U.S. Government Public Consultation Meeting on
Oversight of Dual-Use Life Science Research
National Institutes of Health

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Comments on Panel II – "Responsibilities and Process for the Identification and Oversight of Dual Use Research of Concern"

I would like to commend the U.S. Government for holding this public consultation meeting, as well as the National Science Advisory Board for Biosecurity (NSABB), whose June 2007 report, "Proposed Framework for the Oversight of Dual Use Life Sciences Research," is the starting point for our discussion today. In that report, the NSABB issued a strong call for an iterative process of consultations with the public and government, and noted that it anticipated modifying its proposed oversight framework in response to input from those consultations.

The comments I will make today concerning the June 2007 proposed framework are offered in the same spirit of cooperation. They are based on nearly 30 years of experience studying biological and chemical threats and developing policies aimed at reducing those threats. This includes eight years coordinating U.S. biological and chemical weapons policy on the National Security Council staff and, most recently, co-directing a project at the Center for International and Security Studies at Maryland (CISSM) on managing the risks from dual-use research.

Issue 1: The June 2007 proposed framework provides a single criterion for individual investigators to use in conducting the initial evaluation of their research to determine whether it is dual-use research "of concern:"

> "Research that, based on current understanding, can be *reasonably anticipated* to provide knowledge, products, or technologies that *could* be directly misapplied by others to pose a threat to public health and safety, agricultural crops and other plants, animals, the environment or materiel." (emphasis added)

Comments: This criterion is very general and highly subjective. Its adoption would deny investigators a level playing field as there would be inconsistent and inequitable treatment across institutions. It would also impede the development of standards for ensuring and enforcing compliance with the oversight process.

Even with more specific criteria, most investigators lack the knowledge and experience required to assess, on their own, the potential risks of their work. Investigators also have

an inherent interest in seeing their proposed research proceed. To ask them to determine whether their own research could be "of concern" is an obvious conflict of interest.

Recommendation: As recommended in the National Research Council's 2003 report, "Biotechnology Research in an Age of Terrorism," (the "Fink Committee" report), individual investigators should identify, based on specific, *objective* criteria, whether their research is subject to oversight, but should not conduct the initial dual-use review themselves.

Issue 2: Under the June 2007 proposed framework, only projects that have been determined by the investigators themselves to be "dual use research of concern" would be given a comprehensive risk assessment, and this would be done only at the institution level.

Comments: This will almost certainly result in important research proceeding without institution level review for dual-use risks. It also fails to consider the possibility that some research projects may be so consequential that they should be reviewed and approved at a national level

Recommendations: As the Fink Committee recommended, individual investigators should identify whether their research meets the review criteria but the dual-use review process itself should be carried out by independent expert committees at the local or national level.

The review process should be tiered, with the level of oversight a function of the level of risk of the research. It should also build on existing review structures where possible, as recommended by the Fink Committee, the British Royal Society, and others.

Institutional Biosafety Committees (IBCs) could be used to conduct oversight at the local level, but they would need additional funds and personnel to assess, approve, and monitor relevant research projects, ensure proper record-keeping, and serve as an ongoing resource for investigators. Institutions should have the option of utilizing outside review entities, but this should not relieve them of the responsibility of ensuring that all dual-use research conducted in their laboratories complies fully with federal oversight requirements.

A national level body should also be established both to oversee the activities of local review committees and to review and approve more consequential research projects under its jurisdiction.

Both the local and national review committees should be comprised of scientists with expertise in the specific research areas subject to oversight. They should also include individuals with other relevant forms of expertise (e.g. security matters, law, ethics) and whose interests would be affected by the committees' decisions (e.g. public representatives). If necessary, additional experts should be utilized on an ad hoc basis.

Issue 3: Under the June 2007 proposed framework, the risk assessment is focused only on the potential for "intentional" misuse or misapplication of research results by others.

Comments: Intentional misuse by states or non-state actors is a concern, but as a January 2006 National Academy of Science report on "Globalization, Biosecurity, and the Future of the Life Sciences," pointed out, we must also be concerned about "the grave harm that may result from misuse of the life sciences and related technologies by individuals or groups that are simply careless or irresponsible."

Recommendation: The risk assessment should consider not only intentional misuse by others but also the potential for accidental or unintentional consequences arising from the actions of investigators themselves.

Issue 4: The June 2007 proposed framework recommends that the oversight process apply not only to federally conducted or funded dual-use life sciences research but also *all* other research at government or private labs receiving federal funds for dual-use research.

Comments: Even if this recommendation is accepted, it is far from clear how this somewhat broader universe of labs would be determined, given the inadequacies of the proposed process for identifying dual-use research. Moreover, this would still leave dual-use research at private labs not receiving federal funding for such research, as well as classified research, outside the scope of the oversight process.

Whether all such entities would implement the oversight arrangements on a voluntary basis is open to doubt. Even if they did, the federal government would have no ability to take enforcement action against an entity that had adhered voluntarily but was in noncompliance.

Recommendation: The oversight system should apply, without exception, to all relevant research, whether government, private sector or academic, irrespective of the source of funding. Comprehensiveness of scope is essential for the legitimacy and effectiveness of any oversight system.

Issue 5: The June 2007 framework proposes that the federal government embody the dual-use oversight arrangements in voluntary guidelines, pointing to the guidelines for recombinant DNA (rDNA) research as a model.

Comments: Experience has shown the limitations of voluntary guidelines. For example, institutions that should operate review committees for rDNA research have not always had them. In other cases, the committees have existed on paper but have not met; or have issued blanket approvals rather than review each research project individually; or have failed to keep records of their deliberations. Rather than demonstrating the effectiveness of voluntary guidelines, the rDNA experience has raised serious concerns.

Regulations provide a much stronger basis than guidelines for encouraging and ensuring compliance with the oversight process as well as for promoting harmonized approaches to oversight.

Recommendation: Any oversight arrangements that are developed for dual-use research should be based on mandatory federal regulations not voluntary guidelines.

Issue 6: The June 2007 proposed framework notes the importance of mechanisms at both the local and national level for ensuring compliance with the oversight process, but offers few specific recommendations.

Comment: Any oversight system that lacks tools for monitoring and enforcing compliance will be deficient.

Recommendations: In addition to mandatory regulations, mandatory training on the dual-use issue and implementation of federal requirements should be part of the compliance enforcement regime, as is now being considered by NIH for human subject research. The national review body should monitor, through reporting from local review committees and periodic inspections, compliance with the oversight rules.

In addition, both government and private sector *funders* of scientific research should make compliance with dual-use oversight requirements a condition of funding, and both government and private sector *laboratories* should make it a condition of employment. For their part, scientific journals should refuse to publish manuscripts by investigators who have not followed the dual-use oversight requirements.

Finally, to bolster compliance monitoring at both the local and national level, an electronic data management system, like the one developed by CISSM, should be provided for investigators, local and national review committees, and the national oversight body to use in meeting their reporting and oversight obligations.