STATEMENT OF ELISA D. HARRIS

Center for International and Security Studies at Maryland

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Strengthening the Biosecurity of the United States

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Thank you for providing me with an opportunity to provide comments on the select agent regulations and biosecurity. Thus far, the working group appears to have adopted a very narrow definition of biosecurity in so far as the select agent regulations are concerned. Under this approach, biosecurity is concerned with controlling unauthorized access to dangerous pathogens or preventing exposure to them. This is demonstrated by the agenda of this meeting, which emphasizes personnel security and reliability, transportation security, physical and facility security, and facility inspections.

But if we are serious about developing policy recommendations that will strengthen the biosecurity of the United States, as this working group has been charged to do, it is essential that we also consider oversight of select agent research itself, not just the agents or the facilities where the research occurs. This is consistent with a recommendation from an expert panel convened by the National Research Council of the National Academy of Sciences, which in October 2003 called for independent, prior review of what it deemed dual-use "experiments of concern."

These experiments include those that would:

- demonstrate how to render a vaccine ineffective;
- confer resistance to antibiotics or antiviral agents;
- enhance the virulence of a pathogen or render a nonpathogen virulent;
- increase the transmissibility of a pathogen;
- alter the host range of a pathogen;
- enable evasion of diagnosis or detection methods; or,
- enable weaponization of a biological agent or toxin.

Regrettably, nearly 6 years after the NRC report was released, there is still no oversight requirement in place for experiments of concern. Moreover, under the select agent regulations, only 2 categories of research using select agents require prior review and approval. This working group can help begin to fill these critical gaps by recommending the following immediate step:

Revise the select agent regulations to include a requirement for prior review and approval of any NRC experiment of concern that involves a select agent.

But if we are serious about strengthening U.S. biosecurity, we must not stop there. Over the longer-term, we should put in place a more comprehensive oversight requirement for all experiments of concern, not just those involving select agents. Working out the details will require intense, active collaboration between scientists, security experts and policymakers. But based on our work, we believe that the principles that should guide the development of such an oversight requirement already are clear. They include:

First, the research activities subject to oversight should be clearly defined, based on specific, objective criteria. Vague or highly subjective criteria would impede the ability of scientists to determine whether their work falls under the oversight requirement. Such criteria would also lead to inconsistent and inequitable treatment across institutions, thus denying scientists a level playing field.

Second, the review process should be carried out by independent experts under a tiered system, in which the level of oversight is determined by the level of risk. This review process should build wherever possible on existing review procedures, such as those that already exist for work with recombinant DNA.

Third, the risk assessment process should consider not only the potential for intentional misuse or misapplication of results by others but also the possibility of accidental or unintended consequences arising from the actions of scientists themselves.

Fourth, the oversight requirement should apply, without exception, to all relevant research activities, whether government, private sector, or academic. Comprehensiveness of scope is essential for the legitimacy and effectiveness of any oversight process.

Fifth, the oversight requirement should be embodied in mandatory regulations not voluntary guidelines. Regulations provide a much stronger basis than guidelines for encouraging and ensuring compliance.

Finally, any oversight requirement for experiments of concern ultimately needs to be harmonized across countries, regions and internationally. Work with potentially destructive consequences is taking place in laboratories throughout the world. Harmonization is required both to reduce biological risks effectively and to ensure equal treatment across nations.