

March 6, 2002

Christy Schmidt, Executive Coordinator
Regulatory Reform Initiative
Office of the Assistant Secretary for Planning and Evaluation
200 Independence Ave., SW
Washington, DC 20201

Dear Ms. Schmidt:

The Federation of American Societies for Experimental Biology (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. As president of FASEB, I applaud the initiative of the Secretary's Advisory Committee on Regulatory Reform to consult with the public on HHS regulations that unnecessarily or unreasonably inhibit the delivery of health care, the development of pharmaceuticals and biomedical research.

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

A large part of FASEB's mission is made possible through the generous support of the National Institutes of Health (NIH). In its Report on the FY 1998 Labor/HHS Appropriations Bill, the House Committee on Appropriations applauded NIH's efforts to streamline its operations internally and declared the Committee's conviction that "a similar effort should be applied to duplicative and unnecessary Federal regulations which govern the conduct of extramural

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scientific research." In response, NIH commissioned a study "to identify items considered to be burdensome by the research community and to begin the process of identifying potential

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solutions for the issues that emerged."² The Recommendations that issued from the study were reported in the "Mahoney Report". One recommendation resulted in the formation of the NIH

Regulatory Burden Advisory Group (the NIH Group) - a diverse group of scientific experts and institutional officials that has been seeking solutions to problems identified by the Mahoney Report as negatively impacting biomedical research. The Secretary's Advisory Committee has an ambitious agenda. With respect to streamlining regulations that affect biomedical research, the Committee could benefit enormously from initially consulting with the NIH Group. Since both the NIH Group and the Secretary's Advisory Committee on Regulatory Reform are charged with identifying redundancy, a first step in the right direction would be to invite at least one member of the NIH Group to participate in meetings of the Secretary's Advisory Committee as a liaison, to share insights into what work has already been done and to coordinate future efforts.

The Regulatory Burden Human Research Subcommittee is a subcommittee of the NIH Group and has been quite active. This subcommittee has commendably met its charge of identifying unnecessary regulatory burden in the human research protection area and has just recently issued Recommendations for Reducing Unnecessary Burden in Human Research Protection. We concur with those Recommendations. **(See Attachment A – Recommendations of the Regulatory Burden Human Research Subcommittee).**

The protection of human research participants is a paramount concern to both the public and researchers. At the core of the endorsed Recommendations is the recognition that the Institutional Review Board (IRB) system, which was established to protect the rights and welfare of human research participants, is overburdened, understaffed and under great strain, primarily due to increased caseloads. Fear of private litigation and/or suspension by the Office of Human Research Protections (OHRP) has diverted IRB attention away from its primary charge to carefully evaluate the research risks and protections presented by a research protocol and instead focused attention on a strict and literal interpretation of regulations. Too often IRBs spend excessive time on detailed documentation of their deliberations, sometimes producing Minutes that are in excess of 40 pages.

After the April 2003 implementation of the privacy regulations of the Health Insurance [\[3\]](#)

Portability and Accountability Act of 1996 (HIPAA) , IRBs will have a whole new level of responsibilities to document, which will severely exacerbate the current overload. The privacy regulations are so complicated that an entire consulting industry has developed to interpret them. The rule imposes up to \$25,000 in civil fines, with criminal penalties of up to \$250,000 or 10 years in prison. The fear of civil and criminal penalties that attend violations of these regulations will prompt IRBs to devote even more time to documenting discussion of IRB attempts to navigate the shores of these cumbersome and ambiguous regulations. This unnecessary diversion will imperil the protection afforded to human subjects by IRB review.

Moreover, the HIPAA privacy regulations will unnecessarily have a devastating impact on the conduct of biomedical research using human subjects and/or human tissue specimens.

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Essentially, the Common Rule already instructs the IRB to determine all risks of research, including the risk of a violation of privacy. We are unaware of any suggestion that the privacy of medical records is *not* being adequately respected and protected by the IRB system. In fact, a 1997 report by the National Committee on Vital and Health Statistics recognized that IRB

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privacy safeguards work. It would be duplicative and burdensome to also have the IRB consider risks to research subjects under a second set of criteria, particularly when there is such concern that IRBs are under such strain.

We strongly believe research that is subject to IRB oversight under the Common Rule should be exempt from the privacy rule. FASEB has joined with 180 research universities, medical schools, teaching and community hospitals, and medical specialty and scientific societies to petition Secretary Thompson to reopen the research provisions to further rulemaking and comment. We strongly urge this Committee to advise the Secretary to heed the concerns voiced by the research community. (**See Attachment B – Letter to Secretary Thompson dated November 20, 2002**).

Another pressing concern of FASEB relates to the unnecessary burden imposed on researchers who use animals in research. Both DHHS regulations and USDA regulations govern animal

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research. The Health Research Extension Act (HREA) is funded through the National Institutes of Health and is implemented by the Public Health Service Policy on Humane Care and

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Use of Laboratory Animals (PHS Policy). This policy is applicable to those activities conducted and supported by the Public Health Service that involve any live vertebrate animal

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used or intended for use in research. The Animal Welfare Act (AWA) is funded and administered through USDA. It overlaps and conflicts with the HREA in some areas.

The Mahoney Report concluded that the regulation of animal research by two Federal agencies constituted a significant burden:

"Beyond differences in approach, the two organizations frequently issue different requirements governing the same issue. Some, but not all, of the differences

emanate from differing authorizing statutes. Depending on the specific item, one organization's requirements may or may not be more restrictive than the other. The practical consequence for the institution, however, is that it must operate on the basis of the more restrictive provision, regardless of the issue, so as to be in compliance with the more restrictive organization.

Specifically mentioned as burdensome were redundant, legally-mandated program reviews and facility inspections, and AAALAC site visits, cumulatively occurring a minimum of 3-4 times per year, and the consequent paperwork burden; yearly reports to OPRR, UDSA, and AAALAC that request different information; and inconsistent requirements by OPRR and USDA on how often the Institutional Animal Care and Use Committees (IACUC), the Committee charged by the research institution to oversee its animal care and use program, should conduct protocol reviews."

The Applied Research Ethics National Association (ARENA) has offered Comments to this Committee that more precisely delineate the regulations that overlap and conflict. We concur with those Comments. **(See Attachment C- Issues Important to Institutional Animal Care and Use Committees (IACUC), ARENA Comments)**

Since the inception of the AWA in 1966, the Secretary of USDA has specifically excluded rats, mice and birds from the protections of the AWA, using the discretionary authority provided to him under the AWA. The Secretary rightly recognized that the costs of regulating the vast numbers of rats, mice and birds used in research would be prohibitive and unacceptable. Since the majority of the animals used in research covered by NIH funding are rats and mice, researchers have only had to deal with the burden of regulation by dual entities with respect to some of the animals used in such research.

Now, however, at the instigation of animal activists, USDA is currently re-commencing a rulemaking process to consider amending the definition of "animal" covered by regulations of the AWA to remove the current exclusion of rats and mice bred for use in research and birds. Such a change would add layers of duplicative and inconsistent regulations and would result in both DHHS and USDA regulating the vast numbers of rats/mice and birds that are used in biomedical research. It is our opinion that the inclusion of rats, mice and birds under the USDA inspection and reporting requirements does little to additionally protect these species already protected under PHS Policy. In Fiscal Year 1999, USDA's Animal Care Division commissioned the research division of the Library of Congress to help determine the number of rats, mice, birds and facilities that would be regulated if the definition of "animal" in the Regulations was amended to include them. The report estimated that more than 500 *million* rats/mice/birds could be added to the AWA should the Act be amended to include them. **(See Attachment D – Library of**

Congress Report)

In response to voter opposition to excessive government intervention and regulation, successive Administrations have recognized the importance of eliminating such redundancy. In December 1995, USDA, FDA, and NIH signed a Memorandum of Understanding (MOU) concerning laboratory animal welfare. This MOU was renewed in 2001. The purpose of the MOU is "to set (s) forth procedures of reciprocal cooperation which will assist each agency in meeting its responsibilities in promoting proper laboratory animal care and welfare. Implementation of this agreement is intended to maintain and enhance agency effectiveness while avoiding duplication of efforts to achieve required standards for the care and use of laboratory animals." (**See Attachment E – Memorandum of Understanding**) The proposed duplication of regulation rats, mice and birds by both DHHS and USDA is *precisely* the kind of duplication of effort the MOU was designed to avoid. We don't need an additional level of bureaucracy that would divert resources from biomedical research without providing any new benefits for laboratory animals. We view this Committee's interest in public comment as an opportunity to re-enforce the goodwill and sense underlying the MOU and we look to the leadership of the Secretary to assure that the intention of the MOU is respected.

Our progress toward improved quality of life is diminished whenever research is limited or curtailed and research funds are wasted due to duplicative regulatory requirements. The scientific community stands prepared to work with DHHS and other Federal agencies to continue its farsighted efforts to promote research productivity by establishing an appropriate level of regulation and oversight. We commend the Secretary for appointing this Advisory Committee and support the continued focus on reducing regulatory burden. We offer the expertise of the scientific community in this endeavor.

FASEB recommends that this Committee invite at least one member of the NIH Group to participate in meetings of the Secretary's Advisory Committee as a liaison; advise the Secretary to modify the privacy rule to exempt research conducted under the supervision of an IRB under the Common Rule; advise the Secretary to reconcile those regulations identified as conflicting and/or overlapping by the Applied Research Ethics National Association, and take a leadership role in implementing the Memorandum of Understanding concerning laboratory animal welfare.

Thank you for the opportunity to comment.

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

Cc: Steven L. Teitelbaum, MD

President-Elect

Bettie Sue Masters, PhD
Vice President for Science Policy

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House Report No. 105-205, p.98.

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Mahoney Report: (See <http://grants2.nih.gov/grants/policy/regulatoryburden/default.htm#toc>).

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Department of Health and Human Services. Standards for privacy of individually identifiable health information. Final rule. Fed Regist 2000; 65(250):82462-829.

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45 C.F.R. Sec 46.111(a) (7).

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Health privacy and confidentiality recommendations of the National Committee on Vital and Health Statistics Washington, D.C.: National Committee on Vital and Health Statistics, June 27, 1997.

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Public Law 99-158, November 20, 1985, Section 495, "Animals in Research".

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March 1996, Public Health Service Policy on Humane Care and Use of Laboratory Animals

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7 U.S.C. 2131 et. seq.

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