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October 7 , 2003

Michael Holland
Office of Science and Technology Policy
Executive Office of the President
Washington, DC 20502

Dear Mr. Holland:

The Federation of American Societies for Experimental Biology (FASEB) appreciates the opportunity to provide input to the Subcommittee on Research Business Models of the National Science and Technology Council (NSTC), as requested in FR Doc. 03-19990. FASEB represents 22 scientific societies, consisting of more than 60,000 biomedical research scientists. FASEB scientists conduct biomedical research at small and large academic institutions, medical and other professional colleges, within industry and within government. They are funded by nearly every federal research and development (R&D) agency, as well as state agencies and private organizations.

We commend the Subcommittee's effort to solicit information from the general public and all interested parties to improve the performance and management of federally sponsored basic and applied scientific and engineering research. However, FASEB does not collect the specific data that the NSTC is seeking, much of which calls for an institutional perspective. While the nature of our membership and broad spectrum of topics covered by the Federal Register notice prevent us from providing detailed answers to the explicit questions listed, we would like to take this opportunity to respond generally to some of the business relationship issues between federal agencies and research performers raised by the Federal Register Notice which we hope will be useful as the Subcommittee moves forward.

Federal role in supporting research

This Administration and the American people have been generous in their support of biomedical research. The critical advances made in human and animal health could not have been made without federal research funding. We lead demonstrably healthier and longer lives as a result of biomedical research supported by the federal government; even more progress will be made with continuing support. FASEB strongly believes that using merit review in funding decisions is the best way to ensure that public investment in science yields the highest quality research. Grant applications should continue to be reviewed using the specific criteria that continue to be used so successfully: creativity and innovation; scientific impact; feasibility; and the qualifications of the investigator and the research environment. The vibrancy and relevance of this process should be applied to newly developing questions and opportunities.

Regulatory burden

There is strong agreement in the research community that it is possible to reduce excessive and redundant regulations without increasing the risk to animal or human research subjects, the environment, or the integrity of the research process. Moreover, it is critical to do so in order to maximize public benefit from the tremendous progress that has been made in the battle against disease. I will comment on a few of the key regulatory impediments to biomedical research of greatest concern to our Federation.

Animal Research Regulations

Research with animals is highly regulated, and many members of the Federation have expressed concern about redundant, excessive, or seemingly arbitrary regulatory requirements. Multiple agencies oversee animal research, including USDA, DHHS, EPA, DOT, DOI, and possibly others. All agencies that fund animal research require research protocols to undergo prior review and approval by an Institutional Animal Care and Use Committee (IACUC). However, the requirements for IACUC membership, protocol reviews, program oversight, and reporting differ between agencies. In addition, agencies that require animal data for regulatory purposes may impose additional standards. These overlapping and sometimes conflicting requirements make institutional compliance unduly complex and resource-intensive.

One specific area of concern is the lack of scientific basis for certain USDA regulatory requirements, some of which have been administratively adopted as "Animal Care Policies." For example, the USDA Animal Care Policy 12 recommends (though does not compel) Principal Investigators (PI) to conduct database searches for non-animal alternatives[1] even when the PI is sufficiently expert to provide credible assurances that no such alternatives are available. Although the USDA permits declarations based upon sources other than database searches, its official policy is that the "Institutional Animal Care and Use Committee (IACUC) and the inspecting Veterinary Medical Officer should closely scrutinize" them. To further complicate this particular expectation, the literature on alternatives is still in development and not sufficiently broad to address adequately the availability of alternatives. This "requirement" is unduly burdensome and reveals a fundamental lack of understanding of the scientific process.

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[1] APHIS Animal Care Policy #12 (issued June 2000) states:

We believe that the performance of a database search remains the most effective and efficient method for demonstrating compliance with the requirement to consider alternatives to painful/distressful procedures. However, in some circumstances (as in highly specialized fields of study), conferences, colloquia, subject expert consultants, or other sources may provide relevant and up-to-date information regarding alternatives in lieu of, or in addition to, a database search. When other sources are the primary means of considering alternatives, the Institutional Animal Care and Use Committee (IACUC) and the inspecting Veterinary Medical Officer should closely scrutinize the results.

A second example is the Policy for the Environmental Enrichment of Non-Human Primates that the USDA proposed in 1999. This policy contained requirements at odds with the recommendations of the 1998 report *The Psychological Well-Being of Non-Human Primates* that was developed by the Institute for Laboratory Animal Research, a branch of the National Academy of Sciences. The USDA has not sought to finalize its proposed policy, but on July 22, 2003, the Animal Legal Defense Fund, the Animal Welfare Institute, and three individual plaintiffs filed suit to compel the agency to do so.

The Federation suggests that attention be given to making certain that there is a sound scientific basis for animal welfare requirements and that there is greater coordination of such requirements among federal agencies.

Environmental Protection Agency Resource Conservation and Recovery Act (RCRA)

The regulatory provisions of the Resource Conservation and Recovery Act (RCRA) are administered by the Environmental Protection Agency (EPA). The RCRA was enacted in 1976 to protect human health and the environment from the hazards posed by waste disposal. Subtitle C of RCRA establishes a system to control hazardous waste from the time of generation until its ultimate disposal. With limited exceptions, many of the hazardous waste regulations apply to academic laboratories that use chemicals, as well as to the industrial sector. However, because a laboratory setting differs dramatically from an industrial setting in the use of relatively small quantities of a large number of chemicals on a non-production basis, the RCRA regulations create difficulty for the laboratory community in the areas of interpretation, application, and compliance.[2]

Scientists report that their laboratories must contend with elaborate record keeping, detailed storage requirements for reagents that are not relevant to their everyday use, and significant costs for technician time to manage inventory, testing, and paperwork. Institutional officials emphasize that regulations ought to be appropriate to the laboratory setting. The hazards of risks involved in the use of low levels of radionuclides or toxins in academic research are significantly different from the use of these materials for industry. These concerns have been widely noted elsewhere in relation to these and other regulations.[3]

In recognition of these difficulties, beginning in August 1999 the Howard Hughes Medical Institute (HHMI) led a two-year collaborative initiative to "establish consensus best practices for managing hazardous wastes in academic research institutions and to demonstrate that a performance-based model can be an effective and practical approach for regulating hazardous wastes in the academic research setting." The initiative resulted

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[2] Report on Consensus Best Practices for Managing Hazardous Wastes in Academic Research Institutions October 2001, accessed April 24, 2002 at http://www.hhmi.org/research/labsafe/projects/report_congress.pdf

[3] See also, Abelson PH. Impact of regulations on universities. *Science*. 1995; 267: 1247, and U.S. Congress, Office of Technology Assessment, *The Regulatory Environment for Science - A technical Memorandum*, OTA-TM-SET-34. Washington, DC: U.S. Government Printing Office, February 1986.

in a Report on Consensus Best Practices for Managing Hazardous Wastes in Academic Research Institutions.[4] **(See Attachment A - Report on Consensus Best Practices)** In response to Congressional requests, EPA evaluated the initiative's consensus best practices and on March 14, 2002, filed a Report to Congress, containing its evaluation of the Consensus Best Practices developed through the HHMI Project.[5] EPA praised the HHMI Report and the participating academic research institutions for their efforts to improve hazardous waste management in their laboratories, noted that the best practices recommended by the Report addressed a wide range of issues, and most importantly encouraged academic research institutions to develop thoughtful approaches to managing their hazardous waste and instilling strong institutional commitment to environmental protection programs.[6] **(See Attachment B – EPA Report to Congress)**

EPA is currently considering making certain changes to the agency's regulations and policies for colleges and universities and FASEB strongly recommends that this Subcommittee endorse the following recommendations developed by the HHMI initiative for the management of hazardous wastes in academic research:

> "1. The U.S. EPA Administrator should recognize the consensus best practices developed through this initiative as a performance-based model for achieving RCRA compliance and for promoting stewardship and responsibility for health, safety, and the environment in academic institutions. The Administrator should determine and initiate appropriate methods for implementing a performance-based model, using the consensus best practices developed through this initiative, for achieving RCRA compliance in academic institutions.
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> 2. The U.S. EPA Administrator should promote conformity and consistency among the U.S. EPA regional offices and state environmental protection agencies in carrying out RCRA assistance and enforcement programs for academic institutions.
>
> 3. Academic institutions should adopt the consensus best practices developed through this initiative as a performance-based model for managing hazardous wastes in their laboratories and for achieving RCRA compliance.
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> 4. Academic institutions should establish dialogue with their regulatory agency officials to plan cooperatively their approaches for implementing the consensus best practices developed through this collaborative initiative."[7]

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[4] Report on Consensus Best Practices, Executive Summary, p.5

[5] Report to Congress Evaluating the Consensus Best Practices Developed through the Howard Hughes Medical Collaborative Hazardous Waste Management Demonstration Project and the Need for Regulatory Changes to Carry Out Project Recommendations, March 14, 2002, Office of Solid Waste, Office of Solid Waste and Emergency Response, United States Environmental Protection Agency.

[6] Report to Congress, p. 10.11.

[7] Report on Consensus Best Practices, Conclusions and Recommendations, pp.31-32.

Technology Transfer Optimization

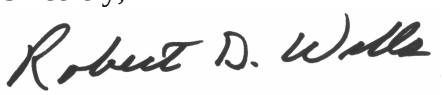
FASEB supports efforts to promote the interchange of research tools between researchers in the public and private sectors, since this sharing of resources often serves as a catalyst for exciting discoveries in biomedical research. As scientists, we endorse the philosophy that the open dissemination of research tools and resources will best advance the interests of science and society. Scientists, along with the public, are the principal beneficiaries of this sharing which lessens the duplication of expensive activities and frees time and money for research into new areas of scientific inquiry. While it is important to promote the obligation to share resources, it is crucial that a workable sharing plan be compatible with protecting the proprietary rights of both institutions and inventors.

Simplification of Federal Practices and Policies

It is important for the subcommittee to be aware of some recent, ongoing or future efforts which may duplicate this policy review. Our progress toward improved quality of life is diminished whenever research is limited or curtailed and research funds are wasted due to duplicative regulatory initiatives. For example, the questions listed in section G (*Multidisciplinary / collaborative*) are very similar to those being addressed by the National Academies of Sciences' Committee on Science, Engineering and Public Policy's (COSEPUP) new initiative begun in March, 2003. Section A of the request for information (*Accountability*) would seem to duplicate some of the efforts of the Office of Management and Budget's Performance Measurements Advisory Council established in May, 2002, as well as the report titled "Assessing the Federal R&D Investment" prepared October, 2002 by the President's Council of Advisors on Science and Technology (PCAST). PCAST has also been investigating technology transfer and their work may be replicated by section J (*Technology transfer optimization*) of the subcommittee's review. There may be other examples as well, and we would encourage the subcommittee or the NSTC to undertake a full exploration of similar efforts to prevent redundant data collection.

We will be closely monitoring the progress of the subcommittee and hope their will be further opportunities for comments as the focus of its information gathering efforts is refined. Many of the issues under review are of great interest to our membership, who represent a substantial portion of the research performer community. We trust that the subcommittee will consider the impact of any recommendations which may result from this review on the working scientist. If we may be of any further help in this regard, please do not hesitate to contact us.

Sincerely,



Robert D. Wells, PhD

Attachment A
http://www.hhmi.org/research/labsafe/projects/report_congress.pdf
Report on
Consensus Best Practices for
Managing Hazardous Wastes in Academic Research Institutions
October 2001
Prepared by the
Howard Hughes Medical Institute Office of Laboratory Safety
in Collaboration with the Project's Principal Participants
October 2001

Attachment B
http://www.epa.gov/epaoswer/osw/specials/labwaste/r02008.pdf
Report to Congress Evaluating the Consensus Best Practices Developed through the Howard Hughes Medical Collaborative Hazardous Waste Management Demonstration Project and the Need for Regulatory Changes to Carry Out Project Recommendations, March 14, 2002, Office of Solid Waste, Office of Solid Waste and Emergency Response, United States Environmental Protection Agency.