

APR 28 1986

UNITED STATES COURT OF APPEALS  
FOR THE FOURTH CIRCUIT

INTERNATIONAL PRIMATE )  
PROTECTION LEAGUE, ETC., ET AL., )  
 )  
Appellants-Plaintiffs, )  
 )  
v. )  
 )  
INSTITUTE FOR BEHAVIORAL )  
RESEARCH, INC., ETC., ET AL., )  
 )  
Appellees-Defendants. )

No. 86-1508

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Appeal from the United States  
District Court for the  
District of Maryland  
(The Honorable John R. Hargrove, Judge)

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BRIEF OF AMICUS CURIAE

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C. FOUNDATION FOR BIOMEDICAL RESEARCH, HEALTH BENEFITS OF ANIMAL RESEARCH (W. Gay, Editor 1986). . . . . A-6

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\*Public Health Services Act, Title IV, 42  
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STATEMENT OF ISSUES PRESENTED

Amici adopt appellees' Statement of Issues Presented and present the following additional issue:

1. Whether the relevant federal and state law governing the use and care of animals in research grant, explicitly or by implication, standing.

STATEMENT OF THE CASE  
AND  
STATEMENT OF FACTS

Amici adopt appellees' Statement of the Case and Statement of Facts.

SUMMARY OF ARGUMENT

The brief of Amicus Curiae is limited to a consideration of the standing issues raised by plaintiffs, particularly the question of federal or state statutory grants of standing.

Court. Tables I and II, as reproduced in addenda A and B, graphically depict, on a time line basis, major contributions of animals species to selected biomedical and behavioral advances from pre-1900 to the 1980's.

The beneficial effect to people through the use of animal models, as depicted in Tables I and II, is well illustrated by the following examples:

Insulin. Prior to the development of insulin through research primarily in dogs, diabetes inevitably ended in death. Today, 11 million diabetics lead normal lives with the aid of insulin injection.<sup>1</sup>

Polio vaccine. Animal research conducted primarily on primates assisted in the development of the polio vaccine without which at least 30,000 people, mostly children, would die each year.<sup>2</sup>

Cancer Therapies. The evaluation of chemotherapeutic drugs in animal models has dramatically increased the possibility of cure for children with cancer. For example, for acute lymphocytic leukemia the percentage cured has risen from 4% in 1960-63 to 65% today.<sup>3</sup>

Transplantation. Heart, lung, liver and pancreas transplant procedures were developed through

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<sup>1</sup>Michael Bliss, The Discovery of Insulin, University of Chicago Press, (1982) and California Biomedical Research Association Series, Research Facts -- Diabetes (1985).

<sup>2</sup>Petricciani, Hopps, Elisberg & Early, The Future of Animals, Cells, Models and Systems in Research Development, Education and Testing 240-51, National Academy of Science (1977).

<sup>3</sup>Miller, R. & McKay, "Decline in U.S. Childhood Cancer Mortality: 1950-1980: 251 JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION 1567-70.

For example, primate research has yielded significant information of benefit to humans in the following areas: the cardiovascular system,<sup>7</sup> reproduction and infertility,<sup>8</sup> learning and memory deficits in the aged,<sup>9</sup> and the understanding and control of diseases such as hepatitis B, polio, cancer and AIDS.<sup>10</sup> The study of the primate brain and the use of primates in drug and procedure testing has yielded significant results in the understanding and treatment of Parkinson's Disease.<sup>11</sup>

Primates are the most relevant system for the evaluation of the structure and function of neural mural pathways that govern motor

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<sup>7</sup>T. Clarkson, Symposium Summary in The Use of Nonhuman Primates in Cardiovascular Diseases (1980).

<sup>8</sup>T. Gordon, Reproductive Behavior in the Rhesus Monkey: Social and Endocrine Variables, 21 AM. ZOOLOG. 1985 (1981).

<sup>9</sup>T. Crook & S. Gershon, Strategies for the Development of an Effective Treatment for Senile Dementia (1981); Martinez, Jensen, & McGaugh, Facilitation of Memory Consolidation in The Psychological Basis of Memory 49 (1983); McGaugh, Hormonal Influences on Memory, 34 ANN. REV. OF PSYCHOLOGY 297 (1983).

<sup>10</sup>Holland & Tross, The Psychosocial and Neuropsychiatric Sequelae of the Acquired Immunodeficiency Syndrome and Related Disorders, 103 ANNALS OF INTERNAL MEDICINE 760 (1965); McClure, Swenson, King, Chermann, Sinousi, Eichberg, Saxinger, Gallo, Alter, Masur and Machur, Experimental Infection of Chimpanzees with Lymphadenopathy Associated Virus 33 MORBID. MORTAL. WEK. REP. 442 (1984).

<sup>11</sup>Kolata, Monkey Model of Parkinson's Disease, 220 SCIENCE 705 (1983).

placing doses of human polio vaccine in food.<sup>14</sup>

If animal experiments were stopped before 1950, there would have been no polio vaccine, no beta blockers, no organ transplantation, no kidney dialysis, no cancer chemotherapy, no open heart surgery, no biofeedback; if it had been stopped at 1935, we may never have known safe antibiotics such as penicillin; if stopped in 1910, we would be deprived of the understanding of vitamins in nutrition which today is yielding the potential for reversal or prevention of many disease processes.<sup>15</sup>

In the future, there is every reason to believe that significant progress can be made in the prevention, treatment and cure of those afflictions yet to be conquered -- Alzheimer's disease, AIDS, multiple sclerosis, birth defects, mental disability, central nervous system injury, cancer and the countless other conditions suffered by millions around the

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<sup>14</sup>University of Western Ontario, Experimental Animals: Their Indispensable Role in Bio-Medical Research - Special Supplement 4 (Sept. 12, 1985); see also, Ellins & Catalano, Field Application of the Conditioned Taste Aversion Paradigm to the Control of Coyote Predation on Sheep and Turkeys, 29 BEHAV. NEURAL BIOLOGY 532 (1980) (taste aversion study that has led to more humane controls to prevent damage to flocks); H. Markowitz, Behavioral Enrichment in the Zoo (1982) (study of social grouping to establish more natural zoo environment.)

<sup>15</sup>Paton, Animal Experiment and Medical Research: A Study In Evaluation I CONQUEST 14(1978).

(1982). At the heart of both considerations is the concern of the federal courts for their proper role in the constitutional system. Allen v. Wright, 468 U.S. 737, 104 S.Ct. 3315, 3324 (1984).

The principles governing standing are intended to "confine courts to a role consistent with a system of separation of powers." Valley Forge Christian College v. Americans United, supra, 454 U.S. at 472. The standing doctrine, as recently articulated by the Supreme Court, "embraces several judicially imposed self-limits on the exercise of federal jurisdiction" including "the rule barring adjudication of generalized grievances more appropriately addressed in the representative branches . . ." Allen v. Wright, supra, 104 S.Ct. at 3325. The Court further reasoned that separation of powers considerations compelled a denial of standing where the effect of granting standing would have been to require the federal courts to be the continual monitors of actions committed by Congress to specific Executive branch agencies. Id. at 3329 quoting Laird v. Tatum, 408 U.S. 1, 15 (1972).

This case involves precisely those considerations articulated by the Supreme Court in Valley Forge, supra, and Allen, supra. Plaintiffs seek to have the Court consider a general grievance as to the proper use of research animals notwithstanding the fact that Congress has dealt with the

done so only where there was no other remedy provided and where the implication was clear and would be consistent with the statute's purposes. See e.g. Universities Research Association v. Coutu, 450 U.S. 754 (1981); Cannon v. University of Chicago, 441 U.S. 677 (1979); Transamerica Mortg. Advisors, Inc. v. Lewis, 444 U.S. 11 (1979); Cort v. Ash, 422 U.S. 66 (1975); Geo. Byers Sons, Inc. v. East Europe Import Export, Inc., 488 F.Supp. 574 (D.Md. 1980). In this case, the statutes involved explicitly create administrative remedies and strongly suggest that those remedies are exclusive.

2.. Federal Law on Use of Animals in Research

a. The United States Department of Agriculture's Animal Welfare Act Does Not Grant These Plaintiffs Standing.

Under 7 U.S.C. §2143 of the Federal Animal Welfare Act ("AWA"), as amended, the Secretary of Agriculture is authorized to establish minimum requirements with respect to the handling, feeding, and care of animals by dealers and exhibitors of animals, as well as by research facilities. This authority to regulate animals used in research has existed since 1966. See H.R. Rep. No. 94-801, 94th Cong., 2nd Sess. 7, accompanying H.R. 5808, reprinted in (1976) U.S. Code Cong. & Ad. News 758, 759.

Like the law governing research supported by the National Institutes of Health ("NIH"), the AWA includes a specific

where the research is being conducted. 7 U.S.C. §2143. These factors clearly reveal the absence in the AWA of not only an explicit but also an implied standing for private party actions. The strong implication is that this extensive scheme governing the use of animals in research is the exclusive system of governance. Id.; see also Transamerica Mortg. Advisors, Inc. v. Lewis, supra, and Universities Research Association, Inc. v. Coutu, supra.

b. The Health Research Extension Act Does Not Grant These Plaintiffs Standing

In 1985, Congress passed and eventually enacted through an override of a Presidential veto, the Health Research Extension Act, Pub. L. No. 99-158, 99 Stat. 820. That legislation created a revised Title IV of the Public Health Service Act ("P.H.S.A."). The explicit purpose of Title IV is to preserve "America's preeminence in medical research" through the establishment of programs and management authority for the National Institutes of Health. H. R. Rep. No. 99-158, 99th Cong., 1st Sess. 3, accompanying HR 2409, reprinted in (1985) U.S. Code Cong. & Ad. News 672.

Evidence of the preeminent role of the NIH and the federal government in medical research is the \$5.5 billion it annually expends on research. Special Analyses, Budget of the United States Government, Fiscal Year 1987, Chapter K, p. K-4. For

Service Grants Administration" at 4-6. The standards for grantees incorporate by reference standards of the Animal Welfare Act administered by the USDA, where applicable. NIH Guide for Grants and Contracts, supra, at 1. The 1985 amendments simply "provide statutory authority and recognition for these guidelines." H. Conf. Rep. No. 99-309, 99th Cong., 1st Sess. 85, reprinted in (1985) U.S. Code Cong. & Ad. News 746.

Section 495(a) of the P.H.S.A. requires the Director of NIH to establish guidelines for the proper treatment of all animals used in research, including specific guidelines relative to the use of anesthetics and appropriate surgical care. Section 495(c) requires all applicants for NIH assistance to include assurances that the guidelines will be met and set forth the reasons for the use of animals in the research. Most important, Section 495(b) requires the establishment of animal care committees within each entity conducting biomedical research with NIH funds, and within the NIH itself.

The responsibility of these committees is to review the care and treatment of animals used in research and to assure compliance with the NIH guidelines. Public Health Service Act §495(b)(3). The committees must file an annual certification with NIH as to its review and findings. Ultimately, the Director of NIH is authorized to terminate or suspend grants where violations of the guidelines are found. Id. at §495(c).

The Congress was also concerned that the design, approval and conduct of research not be interfered with or disrupted by this system. P.H.S.A. §495(a), and H. R. Rep. No. 99-158, supra, at 41, H. Conf. Rep. No. 99-309, supra, at 85. This principle simply reflects the policy of the guidelines in existence prior to 1985. See P.H.S. Grant Administration Manual, Chapter 1-43, pp. 4-6 which sets forth the corrective process. The conference committee report states that there is "no authority to interfere with research goals, methods or decisions" and that the committees "have no authority to second guess the appropriateness of research." H. Conf. Rep. No. 99-309, supra, at 86.

Furthermore, the Conference Report stresses the point that the committees are important because of their flexibility and the process of consultation with the research institutions which are involved. Id. This committee "process recognizes that such sensitivity cannot be captured in any set of rules . . . and that the value of medical research requires such judgments regarding animal care in research to be professionally and scientifically sound." Id. This consultative process is the exact opposite of the process involved in this law suit.

In enacting Pub. L. No. 99-158, Congress could not have been clearer as to how the federal standards relating to animal

trial court did not have to address the issue of preemption because it found no standing under state law, amici believe that to the extent that the Maryland law is inconsistent or incompatible with federal law, it is preempted. Both the Health Research Extension Act and the Animal Welfare Act strive to balance two separate interests, and create certain well defined protections for research. Research and animals are both the beneficiaries of the legislation and research is a major national interest. While we do not know how the 1984 amendments to the state anticruelty statute will be applied by the state, the possibility of conflict is inherent in the language of law. However, even without reference to federal preemption, the Maryland anticruelty laws provide no support for plaintiffs' action.

Subsequent to Taub v. State of Maryland, 463 A.2d 819 (1983), the Maryland state legislature amended Article 27 of the anti-cruelty law to extend coverage to animals in "federally funded scientific or medical activities. . .". While plaintiffs appear to rely principally upon Article 27, §59, the criminal misdemeanor statute, Article 27, §67, which deals with the care of mistreated and neglected animals is also pertinent. (See Addendum E.) Both sections were amended in 1984 though plaintiffs only refer to the amendment to §59.

<sup>18</sup> The criminal statute, Article 27, §59, was amended to add

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<sup>18</sup>The copy of Article 27, §67 attached to plaintiffs' brief does not contain the 1984 amendment

Department of Health and Mental Hygiene, Division of Veterinary Medicine. The Department of Health and Mental Hygiene shall conduct an investigation within 24 hours of the receipt of a complaint and shall, within 24 hours of the investigation, report to the state's attorney of the county in which the facilities are situated." Md. Ann. Code art. 27 §67. (Emphasis added.)

The 1984 amendments thus place animals used in research in a special category. These animals cannot be seized by state agents acting upon their own initiative. Only the Maryland Department of Health and Mental Hygiene can authorize a removal of research animals, and only after an investigation and report.

The legislature left unchanged the provision in Section 67 which provides that whenever an animal is removed from the owner or custodian's possession, he must be notified of the seizure and of any administrative remedies available to him and may file a petition for return of the animal in the district court of the county in which the removal occurred. Clearly, Section 67 contemplates only temporary seizure and is designed to address an emergency situation. Further, without state authorization individuals have no authority to act.

Thus, nowhere in the Maryland anticruelty statutes is there created an express cause of action or standing in favor of private parties. Nor does Maryland law confer any implied private right of action upon plaintiffs in this case. Applying the test set forth for federal statutes, supra at 10, the first

Furthermore, both statutes create specific administrative and judicial procedures for the protection of animals. Where a statute is specific with respect to the remedies it creates, courts are reluctant to find further remedies in favor of private parties. See e.g. Transamerica, supra at 19. (" . . . it is an elemental cannon of statutory construction that where a statute expressly provides a particular remedy or remedies, a court must be chary of reading others into it."); Universities Research Association v. Coutu, supra, 450 U.S. at 772 (less reason to infer private remedy in favor of individual persons where statute is framed as general prohibition or a command to a federal agency).

4. Appellants Have Not Shown a "Bonding" Relationship

Among the claims of appellants for standing is one that they have established a "bonding" relationship with the rhesus macaques. Amici agree with appellees that no legal or factual basis exists to find such a bonding relationship. See e.g. Jones v. Beame, 45 N.Y.2d 402, 380 N.E. 2d 277 (1978).

The existence of a "bonding" relationship between appellants and rhesus macaques is highly unlikely. An attachment relationship or "bonding" is only likely to occur when there has been early, extensive and continuous

where no individual rights would be vindicated and those bringing the action are not the best suited to assert a particular claim. Valley Forge Christian College v. Americans United, supra 454 U.S. at 475; Warth v. Seldin, supra, 422 U.S. at 499-500. In the opinion of amici, this is precisely the nature of plaintiffs' action. Plaintiffs true motivation and objective, for themselves and other similarly situated organizations and individuals, are to thwart all scientific research involving the use of animals. Ultimately, they seek to have the federal courts decide a question of broad social and generalized importance and interest, namely, whether animals should be used in research.

Should this Court grant plaintiffs standing, it will have paved the way for a multitude of lawsuits which have some, but not all the attributes of this case. See Valley Forge Christian College v. Americans United, supra, 454 U.S. at 472. One consequence of such a holding will be a multitude of lawsuits against researchers and research organizations, intended to accomplish one objective - to stop the use of animals in research. The targets of these lawsuits will be

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(Footnote continued from page 24)  
involved in the language project spend eight hours per day with the language board, requiring that a researcher be available to interact with these primates constantly.

e.g. appellants' brief at 19,38,& 41. This latter possibility is a consequence which should be avoided for three reasons.

First, it would result in a breach of the separation of powers doctrine since Congress has clearly delegated the power and authority to decide whether and what research is necessary to the Executive Branch. See discussion of federal regulatory scheme supra at 11-18.


Second, it would destroy the efficacy of the present peer review system. Historically, a panel of accomplished scientists has reviewed all research proposals to be conducted in laboratories supported by federal funds. 42 U.S.C. §289a. A priority score is assigned to each project as determined by the fulfillment of a number of specific qualifying factors, and by the overall merit of the research as judged by the panel. Only the projects with the highest priority scores are funded. See generally, Cappalli, R.B., Rights and Remedies Under Federal Grants (BNA, 1979).

Research projects funded by NIH are also subject to review and recommendation by an Advisory Council, including public and lay members. 42 U.S.C. §§284a, 287a. The 1985 amendments make it abundantly clear that the animal care committees or other related regulatory mechanisms have "no authority to second guess or review the appropriateness of research", leaving such judgments to the NIH review process. H. Conf. Rep. 99-309,

CONCLUSION

Biomedical and behavioral science is a precise and complex endeavor from which society has not only gained much, but stands to gain much more. It is concerned with the interests of both its human and animal subjects. The legal systems and standards created by the AWA and the Health Research Extension Act, and its predecessor regulatory provisions, represent the appropriate balancing of the important interests of research and animal care. Each benefits from these laws. Society does not need additional legal processes, such as private injunctive actions, to implement these carefully balanced Congressional and Executive branch policies and none have been provided. For these and the other reasons set forth in this and appellees' brief, amici urge this Court to affirm Judge Hargrove's decision.

Respectfully submitted,  
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Association of Medical School Microbiology  
Chairmen  
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Department Chairmen  
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Association of Pathology Chairmen, Inc.  
Association of Program Directors in  
Internal Medicine  
Association of University Anesthetists  
Association of University Professors  
of Neurology  
Association of University Professors  
of Ophthalmology  
Association of University Radiologists  
Biofeedback Society of America  
Departments of Otolaryngology  
Pavlovian Society  
Plastic Surgery Research Council  
Shock Society  
Society for Health and Human Values  
Society for Pediatric Research  
Society for Pscophysiological Research  
Society of Academic Anesthesia Chairmen, Inc.  
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Departments  
Society of Critical Care Medicine  
Society of Radiology Research Associates  
Society of Teachers of Emergency Medicine  
Society of University Otolaryngologists  
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University Association for Emergency  
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April 25, 1986

TABLE II

The Heart Transplant and Other Cardiology Advances  
That Depended on Animal Research: A Chronology

<u>WORK INITIATED OR CULMINATED DURING</u>	<u>CARDIOLOGY ADVANCE</u>	<u>SPECIES STUDIED</u>
Pre 1900's:	Management of Heart Failure Asepsis Blood pressure, heart rate Fluid & electrolytes, acid-base balance Surgical instruments & materials Relief of Pain Wounding healing	dogs many species  many species dogs many species many species
Early 1900's	Electrocardiography Cardiac catheterization  Components of blood & plasma Nutrition Surgical techniques	dogs dogs, rabbits, cats monkeys, dogs rabbits, rodents many species dogs
1920's	Intravenous feeding  Ventilation of open thorax	dogs, rabbits rodents dogs
1930's	Transfusion, blood groups & typing Monitoring EEG Modern anesthesia & neuromuscular blocking agents Anticoagulants Pump oxygenator	many species many species rats, mice, rabbits, dogs, monkeys cats cats, dogs
1940's	Antibiotics	many species
1950's	Blood preservation Blood O <sub>2</sub> , CO <sub>2</sub> , pH Chemotherapy Cardiac pacemaker	many species many species many species dogs

1950's:	Electrical stimulation of paralyzed limbs	cats
	Prevention of poliomyelitis	rabbits, monkeys, rodents
	Discovery of DNA	rats, mice
	Chlorpromazine & its tranquilizing derivatives	rats, rabbits, monkeys
1960's:	Hypertension oral diuretics (thiazides)	dogs, other
	Cancer chemotherapy	monkeys, rabbits, rodents
	Prevention of rubella	monkeys
	Radioimmunoassay	many species
	Prevention of surgical post-operative adhesions	dogs
	Therapeutic use of cortisone	rabbits, monkeys
	Corneal transplant	rabbits, monkeys
1970's:	Identification of properties in motor units in paralyzed muscles	cats
	Cimetidine (tagamet) treatment of gastric ulcer	rabbits, rats, other species
	Prevention of measles	many species
	Modern treatment of coronary insufficiency	dogs
	Viral origin of cancer	dogs
	Treatment of leprosy	monkeys, armadillos
	Immunotherapy technology	many species
	Cerebral revascularization procedures	
	Regeneration of unmyelinated nerve fibers*	rats
	Treatment of scoliosis with electrical stimulation*	sheep
Regeneration and axonal sprouting*	rats, fish	
Properties of tissue damage in electrically stimulated muscles*	rats, cats	

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