



City of Cambridge

24.

IN CITY COUNCIL

February 27, 1989

COUNCILLOR GRAHAM

ORDERED: That His Honor, the Mayor, be and hereby is requested to reconvene the Mayor's Blue Ribbon Committee on the Care and Use of Laboratory Animals in Cambridge with the view in mind of reaching firm recommendations for the City Council to review prior to the adoption of any ordinance regarding the subject matter; and be it further

ORDERED: That this Mayoral Committee be and hereby is also requested to outline those matters and recommendations which they agree upon and disagree upon; said report to be delivered within thirty days.

In City Council February 27, 1989.
Adopted by the affirmative vote of 7 members.
Attest:- Joseph E. Connarton, City Clerk.

A true copy:

ATTEST:-

Joseph E. Connarton, City Clerk.

REPORT OF THE MAYOR'S BLUE RIBBON COMMITTEE
ON THE CARE AND USE OF LABORATORY ANIMALS
IN CAMBRIDGE

Dated: February 24, 1989

Submitted by:

Steven M. Wise, J.D.
John Moses, M.D.
Stuart Wiles, V.M.D.

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JOINT REPORT

I. Background of Report

The Blue Ribbon Committee (BRC) was established by order of the City Council on September 21, 1987. Approximately one month later, Attorney Steven Wise, designee of the animal rights community, and Dr. John Moses, designee of the scientific community, were appointed to the BRC by Mayor Sullivan.

During November and December, 1987, Wise and Moses met to establish BRC working rules. In late December, 1987, Mayor Sullivan appointed Stuart Wiles, V.D.M., a veterinarian with expertise in small animal medicine, to the BRC.

The first of 36 meetings of the BRC occurred on January 7, 1988 to reaffirm working rules and determine sources and methods of gathering data. The last meeting of the BRC was held on February 8, 1989.

The BRC obtained information on the regulation of animal care and use from Dr. Melvin Chalfen, Commissioner of Health and Hospitals of the City of Cambridge, William Smith, D.V.M., Regional Director for Veterinary Services of the USDA, Dr. Khalil Sharifzadeh, Chief Veterinarian of the Food and Drug Division of the Department of Public Health of the Commonwealth of Massachusetts. Subsequent individual meetings were held with the animal care committees of the 13 institu-

tions and laboratories conducting research or involved in the production of biomedical products using animals for either research or commercial purposes. Over sixty members of the animal care committees participated in the meetings.

The following institutions were visited by the BRC:

Advanced Magnetics, 61 Mooney Street

Angenics, 100 Inman Street

Applied Biotechnology, 80 Rogers Street

Arthur D. Little, 30 Memorial Drive

Biogen Research Corporation, 14 Cambridge Street

Cambridge Research Laboratory, 195 Albany Street

Clinical Assays, Division of Baxter Health Care Corporation, 600 Memorial Drive

Genzyme, 101 Binney Street

Harvard University, 16 Divinity Street

Massachusetts Institute of Technology,
77 Massachusetts Avenue

Repligen Corporation, 1 Kendall Square

T-Cell Sciences, 840 Memorial Drive

Whitehead Institute, 9 Cambridge Center

Visits to the laboratories and animal holding facilities of these institutions were made for the purpose of inspecting physical quarters, husbandry, and the health and well-being of animals. Inquiry into the nature of some procedures and research investigations

were made in meetings with the animal care committees as well as with some investigators and other personnel working with animals. Inquiries were also made by telephone and mail. Documents were received from most institutions. In some cases, facility managers, research personnel, and animal care committee members accompanied the BRC on inspections of holding facilities and, when appropriate, research laboratories. At the universities, the opportunity to enter laboratories unannounced was offered and this was done on two occasions. Community or nonaffiliated members and veterinarians were not invariably present to answer questions as the animal care committee membership present was usually incomplete. Animal care committees provided information about research upon request. The information provided included research methods as well as the purpose of the investigation. Large numbers of animals of many different species were observed, mostly rodents and including primates.

II. QUESTIONS EXAMINED

This report examines four questions.

- 1) Does inspection of animal quarters and the condition of animals therein suggest cruelty and abuse of animals?
- 2) Are the laboratory procedures carried out in the various institutions cruel or abusive to animals?

- 3) Do adequate standards of care of laboratory animals exist?
- 4) Are the mechanisms for oversight and regulation in these institutions sufficient to ensure that cruelty or abuse of animals does not and will not occur?

III. ON-SITE ANIMAL QUARTERS AND LABORATORY INSPECTIONS

On-site inspection of animal quarters and laboratories consisted of three phases.

- A. Animal quarters, i.e. cage size, environmental elements, sanitation, etc.
- B. Oversight and observation, i.e. routine care, off-hours safety, off-hours care, etc.
- C. Laboratory procedures, i.e. anesthesia, analgesia, stress, deprivation of food and water, mobility, restraint, post-procedural observation and care, euthanasia, etc.

A) ANIMAL QUARTERS AND LABORATORIES

There was one instance of marginal overcrowding of rats in cages. All areas visited had heat, air conditioning and air changes to provide an adequate environment with one exception. In that facility air changes were unknown, although equipment was in place continuously to change the air. This facility did have a detectable strong odor.

With one exception, all facilities had alarm systems to alert personnel to abnormal changes in temperature and/or a loss of electrical power.

All animal quarters were clean and sanitary. However, two facilities were old and not up to date. Consequently certain areas were difficult or impossible to care for adequately, eg. overhead ducts, pipes, high ceilings, and difficult corners. In both cases plans are in effect to move to new quarters within the year.

All of the animal quarters visited had good quality daily care and there were no instances of poor cage cleaning, equipment, nutrition, or general area neatness and cleanliness.

There were two instances where the health of some animals was in question. In one instance the routine veterinary round had not yet been performed. In the second instance, two mice were injured fighting and should have been separated.

B. ON-SITE LABORATORY INSPECTIONS

All of the laboratories visited were clean, neat and well organized.

When questions regarding surgical procedures were discussed, it was determined that anesthesia was appropriately administered. In two instances, anesthesia was used procedurally for blood collection in order to create as little stress and discomfort as possible.

The BRC was concerned about analgesia and discom-

fort. When an inquiry was made, provision for analgesia and post-procedural observation and care was found to be adequate.

When inquiry was made, euthanasia methods were found to be in accordance with AVMA recommended standards, except three instances in which compliance was questioned.

C) OVERSIGHT AND OBSERVATION

All facilities had procedures established for daily routine observation of qualified personnel. All facilities had procedures established for off-hours observation and oversight of the animal quarters. All facilities had veterinary support for routine care as well as emergency care.

IV. THE REGULATORY AND ENFORCEMENT SCHEME

A. FEDERAL REGULATION AND ENFORCEMENT

1. Federal Statutes

a) The Animal Welfare Act, 7 U.S.C. sec. 2131, et seq.

The Animal Welfare Act, 7 U.S.C. sec. 2131, et seq. (1985) (AWA), applies to any research facility that uses or intends to use live animals in research, tests, or experiments, and that purchase or transports live animals affecting commerce or receives Federal funds for research, tests, or experiments, 7 U.S.C. sec. 2132(e).

"Animal," as defined in the AWA, means, in relevant part, any live or dead dog, cat, monkey (non-human primate animal), guinea pig, hamster, rabbit, and any other such warm-blooded animal such as the Secretary of Agriculture (The Secretary) may determine is used or intended for use for research, testing, experimentation, or exhibition, 7 U.S.C. sec. 2132(g). Reptiles, amphibians, and fish are not animals within the meaning of the AWA.

Research facilities must create and retain records with respect to the purchase, sale, transportation, identification, and previous ownership of live cats and dogs, 7 U.S.C. sec. 2140.

The Secretary must establish minimum requirements for handling, housing, feeding, watering, sanitation, ventilation, shelter from extremes of temperatures and weather, adequate veterinary care, and separation of species, 7 U.S.C. 2143(a)(2)(A), for the exercise of dogs, and for a physical environment adequate to promote the psychological well-being of primates, 7 U.S.C. sec. 2143(a)(2)(B).

The Secretary must also establish standards for animal care, treatment, and practices in experimental procedures to ensure that pain and distress are minimized, including adequate veterinary care, with the appropriate use of anesthetic, analgesic, tranquilizing drugs, and euthanasia, 7 U.S.C. 2143(a)(3)(A), that the

principal investigator consider alternatives to any procedure likely to produce pain or distress, 7 U.S.C. 2143(a)(3)(B), that a veterinarian be consulted for any procedure that could cause pain, for the use of tranquilizers, analgesics, and anesthetics for pre-surgical and post-surgical care, against the use of paralytics without anesthesia, and that the withholding of tranquilizers, analgesics and anesthetics, or euthanasia when scientifically necessary shall continue for only the necessary period of time, 7 U.S.C. 2143(a)(3)(C).

With limited exceptions, the Secretary may not promulgate regulations with regard to the design, outlines, guidelines, or performance of actual research or experimentation, as determined by the research facility, 7 U.S.C. 2143(a)(6)(A)(i) and (ii), or that permit the interruption of the conduct of actual research or experimentation, 7 U.S.C. 2143(a)(6)(A)(iii). The Secretary shall require each research facility to show upon inspection and to report annually that professionally acceptable standards governing animal care, treatment, and use, are being followed during actual research or experimentation, 7 U.S.C. 2143(a)(7)(A).

Research facilities must permit reasonable access for inspection, and the Secretary is required to promulgate regulations to permit inspectors to

confiscate or kill any animal suffering as a result of violations of the Act, if the suffering animal is no longer needed for the research, test, or experiment for which it is being utilized, 7 U.S.C. sec. 2146(a). The Secretary is required to inspect each research facility at least once a year, 7 U.S.C. sec. 2146(a).

The Secretary must require each research facility to establish an Institutional Animal Committee (IAC) composed of at least three people appointed by the Chief Executive Officer of the research facility, including at least one veterinarian and one person not affiliated with the research facility who will "provide representation for general community interests in the proper care and treatment of animals," 7 U.S.C. sec. 2143(b)(1). All members of the IAC must possess sufficient ability to assess animal care, treatment, and practices in experimental research and must represent society's concerns regarding the welfare of animals used at the research facility, 7 U.S.C. 2143(b)(1). The IAC must inspect at least semiannually all animal study areas and facilities and review the practices involving pain to animals and the condition of animals and must file an inspection certification report of each inspection signed by the majority, that includes any minority views, 7 U.S.C. 2143(b)(3) and (4).

of 1985

42 U.S.C. 289d requires the Secretary of Health and Human Services, through the Director of the National Institutes of Health, to establish guidelines that cover the proper care of animals to be used in biomedical and behavioral research, the proper treatment of animals while being used in such research, including the appropriate use of tranquilizers, analgesic, and anesthetics, paralytics, euthanasia, and appropriate pre-surgical and post-surgical medical and nursing care, but not methods of research, 42 U.S.C. 289d(a). Each entity that receives Public Health Service funds for animal research must establish an Institutional Animal Use and Care Committee (IACUC) to review at least semiannually, the care and treatment of the animals used to ensure that the entity is in compliance with National Institute of Health (NIH) guidelines, keep appropriate records, and certify the reviews to NIH, 42 U.S.C. 289d(b)(1) and (3). Each Committee must consist of at least three people appointed by the entity's Chief Executive Officer, one of whom must be a veterinarian and one of whom must have no association with the institution, 42 U.S.C. 289d(b)(2). The IACUC has no authority to interfere with research decisions, goals, or methods or to second-guess or review the appropriateness of research, 1985 U.S. Cong. Code and Admin. News 672, 713 (1985).

2. Federal Regulations

a) 9 CFR 1.1, et seq.

9 CFR 1.1, et seq., implement section 2143(a) of the AWA by specifying standards for the humane handling, care, treatment, and transportation of dogs and cats, 9 CFR 3.1-3.17, guinea pigs and hamsters, 9 CFR 3.25-3.41, rabbits, 9 CFR 3.50-3.66, nonhuman primates, 9 CFR 3.75-3.91, marine mammals, 9 CFR 3.100-3.118, and all other warm-blooded animals covered by the regulations, 9 CFR 3.125-3.142. Rats, mice, and birds are not covered by the regulations. 9 CFR 1.1(N).

The standards address the facilities, heating, ventilation, lighting, drainage, shelter, space requirements, feeding, watering, sanitation, pest control, employees, classification and separation, and veterinary care.

Euthanasia is defined as the humane destruction of an animal accomplished by a method that produces instantaneous unconsciousness and immediate death without visible evidence of pain or distress, or a method that utilizes anesthesia produced by an agent that causes painless loss of consciousness and death following such loss of consciousness, 9 CFR 1.1(LL).

Responsibility for administration of the regulations was delegated by the Secretary to the Administrator of the Animal and Plant Health Inspection

Service (APHIS), "Alternatives to Animal Use in Research, Testing, and Education; United States Congress, Office of Technology Assessment, (Washington, D.C., Government Printing Office, OTA-BA 273, February, 1986) (OTA) at 283. Ministerial and enforcement duties are the province of the APHIS Deputy Administrator for Veterinary Services, while initial collection of records and supervision and assignment of inspectors is performed by the Veterinarians-in-Chief, id. Each state has an APHIS office, except for the states of the Northeast region, which are all served by a central Waltham, Massachusetts office, id.

The major activity of APHIS is the protection of domestic plants and livestock from pests, OTA, supra at 286, and animal welfare activities generally account for about two percent of its budget, OTA, supra at 287.

b) Public Health Service Policy on Humane Care And Use Of Laboratory Animals

The Public Health Service Policy on Humane Care and Use of Laboratory Animals (September, 1986) (PHS Policy) implements 42 U.S.C. Sec. 289d(a). It is applicable to all Public Health Service conducted or supported activities involving animals, Section II.

"Animal", as defined in the PHS Policy, means any live vertebrate used or intended for use in research, research training, experimentation, biological testing,

or for related purposes, Section III(A).

Institutions must use the Guide for the Care and Use of Laboratory Animals (Guide) as a basis for developing and implementing an institutional program for activities involving animals, Section IV(A)(1). Research institutions must also comply with the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing Research, and training, which sets forth nine principles, among them that "(p)rocedures involving animals should be designed and performed with due consideration of their relevance to human or animal health, the advancement of knowledge or the good of society" (Principle II), that "investigators should consider that procedures that cause pain or distress in human beings may cause pain or distress in other animals" (Principle IV), that "animals selected for a procedure should be of an appropriate species and quality and the minimum number required to obtain valid results. Methods such as mathematical models, computer simulation, and in vitro biological systems should be considered" (Principle III), and that "(p)rocedures with animals that may cause more than momentary or slight pain or distress should be performed with appropriate sedation, analgesic, or anesthesia" (Principle V), PHS Policy, supra at 27-28; Guide, supra at 81-83. Each institution must provide written assurances to the Public Health Service that it

is complying with the PHS Policy, Section IV(A). There are no inspections of the institutions.

The Chief Executive Officer of each institution must appoint an IACUC composed of at least five people, including a veterinarian with training or expertise in laboratory animal science and medicine, a practicing scientist experienced in research involving animals, a member whose primary concerns are in a nonscientific area, and a person unaffiliated with the institution, Section IV(A)(3)(b). At least once every six months, the IACUC must inspect the institution's animal facilities and review the institution's program for humane care and use of animals and using the Guide as a basis for evaluation, Section IV(B)(1) and (2), review concerns involving the care and use of animals, Section IV(B)(4), review and approve, require modifications in (to secure approval), or withhold approval of activities relating to the care and use of animals as specified in Section IV(C) or changes in the use of animals, Section IV(B)(6) and (7), and be authorized to suspend an activity involving animals if the activity is not being conducted in accordance with the AWA, Guide, the institution's Assurance, or the PHS Policy, Section IV(B)(8) and IV(C)(8).

The IACUC, in approving a research project, is to confirm that it is conducted in accordance with the AWA and is consistent with the Guide, unless acceptable

justification for a departure is presented, Section IV (C)(1). The IACUC must also determine that the project's procedures with animals will avoid or minimize discomfort, distress, and pain, consistent with sound research design, that procedures that may cause more than momentary or slight pain or distress be performed with appropriate sedation, analgesia, or anesthesia, unless otherwise justified for scientific reasons, that animals subjected to procedures that cause unrelieved severe or chronic pain or distress be painlessly killed at the end of the procedure or, if appropriate, during it, that the living conditions be appropriate for each species and contribute to their health and comfort, that medical care be available and provided by a qualified veterinarian, that personnel be qualified and trained, and that methods of euthanasia be consistent with the recommendations of the AVMA Panel on Euthanasia, unless a deviation is justified for scientific reasons, Section IV (C)(1)(a) - (g).

Prior to the review, each IACUC member is to be provided with a list of proposed research projects. Any member may request full committee review of a project, but if this is not requested, one or more designees of the committee chairperson shall have the authority to approve or require modifications in (to secure approval) the projects. No member may participate in the IACUC review or approval of a project in

which the member has a conflicting interest, except to provide information requested by the IACUCS, Section IV (C)(2).

The IACUC may suspend an approved activity if it determines that it is not being conducted in accordance with the AWA, the Guide, the Assurance, or the PHS policy, Section IV (C)(6).

c) Guide for the Care and Use of Laboratory Animals

The Guide sets forth recommendations written in general terms so they can be applied to diverse institutions, Guide at 2. Its recommendations on animal husbandry govern housing, food, water, bedding, and sanitation, Guide at 11-27. It makes further recommendations on veterinary care, including medicine, diagnosis and treatment of disease, anesthesia, analgesia, and euthenasia, Guide at 33-38, and the physical facilities, Guide at 41-47.

B. STATE REGULATION AND ENFORCEMENT

1. State Statutes

a) G.L. c. 140 Sec. 174D

G.L. c.140 sec. 174D requires research institutions that use dogs or cats in scientific investigation, experiment, or instruction, or for the testing of drugs or medicines to obtain a license from the Commissioner of Public Health, which must be issued

unless, after notice and hearing, the Commissioner finds the research institution not a fit and proper institution to receive such a license and that the issuance is not in the public interest. Section (b) permits the Commissioner to make rules and regulations, to visit and inspect a research institution's animal research and care facilities, and to designate the Massachusetts Society for the Prevention of Cruelty to Animals and the Animal Rescue League of Boston to do so. "Animal" is defined in section b as dogs and cats specifically and all sentient beings beside humans.

b) The Cruelty Statute, G.L. c. 272
Sec. 77

G.L. c.272 sec. 77, in relevant part, makes it a crime to overwork, torture, torment, deprive of unnecessary sustenance, cruelly beat, mutilate or kill an animal, to procure these acts or omissions, when having charge or custody of an animal, to inflict unnecessary cruelty upon an animal, unnecessarily fail to provide an animal with proper food, drink, shelter, sanitary environment or protection from the weather, cruelly work an animal when unfit for labor, and knowingly and willfully authorize or permit an animal to be subjected to unnecessary torture, suffering, or cruelty of any kind.

Animals within the meanings of these statutes

include all irrational beings, Commonwealth v. Turner, 145 Mass. 296, 301, 14 N.E. 130 (1887), and all living creatures except man, Knox v. Massachusetts Society for the Prevention of Cruelty to Animals, 12 Mass. App. 407, 425 N.E. 2d 393 (1981).

2. State Regulations

The Research Animal Regulations, 105 CMR 910.000, et seq., implement provisions of G.L. c.174D by specifying licensing requirements for research institutions that use dogs or cats in scientific investigation, experiment, instruction, or for the testing of drugs or medicines, 105 CMR 910.020(A), and specifying standards for the humane, handling, care, treatment, and transportation of cats and dogs, 105 CMR 910.130. Each license must also treat all other research animals in a manner consistent with the intent of the Research Animal Regulations. 105 CMR 910.200(B); Interview with Khalid Sharifzadeh, D.V.M., Public Health Veterinarian of the Massachusetts Department of Public Health, February 10, 1988) (Dr. Sharifzadeh). These standards, promulgated by the Massachusetts Commissioner of Public Health, address the facilities, heating, ventilation, lighting, drainage, shelter, space requirements, feeding, watering, sanitation, pest control, employees, classification and separation, and veterinary care, 105 CMR 910.100 - 910.135. Euthanasia is defined as the humane killing of an animal accomplished by a method

that conforms to the recommendations of the current American Veterinary Association Panel on Euthanasia and which produces instantaneous unconsciousness and immediate death without visible evidence of pain, 105 CMR 910.010.

Three Cambridge research facilities are currently regulated by the Massachusetts Department of Public Health.

State inspectors look for the same things as do the APHIS inspectors and have a policy of not reviewing the scientific protocol and instead rely upon the IACUC's. Like APHIS, inspections are unannounced. Four inspections annually are made under the auspices of the Massachusetts Department of Public Health to each of the Cambridge facilities licensed by the State.

c) The Animal Care Committees of Cambridge

In each institution, animal care committees reviewed all research or production activities, procedures, and facilities, dealing with animals. All had access to veterinary expertise on the animal care committee except one institution which had not yet secured veterinary membership. All animal care committees operated independently, except for one institution in which its autonomy was superceded by management and enabled the latter to override the

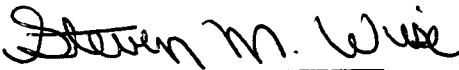
decisions of the animal care committees.

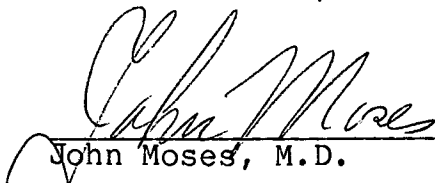
All animal care committees but two had a public member. No public member was a member of the animal welfare/rights movement. The BRC inquired as to the reasons for the absence of such persons.

Animal care committees of several of the larger institutions sponsored courses in animal care. In several other institutions technicians were certified through courses provided by AALAS (American Association for Laboratory Animal Science) or were encouraged by the animal care committees to do so.

Dated: February 24, 1989

Submitted by:


Steven M. Wise, J.D.


John Moses, M.D.


Stuart Wiles, V.M.D.

STATEMENT OF STEVEN M. WISE, J.D.¹
SUMMARY

B

- I. Existing mechanisms are inadequate to ensure that animal cruelty or abuse does not occur in the research institutions of Cambridge (pp. 6-21).
 - A. The membership of the animal care committees, which should be the front lines of defense against cruelty or abuse in the research institutions of Cambridge, are overwhelmingly dominated by research scientists and other institutional representatives infected with conflicts of interest as well as personal, professional and institutional biases, and are therefore unable properly to carry out their functions (pp. 6-11).
 - B. Unlike animal care committees outside Cambridge, no animal care committees inside Cambridge has an animal advocate as a member (pp. 11-18).
 - C. Improper reasons for the failures of the animal care committees to have animal advocates as members include: (pp. 18-21)
 - 1) They are seen as unnecessary (p. 18).
 - 2) It is feared that they will be dissenting voices that will slow the inevitable approval process (pp. 18).

- 3) It is feared that they will act in a counter-productive or disruptive manner, will generate negative publicity for the research institutions, or make researchers feel they are not being dealt with fairly (p. 18-19).
 - 4) There is an institutional ban on them (pp. 20).
 - 5) They are seen as ignorant (pp. 20-21).
- D. Laboratory inspections are inadequate (pp. 21-23).
- 1) Federal laboratory inspections are performed by a reluctant underfunded agency that excludes more than 90% of the experimental animals used in the research institutions of Cambridge, including farm animals, birds, rats, mice, reptiles, amphibians, and fish, and makes only half the desired number of annual inspections (pp. 21-22).
 - 2) State laboratory inspections are limited by statute and regulation to those few Cambridge research institutions that experiment upon cats or dogs (pp. 23).
 - 3) It is extraordinarily unlikely that a research investigator will lose Federal funding for failing to comply with

Federal animal welfare law (p. 22-23).

- II. Numerous activities within the research institutions of Cambridge might be considered cruel or abusive, as those terms are defined in this Statement, by members of a properly-constituted animal care committee or member of the public (pp. 23-37).
- III. Merits and recommendations concerning the proposed Compromise Ordinance and the Second Ordinance (pp. 37-46).
 - A. Each animal care committee should have no less than two community members appointed from a list of animal advocates nominated by animal welfare groups (p. 39).
 - B. There should be one animal advocate on each animal care committee for every three institutional representatives (p. 39).
 - C. No person should be permitted to sit on an animal care committee who has an economic interest in a matter that comes before the committee (p. 39).
 - D. The percentage of persons who sit on animal care committees who engage in projects subject to committee review should be no greater than twenty-five percent. Each such person should be required to leave the committee room during discussion of his or

her matter's merit and vote (p. 39).

- E. Animal care committee meetings should be generally open for the public to observe silently (pp. 39-40).
- F. The Animal Commission should, on an ongoing basis, delineate the Cambridge community's ethical standards for the use of experimental animals in order to assist animal care committees in their deliberations, to stimulate ethical discussion, and to provide needed uniformity among the thirteen research institutions of Cambridge (pp. 40).
- G. Each research institution should be required to obtain prior written approval from the Animal Commission before conducting any painful experiment in which pain or distress cannot be alleviated at all times. Permission should be granted only if the procedure will yield significant information about a serious human disease and no alternatives are available (pp. 41-43).
- H. Each person using or caring for animals within a research institution should complete a comprehensive training program approved by the Animal Commission (pp. 43-45).
- I. The Commissioner of Health and Hospitals should devise educational programs that will

increase public understanding of how animals are treated in research institutions as well as the institutions' awareness of public concern for the humane treatment of animals (p. 44-45).

J. The Animal Commission, and not the Commissioner of Health and Hospitals, should investigate alleged violations of the ordinance (pp. 45).

K. The ordinance should have an appropriate enforcing mechanism and penalties (pp. 45-46).

IV. Necessary medical research will not be impeded by adoption of the Compromise Ordinance or my recommendations. What is "necessary" is not merely a scientific question but a matter of policy, and when the by-products of the inquiring scientific mind are pain, suffering, or death, it is society's duty to demand sufficient justification consonant with a decent respect for the nature of the victim (pp. 46-48).

STATEMENT

"In the world of ethics and science, the 1970s was the decade for overhauling policies on human subjects in research. The 1980s is the decade for animal subjects."²

1. EXISTING MECHANISMS ARE INADEQUATE TO ENSURE THAT ANIMAL CRUELTY OR ABUSE DO NOT OCCUR IN THE RESEARCH INSTITUTIONS OF CAMBRIDGE

A. THE ANIMAL CARE COMMITTEES OF CAMBRIDGE ARE NOT MEANINGFULLY CONSTITUTED SO AS TO CARRY OUT THEIR FUNCTIONS

"(T)he qualities and interests of people who make decisions shape the kinds of decisions they make."³

1. The animal care committees of Cambridge are overwhelmingly dominated by members with conflicts of interest and institutional biases

The Congressional Office of Technology Assessment has recognized that animal research scientists "have a conflict of interest with some of the goals of the (animal care committee) since their jobs and livelihood are involved with research on animals. Ensuring their objectivity, therefore, is important."⁴ Indeed, it was this "inherent conflict between the subject's interests and the researcher's quest for new information" that motivated the development of Institutional Review Boards (IRB's), those committees charged with monitor-

ing research involving human subjects, which were formed twenty-five years ago "(b)ecause professional identity and career advancement depended on research productivity (and) the researcher was pressured to pursue knowledge at the expense of the subject. Peer norms supported such practices and sometimes rationalized them."⁵

Thirty years ago, pressures such as the drive for tenure, promotion, and research grants caused researchers at such local research institutions as the Harvard Medical School, the Peter Bent Brigham Hospital, and the Boston Children's Hospital to experiment upon human beings with impaired capacity or no capacity to consent, such as newborns, the very elderly, and chronic alcoholics with advanced cirrhosis.⁶ The prevailing utilitarian ethic of the greatest good for the greatest number of humans permitted researchers to conduct such experiments "partly because the benefits seemed so much greater than the costs, and partly, too, because there were no groups or individuals prominently opposing such an ethic."⁷

The membership of the Cambridge animal care committees is infected with both institutional and personal biases. They include no one who opposes the current scientific ethic that large numbers of animals are expendable for small or uncertain human benefits. The animal care committee members of Cambridge some-

times number nearly a dozen animal research scientists, research or animal technicians, managers, animal caretakers and administrators, and veterinarians.⁸ Many animal care committees, especially the university committees, are weighted with animal research scientists,⁹ whose own projects are subject to the approval by the very committees upon which they sit. These animal research scientists/committee members generally abstain from voting without leaving the room during the vote. The danger of members voting on a quid pro quo basis is obviously present. The fact that all committee members appear to serve without fixed terms and at the pleasure of the research institution only increases the likelihood that committee members will vote in a manner consistent with the research institution's interest and not in the interests of animal welfare.

The matter of personal researcher bias has grown more ominous with recent revelations of the extent and patterns of growth of the ties between researchers and business.

Ten of the thirteen Cambridge research institutions are already private or public proprietary corporations whose purpose it is to make money. Affiliates of the three non-profit research institutions appear to be moving in that direction.

At least ninety biomedical scientists at M.I.T. and Harvard University have formal ties with bus-

iness.¹⁰ This sharp increase from the recent past has occurred as "researchers realize 'they can get rich off what they're doing.'"¹¹

"You look at a place like Harvard that is perfectly willing to let its faculty become entrepreneurs, or at least part of profit-making firms. You think that is not going to have an effect on what they do?"¹²

It is the opinion of Arnold Relman, M.D., editor of the New England Journal of Medicine that "scientists and teachers ought to have zero-interest in companies in their field of research,"¹³ because it encumbers those charged with making unbiased judgments.¹⁴ The National Institutes of Health forbids its researchers from holding such a financial interest,¹⁵ and its director favors Congressional extension of this policy to all recipients of federal grants.¹⁶ "(T)here is no doubt that equity stakes held by researchers arouse suspicions of bias."¹⁷

I learned of the seriousness of this problem long after my interviews with the animal care committees were concluded. Therefore I do not know whether the research scientists who currently sit on animal care committees have such ties. Whether they do or do not, this provides a further disincentive for an animal care committee wholly or nearly wholly dominated by institutional and researcher interests to subordinate the interests of animals to the financial interests of the

institution, institutional colleagues, or themselves, and makes it imperative that true animal advocates sit on the animal care committees of Cambridge.

Scientists themselves are concerned that science's unwritten code of ethics is being eroded by, among other forces, the commercialization of science by corporate America, the growing bureaucratization of scientific research into almost an assemblyline process involving dozens of researchers who have less autonomy and less incentive to adhere to the highest standards, the increasingly intense competition for federal funding and private grants, and the growing pressure to publish for the sake of quantity, not quality.¹⁸

In a recent report,¹⁹ the National Academy of Science's Committee for the Study of the Responsible Conduct of Research noted that factors contributing to recent allegations of scientific fraud and other research misconduct²⁰ included "an unhealthy research environment that failed to discourage (or even tolerated) sloppy or careless research standards ... funding pressures and an overemphasis on publication as the main means of achieving status and recognition for scientific advancement and research support." The Report considered the problem of obtaining genuinely critical peer reviews of performance and noted that "(c)ollegial relationships are essential to the smooth

functioning of the academic unit and these may be threatened by too frank criticism."²¹

2. Affiliated animal advocates are necessary animal care committee members

The job of an animal care committee "is not simply to block improper research," but to "educate researchers about the issues of animal pain or discomfort when designing their research protocols."²² "(P)erhaps the most crucial function of (an animal care committee) is education. Only if individual investigators recognize that animal interests matter will the laboratory animals' lot improve."²³

As "it is questionable whether research institutions will invariably appoint to committees employees eager to question their colleagues' proposals,"²⁴ at least one knowledgeable affiliate of the animal advocacy community is a necessary member of an animal care committee if it is to function properly.²⁵ Such persons bring desirable diversity and objectivity to an animal care committee and thereby counteract, to some small degree, the conflict of interest, institutional, and personal biases of the institutional committee members.

The animal advocate alone would not be biased in favor of the research, academic, or commercial interests of the research institution or its scientists.

The animal advocate alone would have as a primary concern the welfare interests of the animals and would fulfill his or her function by consistently raising appropriate ethical concerns about proposed research protocols and acting as the conscience of the wider non-research non-institutional community.²⁶

That an IACUC must ensure that procedures involving animals are designed and performed "with due consideration of their relevance to human or animal health, the advancement of knowledge, or the good of society,"²⁷ means that "(j)udgments on research justification ... incorporate moral, social, and scientific conclusions,"²⁸ and "entails making judgments regarding which research aims are most important to our society,"²⁹ so that "(i)t is in this area that the views of nonscientists may be most crucial to the screening of proposals for laboratory animal use."³⁰

The requirement of the Animal Welfare Act (7 U.S.C. sec. 2143(b)(1)) that one member of an institutional animal committee represent society's concerns regarding the welfare of animals used at a research facility was an attempt by Congress to provide some minimal diversity of views on the committee. As the minimum number of IACUC members is generally five,³¹ and there is no maximum number, obviously neither Congress nor the Public Health Service expected a solitary animal advocate to outvote the numerous

institutional representatives. The animal advocate's job then is to educate, question, persuade, and speak with the animals' voice.

3. At least two animal advocates should sit on each animal care committee

At least two animal advocates should sit on each animal care committee. The position will be difficult for a knowledgeable, dedicated, and affiliated animal advocate. An animal advocate, unaffiliated with an animal advocacy organization, would alone among the animal care committee members, not have an institution upon which he or she could rely for support and resources. A public member, not both an animal advocate and an affiliate of the animal advocacy community, is therefore unlikely to be effective, as he or she might often be unable or unwilling to "ask the critical question necessary to ensure the application of ethical principles of animal experimentation,"³² or to press the points effectively in the face of numerous highly educated, specialized, and sometimes hostile research institutional representatives or investigators. The animal advocate needs support.

For example, when the Blue Ribbon Committee met with institutional primate research investigators, my inquiry as to whether paid consenting human volunteers could be substituted for captive monkeys as subjects in

a seemingly benign procedure was met by a veteran research investigator's angry condemnation of the question alone as odious and reprehensible, a sarcastic inquiry as to whether I intended the use of prisoners, and the comparison of me to the Nazis.³³

However, the value of at least one animal advocate on a committee overwhelmingly dominated by scientists was recently demonstrated by the report of Committee on the Use of Laboratory Animals in Biomedical and Behavioral Research of the National Academy of Sciences,³⁴ where the solitary affiliated animal advocate filed a supplemental "individual statement" in which she noted numerous deficiencies and inaccuracies in the report otherwise unanimously approved by the fourteen scientist members.³⁵

3. Committees regulating research on vulnerable human subjects provide for advocates

As with an IACUC, an IRB, charged with overseeing research on human subjects, must have at least five members.³⁶ The members must include both males and females from at least two professions, an unaffiliated member, and a non-scientist.³⁷ Even so, "(e)thicists frequently recommend that institutions appoint more non-scientist and unaffiliated members to their review boards."³⁸

IRB's that regularly review research on "a vulner-

able category of subject,"³⁹ must have at least one member "primarily concerned with the welfare of these subjects."⁴⁰ Vulnerable categories of subjects include those humans who cannot freely and intelligently consent, such as fetuses and pregnant women,⁴¹ prisoners,⁴² and children.⁴³

Recently, the United States Department of Health and Human Services (DHHS) announced the reconstitution of its Ethics Advisory Board.⁴⁴ Its purpose is to "advise DHHS on the ethical acceptability of the conduct and funding of certain proposals for research involving human subjects."⁴⁵

Human research subjects within the purview of the Ethics Advisory Board may include demented patients, children, prisoners, AIDS patients, and fetuses.⁴⁶ The proposed twenty-one member Ethics Advisory Board is to include "authorities knowledgeable in the fields of law, ethics, medicine, social and behavioral science, and from the general public At least one member shall be an attorney, at least one member shall be an ethicist, at least one member shall be a practicing physician, and at least one member shall be a theologian. No less than one third, nor more than one half of the total membership shall be ... scientists."⁴⁷

Both the IRB's and the proposed Ethics Advisory Board point to deficiencies in the homogeneous manner in which the animal care committees of Cambridge are

constituted. Animals, unable to consent, are as vulnerable as children, demented human beings, and fetuses, and need at least one animal care committee advocate primarily concerned with their welfare.

4. Animal care committees outside Cambridge have animal advocates

Both Massachusetts research institutions outside Cambridge and research institutions outside Massachusetts have members in something like an animal advocate's role. The Boston University animal care committee includes Jerrold Tennenbaum, a lawyer/ philosopher who teaches animal law at Tufts School of Veterinary Medicine and who has written widely on the subject.⁴⁸ The Tufts University animal care committee (Medford) includes Arnold Arluke, a social anthropologist from Northeastern University, knowledgeable in the issues.⁴⁹

The "Policy Statement on Principles for the Ethical Uses of Animals at the Wisconsin Regional Primate Research Center"⁵⁰ states

Advocates of animal rights, along with scientific peers, will be appointed by the Director to participate with full voice and vote
...

The University of Southern California's "Policies Governing the Use of Live Vertebrate Animals" requires, at 8, "a public member representing the animal advocate community."⁵¹ The University of California, San Fran-

cisco, animal care committee has a humane society member.⁵² The University of California, Davis, animal care committee had a veterinarian active in the animal rights movement.⁵³ The NASA animal care committee includes an employee of a Humane Society.⁵⁴ Lawrence Berkeley Laboratory has an animal rights philosopher on its animal care committee.⁵⁵

5. Cambridge animal care committees have no animal advocates

The animal care committees of Cambridge are virtually homogeneous, as all or almost all members are scientists and/or institutional members. No Cambridge research institution has an animal care committee member who is an animal advocate, an affiliate of the animal advocacy community, or a person primarily concerned with the welfare of the animal subjects.

One research institution had no public member.⁵⁶ Another public member was so unknown to the research institution that it could not provide any information about him.⁵⁷ The public members of the other research institutions included a pediatric psychiatric nurse suggested by the animal care committee's chairman,⁵⁸ a lawyer chosen by a corporate community liason,⁵⁹ a nun/school principal/former biology teacher chosen by the University Office of Community Affairs,⁶⁰ a Cambridge resident suggested by a company secretary,⁶¹ a

biochemist,⁶² a former Cambridge official who served on the Cambridge Biohazards Committee,⁶³ a former aircraft engineer suggested by a librarian who knew him through a music group,⁶⁴ an animal technician employed by a similar company in the same building,⁶⁵ an aerobics teacher and manager of a fitness studio suggested by a company employee,⁶⁶ and a television editor recommended by the Cambridge Community Development Office.⁶⁷ The fact of Cambridge residency was often a primary or important factor in the selection of the public member.⁶⁸

6. There are no animal advocates on Cambridge animal care committees because they are wrongly viewed as unnecessary, disharmonious, counterproductive, or ignorant

One reason for the lack of animal advocates on the animal care committees of Cambridge is that many animal care committee members, out of arrogance or ignorance, regard them as unnecessary. When I asked the members of one animal care committee whether they would object to having an animal advocate as an animal care committee member, the public member, a medical professional herself, replied that they were "all animal activists" and that the university's animals were treated better than the children in many hospitals.⁶⁹ When I asked the members of the other university's animal care committee whether there were any philosophers on the

committee, one research investigator member replied that "they were all philosophers."⁷⁰

That even a public member of an animal care committee fails to recognize the need for diversity of animal care committee opinion leads to the second reason, the overweening desire for animal care committee harmony and efficiency. Numerous animal care committees rejected the idea of having an animal advocate as a committee member because they feared a permanent dissenting voice, one who would file minority reports, be close-minded, or slow the consideration process.⁷¹ I am unaware of a single dissenting vote ever cast by any animal care committee member. Such persistent unanimity is not to be desired nor commended. The consideration process is not supposed to be viewed as inevitably heading towards approval and the public member is supposed to come to the committee table with different views.⁷² These attitudes merely emphasize the finding of the Committee for the Responsible Conduct of Research that frank criticism by colleagues is rare.⁷³ The reason for the present homogeneity becomes even more clear when one recalls that the Public Health Service Policy requires full committee review of a project if even a single committee member so requests.⁷⁴

A third reason is that animal care committee members believe that animal advocates are counter-

productive and fear that they will distort information received through committee work, will generate negative publicity for the research institutions, will make investigators feel they were not being dealt with fairly,⁷⁵ or will disrupt the animal care committee meetings.⁷⁶

This echoes Melvin H. Chalfen, M.D., Commissioner of the Department of Health and Hospitals of the City of Cambridge, who stated in an April 9, 1987 letter to the City Manager that "the inclusion on the institutional Animal Care Committee of a representative of animal rights organizations ... would ... lead to counter-productive, time consuming, and adversarial committee meetings"⁷⁷ His opinion was unsupported.

Fourth, one research institution refused, as a matter of corporate policy, to permit an animal advocate on its animal care committee.⁷⁸

Fifth, research institutions may simply reflect the attitudes of David Baltimore, Director of the Whitehead Institute for Biomedical Research, associated with M.I.T., who told the February 11, 1988 meeting of the American Association for the Advancement of Science in Boston in his keynote address that critics of animal experimentation were seeking to hold back progress out of "fear and ignorance," that their "weight of ignorance will drag us back toward superstition,"⁷⁹ and

that they "threatened the whole enterprise of modern biology, putting animal rights ahead of the human right to optimum health."⁸⁰ Dr. Baltimore has also been quoted as saying that "he did not think that experimenting on animals raised a moral issue at all."⁸¹ Similarly, it is the opinion of Charles McCarthy, head of the Office for the Protection from Research Risks at NIH, that animal rights advocates are urban dwellers who know animals only as pets and that "this has led them to anthropomorphize animals, with help from television programs that show them acting like people."⁸²

In truth, the animal welfare/rights movement includes professional organizations of attorneys, veterinarians, physicians, nurses, psychologists, professors, and others. Scientists must realize that animal advocates are neither children nor adults with childish ideas.

B. LABORATORY INSPECTIONS ARE INADEQUATE

In violation of the Animal Welfare Act, the United States Secretary of Agriculture has excluded rats, mice, and birds from the animals covered by the regulations.⁸³ Because of these exclusions, the regulations do not affect more than 90% of the 60,000 animals of thirty species annually consumed in Cambridge research institutions.⁸⁴

Dr. William Smith, Veterinarian-In-Chief of the Northeast Region of APHIS (Animal Plant Health Inspec-

tion Service of the United States Department of Agriculture) further, and probably illegally, excludes all farm animals from the coverage of the regulations.⁸⁵ The Northeast region of APHIS therefore excludes farm animals, mice, rats, birds, reptiles, amphibians, and fish from coverage.⁸⁶

From the beginning, the United States Department of Agriculture (USDA) has not desired to inspect laboratories.⁸⁷ Since fiscal year 1983, USDA has proposed that funding for animal welfare inspections be reduced or eliminated and that local governments, industry groups, and humane societies take on more responsibility for enforcing animal welfare regulation.⁸⁸

"APHIS reportedly has a chip on its shoulder because animal research is not its main line of work, and it has suffered severe drubbings from critics who say its inspections are terrible. The agency is still short on money (The Administration wants to eliminate its laboratory inspection rule altogether) and critics say its inspectors are poorly trained."⁸⁹

Even APHIS has stated, and Dr. Smith agrees, that a desirable research facility inspection rate for an effective program is four times a year.⁹⁰ In the Northeast region, on average, most research facilities are inspected twice a year by a veterinarian.⁹¹

Animal researchers frequently claim that lack of compliance with NIH or Public Health Service policies

can mean withdrawal of funding.⁹² However, if members of the animal rights movement do not take action against his or her laboratory, it is more likely that a research investigator will be struck by lightning than lose Federal funding for lack of compliance with Federal law. As of June, 1987, only the funding grant of Dr. Edward Taub, of the Insitute for Behavioral Research in Maryland, had been totally terminated, while only a single portion of a larger grant has been terminated, that of the University of Pennsylvania's Experimental Head Injury Laboratory.⁹³ Both investigations resulted from actions initiated by members of the animal rights movement in research institutions that had otherwise passed federal inspections.⁹⁴

State inspections are limited, by statute, and regulation, to those two or three of thirteen Cambridge research institutions that experiment upon cats or dogs.

II. IS THE TREATMENT OF EXPERIMENTAL ANIMALS IN THE RESEARCH INSTITUTIONS OF CAMBRIDGE CRUEL OR ABUSIVE?

1) CRUELTY OR ABUSE DEFINED

Massachusetts, unlike some states, has no exemption for scientific or medical experimentation in its cruelty law. "Cruel" has been defined as "causing or conducive to injury, grief, or pain," "abuse" as "improper use or treatment."⁹⁵ Cruelty or abuse are

difficult concepts to apply to animal experimentation because much of what occurs in animal laboratories would clearly be considered cruel or abusive if it occurred in any other context.

The Animal Welfare Act does not define cruelty. It is not and was not intended to be an anti-cruelty statute,⁹⁶ and the mission of APHIS is not to stop cruelty to animals or even practices distasteful to the veterinarian inspectors, but merely to enforce the standards of the Act and the regulations.⁹⁷

I propose that cruelty or abuse, when applied to animal experimentation, be defined as follows.

- 1) It is cruel or abusive to violate federal, state, or local standards concerning laboratory animals if animal pain, suffering, or death results.⁹⁸
- 2) It is cruel or abusive to inflict pain, suffering, or death upon an experimental animal when alternate ways to gain the data exist, not to provide appropriate medical care, or not to alleviate all pain or suffering that can be alleviated.⁹⁹
- 3) It is cruel or abusive to inflict pain, suffering, or death upon an experimental animal disproportionately to a) the importance of the data sought and society's need for it, b) the directness of the data's

relationship to the alleviation of human disease, c) the seriousness of the human disease, and d) the degree of certainty that the experiment will gain the desired data, taking into consideration the complexity of the species of animal used. This is related to, but broader than, the duty of an IACUC to consider the relevance of the proposed procedures to human or animal health, the advancement of knowledge, or the good of society.¹⁰⁰

A first step in the weighing of human ends and animal means has already been mandated - muscle relaxants and paralytic drugs are not permitted to be employed alone for surgical restraint, but only in connection with drugs producing adequate anesthesia.¹⁰¹ Because no Cambridge animal care committee has an animal advocate as a member and because the animal care committees are dominated by biased institutional animal researchers and other representatives, I am not satisfied that an appropriate weighing of ends and means necessarily occurs before approvals of protocols.

2) CRUELTY OR ABUSE IN THE RESEARCH
INSTITUTIONS OF CAMBRIDGE

I reviewed only a small percentage of procedures and had to determine which to review solely from the name and the animal species used. The following facts are generally taken from data furnished me or from conversations with research investigators and are examples of what a properly constituted animal care committee or member of the public could consider cruel or abusive, as I defined these terms in the previous section.

- A. On July 5, 1988, four squirrel monkeys died of heat exhaustion and six squirrel monkeys were overcome in their cages after being exposed to temperatures in excess of those recommended in the Guide.¹⁰²
- B. Animals at several research institutions appear routinely to be killed in a manner not in compliance with the spirit of 105 CMR 910.010 and 910. 200(B).¹⁰³ The former section defines euthanasia as "the humane killing of an animal accomplished by a method which conforms to the recommendations of the current American Veterinary Medical Associations

Panel on Euthanasia and which produces instantaneous unconsciousness and immediate death without visible evidence of pain (my emphasis)."

The 1986 Report of the American Veterinary Association Panel on Euthanasia¹⁰⁴ states that carbon dioxide asphyxiation works moderately rapidly (as opposed to rapidly or very rapidly), that, in immature animals, the time required for death may be substantially prolonged, that it is effective (as opposed to highly effective), and should be used in a chamber that permits precharging and has a flow rate of about 20% of chamber volume per minute.¹⁰⁵

The Report further states that cervical dislocation, which involves placing the thumb and index finger on either side of the neck, or a rod at the base of the skull, then quickly pulling the base of the tail or hind limbs, may be a humane technique for the euthanization of small animals, is moderately rapid (as opposed to rapid), requires training and skill and, because unconsciousness may not occur immediately, is acceptable if the

animal has been lightly anesthetized or sedated prior to the cervical dislocation.¹⁰⁶

- 1) Two research institutions euthanized animals by placing them in plastic bags or baggies.¹⁰⁷ The AVMA Report requires a "chamber" that permits precharging and a certain flow rate. It is unclear if this is an acceptable chamber.
- 2) One research institution euthanized animals by placing them in a styrofoam container in which they place dry ice then cover with Kemwipes.¹⁰⁸ The AVMA report does not recommend the use of dry ice.¹⁰⁹
- 3) At least three research institutions, and probably more, euthanized animals by the use of cervical dislocation,¹¹⁰ which violates the spirit of 105 CMR 910.010, because it does not produce instantaneous unconsciousness and immediate death and because the animals are not lightly anesthetized or sedated prior to the cervical disloca-

tion.¹¹¹

C. At two research institutions the Blue Ribbon Committee found obviously very sick animals who were receiving neither veterinary care nor euthanasia.¹¹² The Guide¹¹³ requires that sick animals receive prompt veterinary care.¹¹⁴ At one institution, when the sick animals were pointed out by Blue Ribbon Committee members to the chairperson of the research institutions' animal care committee, she stated that she did not have the authority to order euthanization.¹¹⁵

D.¹¹⁶ At one institution, rabbits had been euthanized through the nonrecommended procedure of air embolism.

E.¹¹⁷ This study involves the surgical process of drilling small holes into the skulls of macaque monkeys and injecting tracer compounds into their brains. Several days later, the monkeys are killed and their brains removed and examined. The purpose is to develop an animal model of the basic anatomical organization of human language circuits.

The proposal's justification notes that "(p)recisely what sets us apart from other primates is the evolutionary development of

our brains, particularly with respect to language." As the evolutionary lineages of humans and monkeys diverged approximately forty million years ago, monkeys are believed to have no language circuits. If they possess structural homologues of human language circuits complex and similar enough to be of significant use in the treatment of human language disease, this raises the serious ethical question as to whether we should be treating such creatures in such a way.

F.¹¹⁸ This study involves the surgical insertions of two stainless steel tubes into the eye of paralyzed anesthetized juvenile rhesus macaque monkeys, the injection of a substance into the eyes of anesthetized monkeys, the infliction of lesions with ibotenic acid into the eyes of paralyzed anesthetized monkeys, the implantation and use of search coils into the eyes of monkeys, and the fixing of posts in the monkeys' skulls by screwing mountings into the skulls, aided by the use of dental cement. Monkeys are water deprived and work for rewards of apple juice, are generally used for three or four years, can suffer up to four surgical

procedures, and are ultimately killed.

According to the proposal, "(t)he findings of this research on the neural mechanisms of vision should provide significant new hints about the nature, cause and locus of visual deficits in patients, especially as it pertains to binocular vision where defects are most common in our society."

Primates require a complex and stimulating environment, a fact recognized by Congress when, in 1985, it amended the Animal Welfare Act to require the promulgation of regulations setting forth minimum requirements "for a physical environment adequate to promote the psychological well-being of primates."¹¹⁹ Despite the fact that primates generally require "contact comfort," social interaction, and physical and mental stimulation that can be furnished by contact with conspecifics and other compatible animals, swinging milkcrates, chains, ropes, garden hoses, food searches, Fisher-Price Child Development Toys, and perches,¹²⁰ the cages were barren and devoid of playthings, objects to manipulate, or any other environmental enrichment to promote their psycho-

logical well-being. Primates are also social beings. These monkeys were housed singly in stainless steel cages I estimated as about 3 feet x 2 feet x 1 1/2 feet.

G.121 This study involves surgery on squirrel monkeys, injections into their brains, perfusions of deeply anesthetized monkeys with paraformaldehyde, and post-surgical survival times of two to twenty-one days in order to map their brain striata. The main goal of the proposal is to "gain an understanding of the functional organization of the basal ganglia and its dopamine-containing input systems in the primate and to relate findings from experiments on normal and MPTP treated primates to observation on postmortem human brains from normal individuals and from persons who suffered premortem extrapyramidal disorders such as Parkinson's Disease, progressive supra-nuclear palsy and Huntington's Disease By coordinating observations in monkey and human, it is hoped that significant progress can be made toward an understanding of the basal ganglia in health and disease."

Squirrel monkeys are extremely social animals who normally live in large

groups high in the tropical forest trees. On June 10, 1988, I saw them housed at the research laboratory singly in stainless steel cages bare but for a wooden pole.

H.¹²² This study involves blocking nerve impulses to selected arm muscles of adult rhesus monkeys by placing, under anesthesia, a cuff around a musculo-cutaneous nerve, permanently implanting tubing in muscles or severing muscles in order to investigate arm trajectory formation. The monkeys are housed singly in stainless steel cages, fed ten biscuits and two pieces of fruit twice daily, and "restrained in chairs for 4 1/2 days per week" while being trained.

I understand that the anatomy of monkeys does not closely resemble humans, the forelimbs are oriented differently, and they have different muscles and relative muscle masses. These monkeys are highly social and live in large groups predominantly on the ground. All their basic means of handling stress are denied them. They are provided an extremely boring diet and are apparently restrained in chairs for long periods of time, a procedure generally to be avoided.¹²³

I.¹²⁴ This ongoing procedure involves the use

of 1200 to 1500 mice per year in monoclonal antibody production. Cage deaths of the mice are five to seven percent per month from the shock of the tumor load in their bodies.

J.125 This study involved the surgical destruction of parts of the brain of newborn ferrets that normally send sensory data from the eyes to the visual cortex of the brain and destruction of other parts of the brain so that the sensory data would go to the auditory cortex. The ferrets were raised to adulthood when they were anesthetized and injected in the eyes with a tracer. Several days later they were killed. Ferrets were also subjected to physiological experiments in which they were anesthetized, paralyzed, and artificially respired.

According to Science News,¹²⁶ "the experiments appear to underline the importance of sensory experiences before birth and during infancy in determining an individual's ability to process information later in life."

K.127 This study involves the use of anesthetized cats, chinchillas, guinea pigs, alligator lizards, and chickens in procedures involving the surgical cutting off of their

external ears for measurement and investigating accessory pathways to the middle ear and the structure and function of the tympanic membranes. The animals are then killed.

The long-term goals are to "completely describ(e) the relationship between middle and external ear structure and function, we expect to determine general concepts, which will be useful in relating adaptations to hearing to different ecological niches It seems possible ... that even the relatively small pars flaccida in human makes an important contribution to tympanograms. If this contribution could be understood, the diagnostic value of tympanograms might be increased. Also, quantitative understanding of the influence of structural features on acoustic performance could guide surgical improvements in procedures where the conductive apparatus of the air is reconstructed after chronic otitis media, cholesteatoma, or congenital defects."

L.128 This study involves the amputation of the left hind feet of anesthetized cats at the ankle. The insertion tendons of hind foot muscles are clamped to wire rope, which is attached to a force transducer coupled to

a computer-controlled torque motor that provides simulated loads. Electrodes are wrapped around the peripheral nerves of the hind foot muscles. A human with a joystick connected to a control algorithm running on a computer manipulates the cat's muscles to perform tasks through electrical stimulation while watching on a display screen.

The proposal notes that the two traditional methods of designing so-called neural prosthetic controllers are computer model simulations and experimentation on disabled human subjects.

M. Numerous Cambridge research institutions engage in monoclonal or hybridoma antibody production. The former involves injecting a mouse with an adjuvant that contains a bacterial or viral antigen mixed with oil and water. The animals then produce antibodies which are removed.¹²⁹

The latter involves intraperitoneal injections of hybridoma cells derived from animal spleens. The animals then develop peritoneal fluid containing large quantities of antibodies.¹³⁰

The Health Commissioner of Health and Hospitals stated to the City Manager that

"for good results ..., the animals have to be healthy, so they are given very good care. A sick animal represents loss of time, results, and costs."¹³¹ However, the procedure is designed to make the animals sick, in that they develop peritoneal fluid and sometimes suffer severe abdominal distention and other signs of poor health. They are generally checked once a day, but because the animals have been induced with poor health, they should be checked more frequently. Terminally sick animals, such as the BRC found on two of our announced visits to labs, should not have to wait a day for death.

III. THE MERITS OF THE PROPOSED ORDINANCES REGULATING THE CARE AND TREATMENT OF ANIMALS IN CAMBRIDGE

In 1986, an ordinance was proposed by Mayor Vellucci to improve the conditions of laboratory animals in Cambridge. At the request of Councillors, the City Solicitor drafted a Second Ordinance. A third Compromise Ordinance was then proposed as a substitute for the initial proposed ordinance. This last Compromise Ordinance addresses many of the concerns set forth in my Statement.

On November 21, 1988, Mayor Vellucci requested his

Blue Ribbon Committee to assess how the proposed ordinance(s) may improve current conditions of laboratory animals.

A. ANIMAL CARE COMMITTEES

1) The Compromise Ordinance

Proposed section 11-36(a) would require each research institution to appoint an Animal Care Committee "broad-based in its composition" that includes "at least one member unaffiliated with the research institution who shall be appointed by the Animal Commission in cooperation with local animal welfare groups" who "shall represent the community's concerns about the welfare of animals." While this increases the probability that proper weighing of human ends and animal means will occur, it fails to ensure balanced viewpoints on an animal care committee.

Proposed sections 11-36(b) and (c) provide access by the animal care committees to the animals and sufficient information to enable them to understand what they see.

2) The Second Ordinance

Proposed section 11-32 would essentially require each institution to have an animal care committee as mandated by Federal law, with the public representative to be appointed by the City Manager, who is given no standards with which to guide the appointment. As it does not ensure appointment of even a single citizen

concerned about animals, it retains some of the weaknesses of the present system.

3) FURTHER RECOMMENDATIONS

I recommend that the community member be an animal advocate appointed from persons nominated by animal welfare groups.

I recommend that there should be no less than one community member appointed for every three institutional representatives and that there be no less than two community members on each committee.

I recommend that no person be permitted to sit on an animal care committee who has an economic interest in research that comes before the committee (i.e. - stock management role or other formal or business tie).

I recommend that the percentage of persons who sit on an animal care committee who engage in projects subject to committee review be no greater than twenty-five percent.

I recommend that when the animal care committee discusses the research proposals of a committee member, the affected member be given a chance to speak, then be required to leave the room during subsequent discussion and vote.

I recommend that animal/care committee meetings be open for the public to observe, but not to participate in, with the committee able to go into executive session to protect trade secrets and similar informa-

tion.¹³²

B. COMMUNITY ETHICAL STANDARDS

1) Compromise Ordinance

Proposed section 11-37 would require the Animal Commission to delineate the community's ethical standards for the use of animals in experiments in order to aid its determinations and to assist animal care committees in their deliberations. Such delineation would stimulate ongoing discussions on this important matter and provide needed uniformity among the thirteen research institutions of Cambridge.

Two normative judgements are implicit in the Animal Welfare Act and the Public Health Service policies, recognition of the existence and moral significance of laboratory animal pain, distress, and well-being, and that the harming of laboratory animals must be scientifically necessary and relevant to the advancement of knowledge, human or animal health, or the good of society.¹³³ Yet,

(T)he conceptual and moral ambiguity characterizing the federal directives make them subject to a range of interpretations. The directives could be construed to demand very little scrutiny of an investigator's claimed need to use animals or to compromise their welfare. Conversely, a stringent interpretation of the provisions could support a significant tightening of the process for evaluating biomedical research proposals regarding animal use.¹³⁴

In light of the entire absence of animal advocates

from the animal care committees of Cambridge, the former construction is more likely than is the latter. In conjunction with the requirement that each animal care committee have at least one animal advocate (and I recommend two), such a delineation of community ethical standards would increase the probability that the subject of ethical standards would receive the attention it deserves in animal care committee discussions.

2) The Second Ordinance

This proposed ordinance has no requirement that ethical standards be delineated citywide. This omission means that each of the thirteen animal care committees will discuss them ad hoc, if they discuss them at all, and that there will be no uniformity of ethical standards within the city of Cambridge.

c. GUIDELINES FOR PAINFUL EXPERIMENTS

1) Compromise Ordinance

proposed section 11-34(a) would require each research institution to monitor each animal's pain and distress continuously and alleviate it except to the extent it has been described in the protocol. Proposed section 11-34(b) would require each research institution to obtain prior written approval of the Animal Commission before conducting any painful experiment in which anesthesia, analgesia, and tranquilizers used are inadequate to alleviate pain or distress at all times. Permission would be granted only if the experiment is

judged to yield significant information about a serious disease or illness afflicting human or animals such as cancer, heart disease, arthritis, or diabetes, and if no alternatives are available.

Current Public Health Service requirements limit the imposition of unrelieved pain and distress to cases where the "procedure is justified for scientific reasons in writing by the investigator."¹³⁵ The Public Health Service Policy and the Guide state that animals that would otherwise suffer severe or chronic distress that cannot be relieved should be painlessly killed at the end of the procedure or, if appropriate, during the procedure.¹³⁶

The Animal Welfare Act requires the Secretary of Agriculture to promulgate standards (as yet unpromulgated) that require that the withholding of tranquilizers, anesthesia, analgesia, or euthanasia "when scientifically necessary."¹³⁷ However, these standards may not generally regard the design, outlines, guidelines, or performance of actual research or experimentation.¹³⁸ Both the Guide and the Public Health Service Policy require that "due consideration (be given to the proposal's) relevance to human or animal health, the advancement of knowledge, or the good of society."

The Animal Welfare Act's standards (when they are finally promulgated) will require "that the principal investigator consider() alternatives to any procedure

likely to produce pain or distress in an experimental animal."¹³⁹ The Public Health Service Policy is silent as to alternatives.

At some point, severe pain, deprivation, and distress become worse than death for the sufferer. The research animals' interest in avoiding these states presents the strongest case for some sacrifice of the human interests in conducting animal research. As an animal's interest increases in importance, so does the ethical basis for interfering with what humans have at stake.¹⁴⁰

Proposed section 11-34(b) would ensure that in the circumstances where an animal will suffer unrelieved pain or distress, the experiment has high purpose that can be achieved in no other way, and that the animal is monitored continuously.¹⁴¹

2) The Second Ordinance

This proposed ordinance has no similar requirement. It would continue to permit animals to suffer unrelieved pain and distress unmonitored for any reason deemed scientifically justified by an animal care committee that contains no animal advocate.

D. TRAINING OF PERSONNEL

1) Compromise Ordinance

Proposed section 11-35 would require that each person involved in the care or use of animals at a research institution successfully complete a training program approved by the Animal Commission that teaches

the requirements of proposed section 11-33 (that all experiments be undertaken in conformity with all Federal, state, and local requirements) and proposed section 11-34 (the guidelines for painful experiments).

The Public Health Service Policy and Guide require that "(a)adequate arrangements shall be made for (investigators and other personnel's) inservice training, including the proper and humane care and use of laboratory animals."¹⁴² The Animal Welfare Act requires each research facility to "provide for the training of scientists, animal technicians, and other personnel involved with animal care and treatment in such facility as required by the Secretary."¹⁴³ The Secretary has required nothing yet.

The training should, eventually, "include instruction on (1) the humane practice of animal maintenance and experimentation; (2) research or testing methods that minimize or eliminate the use of animals or limit animal pain or distress; (3) utilization of the information service at the National Agricultural Library ..., and (4) methods whereby deficiencies in animal care and treatment should be reported."¹⁴⁴ The proposed section is more explicit in requiring that the training be expressly focused on the legal requirements to a degree not otherwise required.

2) The Second Ordinance

Proposed section 11-34 would require that the

Commissioner of Health and Hospitals devise educational programs that will increase public understanding of how animals are treated in research institutions and for what purposes and that will increase the institutions' awareness of public concern for the humane treatment of animals. I recommend this as a supplement to the requirements of the Compromise Ordinance. Otherwise, the matter of personnel training is not addressed.

E. INSPECTIONS AND INVESTIGATIONS

1) The Compromise Ordinance

Proposed section 11-38(a)(2) makes it the duty of the Animal Commission to investigate alleged violations of the ordinance. This is appropriate as the welfare of animals is an institutional concern.

2) The Second Ordinance

Proposed section 11-33 makes it the duty of the Commissioners of Health and Hospitals to investigate complaints that relate to lack of compliance with the Guide or the PHS Policy. No one has the power to investigate violations of the ordinance. There are no City sanctions for violating the Guide or PHS Policy.

The Commissioner has neither institutional experience or concern with the welfare of animals, and, as a scientist, could even be indifferent to the matter of animal welfare. The Commissioner therefore is an inappropriate investigator.¹⁴⁵

F. VIOLATIONS

1) The Compromise Ordinance

Proposed section 11-40 provides for a fine for violations of the ordinance, closure of any research institution that repeatedly violates the ordinance, and jurisdiction for the Animal Commission or a charitable animal welfare corporation to bring suit to enjoin violations of the ordinance, with the research institution to pay attorney's fees if it loses.

2) The Second Ordinance

This ordinance has no mechanism for assuring compliance or punishing violations. It is therefore little more than a recommendation.

IV. NECESSARY MEDICAL RESEARCH WILL NOT BE IMPEDED

Research scientists frequently claim that any regulation of what they do will "impede necessary medical research." However, necessary medical research will not be impeded by adoption of the Compromise Ordinance and my recommendations.

To a significant degree, scientists define "necessary" animal research as that research they do. "Among scientists, the interest in free inquiry can take on an almost religious significance."¹⁴⁶ Yet, scientists admit that "there is no way to predict what will and will not be productive research,"¹⁴⁷ and that "(t)he concept that scientists should use animals only for studies that lead to therapeutically useful results is therefore inconsistent with the foundations of sci-

ence."¹⁴⁸ Indeed, "(t)hat animals must suffer and die for the benefit of mankind is a law ... of nature"¹⁴⁹ and that animal biological investigation involves a "trifling amount of suffering"¹⁵⁰ have remained twin articles of scientific faith for nearly a century.

But this conflicts with the commonly understood definition of the word "necessary," which means "of an inevitable nature: inescapable," "logically unavoidable," "absolutely needed."¹⁵¹

When citizens seek to regulate animal research, it is not that they fail to understand the scientific process; they understand the tenuousness between scientific means and ends full well. They also understand

"that inherent in the milieu of contemporary science are 'shoddy' science or a steady stream of largely useless publications that serve as proof of continued competence, 'entrepreneurial science' or research that does not reflect the desire of the scientist to investigate a problem other than for her ability to obtain necessary funding from government or industry, 'reckless science,' or science that is pursued for a profit motive without consideration of the 'degradation of the natural and human environment' and where acceptable profit is 'determined by the judgment of men in State agencies, in co-operation with the industrial promoters themselves,' and 'dirty science,' or projects whose intended application lies beyond the pale of civilized practice and morality."¹⁵²

Citizens acknowledge the value of unfettered inquiry and when it involves excavating ancient ruins or developing new plant hybrids or sending astronauts

to the moon, they have shown themselves over and again to be exceedingly tolerant of scientists' choosing what research is "necessary" and what is not, within the constraints of public finding.

But when the by-products of the inquiring scientific mind are pain, suffering, or death to a degree not viewed by the public as "trifling," it is society's duty to demand of scientists sufficient justification for what they do consonant with a decent respect for the nature of the victim.

V. RESPONSE TO THE STATEMENT OF JOHN MOSES

I first reviewed the Statement of John Moses a day and a half before the BRC's report was presented to the City Council (I have never seen the Statement of Stuart Wiles). We have several differences.

First, we do not agree on the depth of the BRC's work. We formally interviewed several M.I.T. primate investigators and three others, Dr. Chalfen, Dr. Smith, and Dr. Sharifzadeh. The sixty or so animal care committee members who attended the meetings we attended were, of course, able to speak, but individual members were not interviewed. Many were animal researchers. The only other persons engaged in animal research or other procedures with whom we talked were those we met while touring the laboratories or animal quarters.

If we observed 3,000 animals - I did not count - then we observed a mere 5% of the 60,000 animals

consumed annually in Cambridge.

Second, I cannot say that the members of the thirteen animal care committees are committed to the welfare of animals and are able to take measures to ensure their compassionate treatment. Many appeared committed to interests antagonistic to the welfare of animals and some appeared committed to nothing at all.

Third, the BRC, as a committee, inquired very little into the kind of research being performed in Cambridge. At my request, research information was sent to me, which I reviewed. I do not believe that either of the other BRC members reviewed it. John Moses, as he is the chairman of the M.I.T. animal care committee, may have already been familiar with much of it. To his mind, it may have all been profound and meaningful. It was not to mine.

Fourth, the fact that the BRC found sick animals in two institutions is evidence that on a typical day there are sick untreated animals in Cambridge laboratories.

Fifth, BRC members came to the committee with different points of view; indeed, that was the City Council's objective in having representatives of both the animal experimenter and animal welfare community sit on the BRC. Initially we hoped for consensus. However, consensus requires debate and, despite my requests, the BRC failed to commence the debate that

might have led to the filing of a consensus report. Perhaps we mirrored the outside world.

VI. CONCLUSION

Adoption of the Compromise Ordinance and my Recommendations would be an important step in ensuring that laboratory animals are not subjected to cruelty or abuse in the research institutions of Cambridge.

FOOTNOTES

¹ B.S. in Chemistry, College of William and Mary, J.D., Boston University School of Law.

² "Animal Regulations: So Far So Good," 238 Science 880 (November 13, 1987).

³ D. Stone, Policy, Paradox and Political Reason 291 (1988).

⁴ Alternatives to Animal Use in Research, Testing, and Education (U.S. Congress, Office of Technology Assessment Washington, D.C., Government Printing Office, OTA -BA - 273 (February, 1986) at 342 (OTA)).

⁵ J. Robertson, "The Law of Institutional Review Boards," 26 UCLA L. Rev. 484, 487 (1979).

⁶ D. Rothman, "Ethics and Human Experimentation - Henry Beecher Revisited," 317 New Eng. J. Med. 1195, 1196, 1198 (November 5, 1987); H. Beecher, "Ethics and Clinical Research," 274 New Eng. J. Med. 1354 (June 16, 1966). Research institutions outside the Boston area experimented upon institutionalized mentally retarded children (New York University) and the terminally ill (Ohio State University), Rothman, supra at 1196, 1198.

⁷ Rothman, supra n.6, at 1198. "Celsus recalls and approves the vivisection which Herophilus and Erasistratus performed on criminals with the Ptolemies' consent. It is not cruel, he said, to inflict on a few criminals, sufferings which may benefit multitudes of innocent people throughout all centuries," C. Bernard, An Introduction to the Study of Experimental Medicine 100 (Dover Publications 1957).

⁸ Harvard had eleven members, M.I.T. twelve. Veterinarians are not to be confused with animal advocates. "The public sees veterinarians as exemplary leaders of animal welfare in society. Yet those who make a living in ways that harm or exploit animals - be it scientific research or intensive agriculture - are the people who pay the bills for a substantial amount of veterinary care and employ veterinarians as a major component of their activities This problem is exacerbated by traditional hostility ... between

veterinarians and animal welfare advocates," J. Wilson, Law and Ethics in the Veterinary Profession 36 (Priority Press Ltd. 1988) (my emphasis).

⁹ E.g., M.I.T., 50%; Harvard, about 50%; Biogen, 40%, Advanced Magnetics, 42%.

¹⁰ "Rise of spin-off businesses sparks growing controversy," Boston Globe at 16 (October 19, 1988). About thirty percent of biomedical researchers in the National Academy of Sciences own large blocks of stock, play management roles, or sit on scientific panels of private companies, id.

¹¹ Id., quoting Janett Trubatch, an associate vice-president for research at the University of Chicago.

¹² Boston Globe, supra, n.10, quoting Leon J. Kamin, Chairman of the Psychology Department at Northeastern University, at 16.

¹³ Wall Street Journal, January 26, 1989, at A1.

¹⁴ Id. at A6.

¹⁵ Id. at A1.

¹⁶ Id.

¹⁷ Id.

¹⁸ Boston Globe, supra, n.10, at 16.

¹⁹ The Responsible Conduct of Research in the Health Sciences, Institute of Medicine, Division of Health Sciences Policy (National Academy Press 1989).

²⁰ The Committee for the Study of the Responsible Conduct of Research noted, id. at 10, that in September, 1988, the Public Health Service proposed draft

regulations that set forth among the definitions of "'misconduct in science,'" the "'material failure to comply with federal requirements that (are) uniquely related to the conduct of research' (including) federal regulations governing the use of animals ... in research."

²¹ Id. at 90, 91; Id. at 3. Some argue that experimentation is protected First Amendment activity as it fulfills the experimenter's "interest in personal expression," J. Robertson, "The Scientist's Right to Research: A Constitutional Analysis," 51 S. Cal. L. Rev. 1203, 1215 (1977), or in "self-fulfillment," Delgado and Millem, "God, Galileo, and Government: Toward Constitutional Protection for Scientific Inquiry," 53 Wash. L. Rev. 349, 364-365 (1978), cited in G. Francione, "The Constitutional Status of Restrictions on Experiments Involving Non-Human Animals: A Comment on Professor Dresser's Analysis," 40 Rutgers L. Rev. 797, 802 n.30 (1988).

²² M.J. Baker, "A Layperson's Role" in Effective Animal Care and Use Committees 85 (Scientists Center for Animal Welfare 1987) (SCAW).

²³ R. Dresser, "Research on Animals: Values, Politics, and Regulatory Reform," 58 So. Cal. Law Rev. 1147, 1199 (1985) (Dresser I).

²⁴ R. Dresser, "Assessing Harm and Justification in Animal Research: Federal Policy Opens the Laboratory Door," 40 Rutgers L. Rev. 723, 772 (1988) (Dresser II).

²⁵ "Out from Under the Microscope: A Case for Laboratory Animal Rights," 2 Det. Coll. of L. Rev. 511, 543 (1987).

²⁶ Guidelines for Lay Members of Animal Care Committees 20-21 (Canadian Federation of Humane Societies 1986).

²⁷ PHS Policy, supra at 27. An "IACUC" is the Institutional Animal Care and Use Committee required by the Public Health Service Policy; an "Institutional Animal Committee" is that committee required by the Animal Welfare Act; an "animal care committee" is the generic term for a committee set up by an institution

to supervise the care or use of laboratory animals.

28 Dresser II, supra, n.24, at 761.

29 Id. at 770.

30 Id. at 761.

31 PHS Policy, Section IV (A)(3)(b).

32 H.C. Rowsell, "Animal Care and Use Committees and the Public Concern," in SCAW, supra, n.22, at 122.

33 M.I.T.

34 Use of Laboratory Animals in Biomedical and Behavioral Research (National Academy Press 1988).

35 Id. at 84-87. In her opinion, the report was unbalanced and "refuse(d) to face the widespread ingrained problem of unnecessary suffering among the millions of laboratory animals used yearly in our country, nor (did) it make so much as a passing reference to the serious problem of problem of poor research using excessive numbers of animals," id. at 84.

She noted that report data documenting a decrease in laboratory use of nonhuman primates conflicted with data from the United States Department of Agriculture, id., that committee members expressed hatred of the idea of emphasizing alternatives to the use of animals, and asserted that humans had no moral obligation to animals and that everyone cheated and prevaricated on that portion of their grant proposals that requires that there be an advancement of knowledge of immediate or potential benefit to humans or animals, id. at 85. She also noted that the report's assertion that "most research animals are humanely killed at some point" was unsupported and, indeed, unsupportable, id. at 86, that the report's executive summary misstated the Animal Welfare Act by asserting that under it "all animals used receive adequate presurgical and post-surgical care and pain-relieving drugs," when USDA reports for 1987 showed 130,373 animals were denied pain-relieving drugs under the AWA's exemption provision, id., and that the report falsely claimed that all serious

violations have resulted in suspension of funding and/or fines, id.

36 45 C.F.R. sec. 46.107(a).

37 45 C.F.R. sec. 46.107(b)(d).

38 Dresser I, supra, n.23, at 1190.

39 45 C.F.R. sec. 46.107(a).

40 Id.

41 45 C.F.R. secs. 46.205, 46.207, 46.208.

42 45 C.F.R. sec. 46.305.

43 45 C.F.R. sec. 46.403.

44 53 Fed. Reg. 35232 (September 12, 1988).

45 241 Science 168 (letter from Gary B. Ellis, Biological Applications Program, United States Congress Office of Technology Assessment).

46 Id.

47 53 Fed. Reg. 35232 (September 12, 1988).

48 Personal communication from Andrew Rowan, Assistant Dean of the Tufts Veterinary School.

49 Id.

50 3 American Journal of Primatology 345, 346 (1982).

51 J.D. Peck, "Reflections of a Public Member," in

SCAW, supra, n.22, at 85-86.

52 K.J. Hittelman, "Operating Principles for Committees on Animal Research," in SCAW, supra, n.22, at 98.

53 N. Buyukmichi, V.D.M., "Minority reports from Animal Activists on Institutional Animal Care Committees", NewPaths, Vol. 1, No. 1 (Fall, 1986), at 1.

54 J. Hutchinson, "The Role of Lay Members on Animal Care Committees," id., at 6.

55 S. Sapontzis, "On Adopting Animals from Labs," NewPaths, Vol. 1, No. 2 (Spring, 1987), at 1.

56 Angenics.

57 Clinical Assays.

58 M.I.T./Whitehead.

59 Advanced Magnetics.

60 Harvard.

61 Biogen.

62 Genzyme.

63 Arthur D. Little.

64 Cambridge Research.

65 Repligen.

66 T-Cell Sciences.

67 Applied Biotechnology.

68 Advanced Magnetics, Applied Biotechnology,
Biogen, M.I.T., T-Cell Sciences.

69 M.I.T.

70 Harvard. However, the Committee for the Study of the Responsible Conduct of Research, supra, n.19, found, at 2, that "(t)here were very few courses of instruction dedicated to communicating professional standards and the ethics of research practice to young scientists."

71 Harvard, ADL, M.I.T., Biogen.

72 Even I was unsuccessful in my attempt to get my fellow BRC members to discuss the inadequacies I perceived in the functioning of the animal care committees, as well as the other matters I address in my Statement. I therefore note that the matters included in my Statement are not those upon which the BRC disagreed, but those it never discussed.

73 Supra, at 10 and n.21.

74 PHS Policy, section IV(C)(2). Full committee review of a significant member of proposals would require some animal care committees to meet more frequently, e.g., Harvard, which meets semi-annually for breakfast at the Faculty Club.

75 M.I.T.

76 Harvard.

77 Letter from Melvin H. Chalfen, M.D. to Mr. Robert Healy dated April 9, 1987, at 4.

78 Cambridge Research.

79 "Push and pull in the world of science," Boston

Globe, at 1, February 12, 1988.

⁸⁰ 239 Science 972 (February 26, 1988).

⁸¹ OTA, supra, n.4, at 71; P. Singer, Animal Liberation 63 (1975) (my emphasis).

⁸² 238 Science 880, 883 (November 13, 1987).

⁸³ 9 CFR 1.1(n); OTA, supra, n.4, at 278, 298; H. Cohen, "Two Questions Concerning the Animal Welfare Act," No. 85-927A, Congressional Research Service, U.S. Congress 4-5 (August 7, 1985). See also, statement of Senator Alan Cranston, 116 Cong. Rec. S31525 (September 14, 1970) ("The bill ... extends coverage to all warm-blooded animals"); Statement of Senator Robert Dole, 116 Cong. Rec. S38660 (November 24, 1970) ("The proposed legislation will broaden coverage to all warm-blooded animals ...").

⁸⁴ The numbers and species are approximately as follows:

- A) Advanced Magnetics - 1600
 - 1. Rabbits - 5
 - 2. Mice - 1,500
 - 3. Rats - 100
 - 4. Pigs - 40
- B) Angenics - 600
 - 1. Mice - 600
- C) Applied Biotechnology - 8,000
 - 1. Mice - 8,000
 - 2. Rats - Unknown
 - 3. Rabbits - Unknown
- D) Arthur D. Little - 20,000
 - 1. Mice - Unknown
 - 2. Rats - Unknown
- E) Biogen - 2,000 - 3,000
 - 1. Mice - 1,000 - 2,000
 - 2. Rats - 1,000
- F) Cambridge Research - 1,200 - 1,500
 - 1. Mice - 1,200 - 1,500
- G) Clinical Assays - 500
 - 1. Mice - 500
- H) Genzyme - Several hundred
 - 1. Mice - several hundred
- I) Harvard - 4,000
 - 1. Mice - 2,500
 - 2. Rats - 30

3. Primates - 8-10
 4. Frogs - 600
 5. Alligators - 6
 6. Lizards - 8
 7. Pigeons - 124
 8. Rabbits - 92
 9. Starlings - 16
 10. Robins - 6
 11. Budgerigans - 6
 12. Guineau fowl - 25
 13. Perch - 300
 14. Carp - 100
 15. Cat fish - 50
 16. Opposums - Unknown
- J) M.I.T./Whitehead - 17,225 (number of animals purchased between July 1, 1987 and June 30, 1988)
1. Mice and rats - 16,276
 2. Dogs - 45
 3. Primates - 63
 4. Ferrets - 235
 5. Swine - Unknown
 6. Turtles - Unknown
 7. Sheep - Unknown
 8. Chinchillas - Unknown
 9. Lizards - Unknown
 10. Hamsters - Unknown
 11. Guineau pigs - Unknown
 12. Frogs - 212
 13. Chickens - Unknown
 14. Goldfish - Unknown
 15. Rabbits - Unknown
 16. Cats - 16
- K) Repligen - 200
1. Mice - 200
 2. Rabbits - 8-9
- L) T-Cell Sciences - 1,000
1. Mice - 1,000

85 Interview with William Smith, D.V.M., January 19, 1988 (Dr. Smith).

86 Id.

87 In 1966, the USDA stated to Congress that "the function of this department relates basically to livestock and poultry," requested that another Federal agency be given the duties of inspection, and sought to limit the Animal Welfare Act to cats and dogs, 1966 U.S. Code Cong. & Ad. News 2635, 2643. In 1970, the USDA sought to have its enforcement duties transferred to the Department of Health, Education and Welfare,

1970 U.S. Code Cong. & Ad. News 5103, 5105-5106. In 1976, the USDA opposed proposed Amendments to the Animal Welfare Act that would have strengthened the authority of the USDA, 1976 U.S. Code Cong. & Ad. News 758, 766. See L.S. Rikleem, "The Animal Welfare Act: Still a Cruelty to Animals," 7 B.C. Envir. L. Rev. 129, 135-136 (1978).

88 U.S. Congress, General Accounting Office, Report to the Chairman, Subcommittee on Agriculture, Rural Development and Related Agencies, Committee on Appropriations, United States Senate: The Department of Agriculture's Animal Welfare Program GAO/RCED-85-8 (Gaithersburg, MD: May 16, 1985) 33 (GAO).

89 238 Science 880, 881 (November 13, 1987).

90 GAO, supra, n.88, at 21, 22; Dr. Smith, supra, n.85.

91 Dr. Smith, supra, n.85. Even the Committee on the Use of Laboratory Research in Biomedical and Behavioral Research recognized the problem of insufficient funding for inspections and recommended "that sufficient federal funds be appropriated for the inspections required for the enforcement of the Animal Welfare Act," supra, note 34, at 71.

92 Chalfen Letter, supra, n.77, at 2.

93 Letter from Blanchard Randall IV, analyst in Social Sciences, Science Research Policy Division, Congressional Research Service, the Library of Congress to the Honorable Robert K. Dornan, Subject: Oversight of Animal Care and Use in Research by the U.S. Department of Agriculture and the Public Health Service, at 3, dated June 23, 1987.

94 "Evaluation of Experimental Procedures Conducted at the University of Pennsylvania Head Injury Laboratory 1981-1984 in Light of the Public Health Service Animal Welfare Policy," prepared by the Office for Protection from Research Risks for the Office of the Director of the National Institutes of Health, dated July 17, 1985, at 1; "Report and Recommendations of the NIH Committee to Investigate Alleged Animal Care Violations at the Institute of Behavioral Research," dated October 5, 1981, at 7. See also "Evaluation of

Allegations of Non-Compliance with the Public Health Service Animal Welfare Policy," prepared by the Office for Protection from Research Risks for the Office of the Director, National Institutes of Health, dated June 11, 1986, at 1 (After evidence stolen from the City of Hope Medical Center was presented to the Department of Health and Human Services, an investigating committee was formed that found "significant and continuing non-compliance with the PHS Policy." This led to withdrawal of approval of the Animal Welfare Assurance of the City of Hope Medical Center for nine months).

95 Webster's Ninth New Collegiate Dictionary (1983).

96 Dr. Smith, supra, n.85.

97 Dr. Smith, supra, n.85.

98 See Alaska Statutes, sec. 11.61.140(3)(b), which exempts scientific research from its cruelty definition when the research is "governed by accepted standards." I include "death" along with "pain" and "suffering" because the painless killing of a laboratory animal "violates the animals interests in the fundamental enjoyments of life Therefore, only by recognizing of right to life may an animals' interest in how its life is led be protected," R. Hanula and P. Hill, "Using Metaright Theory to Ascribe Kantian Rights to Animals Within Nozick's Minimal State," 19 Ariz. L. Rev. 242, 264 (1977).

99 See, Maryland Public Health Code Annotated Art. 27, secs. 57, 59, which protect animals used in "scientific or medical activity," but exempt "normal human activities to which the infliction of pain to an animal is purely incidental and unavoidable" (my emphasis); People v. O'Lary, 382 Mich. 559 (1969) (There is a duty to provide medical attention).

100 The Massachusetts Cruelty Law, G.L. c.272 sec. 77, forbids one from "knowingly and wilfully authorizing) or permit(ing) it to be subject to unnecessary torture suffering or cruelty of any kind."

"The protagonists of the practice of human experimentation justify their views on the basis that such experiments yield results for the good of society that are unprocurable by other methods or means of

study. All agree however, that certain basic principles must be observed in order to satisfy moral (and) ethical ... concepts: ...

2. The experiment should be such as to yield fruitful results for the good of society unprocurable by other methods or means of study, and are not random or unnecessary in nature.

3. The experiment should be so designed and based on ... the knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.

4. The experiment should be so conducted as to avoid physical and mental suffering and injury." The Nuremberg Code, reprinted in Appendix II of T.L. Beauchamp and J.F. Childress, Principles of Biomedical Ethics 287-288 (Oxford University Press 1979).

Cf, N.Y. Admin. Rules and Regs. Title 10 sec. 55.1.1(b) ("Approval will not be granted to laboratories for the use of living animals unless evidence is presented that the general research or teaching program of the institution or laboratory will contribute to the problems of human or animal health") (my emphasis).

101 Guide, supra at 37; 105 CMR 910.134(B)(5).

102 M.I.T.

103 A research institution is not subject to state regulations unless it uses at least one dog or cat, 105 CMR 910.020(A). These research institutions do not use cats or dogs.

104 Journal American Veterinary Medical Association, vol. 188 No. 3 (February 1, 1986) (JAVMA).

105 Id. at 261 and Table 2.

106 Id. at 265 at Table 2.

107 Agenics; Repligen.

108 T-Cell Sciences.

109 JAVMA, supra, n.104, at 261.

110 Biogen, T-Cell Sciences, Applied Biotechnology.

111 Most of these institutions, not using cats or dogs, are not subject to the letter of state regulations.

112 T-Cell Sciences, Whitehead Institute for Biomedical Research.

113 Supra at 36.

114 See also 910 CMR 134(B), (B)(1)(b)(2) and 200(B).

115 T-Cell Sciences.

116 M.I.T. Animal Care Committee #87-029. This had gone on for several years and was disapproved by the animal care committee in 1986 and the method abandoned at an unknown time.

117 Harvard Animal Care Committee #88-27A.

118 M.I.T. Animal Care Committee #87-189.

119 7 U.S.C. sec. 2143(a)(2)(B). See International Primate Society International Guidelines for Breeding and Capture Care of Nonhuman Primates at 6 (July 1988); "Experts ponder simian well-being," 241 Science 1753 (September 30, 1988).

"It is widely believed that caging, its attendant lack of activity, and its social isolation can lead to pathological behavioral and physiology The single greatest step we could take in improving the lot of the animals we use in research would be to return to them some of the power to cause changes in their environment when they 'wish' to do so," J. Spinelli and H. Markowitz, "Prevention of Cage-Associated Distress," Lab Animal 19, 20 (November/December 1985).

120 P. O'Neal, "Enriching the Lives of Primates in

Captivity," Humane Innovations and Alternatives in Animal Experimentation: A Notebook, volume 1 (Psychologists for the Ethical Treatment of Animals 1987).

- 121 M.I.T. Animal Care Committee #87-21 or 88-047.
- 122 M.I.T. Animal Care Committee #86-135.
- 123 Guide, supra at 9.
- 124 Cambridge Research.
- 125 M.I.T. Animal Care Committee #87-213 and 88-016.
- 126 Volume 134, No. 24 (December 10, 1988) at 374.
- 127 M.I.T. Animal Care Committee #87-169.
- 128 M.I.T. Animal Care Committee #87-095.
- 129 Dresser II, supra, n.24, at 791.
- 130 Id., at 792.
- 131 Chalfen Letter, n.77, at 1.
- 132 The Animal Care Committee of the University of Washington has been held subject to that state's Open Meeting Law, Progressive Animal Welfare Society v. University of Washington, No. 87-2-03095-4 (April 28, 1987). A similar suit, in which I am plaintiff's counsel, is pending against the University of Massachusetts and the University of Massachusetts Medical School, Medlock v. Board of Trustees of the University of Massachusetts, C.A. 87-6002 (Suffolk Superior Court).
- 133 Dresser II, supra, n.24, at 733.

134 Id.

135 PHS Policy, sec. IV(c)(1)(b).

136 PHS Policy, supra at 27, Guide at 83.

137 7 U.S.C. sec. 2143 (a)(3)(C)(V).

138 7 U.S.C. sec. 2143(a)(6)(A)(i) and (ii).

139 7 U.S.C. sec. 2143(a)(3)(B) (my emphasis).

140 Dresser II, supra, n.24, at 762-763.

141 No Cambridge research institution states that it conducts such experiments.

142 PHS Policy, supra at 28; Guide, supra at 83.

143 7 U.S.C. sec. 2143(d).

144 7 U.S.C. sec. 2143(d)(1)-(4).

145 The present Commissioner has already given his opinion that both community review of research protocols, which he estimates as 100,000 pages per year (I estimate annual research protocols as containing between 5% and 10% of this number of pages), and the inclusion of an animal advocate on the animal care committees would "inhibit necessary medical research." Chalfen letter, supra, n.77, at 3-4.

146 Dresser II, supra, n.24, at 761.

"The (Office of Technology Assessment Report) makes very clear that human justification of abuse of non-human animals is very closely connected to religious doctrines that animals have souls," Francione, supra at 817, n.80.

Indeed, "Acceptance of vivisection as a general practice was occasioned in large part by Descartes, who argued that animals were no more than machines and were therefore incapable of thinking or feeling."

Descartes' views were fortified by various religious doctrines that recorded little or no concern to non-human animals," Francione, supra, n.21, citing A. Rowan and B. Rollin, "Animal Research - For and Against: A Philosophical, Social, and Historical Perspective," 27 Persp. Biology and Med. 3.

147 Use of Laboratory Animals in Biomedical and Behavioral Research, supra, n.34, at 48. C.R. Gallistel, "Bell, Magendie and the Proposal to Restrict the Use of Animals in Neurobehavioral Research," American Psychologist 357, 358 (April 1981) ("(M)ost experiments conducted by neurobiologists, like scientific experiments generally, may be seen in retrospect to have been a waste of time, in the sense that they did not prove or yield any new insight.")

148 Use of Laboratory Animals in Biomedical and Behavioral Research, supra, n.34, at 48.

149 1896 Report of the National Academy of Sciences, Use of Laboratory Animals in Biomedical and Behavioral Research, supra, n.34, at Appendix A, at 91 (authored by Harvard physiologist H.P. Bowditch).

150 Id.

151 Webster's New Colligiate Dictionary for 1983.

152 J. Ravetz, Scientific Knowledge and Its Social Problems 55-57 (1971), quoted in G. Francione, "Experimentation and the Marketplace Theory of the First Amendment," 136 U.Pa L. Rev. 417, 454 n.46 (1977).

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150 Id.

151 Webster's New Collegiate Dictionary (1983).

152 J. Ravetz, Scientific Knowledge and Its Social Problems 55-57 (1971), quoted in G. Francione, "Experimentation and the Marketplace Theory of the First Amendment," 136 U.Pa L. Rev. 417, 454 n.46 (1977).

C

Report to the Cambridge City Council
John Moses' Statement on the Findings of the
Blue Ribbon Committee

OVERVIEW

In the course of its 14 month study, the Blue Ribbon Committee on Animal Research in Cambridge (BRC) visited 13 Cambridge institutions conducting research or biomedical activities using animals. Approximately 100 persons actively engaged in research or other animal procedures such as antibody production and the majority of members of 13 animal care committees were interviewed. Approximately 3,000 animals representing 14 different species were observed and about 900 pages of written material describing laboratory and administrative procedures were provided to the BRC. A spectrum of species and endeavors from rodents to primates and the study of Alzheimer's disease to production of biomedical therapeutics was represented in the BRC investigations.

After review of all of the data, observations, supporting documents, and analysis of the deliberations of the BRC, the following conclusions are warranted on the basis of objective information:

1. There is no evidence of mistreatment of animals in the 13 institutions scrutinized by the BRC.
2. Research procedures including methods of anesthesia and euthanasia were performed in a manner which avoids



pain and suffering and which is in compliance with established guidelines for humane care.

3. The adoption of the NIH Guide for the Use and Care of Laboratory Animals and the AVMA Panel on Euthanasia was universally accepted as the standards for ethical care and use of animals in Cambridge institutions.
4. Animal care committees in each of the 13 institutions are composed of members committed to the welfare of animals and are able and willing to take measures to ensure compassionate treatment of them. The animal care committees of Cambridge are effective bodies for the assurance of high standards and practices of animal use and care.
5. The Animal and Plant Health Inspection Service (APHIS) and the State Department of Public Health conduct unannounced inspections of Cambridge research institutions as frequently as six times annually.
6. Five species account for more than 99% of the animals purchased in Cambridge annually by research and biomedical laboratories. Rodents account for by far the largest number and constitute 96.3% of all animals used. In order of frequency the other four categories are frogs, rabbits, fish and birds which account for an additional 3%.

MEMBERS OF THE BRC

Two members of the BRC were appointed by the Mayor in

December, 1987. They were Attorney Steven Wise who has established his commitment to the animals welfare movement chiefly through effective legal efforts sympathetic to the purpose of that movement and Dr. John Moses, a practicing internist who as chairman of an animal care committee has demonstrated his interest in the establishment of high standards of animal care in research and support of the research community. Both of these BRC members were selected with the agreement of persons of many viewpoints concerned with issues of animal welfare and research. The third member of the BRC, Stuart Wiles, DVM was subsequently appointed by the Mayor on the recommendation of Attorney Wise and Dr. Moses. In the process of arriving at that recommendation a large number of veterinarians and other persons interested in the welfare of animals were consulted including two past presidents of the Massachusetts Veterinary Association. Dr. Wiles was the choice of Wise and Moses for recommendation to the Mayor because of his experience as a practitioner of small animal medicine, his clinical background in an institution supported by the animal welfare movement, his understanding of laboratory veterinary medicine, his ongoing public service on the Massachusetts Board of Examiners in Veterinary Medicine, and because of his neutrality in issues which were anticipated to confront the BRC.

RESEARCH PROCEDURES

Research investigation, laboratory technicians, and other personnel directly involved in research projects were among

those interrogated by the BRC. Representative research projects considered by the BRC included investigations impacting on skin grafting, reconstitution of disrupted nerves, Alzheimer's disease, stroke, blindness, and gastrointestinal infections. These and other research endeavors were carried out in birds, rats, rabbits, ferrets, and primate models. Nine of the ten principle investigators engaged in primate research in Cambridge were questioned about their purpose and research goals, alternatives such as the use of humans in research, and their research methods. Primates which had undergone insertion of eye movement sensors 24 hours previously were inspected by the BRC. These animals were engaged in research designed to study visual extinction, a disabling phenomenon manifest in stroke. Other primates engaged in the study of the role of the frontal lobes in aphasia, visual and motor functions of the central nervous system, and developmental sensory defects of infants were viewed by the BRC. On an unannounced visit the BRC inspected rats which had recently undergone intracerebral injections of chemical agents affecting brain dopamine, a substance affecting certain degenerative brain syndromes of humans, emotional stability, and obesity. These animals were inspected in the laboratory and a technician was present to answer questions about the procedures. Pigeons used as subjects in long term experiments investigating information processing and behavior were examined in the course of another unannounced laboratory visit. These birds were undergoing training which required limited access to food. In none of the above, and many more

observations and discussions of research conducted in Cambridge, did the BRC find evidence of cruelty or abuse, or research which was other than profound and meaningful. In all facilities methods and policies of anaesthesia and euthanasia employed in research were humane, appropriate, and in conformity with NIH and AVMA guidelines. In fact, on visits to all of the Cambridge institutions engaged in research (as many as three times in one institution) there was strong evidence that high standards of animal care and use were practiced.

BIOMEDICAL PROCEDURES

The preponderance of non-research biomedical procedures involve rodents and very much less frequently lagomorphs (rabbits) and related species. The high standard of these non-research laboratories were similar to those in which research predominated. Antibody production for use in vaccines or medical and veterinary diagnosis or as therapeutic agents to be used in human and animal disease constituted the usual scientific effort in most of these laboratories. Methods of anaesthesia and euthanasia were in keeping with NIH and AVMA standards. In one facility a plastic bag was used for the introduction of carbon dioxide rather than the usual rigid chamber used for euthanasia by other institutions. The AVMA guidelines do not prohibit this procedure but because it was unique in the BRC experience it was the subject of special scrutiny. Another institution used dry ice to generate carbon dioxide. This procedure is approved by the AVMA but is

considered less desirable than the usual method of introducing gas under conditions of better control of flow and volume.

Thousands of mice were observed and appeared healthy and well cared for except for three. In one cage a pair of mice showed evidence of physical trauma from inflicted bites. Another mouse in another institution appeared ill, presumably as a consequence of a laboratory procedure. The rarity of ill health among these animals provided evidence for the conscientious concern for excellence in animal care found in biomedical facilities in Cambridge.

ANIMAL QUARTERS AND HUSBANDRY

Inspection tours were made of animal quarters in all 13 institutions by the BRC accompanied by either facility managers, scientists, animal care committee members or all of these persons concerned with animal care. The standards for maintenance of the physical plant, environmental conditions, husbandry, and provision for emergencies and other contingencies were documented by the excellence of the conditions found in almost all of the facilities visited by the BRC. There were a few minor exceptions in husbandry and facility cleanliness and one example of inadequate emergency surveillance which became apparent from these inspections.

ANIMAL CARE OVERSIGHT

The BRC met with each of the animal care committees (Institute Animal Care and Use Committee or IACUC) of the 13

institutions. These visits were as short as one hour and as long as three hours. All IACUC's had adopted the standards set forth by the Animal Welfare Act and its amendments, the NIH Guide, the AVMA Panel, as well as State regulations where they applied. In most cases compliance with Federal regulations was voluntary but such compliance was universal. The nature of protocols reviewed by the IACUC and the IACUC responsibility and membership were carefully reviewed by the BRC. In smaller institutions the IACUC function was usually quite simple because the number of protocols was small and the scientific procedures were routine and unvaried, usually limited to antibody production in rodents and, occasionally, tissue harvest. In the larger research institutions, procedures were often complex, subject to continuing intense scrutiny by the IACUC, requiring Committee evaluations of changing procedures and personnel and detailed examination of alternatives to animal use.

In one institution the authority of the IACUC to prohibit or alter animal procedures was potentially limited by another committee but in the other 12 institutions the autonomy of the IACUC was sufficient to exert ultimate control over laboratory activities. In this way these IACUC's were able to ensure ethical and compassionate animal care.

Suggestions for IACUC membership came from a variety of sources but in all institutions where inquiry was made, all members were appointed by an administrative official of the institution. The membership of IACUC's was generally representative and met NIH standards with the exception of one

institution which had available veterinary consultation but lacked membership by a veterinarian on its committee. The BRC placed much emphasis on the non-affiliated or "community" member of the IACUC's. None of the 13 institutions had a non-affiliated members who were animal rights activists. Many explanations were offered for this. Several members cited their own commitment to the welfare of animals. A veterinarian referred to the oath taken by all veterinarians (" ... to use my knowledge and skills for .. the protection of animal health and the relief of animal suffering" AVMA House of Delegates, July, 1968.). Other IACUC members expressed the viewpoint that because the intent of the Animal Welfare Act, and hence the IACUC, was to support animal research, the selection of an IACUC member from a movement which promotes dissolution of animal research would be self-defeating. IACUC members felt that such an appointment would result in counter-productive disruption of committee effort. The development of meaningful exchange, candor, and cooperation between research scientists and the IACUC was emphasized as an important aspect of the success of IACUC oversight. The opinion that the presence on the animal care committee of an animal rights activist would erode the relationship of the scientist and the IACUC was cited as a strong argument against inclusion of persons obligated to an anti-research movement on these committees. In examining the charge of the IACUC, the function of Institute Review Boards (IRB's) which have a similar role in the protection of human experimental subjects was cited. Because of the many years of

success of the design of IRB's they were used as a model in the development of IACUC's. Specific reference was made to human subjects in the "vulnerable category" (HHS 46.107) such as infants and children or the mentally disabled. Their vulnerability resembles that of animals. It was pointed out that the IRB appointment process of a non-affiliated member is identical to that of the IACUC and has functioned very well in the protection of vulnerable experimental subjects.

The BRC reviewed the provisions of the Animal Welfare Act of 1966 and the 1985 amendments. There was agreement among us that the restriction of federal regulations to federally funded research and only certain species was a deficit with potential impact on the use of animals in Cambridge. The voluntary adoption of the mandates of the Animal Welfare Act by the IACUC's of all 13 Cambridge institutions including compliance with the NIH Guide for Care and Use of Laboratory Animals was reassuring.

The regional Veterinarian-in-Chief of APHIS (Animal and Plant Health Inspection Service of the USDA) provided the BRC with the information that although more funds available to APHIS would be useful, the current budget was sufficient to allow two unannounced inspections yearly, and more if needed. Like APHIS inspections made under the auspices of the Massachusetts Department of Public Health are unannounced. These inspections made four times annually are conducted by the Massachusetts Society for the Protection of Cruelty to Animals (MSPCA) and the Animal Rescue League (ARL) at each of the facilities licensed by

the State. In addition, the larger research facilities undergo rigorous inspection by the American Association for Accreditation of Laboratory Animal Care (AAALAC) as a requirement of annual accreditation by that body.

CONCLUSION

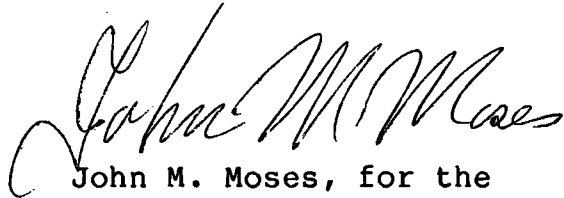
From the very first meeting of the BRC there was agreement among the members that they would not discuss schedules, procedural conduct, opinions relating to the observations made, or philosophical differences unless all three members agreed to do so. That basic rule was not abrogated during the process of developing the report to the Cambridge City Council until recently. The three members were able to agree upon most activities and where agreement was not possible, compromise often was. However, it became apparent that agreement and even compromise were not adequate to render a comprehensive report which would be far-reaching enough to satisfy each member. Hence, it was decided that the report should be amended by observations which would supplement a somewhat abbreviated document and, of course, those statements would be submitted without requirement for mutual agreement. This statement has been made in that spirit and in response to the charge of the City Council of Cambridge with the following conclusions:

The considerable effort by the BRC and its makeup were effective in determining that cruelty and abuse are not existent in Cambridge.

Animal care committees are effective bodies for the

assurance that cruelty and abuse will not occur and that facilities are managed for optimal protection of animals in Cambridge.

The mandated and voluntary compliance with federal regulations and guidelines assure the compassionate and ethical treatment of animals in the laboratories and facilities of Cambridge.

A handwritten signature in cursive script, appearing to read "John M. Moses".

John M. Moses, for the

Blue Ribbon Committee on

Animal Research

Cambridge, MA 2/24/89

REPORT ON THE FOUR QUESTIONS PUT BEFORE THE BLUE RIBBON COMMITTEE ON ANIMAL CARE AND USE IN THE CITY OF CAMBRIDGE

I. BACKGROUND

A. City Council

The City Council has stated that the Council is opposed to the imposition of unnecessary regulations and reporting requirement which retard the ability of local laboratories to make scientific progress for betterment of human health and welfare, the Council is firmly committed to insure high standards of animal welfare, so that all animal experimentation in this City is done in a humane and caring way.

The City Council has ordered that certain questions be examined and answered. These questions concern the care, sanitation and internal monitoring procedures of laboratories, current standards and any evidence of cruelty or abuse concerning animals used for research in the City of Cambridge.

B. Evaluation of the Animals Used for Research in the City of Cambridge

The goal should be to establish and maintain an environment whereby stressful situations are minimized and whereby animals can successfully cope with that environment. Elimination of all stress for laboratory animals is unrealistic because a stress free environment is impossible to attain.

When stress is elevated to a certain point or threshold it is no longer a neutral factor and the stress presents a problem. The stress evokes harmful responses which will, or probably will, interfere with an animal's well being. The responses range from discomfort, to pain, to disease and one can expect changes in behavior and/or physical condition.



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Some of the stress related problems which we must consider are fear, loneliness, boredom, cramped quarters, physical discomfort related to laboratory procedures and inappropriate environmental factors such as temperature and noise.

How does one measure stress? There is no simple test that can be performed. There is also great variability between species, animals of the same species and even in the individual animal with regard to reaction to stress.

Behavior is one measurement of stress. Qualitative behavior is that which occurs to animals in captivity. Examples in primates are bizarre postures, such as self grasping and eye poking, as well as certain motor acts; e.g. pacing, head tossing and bouncing. Quantitative behavior is that which occurs more or less frequently in captivity as compared to a natural setting. Examples are apathy, depression and appetite disorders. Further measurement of stress is an evaluation of the physical condition of animals in question. It follows that if stress is a problem to an animal and it continues, health will be affected.

In summary the most likely reflections of stress which cannot be handled are behavior and/or physical condition. These were major considerations in making determinations of the welfare of the animals used in research in the City of Cambridge.

The other forms of evaluations used to answer the questions posed by the City Council were based on the standards of care and research procedures and the mechanisms of oversight and controls used in the research facilities.

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Our functions as an investigatory committee are to recognize if there are any animals in distress and to uncover and expose any cracks, deficiencies, inadequacies and oversights that fail to prevent undue stress for animals used for research in the City of Cambridge which, of course, would constitute cruel and abusive treatment.

Reference Material:

1. AVMA Colloquium on Recognition and Alleviation of Animal Pain and Distress. JAVMA November 15, 1987.
2. Public Health Service Policy on Humane Care and Use of Laboratory Animals OPRR.
3. Guide for the Care and Use of Laboratory Animals. U.S. Dept. of Health and Human Services.

II. REPORT ON THE FOUR QUESTIONS

Question #1

Does inspection of animal quarters and the condition of animals therein suggest cruelty and abuse of animals?

With the exception of two mice with illness in one cage, two injured mice in one cage, one instance of marginal overcrowding of some rats in one housing area and one instance of probable inadequate ventilation, there was no evidence of situations suggesting cruelty and abuse.

The situations involving the injured and sick animals were, as explained to us, not yet discovered because the daily round of animal examinations

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had not yet been performed - in part because of our visit. Only repeated visits could determine if there was a continuous problem of this nature.

The ventilation and overcrowding incidents that existed could result in stressful situations with harmful consequences if they were not correctly managed.

Other conditions and functions such as access to food and water, cleanliness, temperature, protection from hazards, prevention of cross infection (where applicable), illumination, extraneous noises, bedding, sanitation of rooms, cages and equipment, evidence of insects, parasites or other vermin, identification and records of animals were adequate and satisfactory and not suggestive of cruelty or abuse.

In many instances in both large and small operations the conditions and facilities were impressive and exemplary.

Primates observed were housed in individual cages. The cages met the space requirements as set forth in the Guide for the Care and Use of Laboratory Animals.

In order to evaluate the degree of stress prevalent relative to being caged alone, many factors must be considered.

On the negative side each primate was kept socially separate from other primates. The cages were adequate but restrictive. The cages were in large part barren.

On the positive side there were always several primates in one area

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(room), rooms were bright and well lighted. Cages and room areas were clean, neat and odor free.

Is there intolerable or unacceptable stress in this situation?

The animals were healthy appearing, bright, alert and active. They were not hyperactive and did not elicit behavior traits that would reflect emotional or physical stress or pain.

The research procedures being performed mandated separation of the animals and therefore this probably creates stress. This seemed to be overcome in several ways. The animals were obviously adapted to the cages. They, as determined through discussions with the handlers and investigators, received individual attention. The manner in which the laboratory exercises were handled; e.g. slow adaptation to restraint and laboratory procedures, attentiveness of handlers during procedures and rewards; provided a positive aspect to their lives and in turn reduced stress.

My evaluation of the primates viewed is that there was no evidence or suggestion of cruelty or abuse.

My evaluation of all of the animals visited and viewed is that there was not evidence of stressful situations that suggest cruelty or abuse.

The potential for abuse and cruelty under the same physical conditions that we encountered could, of course, occur with improper handling and management of animals.

Question #2

Are the laboratory procedures carried out in the various institutions cruel or abusive to animals?

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I was able to observe one laboratory procedure in progress. It was a rat under anesthesia placed in a Magnetic Resonance Imagery apparatus. The animal was adequately anesthetized and under constant observation. Preparations were made for post procedural management and observation which was quite satisfactory. The procedures were those that you would find in any well run veterinary hospital. I was the only member of the committee to observe this procedure.

The committee observed many mice that were actively being used for antibody collection. Out of the thousands that we viewed two were lethargic and appeared ill.

Several primates were observed that had surgically implanted metal posts on their heads. These posts were used to hold the head of the animal in a steady position for the purpose of taking measurements of eye movements. I examined these animals on two separate visits to the research facility. I asked questions regarding the implant procedure and post-operative care. My questions were directed to the veterinarian in charge. There are other veterinarians at the facility that I talked to as well.

My first reaction upon visiting these primates was surprise at the radical appearance of the implanted devices.

The answers to my questions regarding the surgery and post-surgical care of the animals indicated that the work and aftercare were performed in a professional and medically sound manner.

Upon examination of the animals there was no evidence of discomfort, inflammation, infection or any post-surgical problems. The animals were not concerned with the implants at all judging by their behavior. They

They were alert, bright, healthy in appearance and interested in the activity of the visitors.

The committee was able to observe many animals that had undergone laboratory or surgical procedures. We observed animals that had been housed for long periods of time - one year or longer.

There was no evidence or suggestion through observation that the animals were in stress or discomfort based on their condition and behavior.

The committee was exposed to other laboratory procedures through two other means; (1) discussions and interviews with the Animal Care Committees at research areas in the City and with individual investigators plus (2) tours of the laboratory facilities at research areas in the City.

Meetings of the Blue Ribbon Committee with the Animal Care Committees were at a regularly scheduled meetings of all the large research institutions and most of the smaller ones. In some cases we met with representatives of the Animal Care Committee.

The Blue Ribbon Committee was able to question at will any member of the Animal Care Committees which included investigators, non-research personnel and community representatives. The individuals interviewed and questioned were cooperative on the whole, answered questions directly and were quite free with the information we requested. We did encounter some situations where the atmosphere and attitudes were defensive, especially early but improved as the meeting progressed.

At each large institution we questioned the veterinarian in charge regarding animal health procedures, safeguards, off-hours care and training of personnel. In some instances at small research facilities the

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veterinarian was not present.

The Blue Ribbon Committee made special arrangements to interview several investigators at one institution (No. 5) who used primates for their work.

The investigators explained their laboratory procedures to us as well as the manner in which the animals were adapted to being restrained and to the laboratory procedures. We asked questions regarding these same matters as well as veterinary care.

The information obtained from these interviews did not suggest that there was any cruelty or abuse associated with these research projects due to poor adaptation techniques, negligence, lack of sensitivity or inadequate routine and medical care.

Laboratories throughout the City were visited, investigators were interviewed, animal care personnel were interviewed and veterinarians were interviewed. Considering all of the information gathered, as well as visual inspection of the laboratories seen, my feeling is that there were no research activities encountered that suggested any abusive or cruel treatment.

Euthanasia procedures were investigated at all of the laboratories. Euthanasia was performed in accordance with the standards put forth by the American Veterinary Medical Association Panel on Euthanasia. However, I will comment on some procedures.

In two laboratories visited (No. 3 and No. 4) euthanasia by carbon dioxide inhalation, which is acceptable, was performed using plastic bags as an euthanatizing chamber rather than a specifically designed rigid

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chamber. This may or may not fall within the realm of A.V.M.A. standards (the Chairman of the A.V.M.A. Panel did not respond to my inquiry for clarification of this) but it is certainly unorthodox and in my opinion should be changed.

Cervical dislocation is another A.V.M.A. Panel form of euthanasia restricted to poultry, mice, immature rats and rabbits. In my opinion this method, if not handled perfectly, could result in discomfort or pain unless anesthesia is used prior to the procedure. Some of the City laboratories use this technique - I personally do not like it.

Question #3

Do adequate standards of care of laboratory animals exist?

There are adequate Federal standards and regulations that are applicable to research animals.

There are adequate State and Department of Public Health standards and regulations that are applicable to research animals.

As with any regulation or standard, they must be constantly re-evaluated and changed, if necessary.

Federal and State enforcement and inspection procedures do not cover all kinds of animals in all research laboratories. This I feel is not a satisfactory situation.

The standards of care of laboratory animals are adequate if there is conscientious adherence to these standards. My proposal would be for a qualified City appointee to oversee the adherence to these standards through observations and evaluations of procedures in laboratories and in-

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spections of animal quarters. Also to meet with Animal Care Committees and to investigate and follow-up on potential problem areas. This would help assure continued compliance to existing standards is maintained and those areas that may be overlooked by existing enforcement and inspection procedures will be included.

Question #4

Are the mechanisms for oversight and regulation in these institutions sufficient to ensure that cruelty or abuse does not and will not occur?

The most important structured mechanism for oversight and regulation is the Animal Care Committee.

The institutions dealing with a large number of animals and/or varied species of animals and with multiple protocols are more organized and structured in order to adequately deal with internal inspections, monitoring of research protocols, animal housing and animal care.

The Animal Care Committees dealing with relatively small numbers of animals and much less varied species of animals (mainly rats and mice) were, in some instances, more loosely organized and structured more casually. The simplicity of these operations do not mandate a complex Animal Care Committee, in my opinion, and according to my observations, animal care, monitoring and oversight does not appear to suffer.

There is one Animal Care Committee that did not have autonomy in rendering decisions in terms of immediately halting a research protocol or performing euthanasia. In my opinion this is not a satisfactory situation.

The internal monitoring, oversight and regulation within the research

don

institutions is sufficient to ensure that cruelty and abuse do not occur.

Whether cruel and abusive treatment of animals will occur depends on the integrity, sensitivity and the attitudes of the people on the Animal Care Committees, persons in charge and the people working with animals. These are the people that must recognize and control situations that are distressful to the animals used in research.

Here again I can visualize the usefulness of a City of Cambridge appointee to oversee the internal monitoring mechanisms of the research areas and to be able to hold a helpful and constructive dialogue with responsible people associated with the research facilities.

Conclusion

Based on my total experiences of the past year it is my opinion that the incidents of animal abuse and cruelty that have been documented anywhere in the past are not at all representative of the laboratories that use animals for research purposes in the City of Cambridge, Massachusetts.

Stuart C. Miles, V.M.D.

REPORT ON THE FOUR QUESTIONS PUT BEFORE THE BLUE RIBBON
COMMITTEE ON ANIMAL CARE AND USE IN THE CITY OF CAMBRIDGE

ADDENDUM

This report does not address the incident resulting in the deaths of some primates at the Massachusetts Institute of Technology in 1988.

The primates involved in the incident were not observed by the Blue Ribbon Committee at M.I.T. at the times of our inspections and investigations.

Handwritten initials

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Comm. from Joseph E. Connarton, City Clerk,
transmitting the Report of the Mayor's Blue
Ribbon Committee on the Care and Use of
Laboratory Animals in Cambridge, dated Feb-
ruary 24, 1989.

In City Council,

February 27, 1989

2-27-89

Hearing held.

See Order Adopted