

January 8, 2002

The Honorable John D. Graham, Ph.D.
Administrator for the Office of Information and Regulatory Affairs
Office of Management and Budget
Executive Office of the President
Old Executive Office Building, Room 262
Washington, DC 20502

Dear Dr. Graham:

This letter follows up on our November 8 meeting and my subsequent correspondence of November 19. As you are aware, The Federation of American Societies for Experimental Biology (FASEB) is an umbrella organization representing 60,000 researchers in more than 21 scientific societies. FASEB's mission is to enhance the ability of biomedical and life scientists to improve, through their research, quality of life for all people.

As a consequence of settlement of litigation brought by an organization of "animal activists," the United States Department of Agriculture (USDA) is re-commencing a rulemaking process to consider amending the definition of "animal" covered by regulations of the Animal Welfare Act (AWA) to remove the current exclusion of rats and mice bred for use in research and birds. Such a change would severely curtail vital biomedical research by adding layers of regulations to a field already heavily regulated without producing a commensurate benefit for human or animal welfare. Aside from the moral imperative to treat animals humanely, researchers have a powerful reason to provide high quality care for animals. Such care is key to the integrity of the scientific results produced by the research. However, FASEB maintains that such care is currently being provided with appropriate oversight and we strongly object to removing the current exclusion of rats and mice bred for use in research and birds, under the AWA regulations.

Preliminarily, I would like to describe the confusing history of this issue. From the inception of the AWA in 1966, the Secretary of USDA had 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. Although the AWA was amended in 1970, 1976, 1985, and 1990, rats, mice and birds continue to be excluded from coverage.

On April 29, 1998, USDA received a petition for rulemaking from Alternatives Research and Development Foundation (ARDF) and others, requesting that the USDA amend the definition of "animals" covered by regulations in the Animal Welfare Act to include rats, mice and birds. In accordance with its rulemaking procedures, USDA published ARDF's Notice of Proposed

Rulemaking in the Federal Register on January 28, 1999 (64 Fed.Reg. 4356). In so doing, the Department stated that it opposed ARDF's efforts to extend coverage of the AWA. I am attaching a copy of the Department's Notice published in the Federal Register which articulates the Department's position. **(See Attachment A)**

The thrust of the Department's position is that the inclusion of these animals would drain USDA resources to such a point that enforcement efforts for the protection of other species covered by the AWA would be severely compromised. The Department referenced a 1990 study which concluded that the annual costs just for conducting inspections of the additional research facilities involved if the AWA was expanded to cover rats, mice and birds, would be at least \$3.5 million (*in 1990 dollars*) - roughly one-third of the 1999 USDA Animal Care budget. The report also concluded that extending AWA protection as requested would have *doubled* the number of regulated research facilities, necessitating an enormous staffing increase while the appropriation for AWA enforcement was anticipated to remain constant, as it had for the prior 7 years. This estimate does not include the vastly greater costs (possibly well in excess of \$100M per year) that would be imposed upon research universities for mandated record keeping and reporting.

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 500 plus *million* rats/mice/birds could be potentially added to the AWA should the Act be amended to include them. **(See Attachment B)**

In March 1999, *before* the comment period concluded in the rulemaking proceeding, ARDF and others filed a lawsuit in US District Court for the District of Columbia, requesting that the Court provide the very relief requested in the rulemaking. Obviously, the Department's unequivocal statement of its position in response to the rulemaking process convinced ARDF to try a different forum. Although Comments were received in response to the Department's Federal Register Notice, no further action was taken.

On August 25, 2000, the parties requested that the Court stay all proceedings while they engaged in settlement discussions. The Court granted the request. On October 5, 2000, ARDF and USDA filed a Stipulation of Dismissal. Under the terms of the Stipulation, USDA agreed to grant the Petition for Rulemaking and also agreed to initiate and complete a rulemaking on the regulation of birds, rats and mice within a reasonable time.

An explanation of USDA's settlement of the lawsuit is posted on the website of USDA. It states that USDA entered into the settlement "first and foremost in order to preclude the potential for an adverse judgment by the U.S. District Court that might have dictated the nature and timeframe for coverage of rats, mice, and birds." **(See Attachment C)**

USDA never completed agency action as contemplated by the Stipulation because FY 2001 appropriation language prevented USDA from spending any funds “ to issue a notice of proposed rulemaking, to promulgate a proposed rule, or to otherwise change or modify the definition of “animal” in existing regulations pursuant to the Animal Welfare Act.” Pub L. No.106-387, Sec.772. Recent FY 2002 appropriation language permits USDA to begin the regulatory process so long as the agency does not issue a final rule on coverage until after October 1, 2002.

The Health Research Extension Act, another federal law that overlaps the AWA, already provides oversight of animal care and use in research funded by the Public Health Service. While the AWA is funded and administered through USDA, the Health Research Extension Act is funded through the National Institutes of Health and is implemented by the Public Health Service Policy on Humane Care and 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 used or intended for use in research. The PHS Policy is based on the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training *and* also requires institutions to develop and implement institutional programs for activities involving animals, using a Guide for the Care and Use of Laboratory animals as a basis to develop institutional programs for activities involving animals. As reported in the Library of Congress Report, the Institute of Laboratory Animal Research at the National Resource Council (ILAR) claims that NIH funding covers 95% of all research facilities. Thus 95% of rats/mice and birds are already subject to extensive regulation under the Health Research Extension Act/PHS Policy.

Both the AWA and the PHS Policy require that an institution have an institutional animal care and use committee (IACUC) charged with reviewing the institutions animal care procedures related to the care and use of laboratory animals and of the facilities where the animals are housed. The IACUC reviews all protocols that will use animals in research, education, or testing and ensures that the numbers of animals used are minimized, that experiments are not redundant, that surgeries are performed with appropriate anesthesia and post-operative analgesia, and that a humane method of euthanasia is employed.

Aside from the IACUCs, many of the large commercial facilities have voluntary accreditation with the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC). These accredited facilities, while not receiving public funds, must nevertheless still comply with the provisions of the Guide for the Care and Use of Laboratory Animals of the National Research Council regarding the care of all research animals, including rats, mice and birds.

Voters continue to voice their opposition to excessive government intervention and regulation,

and 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 D)**

The proposed petition for rulemaking is precisely what the MOU was designed to avoid. It is our opinion that the inclusion of rats, mice and birds under the USDA inspection and reporting requirements does very little to additionally protect these species while resulting in very large new costs both to the government and the universities. Any cost-benefit analysis would reveal that there is enormous cost in acceding to the request of ARDF, with no proof of added benefit. New record-keeping and reporting requirements would needlessly encumber the research process. Money that is spent on duplicative record-keeping cannot be spent on potentially life-saving research. For example, one can imagine the difficulty of a large research facility producing meaningful counts of rapidly reproducing rats and mice. Richard Traystman, Ph.D., Director of Research Laboratories at the Johns Hopkins University School of Medicine and Chair of that institution’s IACUC for more than 20 years, has stated that under PHS Policy, “research facilities such as Johns Hopkins do not count each bird, rat or mouse, nor as a general practice do they keep records according to individual animals unless required by the governing research protocol. Since there are tens of thousands of animals of the mouse and rat species housed at Johns Hopkins the maintenance of records on every individual animal on a daily basis would be impractical, present an insupportable financial and personnel burden on the research being conducted at Johns Hopkins, and would undermine the cost-based reasons for using these animals in research.” **(See Attachment E)**

Another USDA policy requirement compels documentation of a literature search to demonstrate the consideration of alternatives to procedures likely to cause pain or distress. This time-consuming requirement assumes that researchers are not guided by scientific or ethical principles when they design their experiments. The frustration and expense of complying with these requirements if the AWA was extended to rats, mice and birds, could well convince some researchers who found themselves spending more time in the office doing paperwork than in the laboratory doing research, to discontinue animal-based research.

This Administration and the American people have been extraordinarily generous in support of research. The critical advances made in human and animal health could not have been made without using animals in research. If such research is limited or curtailed due to duplicative regulatory requirements, future medical breakthroughs may be lost. This would be particularly

tragic now that we are so dependent on rapid advances to secure both the Nation's health and its safety. We urge you to stop this misguided and unwarranted effort by some in your Administration to appease those who would cripple medical research.

As President of FASEB, I am requesting that the OMB undertake a comprehensive analysis of the implications of expanding the AWA's coverage to rats, mice and birds. I look forward to further discussion of this matter with you.

Sincerely,

Robert R. Rich, M.D.
President

Cc: Steven Teitelbaum, M.D., Ph.D.
Howard Garrison, Ph.D.
F. Patrick White
Debra Aronson, Esq.