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More Regulation of Rodents

Frankie L. Trull and Barbara A. Rich

When enacted more than 30 years ago, the Animal Welfare Act initiated federal regulation of the use of laboratory animals. The act defines "animal" as "any live or dead dog, cat, monkey (nonhuman primate mammal), guinea pig, hamster, rabbit, or such other warm-blooded animal, as the Secretary [of Agriculture] may determine is being used, or is intended for use, for research, testing, experimentation, or exhibition purpose, or as a pet." Congress explained this definition by saying that it is "expect[ed] that the Secretary would designate additional species of animals not previously covered as permitted by available funds and manpower." The Alternatives Research and Development Foundation (ARDF), an affiliate of the American Anti-Vivisection Society, recently petitioned the U.S. Department of Agriculture (USDA) to add rats, mice, and birds to its Animal Welfare Act regulations, and USDA has published the petition with a request for comments. Claiming that Congress intended the Animal Welfare Act to protect all warm-blooded animals used in research and that USDA unlawfully excludes rats, mice, and birds, ARDF later filed a federal lawsuit. However, the legal system is not the proper venue for resolution of this policy question.

Rats and mice, and, to a lesser extent, birds, are widely used in research. The National Association for Biomedical Research (NABR) estimates that 23 million rats and mice were used in 1998 and made up 95% of all laboratory animals. Reliance on these important research subjects, especially transgenic mice, is expected to increase by one-half in the next 3 to 5 years. Like all other laboratory animals, rodents deserve humane treatment. Ethical and scientific excellence require it, as does federal law. Rats, mice, and birds are already sufficiently protected by the voluntary program of the Association for Assessment and Accreditation of Laboratory Animal Care International, as well as by government programs put in place after the Animal Welfare Act, namely, the U.S. Public Health Service assurance program and the animal welfare requirements in the Food and Drug Administration–Environmental Protection Agency Good Laboratory Practice Standards. More than 90% of research rats, mice, and birds are covered by one or more of these programs, and the compliance requirements of these initiatives duplicate those of the Animal Welfare Act.

So, one might argue, if they are already treated in the same manner as species covered by the Animal Welfare Act, why not add rats, mice, and birds to USDA regulations? The main reason is cost. A recent NABR survey indicates that many USDA-registered research facilities will have to make administrative changes to comply with the Animal Welfare Act for rats, mice, and birds. Researchers, veterinarians, and other staff will have to spend more time on Animal Welfare Act recordkeeping, annual reporting, and other compliance procedures. These activities will likely increase costs by \$84 million, an investment that would not actually benefit animals. In addition, if the animal definition is revised, academic institutions and research-related companies that house only rats, mice, or birds will have to register with USDA for the first time and spend as much as \$80 million to \$200 million to comply with all statutory requirements. Federal funding always has been meager for Animal Welfare Act enforcement and USDA inspections. The annual budget for this purpose is only \$9.2 million and must be stretched to monitor over 10,000 sites. Because this funding has been stagnant since 1991, the number of Animal Welfare Act inspections has declined by 50% to an average of just one annual visit per site. Regulating the additional animals proposed could double or even triple the inspection workload at research facilities. The Animal Welfare Act enforcement program should not be further compromised by new duties.

Therefore, USDA must request an appropriation sufficient to finance any new regulatory demands. Federal lawmakers can then consider whether the public's interest in laboratory animal welfare will be served by further regulation. We think not, but ultimately Congress needs to decide whether taxpayers want research time and dollars diverted into redundant federal rules—a luxury we can do without.

The authors are the president and executive vice president, respectively, of the National Association for Biomedical Research in Washington, DC.

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