U.S. Government Public Consultation Meeting on the NSABB's Proposed Oversight Framework

A Summary

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Public Consultation Meeting

- **What: Meeting to provide an opportunity for stakeholder input on the NSABB's *Proposed Framework for the Oversight of Dual Use Life Sciences Research***
- **Where: NIH Campus in Bethesda Maryland**
- **When: July 15, 2008**
- **Who: Panelists and participants representing various key stakeholder perspectives**
  - **Biosafety officers**
  - **IBC chairs**
  - **Senior institutional administrators**
  - **Policy think tank analysts**

Panel I – Criterion for Identifying Dual Use Research of Concern

- **Questions for Discussion**
  - **Is the criterion sufficiently specific and understandable so that it can be applied consistently? Is the criterion too broad? Is the criterion too narrow?**
  - **Is the guidance that follows the criterion for identifying Dual Use Research of Concern (DURC) helpful and sufficient? Is it clear and understandable?**
  - **What share of research at your institution or company would likely be captured with the proposed criterion for DURC?**

Comments on the Criterion

- **Greater specificity would promote more consistent implementation.**
- **List-based approaches are more concrete, e.g., lists of experiments of concern based on:**
  - **the Select Agent list,**
  - **research with agents classified as Risk Group 3 or 4 under the NIH Guidelines for Research with Recombinant DNA Molecules,**
  - **the seven experiments of concern in the NRC report on *Biotechnology in an Age of Terrorism* , or**
  - **the seven illustrative examples used in the NSABB report**
- **The NSABB was wise to narrow the scope to "dual use research of concern"**
  - **Key to focusing on research that poses the greatest potential risk**

Panel II –Identification and Oversight of Dual Use Research of Concern

- **Questions for Discussion**
  - **Should the PI bear primary responsibility for initially determining whether research might be considered DURC? If so, how?**
  - **What are the characteristics of a dual use research review committee? What expertise will be needed? How should institutional review responsibilities be fulfilled?**
  - **What tools would be appropriate to promote, evaluate, and ensure compliance with investigator and institutional responsibilities?**

Comments on Identification and Oversight of DURC

- Varied comments regarding whether requirements should be in the form of
  - Guidance
  - Term and condition of award
  - Regulation
- Differing views on degree of reliance on PI determinations
- An Institutional Biosafety Committee (IBC) or an IBC-like body as a key element in the risk assessment process
- Federal requirements should be harmonized

Panel III – Guidance and Educational Resources

- **Questions**
  - **Has the NSABB identified the major educational and outreach priorities in its report? If not, what other priorities should there be?**
  - **How might the various elements of the Oversight Framework (criterion, code of conduct, guidance on communication) be used as educational tools?**
  - **What other kinds of educational resources, tools, and strategies would be helpful or particularly effective in educating various audiences, such as investigators, research administration, biosafety staff, and others?**

Comments on Guidance and Educational Resources

- Several private sector initiatives featured
  - Southeast Regional Center for Excellence for Emerging Infectious and Biodefense
  - Federation of American Scientists
- Educational efforts must have a broad reach:
  - Academic scientific community
  - Precollegiate students
  - Commercial laboratories
  - International audiences
  - Public

Comments on Guidance and Educational Resources

- **Education about DURC must also stress close communication and mutual learning among all stakeholders with the goal of developing and sharing management and communication strategies and continual refinement of best practices.**
- **A full communications plan is critical and should exploit the power of the Internet.**

Suggested Message Points

- **The scientific community should actively participate in defining the problem and solutions.**
- **Awareness is necessary, but it may not be sufficient; some guidance or requirements must be developed so all know how to respond appropriately to the problem.**
- **Scientific associations and professional societies have an important role to play as conduits of information among scientists; they are the educators of each other, the scientific community, and the public.**

Views on the Roles of the NSABB and Federal Government

- **The NSABB should play a continuing advisory role in outreach and education strategies by**
  - **Reaching out to stakeholder groups (professional societies, research institutions, and the public)**
  - **Participating in message formulation**
  - **Recommending training curricula mapped to Federal policy, and**
  - **Suggesting tools and educational materials.**
- **As for the Federal government,**
  - **DUR should be a required topic for NIH-mandated ethics training.**
  - **The Federal government should stimulate development of private-sector training initiatives to include roundtables, community outreach, and educational materials.**

Next Steps

- **The Federal government is**
  - **Working through an interagency process to develop federal policy.**
  - **Balancing the priority of the issue with the need for ample stakeholder input.**
  - **Contemplating future opportunities and means for stakeholder input.**
    - **Additional public consultation meetings**
    - **Take into account stakeholder concerns and the public interest in an effective oversight system.**