



FASEB

Member Societies

The American Physiological Society
American Society for Biochemistry and
Molecular Biology
American Society for Pharmacology and
Experimental Therapeutics
American Society for Investigative
Pathology
American Society for Nutrition
The American Association of
Immunologists
American Association of Anatomists
The Protein Society
Society for Developmental Biology
American Peptide Society
Association of Biomolecular Resource
Facilities
The American Society for Bone and
Mineral Research
American Society for Clinical
Investigation
Society for the Study of Reproduction
Teratology Society
The Endocrine Society
The American Society of Human
Genetics
Society for Gynecologic Investigation
Environmental Mutagen Society
International Society for
Computational Biology
American College of Sports Medicine
Biomedical Engineering Society

President

Richard B. Marchase, Ph.D.
Vice President for Research
Professor of Cell Biology
University of Alabama at Birmingham



9650 Rockville Pike
Bethesda, MD 20814-3998
Telephone (301) 634-7090
Fax (301) 634-7049
<http://www.faseb.org>

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