

Chapter Twenty

The History of the Animal Welfare Act

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In the United States the development of federal legislation to protect research animals has evolved in response to a growing public opinion that society has an ethical responsibility to consider the needs of animals which are used by man (1). During the first years of this century, a small number of American antivivisectionist organizations advocated that all animal experimentation be halted. The actions of the antivivisectionists had little effect in contention with a strong public inclination to maintain freedom of scientific inquiry. However, during the last half of the 1900s animal protection groups have adopted a more gradual approach and have become more sophisticated in working through the legislative process. They have used the media effectively to focus public awareness on specific issues, including conditions of animals used for purposes of research. One campaign which set the stage for the enactment of the Laboratory Animal Welfare Act (LAWA) of 1966, used a photo essay in LIFE magazine to bring public attention to inhumane handling by dealers of dogs being sold for research (2).

But a comprehensive understanding of the Animal Welfare Act must also consider the significant role which animal care veterinarians and technicians were already playing to improve conditions for laboratory animals. The Animal Care Panel, predecessor of the American Association for Laboratory Animal Science, was already developing programs to improve professional training for laboratory animal scientists and technicians before legislation was passed. This group, along with other laboratory animal scientists, sponsored the formation of the American Association of Accreditation of Laboratory Animal Care (AAALAC) in 1965. By the time the LAWA was enacted,

there was already a body of trained professionals whose input over the 30-year history of the Act has made a significant contribution. In turn, the minimum standards required under the Act have caused administrative officials in research facilities to focus on laboratory animal care needs and have assisted laboratory animal scientists in speaking for improved conditions.

Legislative History

Laboratory Animal Welfare Act of 1966

The Laboratory Animal Welfare Act (LAWA) of 1966 (3) was passed on a wave of public sentiment which produced thousands of letters to Congress, protesting the alleged theft of pet dogs for sale to research. The LAWA, Public Law 89-544, was the final version of a bill introduced initially by Congressman Joseph Y. Resnik of New York. It followed an incident in which a pet dalmatian dog, "Pepper," allegedly was taken from a Pennsylvania family and sacrificed in an experiment in a New York hospital (4). Other bills also were introduced to provide legislation to regulate animals in research, including one by Sen. Warren Magnuson. The Society for Animal Protective Legislation worked diligently with congressional staffs on behalf of the legislation as the contentious debate proceeded.

Several biomedical groups vigorously opposed the idea of legislation to regulate the care of research animals. They pointed to the creation in 1950 of the Animal Care Panel and in 1965 of the American Association for Accreditation of Laboratory Animal Care. Humane groups, however, asserted the position that only legislative intervention could address perceived abuses of animals in the care of dealers and research facilities. There was something in the final version of the LAWA for both sides. The humane groups prevailed in their viewpoint that researchers, as the main users of laboratory animals, would not be able to enforce measures to correct animal care abuses objectively; authority for implementation and enforcement of the LAWA was given to the Secretary of Agriculture. A significant amendment; however, introduced late in congressional debate, limited regulation to animals in holding facilities. It allowed research facilities to make the judgment of when an animal entered actual conduct of research, where it would not be subject to regulation (5).

Under the LAWA of 1966 only those research facilities which used dogs or cats and received federal funds or used dogs and cats which were obtained in interstate commerce had to register with the United States Department of Agriculture (USDA). Four additional animal categories—rabbits, hamsters, guinea pigs, and nonhuman primates were covered only in those facilities which qualified under the limiting registration criteria. Similarly, only those dealers who bought or sold dogs or cats across state lines had to be licensed. Inherent in the responsibility of dealers was the need for individual identification and record keeping for dogs and cats bought, sold, or transported for research. Registered research facilities were required only to maintain records of acquisition for dogs and cats.

In order to implement the LAWA of 1966, the United States Department of Agriculture was charged with developing minimum standards of care and treatment with respect to eight areas: housing, feeding, watering, sanitation, ventilation, shelter from extremes of weather and temperature, separation by species, and adequate veterinary care (3). USDA consulted with many groups with various points of view about and interests in laboratory animal care during the process of developing rule making and publishing the regulations which implemented the law.

The Department contracted with the Institute for Laboratory Animal Resources of the National Research Council (National Academy of Sciences) to draft the standards to be enforced in the covered areas of care. These requirements by statute had to define minimum levels of care which would be enforced. Research facilities not meeting this floor level of care are subject to civil penalties and cease-and-desist orders; dealers who did not meet the minimum standards could be fined and/or have licenses suspended or revoked. Most requirements under the LAWA of 1966 were expressed as design standards, for example specified dimensions for cage size.

The principal mechanism for monitoring and enforcement of the LAWA of 1966 was a system of unannounced inspections of research facilities and dealers' premises by USDA personnel from the Animal Health Division, now the Animal and Plant Health Inspection Service (APHIS). In the beginning this inspection responsibility was added to the duties of field veterinarians and inspectors of this agency. Since 1988, animal care has become a separate division of APHIS. Initial implementation required a vigorous training program for USDA inspectors, which was undertaken across the country. Laboratory animal scientists and technicians frequently participated in these training sessions.

Two principles which were established in the LAWA of 1966 are still significant today. First, the LAWA and subsequent legislative amendments have all stated that standards and regulations must permit continuation of animal research (3) (6) (7). The second principle is the Secretary of Agriculture's definition of "adequate veterinary care" as requiring the supervision of a doctor of veterinary medicine, a member of a profession with a declared primary responsibility to animal well-being. These two principles express the intent of the LAWA to balance the needs of research and those of public concern for the welfare of laboratory animal subjects.

1970 Amendments

With enactment of the 1970 Amendments to the LAWA USDA requirements were extended beyond the animal holding facilities into the laboratory, with the provision that requirements should not interfere with research. Other 1970 changes which had direct impact on biomedical research included the following:

- Research facilities were required to report certain information to USDA,—the number of animals used (by species); whether pain-relieving drugs were administered or a justification for causing pain, if pain-relieving drugs were not used. USDA was required to compile this data in a report to Congress, to be made available to the public.
- The requirement for adequate veterinary care was modified to include appropriate use of anesthetics, analgesics, tranquilizers, and other pain-relieving drugs.
- The term "commerce" was re-defined to include both intra- and inter-state traffic in animals for research, for both facility registration and dealer licensing.

The LAWA was renamed the Animal Welfare Act (AWA) (6) with passage of the 1970 amendments reflecting the extension of the Act's coverage to include all warm-blooded species and additional animal uses. The expansion brought animals in zoos, circuses, and shows, and in the wholesale pet trade under its coverage. The effect of this was that USDA Animal Care had the responsibility to other regulated constituencies, as well as to research. On the other hand, this expansion in scope also meant that biomedical research was no longer the only sector among animal users which had to comply with federal animal welfare

regulation. The AWA also required that USDA consult with other federal agencies in writing standards and regulations.

In implementing the 1970 amendments the Secretary of Agriculture, by regulation, excluded certain species from coverage, and succeeding Secretaries have followed this policy. Rats, mice, birds, domestic farm animals, and marine mammals were excluded under this discretionary authority. Authority for discretionary exclusion of marine mammals has been superseded by later legislation, with USDA maintaining and exercising authority to regulate marine mammals in captivity. Domestic farm animals used for nonagricultural research were returned by the Secretary to the list of regulated species in 1990. Animal Care is now establishing standards for this area. At this writing, rats, mice, and birds are still excluded. However, in early 1999, several concerned persons and groups have submitted a formal petition requesting the Secretary of Agriculture to eliminate exclusion of these species.

1976 Amendments

The 1976 Amendments (7) focused on transportation. The LAWA of 1966 covered only transportation by dealers or research facilities. The 1976 provisions extended regulation to commercial carriers and intermediate handlers of animals being transported for research, exhibition, and the wholesale pet trade. Rats, mice, and birds are currently excluded under USDA's discretionary authority. However, if those species are ever returned to the regulated list, transportation for these animals will become subject to coverage.

The sizes of primary enclosures for transportation were standardized and regulations for ventilation, ambient temperature ranges, and handling procedures were implemented. Some rail and truck carriers ceased transporting animals for the stated purposes. However, major air carriers initiated training programs for cargo handling personnel. These training programs helped minimize human handling errors in transporting animals.

1985 Amendments

The 1985 Amendments (8) once again focused on laboratory animal research, requiring development of very detailed and comprehensive regulations. Many of the statute's provisions had previously been required by the National Institutes of Health and the Public Health Service Policy for the projects they funded. The 1985 Amendments:

- Extend coverage to all USDA-registered research facilities.
- Make compliance a requirement under federal law.

Furthermore, in response to concerns about laboratory animal welfare expressed to Congress by concerned citizen groups, the legislative intent expressed in the 1985 Amendments is to build in accountability, assuring that: 1) alternatives to experiments which inflict pain or stress on research animals are used when possible; 2) pain/stress-relieving measures are used during research when needed; and 3) a committee is established within each research facility to review animal care and use; and 4) responsibility and accountability is assigned to the chief executive officer for meeting AWA requirements. (Prior to 1985, registered research facility compliance was primarily the responsibility of the attending veterinarian.) In addition the 1985 statute expands the animal care concept to include "animal well-being", i.e., exercise for dogs and enhanced physical environment for primates (9)(10). The 1985 AWA requires that USDA consult with the Secretary of Health and Human Services before publishing regulations and standards.

Institutional Animal Care and Use Committee (IACUC)

The 1985 Amendments mandated the establishment by every USDA-registered research facility of a committee at the institutional level which has the overall responsibility of reviewing and assessing planned experimental activities and of monitoring ongoing laboratory animal care and treatment throughout the institution under the AWA. Members of the IACUC are appointed by chief executive officers of the facilities and act as their agent in carrying out responsibilities. Reports of the IACUC are submitted to that official.

The composition of the IACUC must include at least one member who is neither affiliated with the research facility nor a relative of facility personnel. There must also be a doctor of veterinary medicine on the committee, qualified in laboratory animal science and medicine and responsible for professional duties in the animal care and treatment program. Investigators present plans for experimental procedures to the IACUC before research begins. The net effect of these regulatory requirements is to spread responsibility for animal care and treatment over a wider range of personnel within a research facility.

In addition to reviewing research plans for compliance with provisions of the AWA, representative members of the IACUC must inspect the animal facilities at least semi-annually. The IACUC is responsible for investigating complaints of noncompliance in the facility and may suspend or ask for changes in research procedures to meet legal responsibilities. The IACUC maintains records of meetings, reviews, and other activities.

USDA personnel must conduct unannounced inspections of research facilities at least once annually. During those visits, the inspectors are authorized to review IACUC documentation of activities, including minutes, complaint records, and reports.

In reviewing research proposals and making an overall assessment of its facility's research activities, the IACUCs refer to the following criteria established in the 1985 Amendments:

- a) Procedures involving animals must avoid or minimize discomfort, distress, and pain to the animals.
- b) The principal investigator must consider alternatives to procedures which may cause more than momentary or slight pain or distress to the animals, and must provide a written description of the methods and sources used to determine that no alternatives were available, e.g. Animal Welfare Information Center database or National Library of Medicine resources.
- c) The principal investigator must provide written assurance that the activities do not unnecessarily duplicate previous experiments.
- d) Procedures which may cause more than momentary or slight pain or distress to the animals must satisfy the following requirements:
 - Such procedures must be performed with appropriate sedatives, analgesics, or anesthetics, unless withholding such agents is justified for scientific reasons.
 - The planning of such procedures must involve consultation with the attending veterinarian or his/her designated replacements.
 - Such procedures must not involve the use of a paralytic without anesthesia.
- e) Animals which would otherwise experience severe or chronic pain or distress without the possibility of relief must be painlessly euthanized at the end of the procedure or, if appropriate, during the procedure.
- f) Personnel conducting procedures on the species being

maintained or studied must be appropriately qualified and trained in the relevant procedures. Training of such personnel must be assured by the chief executive officer or delegated to the IACUC.

- g) Activities which involve surgery must include appropriate provisions for pre- and post-operative care of the animals, in accordance with established veterinary medical practices.
- h) No animal may be used in more than one major surgical procedure from which it is allowed to recover, except with special permission of the IACUC or USDA.
- i) The living conditions of the animals must be appropriate for the species in accordance with Part Three of the USDA regulations (10), and must contribute to the health and comfort of the animals. The housing, feeding, and nonmedical care of the animals will be directed by the attending veterinarian or another scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied.
- j) Medical care must be available for animals and provided, as necessary, by a qualified veterinarian.

Training Requirements

The 1985 Amendments prescribed in some detail the areas of training that are required of all personnel who handle, care for, or perform procedures on animals in a research project. Accountability for providing this training was placed with the chief executive officer, who often delegates this responsibility to the IACUC. All facility personnel associated with animals must be trained in the following areas:

- a) Humane methods of animal maintenance and experimentation, including the following:
 - the basic needs of each species of animal being used;
 - proper handling and care for the various species of animals;
 - proper pre- and post-procedural care of animals; and
 - aseptic surgical methods and procedures.
- b) The concept, availability, and use of research or testing methods which limit the use of animals or minimize animal distress.
- c) The proper use of anesthetics, analgesics, and tranquilizers for any species of animals used by the facility.
- d) Methods by which deficiencies in animal care and treatment are reported by employees of the facility and knowledge that no employee, committee member, or laboratory personnel may be discriminated against or be subject to reprisal for reporting violations of the AWA.
- e) Use of available services to provide information with regard to:
 - appropriate methods of animal care and use;
 - alternatives to the use of live animals in research;
 - information which could prevent unintended and unnecessary duplication of research involving animals; and
 - information with regard to the intent and requirements of the AWA.

Animal Well-Being Requirements in the 1985 Amendments

Two of the measures passed with the 1985 Amendments were very controversial. One required USDA to develop and implement standards for exercise of dogs being used for research purposes. The other mandated the provision of a physical environment adequate to "promote the psychological well-being of primates." (8)

Although relatively little published scientific evidence was

available in the early 1980s, after the 1985 Amendments were enacted, a body of research emerged which focused in large part on environmental enhancement for nonhuman primates, and to a lesser extent, on the exercise requirements for dogs.

The first proposed rule making on these two issues was published in the Federal Register, with specific design proposals for housing and standards for the handling of animals. Thousands of comment letters were received, pro and con. At the same time a vigorous movement for deregulation was underway throughout government. The proposed standards were modified and republished as performance-based requirements. Parameters were established in terms of outcomes for the animals covered, e.g. opportunity for exercise for dogs, opportunity for stimulation and socialization for primates (9). Appropriate plans for facility compliance within such parameters must be developed, documented, and followed with approval by the attending veterinarian. The implementation of the performance standards continues to be a decision with which animal protection groups take issue and legal action (11).

Establishment of the Animal Welfare Information Center

Also resulting from the 1985 Amendments was the establishment of the Animal Welfare Information Center (AWIC), located at the National Agriculture Library in Beltsville, Maryland. The mission of this organization is to provide a database of information online, regarding all animal research, available to investigators and others worldwide. This database allows researchers to check for alternatives to the use of animal models and assists them to avoid unnecessary duplication of research. A small staff maintains this important resource and also conducts workshops to train individuals in use of the database.

Legislative Activity Since 1985

The Pet Theft Act of 1990 (12), was passed as a part of the 1990 Farm Bill. This legislation required that licensed research facilities, animal pounds and shelters hold acquired dogs and cats for at least five days before selling them to a dealer, who in turn must provide certification to the research facility of the source of the animal. This law affects only a few research entities and does not impact the registered research facilities.

Judicial and Executive Actions and the AWA

In a democracy no statute is implemented in a vacuum. Whatever the legislative intent behind a law may be, its implementation and enforcement are subject to the influence of many other factors. The controversial history of the AWA is certainly no exception to this maxim. Many views about animal care issues contend, and, in a democracy, they all deserve equitable and fair consideration. The implementation of the AWA has always had that goal as a principle.

When the LAWA of 1966 was enacted, Dr. Francis J. Mulhern was director of the Animal Health Division, one of APHIS' organizational predecessors. Under his direction, Dr. Earl Jones and Dr. Dale Schwindaman began implementation of USDA animal care regulation with this goal of even-handedness as a high priority. Over the intervening years, there have been many changes in organizational structure and in animal care staff personnel. Among the individuals on the animal care staff with whom the biomedical community has had association are Drs. Richard L. Rissler, Robert Whiting, Timothy Mandrell, Richard Crawford, Morley Cook, and Debra Beasley. Dr. Schwindaman served as chief staff veterinarian for laboratory animals, as senior staff



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veterinarian for animal care, and as deputy administrator of APHIS for animal care and regulatory enforcement, a twenty-year association with biomedical research. Currently, Drs. Bettye Walters and Jerry DePoyster are the animal care staff liaison for research issues. Dr. Ron DeHaven, the present deputy administrator of APHIS for animal care, represents USDA at many scientific and medical research conferences.

Although, Judicial decisions have not played a major role in altering the course of AWA implementation, there is the potential for the courts to have a significant impact. An example of that potential is the legal action brought by animal protection groups seeking to force the implementation of design rather than performance standards (10). If successful, this action would require lengthy rulemaking—inevitably contentious.

Over its 32 year life, the AWA has been administered under seven U.S. Presidents, and even more Secretaries of Agriculture, each with a different emphasis, style, and interest level in animal welfare. In the Clinton administration, there have been initiatives to reduce the size of government while providing improved customer-oriented services (13). Departments, including USDA, have focused attention on fostering cooperative arrangements, both among agencies and with the private sector. This cooperation is not new in implementing the AWA. Over the years, a growing willingness to discuss controversial animal care issues with civility has often been a saving grace in difficult situations. Most of the animal protection groups have become more reasonable and more effective by adopting a more gradual approach to reform. The scientific community has become more accepting of reasonable regulation under AWA. Readers who go back as far as the 1960s and 1970s recall a more disagreeable time. They will be gratified, for example, to observe recently that AAALAC, the Animal Welfare Institute (AWI), and WARDS all contributed to funding the publication of proceedings of the symposium held in 1996 to commemorate thirty years of the AWA. These organizations joined APHIS' Animal Care and the Agricultural Research Services' (ARS) Animal Welfare Information Center in celebrating the 30th and 10th anniversaries, respectively, of those agencies (14). This kind of trend can only improve communication, increase understanding, and focus energies on improving conditions both for laboratory animals and research. Therefore, in concluding this history of the AWA for the 50 year anniversary of the American Association for Laboratory Animal Science, it is appropriate to acknowledge some of the scientific groups which have cooperated directly and indirectly in implementing the AWA.

Governmental and Quasi-Governmental Agencies

- The Institute of Laboratory Animal Research (ILAR), a division of the National Academy of Sciences, drafted the first standards under the LAWA. The validity of these standards has endured over time.
- The NIH Office for Protection from Research Risks (OPRR), initiated the first formal cooperative agreement among NIH, USDA, and FDA. The cooperative relationship with NIH is a long-term and continuing one. Drs. John Miller and Nelson Garnett have been instrumental in fostering this productive

relationship, which was critical in resolving the stalemate over implementation of the 1985 Amendments.

Private Organizations

- The American Society of Laboratory Animal Practitioners (ASLAP) developed and carried out a training program in which selected animal care veterinary inspectors are given the opportunity for hands-on training and experience in research facilities where members direct animal care activities. These inspectors then share the knowledge gained through this experience in animal care regional training meetings.
- The Association for the Assessment and Accreditation of Laboratory Animal Care, International (AAALAC) conducts assessments and provides accreditation to institutions which apply for that status and meet its criteria. While their confidential site visit assessments are based mainly on the *Guide for the Care and Use of Laboratory Animals* (15), AAALAC also requires compliance with the regulations promulgated under the AWA.
- The Scientists Center for Animal Welfare (SCAW) is an independent organization of scientists and others concerned about humane responsibilities to research animals. Through its numerous education and information programs, SCAW provides a forum where scientifically-based data and observations about animal care issues can be presented and discussed. Such objective information and discourse is a much-needed resource for decision-making in the ongoing implementation of the AWA.
- Public Responsibility in Medicine and Research (PRIM&R) is an organization which presents conferences and other events related to ethical issues in medicine and biomedical research. Its annual conference devoted to animal care and use provides a valuable opportunity for exchange of information and viewpoints among scientists, veterinarians, and animal protection advocates.

AALAS and the Animal Welfare Act

The American Association for Laboratory Animal Science (AALAS) and its predecessor, the Animal Care Panel, have maintained an objective and progressive stance toward the regulation of laboratory animal care and treatment. AALAS has been successful in its founding purpose of improving knowledge and training for laboratory scientists and technicians. In the early days of the AWA, although there were dissenters among the AALAS membership, the expressed acceptance by many members lent a core of support that was critical in getting the animal care program started. Many individual members of the organization, along with other laboratory animal scientists and technicians, have spoken out about AWA proposals, and have assisted in federal training program. This combination of input has been a very beneficial factor in making the AWA program work. AALAS, in its regional and national program meetings and

conferences, has included topics directly related to AWA regulations and has invited animal care personnel to participate.

In the final analysis, it is, in large part, the professionalism of laboratory animal care specialists in a research facility that produces compliance with the minimum standards prescribed by the AWA regulations and goes on to achieve higher levels of care for laboratory animals. In turn, the Animal Welfare Act has made an essential contribution to that effort by bringing the needs of laboratory animals to the attention of facility administrators and assisting laboratory animal specialists in speaking out for improved facilities and funding. This relationship is one that fosters both scientific inquiry and humane concerns for laboratory animals.

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