U.S. Government Public Consultation on
Oversight of Dual Use Life Sciences Research

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The Criterion for Identifying Dual Use Research of Concern

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I would like thank the U.S. Government for its invitation to participate in this important public consultation meeting, which seeks feedback on the proposals developed by the National Science Advisory Board for Biosecurity (NSABB) for the oversight of dual use research in the life sciences. As the NSABB states in its framework document, such oversight will provide "a means of minimizing the potential that information, products, or technologies resulting from this research will be misused for harmful purposes" to "threaten public health and safety or other aspects of national security" "while still maintaining a vibrant research enterprise."

The NSABB proposals focus on minimizing risks that may arise from individual research projects. A well designed and implemented oversight system can do even more to help prevent the use of the life sciences to cause harm. It can make willful violations of the norm against such use riskier and more likely to be detected and successfully prosecuted; it can safeguard against harm arising from individual or institutional drift into ethically questionable areas of research activity; it can safeguard against harm arising from misunderstanding or misjudgment; and it can help mitigate the risks inherent in what the 2006 National Research Council report on "Globalization, Biosecurity, and the Future of the Life Sciences" (Lemon/Relman Committee report) termed a "biological arms race … with the malevolent application of potentially beneficial basic research" and biotechnologies.

The criterion and guidance that we are discussing this morning were designed to support an investigator driven system of oversight in which oversight is initiated only after an individual investigator determines that his or her own research qualifies as dual use research of concern. Unfortunately, the proposed criterion and guidance will not enable even the modest system of oversight proposed by the NSABB to be consistently and effectively applied to address the dual-use challenges facing us today. There are three critical problems, all of which can be corrected.

First, the criterion establishes a vague and subjective test for researchers to use in determining whether their research should be subject to independent review and oversight. This shifts the burden of risk assessment from oversight committees holding a range of relevant knowledge and expertise to individual investigators who will usually lack the knowledge and expertise needed to determine whether their research is "dual use research of concern." It also exacerbates the inherent conflict of interest that researchers have in the oversight of their own research. The addition of various qualifiers, including "based on current understanding," "reasonably anticipated," and "directly," compounds these problems: it increases the chance that researchers will unknowingly overlook the need for oversight of their own research and, for some, it will be an open invitation to find ways to avoid or minimize oversight.

The proposed criterion effectively short-circuits the oversight process. It virtually guarantees that there will be inconsistent and inequitable oversight across institutions, and that highly relevant research will receive inadequate oversight, or perhaps no oversight at all. The seven categories developed by the NSABB as guidance to aid in the identification of dual use research of concern improve on the categories identified in the 2003 National Research Council Fink report "Biotechnology Research in an Age of Terrorism" (the Fink Committee report), but they do no fix the fundamental problem. The criterion itself, which lies at the

foundation of the entire oversight system, will remain subjective and is an overall step backwards from the objective criteria developed by the Fink Committee.

The NSABB points to the NIH guidelines as a model for dual-use oversight, but the contrast between its proposed oversight framework and that of the NIH guidelines is stark. The Guidelines establish clear and objective criteria and thresholds for determining whether research requires independent oversight and the degree of oversight required. The Guidelines do not say, as the NSABB criterion does, if you think your research is risky enough, submit it for oversight. Rather, the Guidelines say, if your research falls into this or that category, it has great enough potential risk that it warrants a certain degree of oversight.

Let me be clear, considerations of reasonableness and directness must be central to the risk management process. But they can not be set by individual researchers to determine whether their research should be subject to that process. Subjective, individual risk assessment does not provide a sound basis for determining whether collective risk assessment is needed. The NSABB notes that even among its members "there may be significant variation in the assessment of the dual use potential of any particular research project when it is considered by two or more different, equally expert reviewers. … In such cases, interactive discussion among multiple evaluators helped in the development of consensus regarding the dual use potential."

This is exactly why the Federal government should establish objective criteria by which investigators can identify whether their research is subject to independent oversight. The criteria should include, with some revision, the seven categories of research identified by the NSABB as objective triggers for entry into the oversight system.

Second, although the NSABB correctly asserts that an oversight system must be carefully and clearly bounded to be effective, the current criterion is neither. Thus, in addition to establishing objective criteria, the Federal government should further elaborate the criteria in several ways. For example, the criteria should incorporate consideration of the nature of the agent. Biological agents differ in their dual-use potential, and manipulations of some agents will have greater risks than manipulations of others. Adding the nature of the agent to the other considerations in the criteria would help focus oversight on that research which is of greatest concern. In addition, it may be useful to develop criteria that support a tiered approach to oversight, one that links the level of oversight (local, national) to the level of potential risk.

Further, some of the categories should be revised. Category 1 should read "enhance the virulence, infectivity or toxicity of a biological agent or toxin." This would bring greater clarity to the term "harmful consequences" and reduce any confusion that may be caused by the apparent overlap between categories 1 and 4. In category 2, the qualifier "without clinical and/or agricultural justification" should be dropped. Research that could disrupt immunity or the effectiveness of an immunization for justified reasons could also enable disruption for unjustified reasons - that is the essence of the dual-use problem. The qualifying phrase effectively excludes an entire, but critical, category of research from the oversight system.

Finally, the meaning of the term "misapplied" should be made clear lest the oversight system be too broad or too narrow to be effective. Does inclusion of the term "misapplied" in the criterion imply that there are situations in which biotechnology can legitimately be used to threaten public health and safety, agriculture, and so on? Does misapplication include only the malevolent use of biological knowledge and technology? What about use for so-called "nonlethal weapons?" Does misapplication also include what the Lemon/Relman committee termed "inappropriate use," or use with the potential to cause unintended harm, including irresponsible or careless use or the conduct of "experiments or other activities … with inadequate oversight or without an awareness of the consequences of certain outcomes?" In a fundamental way, conducting research that can be used to cause harm without taking appropriate steps to minimize the potential for such harm IS misusing knowledge, products or technology. The criteria should include all of these aspects of misuse.

This brings me to the third critical problem. The NSABB report repeatedly makes statements such as "minimize the risk of misuse," "minimize the potential for misuse," "mitigate the risks [that] the information

from the research could be misused," and "the goal of identifying dual use research of concern is to initiate a process aimed at reducing the potential that knowledge, products, or technology derived from certain life science research could be misapplied." So it is surprising to see that, when it comes to setting the actual criterion, the report refers to "knowledge, products, or technologies that could be … misapplied *by others*.**"**

There is no justification for this profound qualifier. At best, it is unnecessary. More problematically, it creates a loophole for those who would seek to escape oversight for non-malicious purposes, to say nothing of the loophole it would create for those who would seek to deliberately misuse biological knowledge, products or technology. Fundamentally, the biosecurity issue is not misuse *by others*, it is misuse *by anyone*. The inclusion of the words "by others" suggests that the NSABB has not yet come to grips with the reality that certain life sciences research can be used to cause harm, deliberately or otherwise, by anyone who has the right skills. Not every scientist should be a suspect. But every scientist should very clearly understand that "do no harm" means more than "do not enable others to do harm," though that too is very important. The words "by others" impede that understanding.

The inclusion of the words "by others" raises questions about the credibility and effectiveness of the entire oversight system proposed by the NSABB. It sends the wrong message to scientists, governments and the public. To researchers, it sends a message that the dual-use problem is manifested "over there," not with them or in their research. This may encourage scientists to make assessments based on their own benign intent rather than on a more objective consideration of the risks their research may pose. To other governments, it sends the message that they need not take real steps to ensure that biotechnology is not being used for harmful purposes under their jurisdiction. To the public, it sends a message that scientists are exempting themselves from concerns about the misuse of their science. At the level of the language of the criterion, this problem is easily solved – delete the words "by others." I strongly recommend that the Federal government do so.