

REGULATION OF ANIMAL EXPERIMENTS

History and Background of Regulation

Regulation of animal experimentation by law in the western world began in the late nineteenth century. The first proposal for regulation in the United States was put forward for the District of Columbia in 1880. Roughly similar to the regulatory law enacted in Britain in 1876, the American bill was dropped when it was opposed by the scientists whose opinions were asked, and from that time till 1960, there was no serious effort to legislate humane treatment of experimental animals on the federal level. Instead, anti-vivisection societies, committed to abolition of animal experiments confronted medical research societies who were equally committed to an all or none position, making assertions such as, "laboratory animals are more pampered than pets" and conducting aggressive legislative campaigns to force humane shelters to provide dogs and cats for experiments.

Meanwhile, although the federal government did not become seriously involved in animal protective legislation until the passage of the 1958 Humane Slaughter Law, general anti-cruelty laws were passed in every state between 1828 and 1913. Twenty-three states specifically exclude animal experiments conducted in scientific institutions from the provisions of the anti-cruelty statutes. In the states without exemptions, prosecution for cruelty to laboratory animals has been rare. Only two cases, (Massachusetts, 1958 and Maryland, 1982) are recorded. As for the minimal provisions relating to the care of animals which accompany laws requiring their surrender from pounds and humane society shelters, there appears to be no record of any enforcement proceedings.

Historically, as a result of a different climate of opinion in scientific circles, other countries acted earlier than the United States to develop laws regulating the use of experimental animals. Fourteen European countries have substantial legislation regulating the use of laboratory animals: Austria, Belgium, Denmark, The Federal Republic of Germany, France, Great Britain, Iceland, Ireland, Italy, Luxembourg, the Netherlands, Norway, Switzerland and Sweden. Each requires permission or a license to carry out animal experimentation. In 1986, after ten years of consideration and repeated re-drafting, the Council of Europe adopted a Convention for the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes. In the European Economic Community, legislation is under consideration. The Federal Republic of Germany substantially strengthened its 1972 law in 1986 ruling out tests for cosmetics, detergents,

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tobacco products and weapons testing. In the UK, the pioneering 1876 Cruelty to Animals Act was replaced with the Animals (Scientific Procedures) Bill, in 1986. When a project license is issued under the new law, the Secretary of State is required to "weigh the likely adverse effects on the animals concerned against the benefit likely to accrue." Both project licenses and individual licenses are mandatory. This law, like its Swiss counterpart, sets a limit on the severity of pain infliction.

In the United States, a bill based on the principles of the British Act of 1876 attracted an impressive group of Senate co-sponsors when it was introduced in 1960. Public interest in the legislation was substantial. Nevertheless, in response to opposition from the scientific community, the chairman held it in committee for six years without hearings. (Senate rules no longer permit this.) But when Life magazine reported an incident involving the theft of a family pet by dog dealers who supplied research institutions, public and Congressional indignation led to action.

The Animal Welfare Act

The federal Laboratory Animal Welfare Act was passed in 1966. It set minimum standards for handling, housing, feeding, watering, sanitation, ventilation, shelter from extremes of weather and temperatures and adequate veterinary care for dogs, cats, primates, rabbits, hamsters and guinea pigs in the premises of animal dealers and in laboratories, and required identification of dogs and cats to prevent theft. Dealers were required to be licensed, and laboratories to be registered.

In 1970, the Laboratory Animal Welfare Act was amended to extend protection to all species of warm-blooded animals, throughout their stay in the laboratory and in the wholesale pet and exhibition trades as well. Passed unanimously by both houses of Congress, the bill was renamed the Animal Welfare Act.

In 1976, the Act was broadened to (1) regulate carriers, intermediate handlers, and animal brokers, requiring them to adhere to humane standards; (2) specify that all dogs--including dogs for hunting, security or breeding purposes--be protected by the Act; (3) prohibit C.O.D. transportation of animals unless the shipper guarantees payment of round-trip fare and costs for care of animals not claimed at destination. Also, animals cannot be transported at an age less than the Secretary permits, and dealers, exhibitors, auction sale operators and Federal, State and local agencies are required to obtain a veterinarian's certificate before

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delivering animals for transportation affecting commerce; (4) authorize a civil penalty of up to \$1,000 for each violation of the humane standards, imposing a uniform penalty on all persons regulated under the statute, and eliminating the requirement that the Secretary issue a cease and desist order before imposing a civil penalty on research facilities; (5) make it a crime punishable by fine and imprisonment knowingly to sponsor, participate in, transport in interstate commerce or use the mails to promote fights between dogs or other mammals or between cocks, except where state law permits it; (7) require all government agencies--including the Army, Air Force and National Institutes of Health--using laboratory animals to prove that they are fully in compliance with the Act.

In 1985, the Improved Standards for Laboratory Animals Act passed unanimously. The new law, which amends the Animal Welfare Act, is designed to minimize animal pain and distress. It establishes an information service in the National Agricultural Library, in cooperation with the National Library of Medicine, to provide data on alternatives to the use of laboratory animals, to help prevent unintended duplication of experiments and tests, and to provide information on humane practices required by the new law to institutions for the instruction of scientists and other personnel. Each registered research facility must appoint an institutional animal committee including a veterinarian and a person unaffiliated with it to represent the general community interests in the proper care and treatment of animals. The committee must inspect the animal laboratories twice a year and report deficiencies to the institution for correction. If not corrected promptly, the U. S. Department of Agriculture must be notified for enforcement action, and any funding agency involved informed for a decision on whether the grant should be suspended or revoked. Investigators are required to consider alternatives and to consult with a veterinarian before beginning any experiment which could cause pain. They must adhere to standards set by the Secretary of Agriculture for exercise for laboratory dogs, an environment adequate to promote the psychological well-being of primates and for pre-and post-surgical care, use of pain relieving drugs or euthanasia, against use of paralytics without anesthesia, and unnecessary use of the same animal for more than one major operation. Exceptions to the standards may be made only when specified by a research protocol and an explanation given for any deviation. Fines for violations were raised from \$1,000 to \$2,500 and from \$500 to \$1,500 for each day a cease and desist order is violated.

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NIH Reauthorization Act

Also in 1985, for the first time, the National Institutes of Health Reauthorization Act included animal welfare provisions. It requires appointment of a non-affiliated member of the Institutional Animal Care and Use Committee, corresponding to a similar requirement of the Improved Standards for Laboratory Animals Act. The revised Public Health Service Policy Statement (1986) conforms substantially with the new amendments to the Animal Welfare Act. This policy statement serves a purpose similar to regulations.

FDA Good Laboratory Practices

A 1984 Memorandum of Understanding among NIH, the U.S. Department of Agriculture and the Food and Drug Administration provides for sharing of information on observations made by the different agencies on site visits or inspections. The FDA's Good Laboratory Practices regulations are aimed at ensuring efficiency and accuracy in testing procedures and do not address animal welfare directly. However, requirements for sanitation and proper maintenance of test animals make a useful contribution to animal well-being.

Toxicity Tests

Food and Drug Administration requirements for product testing have been severely criticized in recent years especially as they apply to painful procedures. The Draize eye irritation test and LD50 test in particular have been challenged. As a result, a "limit test" using approximately one tenth as many animals as the "classic" LD50 has been approved by the Food and Drug Administration, Environmental Protection Agency, Consumer Product Safety Commission, and other regulatory agencies, and by the Pharmaceutical Manufacturers Association and other groups; however, there is no requirement to substitute the "limit test," and large numbers of animals continue to be used in old fashioned LD50 tests because there is no legislation to prevent it. The same holds true of modifications in the Draize test such as anesthetization of the test rabbits or dilution of the test material used by some institutions but not others.

State Laws

The majority of state "pound seizure" laws passed in the post-war years have been repealed: five states still require release of impounded dogs, while eleven prohibit such release, for instance, Massachusetts law now prohibits any experimental use of impounded dogs, including those impounded

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in jurisdictions outside the state, and provides for inspection of laboratories by the Massachusetts Society for Prevention of Cruelty to Animals and Boston Animal Rescue League. In New York State the Department of Health Center for Laboratories and Research has issued regulations (1983) on approval of laboratories under article 5 of the Public Health Law. The standards follow the federal Animal Welfare Act and the NIH Guide. California and Michigan are the only other states with a free-standing law requiring humane treatment of experimental animals.

Summary

Instances of severe suffering inflicted on animals in projects for science fairs led to the state laws prohibiting painful experiments on animals by students below the college level. Such laws were passed in California (1973), Maine (1975), Massachusetts (1979), New Hampshire (1985) and Florida (1985). In addition, voluntary guidelines have been widely adopted.

The new laws and changes to existing laws enacted in the last twenty years have won the support of many major scientific organizations which had formerly feared and opposed federal regulation, and the United States has progressed to a more internationally acceptable level in its determination to continue significant research without causing unnecessary animal suffering.

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