

May 16, 2002

John Morrall
Office of Information and Regulatory Affairs
Office of Management and Budget,
NEOB, Room 10235,
725 17th Street, N.W., Washington, D.C. 20503.

Dear Mr. Morrall:

The Federation of American Societies for Experimental Biology (FASEB) appreciates the opportunity to comment on the March 28, 2002 Draft Report to Congress on the Costs and Benefits of Federal Regulation. FASEB is comprised of 21 societies with more than 60,000 members, making it the largest coalition of biomedical research associations in the United States. The mission of FASEB is to enhance the ability of biomedical and life scientists to improve, through their research, the health, well-being and productivity of all people.

We are joined in these comments by the Association of American Medical Colleges (AAMC), representing all 125 U.S. medical schools, over 400 teaching hospitals, and 98 academic and medical societies representing over 100,000 faculty.

The investigators and institutions represented by these two organizations manage and conduct a substantial share of the nation's publicly supported biomedical research and are stewards for the safe and responsible conduct of this research.

General Comments

We commend the Office of Management and Budget through the Office of Information and Regulatory Affairs for its commitment to approaching regulatory review in an open, transparent and analytically sound manner.

Standards for Privacy of Individually Identifiable Health Information

We are particularly appreciative of the proactive role that OIRA has taken in suggesting regulatory priorities for agency consideration. In response to suggestions solicited in OMB's draft version of last year's annual report, OIRA identified as a high priority review the Department of Health and Human Services (HHS) Standards for Privacy of Individually Identifiable Health Information. HHS has since issued guidance clarifying the requirements of this rule, has publicly committed to making regulatory changes to certain aspects of the rule and is presently considering significant modifications.

Data Dissemination Guidelines

On January 3, 2002, OIRA issued government-wide guidelines implementing Section 515 of P.L. 106-554 to enhance the quality of information that federal agencies disseminate to the public. We are pleased that OMB responded to the concerns of the academic and scientific community in revising the guidelines to explicitly recognize the objectivity of scientific information and allow research to be disseminated where "the results have been subject to formal, independent, external peer review."

Mr. John Morrall
May 16, 2002
Page 2

OIRA Scientific Advisory Panel

The Draft Report announces that “OIRA is in the process of forming a scientific advisory panel that will suggest initiatives to OIRA, evaluate OIRA’s ongoing activities, comment on national and international policy developments of interest to OIRA, and act as a resource and recruitment mechanism for OIRA staff.”¹ We applaud this effort to solicit input from the scientific community and we would be pleased to nominate candidates for this panel. We note that both the National Institutes of Health Regulatory Burden Advisory Group and the Department of Health and Human Services Secretary’s Advisory Committee on Regulatory Reform are charged with making recommendations on regulatory reform. It would be useful to invite at least one member of the NIH Group and at least one member of the Secretary’s Advisory Committee on Regulatory Reform to participate on the new OIRA advisory panel to share insights into what work has already been done and to coordinate future efforts.

Proposals for Reform of Regulations

Resource Conservation and Recovery Act (RCRA)

Chapter IV of the Draft Report invites recommendations from the public for the reform of Federal rules that, if adopted, would increase net qualitative and quantitative benefits to the public. We offer the following comments to the regulatory provisions of the Resource Conservation and Recovery Act (RCRA), which is 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

¹ Draft Report to Congress on the Costs and Benefits of Federal Regulation, accessed at <http://www.whitehouse.gov/omb/inforeg/cbreport.pdf>

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

Mr. John Morrall
May 16, 2002
Page 3

Our campuses report that they 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 in a Report on Consensus Best Practices for Managing Hazardous Wastes in Academic Research Institutions.⁴ **(See Attachment A - Report on Consensus Best Practices)**

The House Committee on Appropriations (House Report 106-674) and the Senate Committee on Appropriations (Senate Report 106-410) supported the initiative and encouraged the Administrator of EPA to participate in it. The Committees requested a report from the EPA evaluating the initiative’s consensus best practices and the need for regulatory changes, if any, to carry out the recommendations of the initiative. In response to the Committees’ request, on March 14, 2002, EPA filed its Report to Congress, containing its evaluation of the Consensus Best Practices developed through the Howard Hughes Institute’s 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)**

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.

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.

Mr. John Morrall
May 16, 2002
Page 4

FASEB and AAMC strongly recommend that OIRA 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.

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.

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

Sincerely,

Robert R. Rich, M.D.
President, FASEB

Jordan J. Cohen, M.D.
President, AAMC

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