

FASEB

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The American Physiological Society
American Society for Biochemistry and
Molecular Biology
American Society for Pharmacology and
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The American Association of
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The Protein Society
Society for Developmental Biology
American Peptide Society
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Facilities
The American Society for Bone and
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American Society for Clinical
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Teratology Society
The Endocrine Society
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Genetics
Society for Gynecologic Investigation
Environmental Mutagen Society
International Society for
Computational Biology
American College of Sports Medicine
Biomedical Engineering Society

President

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Federation of American Societies for Experimental Biology

— *Quality Life Through Research* —

March 16, 2009

Mabel Echols
Office of Information and Regulatory Affairs
Records Management Center
Office of Management and Budget
Room 10102, New Executive Office Building
725 17th Street, NW
Washington, DC 20503

BY ELECTRONIC MAIL TO: oira_submission@omb.eop.gov

Re: Executive Order on Federal Regulatory Review

Dear Ms. Echols:

The Federation of American Societies for Experimental Biology (FASEB) thanks the Office of Management and Budget (OMB) for the opportunity to comment on ways to improve the process and principles governing federal regulation. FASEB represents 22 scientific societies and over 80,000 basic and clinical scientists, making it the largest biomedical research organization in the United States. We are committed to ensuring that scientists uphold the highest standards for the safe and responsible conduct of research, and we appreciate the role regulatory oversight plays in this regard.

Scientists and the institutions at which they work are subject to a wide range of regulations intended to address serious and valid concerns. Compliance with these regulations requires considerable administrative effort. In a 2007 survey conducted by the Federal Demonstration Partnership (FDP), scientists estimated that 42% of the time they spent on federally funded research was devoted to administrative and regulatory activities. Based on these data, the FDP estimated that federal agencies and institutions spend \$85 million on administrative tasks directly linked to those projects. While FASEB has no doubt about the importance of regulatory oversight, we fear that the cumulative burden of these regulations is having a deleterious effect on scientific productivity.

In developing its recommendations for a new Executive Order on federal regulatory review, OMB should make every effort to ensure accountability and transparency in research while minimizing the administrative burden regulations

place on the scientific community. FASEB strongly encourages OMB to review any proposed regulations to determine whether additional burdens and costs are balanced by meaningful improvements to the current oversight system. Where new regulations are necessary, they should be based on sound justification. They should also be harmonized with existing regulations in order to avoid unnecessary duplication, confusion, and inconsistency, all of which have a negative impact on the intended regulatory aims. FASEB also encourages OMB to solicit input from the scientific community when making regulatory decisions related to science. By including researchers, research institutions, and funding agencies in its decision making, OMB can foster an environment of mutual cooperation that will serve both the progress of science and the public good.

On behalf of the FASEB community, thank you for considering these comments. We would welcome the opportunity to engage in further discussion with OMB on this important topic.

Sincerely,

A handwritten signature in cursive script that reads "Richard B. Marchase".

Richard B. Marchase, Ph.D.

FASEB President