB working group on oversight framework development, pp. 22

different determination than a biomedical researcher, based purely on a legitimate difference of opinion. The NSABB provides little guidance on how to deal with such issues and FASEB is concerned with how such procedures might be interpreted via the federal regulatory process.

The security of such a document itself needs to be addressed. If a review committee or individual is filling out a form based on this document, describing in detail the nature of the research and the potential threat, that information itself could raise security concerns. As stated previously, such a document could be subject to public access, depending on local or state laws. Would institutions be forced to assume liability for ensuring the security of these documents or proceedings? What role would the federal government play? As mentioned above, FASEB has serious concerns about the NSABB oversight process generating products of ambiguous security concern and tasking the federal agencies with developing systems to deal with such issues. While FASEB agrees with many of the principles outlined by NSABB regarding the review and communication of dual use research, we think there are larger issues related to balancing science and security that need to be addressed before we can develop a realistic regulatory process for dual use research.

4. Please see the section above on “Identifying the need for review.” While FASEB feels that having the PI self-identify dual use research potential is extremely problematic, we would find it difficult to support a vague consultative process that is intermediary between PI and a designated review committee. Designating one or more institutional officials, either at the local or national level, to assist the PI in making the initial evaluation places a tremendous burden on the institution and could result in a long delay in the research process. As NSABB points out “interactive discussion among multiple evaluators helped in the development of a consensus opinion regarding dual use potential.<sup>13</sup>” If a review body is needed just to determine whether or not further review is warranted, major disruption of research would occur, contrary to NSABB’s aims. We also feel strongly that if an oversight system is adopted, such as that proposed by NSABB, that 1) there needs to be an ultimate, scientifically based, decision making group, like the RAC; and 2) there needs to be a transparent appeals process for investigators whose work has been recommended for discontinuation or modification.
5. There are a number of areas that are vague, many of which FASEB has detailed in the above comments. In particular, the lack of detail regarding liability issues, security concerns over products generated by the oversight process, the feasibility of consistently identifying and reviewing DURC, and how to incorporate the review process into dual use issues that arise midstream during the research process could all use further guidance.
6. FASEB greatly appreciates NSABB’s mindfulness of the potential regulatory burden this new oversight system might impose. While we cannot calculate the impact, the level of burden will depend on how the guidance provided by the NSABB is interpreted by different agencies and institutions. While none of the proposed activities, (i.e., incorporating additional training into research ethics courses, checking off a box on a grant application, signing a yearly attestation, expanding the scope of the IBC), seem especially burdensome in and of themselves, the potential for them becoming so is great because of variations in institutional policies, the ambiguous nature of dual use research itself and parts of the NSABB guidance. Institutions with IBCs in place that are already, based on institutional policies, reviewing research related to the advisability of creating mutant pathogens or select agents, for example, might have no problem undertaking a DURC review, while smaller institutions, whose IBC has expertise solely related to recombinant DNA, may require a great deal of investment or change. To a researcher whose work may already be subject to oversight by an IRB, IACUC, ESCRO and other committees, an additional level of review and its accompanying paperwork will clearly add to the workload. The concerns we raised above regarding liability and security concerns could add another layer of responsibility, which will in turn contribute to the burdensome nature of these requirements. If universities or research

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<sup>13</sup> *Ibid*

institutions, in an effort to ensure compliance, categorize a large percentage of their research portfolio as needing additional levels of review, current review systems could be overwhelmed, research delayed, or significant costs incurred. One possible solution, to reduce the burden on institutions would be to have DURC reviewed only at the national level. If true DURC incidents are as rare as evidence suggests, than it seems feasible that they could be reviewed solely by the NSABB or equivalent. Again, to make this a realistic option, there would have to be a robust system in place to identify DURC at multiple stages in the research process, which may just not be a feasible undertaking.