



CITY OF CAMBRIDGE
DEPARTMENT OF HEALTH AND HOSPITALS
1493 CAMBRIDGE STREET
CAMBRIDGE, MASSACHUSETTS 02139
498-1349

MELVIN H. CHALFEN, M.D.
COMMISSIONER

April 9, 1987

Mr. Robert Healy
City Manager,
City of Cambridge
Cambridge, MA., 02139

PROPOSED ANIMAL RESEARCH ORDINANCE
COUNCIL ORDER #3
COUNCILOR WOLF

Dear Mr. Healy:

The proposed ordinance addresses the proper use and care of laboratory animals in Cambridge research institutions. There is no doubt that all agree that laboratory animals should be well cared for and that there be no unnecessary pain to the animals. There is also wide spread recognition and agreement that the goal of research with animals to reduce human suffering and disease has been and will continue to be of enormous value and importance to all of us.

Three avenues of inquiry were used to examine the issue. First, personal inspections of the institutions in Cambridge where animal research is carried out. Second, the review of records of inspections and opinions of persons associated with the inspections. Third, the review of the many existing laws and regulations.

Personal visits by myself and/or Mr. Doherty, Cambridge Public Health Coordinator, were made to all of the facilities involved. The 13 facilities are listed in Table I. Three findings stand out. The first is that 10 of the 13 facilities use only mice, rats, rabbits and frogs, and primarily for antibody production, generally monoclonal antibodies for use in diagnostic tests and research. For good results in this work, the animals have to be healthy, so they are given very good care. A sick animal represents loss of time, results, and costs.

The second outstanding finding was that four of the larger facilities are regulated by three sets of regulations. The first set of regulations are Federal, through the Animal Welfare Act. Inspections for compliance with that Act are carried out by members of the Veterinary Services of the United States Department of Agriculture. The local office is in Waltham, Massachusetts. The second set of regulations are State through the Research Animal Regulations administered by the Mass. Dept. of Public Health. Inspections are carried out by members of humane institutions acting as agents for the Massachusetts Commissioner of Public Health. The humane institutions are the Massachusetts Society for the Prevention of Cruelty to Animals and the Animal Rescue League.

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The third set are the Guide and Policy for the Use and Care of Laboratory Animals of the National Institutes of Health (NIHG). The NIHG structure includes Animal Care Committees in institutions where NIH funding is awarded. Lack of compliance with the NIHG can mean stopping the study involved as funding can be withdrawn.

All of these institutions have Animal Care Committees with community representatives. They are all subject to unannounced visits by the inspectors involved.

Of the other nine, the smaller institutions who use mainly mice, rats, rabbits and frogs, four are licensed and inspected by the USDA. The other five, who use only mice and rats are exempt from the USDA and MDPH regulations, but have either followed or are now following the NIH Guidelines with Animal Care Committee and community representatives. The NIHG are followed either because the institutions receive NIH funds or on a voluntary basis.

The third finding was that we saw no evidence of unnecessary cruelty to the animals. In addition, although I'm told there have been in the past, at the time of the inspection, there were no tests involving cosmetics and eyes of rabbits (the so-called Draize tests), nor was there any lethal dose 50 testing of chemicals in mice and rats at the time of the inspections. It is of note, that although the LD 50 tests may be criticized, they are still used by the EPA in assessing chemicals for inclusion on their list of acutely toxic chemicals in The Chemical Emergency Preparedness Program for the prevention of injury to the public health in chemical emergencies. This list will also be made part of The Massachusetts DPH Massachusetts Substance List of The Mass. Right to Know Law. (25 Feb. 1987 Public Hearing Notice from Mass. Comm. of Public Health, Bailus Walker).

In addition, I have not heard of any specific examples in Cambridge of unnecessary cruelty. Both in telephone and personal interviews with those concerned, the concerns were either general concerns about Cambridge, such as the history of Draize tests and LD 50 tests of which I found no evidence on site visits in November '86, anecdotal concerns about research in Boston or historical concerns of two or more years ago in the other parts of the country. I have not received any specific examples from anyone else. I have read various allegations in newspapers, but have not been given any evidence of such.

In summary, all 13 facilities follow specific and humane practices in their work with animals, have Animal Care Committees, and have (or will have) unaffiliated community representatives on the Animal Care Committees.

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The review of the State and Federal records of inspections revealed generally satisfactory results, a conclusion confirmed in discussion with representatives of the Massachusetts DPH, Nancy Ridley and Dr. Sharifzadeh, of the Animal Rescue League of Boston, Carol McCarthy, of The MSPCA, Capt. Robert Susala, and of the United States Department of Agriculture, Veterinary Services, Dr. W.H. Olsen. The one recommendation made by one of them was that institutions exempt from regulations or inspections be inspected periodically.

The existing laws and regulations were also reviewed. They include The Animal Welfare Act, CFR, Title 9, Chapter 1, Subchapter A, first passed in 1966, revised in 1970 and 1976 (78 pages in the 1985 printing). The Massachusetts law is The Dept. of Public Health 105 CMR 910:000, licensure of research institutions using dogs or cats in research and education, adopted under MGL c. 140, s 174D. published December 31, 1984. The Massachusetts law was reviewed before redoing in an advisory committee convened by the State with representatives of the animal research community and the animal rights community on the committee. The law allows the designation of The MSPCA and The ARL as agents of The Massachusetts Commissioner of Health for making inspections of facilities covered by the law.

The NIH Guidelines are specific and encompassing. They have been revised through the years with the most recent revision of policy appearing November 14, 1986. Penalties for noncompliance with the NIHG for institutions receiving NIH funding include loss of funding. The new Guidelines are detailed and rigorous.

The new policy includes legislatively mandated portions passed under The Health Research Extension Act (PL 99-158) and provides a statutory basis for Public Health Service Policy.

These laws and regulations are not only in place, but have been reviewed and revised at intervals as noted above. The Massachusetts law was revised three years ago and NIH Guidelines as recently as November 1986. The NIH Guidelines provide a continuous source of review by The Institutional Animal Care Committees. Balanced viewpoints on The Committee are provided by the mandated membership of not only an institution non-affiliated community representative, but also a member "whose primary concerns are in a non-scientific area" (for example, ethicist, lawyer, member of the clergy). Record keeping and report making requirements are integral parts of the Policy (Guidelines).

The specific reasons that the provisions of the proposed ordinance would inhibit necessary medical research are:

- 1.) The additional review of each protocol and time it would take (estimated at 100,000 pages of protocols per year).

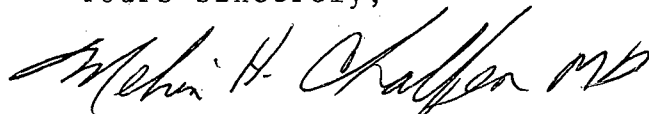
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- 2.) The inclusion on the institutional Animal Care Committee of a representative of animal rights organizations, some of whose basic philosophy is to have no animal research at all would, I believe, lead to counter-productive, time consuming, and adversarial committee meetings not focusing on either the objectives of animal research (such as increased knowledge of basic science in relieving human suffering and disease) or on what is after all, appropriate and proper concerns of the humane care of the animals.
- 3.) The additional time in duplicating reviews already mandated. The pressing need of animal research in areas of human suffering such as Alzheimers disease and in the search for vaccines or other measures to combat and slow the frequency and incidence of AIDS are all too clear examples in areas where there are already claims that progress is too slow.

Lastly, the duplication of regulation will be a cost to the city in tax dollar terms. It would be naive to think that any new city program does not include new costs. These costs would include that of staff in personnel time and salary, that of correspondence and clerical time involved, space for meetings, filings, and unanticipated costs, (which occur in spite of the best planning).

In summary, for the reasons stated above I find no evidence of unnecessary cruelty to animals in recent tests in Cambridge. I also find that the proposed ordinance (s) has a high probability of inhibiting and delaying necessary animal research. In my opinion, the recent revisions of Federal and State laws and regulations mentioned above demonstrate that careful thought and attention has been given to the issue of humane care and use of animals in research, and that the representatives of animal research in Cambridge are well aware of and are in compliance with the spirit and letter of the laws. I see no danger to the public health from humane research using animals and in fact, immense benefit to the public health from such research.

Yours sincerely,



Melvin H. Chalfen, M.D.
Commissioner

TABLE I

CAMBRIDGE FACILITIES WHICH USE ANIMALS FOR RESEARCH

	<u>Site Visit</u>	<u>Types of Animals</u>	<u>Numbers</u>	<u>Regulations</u>		
				<u>State.</u>	<u>Federal.</u>	<u>NIH.</u>
1) Advanced Magnetics	11/12/86	Rats	Small			x
2) ADL	11/13/86	Varied	Large	x	x	x
3) Angenics	1981 1985	Mice Rats	Moderate			x
4) Applied Bio-technology	11/6/86	Mice Rabbits	Small		x	x
5) Biogen	11/17/86	Mice Rats	Moderate			x
6) Cambridge Research Lab	11/7/86	Mice	Moderate		x	x
7) Dade Clinical Assays	11/20/86	Mice Rats	Moderate			x +
8) Genetics Institute	11/12/86	Mice, Frogs Rabbits, Rats	700 mice Large		x	x
9) Harvard	10/27/86	Varied	Large	x	x	x
10) M.I.T.	11/5/86	Varied	Large	x	x	x
11) Repligen	11/6/86	Rabbits	Small		x	
12) T-Cell Sciences	11/13/86	Mice	Small			x
13) Whitehead Institute	11/20/86	Mice, Rabbits, Rats	Large	x	x	x

TABLE II

CAMBRIDGE FACILITIES FORMERLY USING ANIMALS FOR
RESEARCH USDA LISTED OR OTHER

Bioresearch Institute, Inc.	USDA	None 2 years
BTC Diagnostics, now BTD Diagnostics was Hygeia Sciences	USDA	Moved to another city
Cambridge Diagnostics, no animals in Cambridge	USDA	Contracted with facility outside of Cambridge
Genzyme, no animals	Will start in Jan. '87, with USDA	
Sisa Toxicological Labs, Pars) Toxical Sisa	USDA	No longer in business in Cambridge
Molecular Research Lab., no animals		Contract outside of Cambridge

0-59B

Re: enclosed substitute version, Animal experimentation Ordinance.

12/28/87 Placed on file
without prejudice on
Order # 2 of 12/28/87

In City Council,

April 13, 1987

3/28/88 - Pursuant to Order #32 of this date submitted by Mayor Veltrecci this item was pulled from the files of the City Clerk & placed on the table commencing April 4, 1988. The wording of the Mayor's Order (which is attached) was used to describe this + a second Animal Ordinance which was also pulled from the files via the Mayor's Order. Both proposed Ordinance amendments remained on the Calendar through January 30, 1989 at which time they were placed on file pursuant to Calendar Item #22 of 1/30/89 placing on file all unacted upon Calendar Items, without prejudice, subject to resubmittal.