STATEMENT TO THE HOUSE JUDICIARY COMMITTEE ON HOUSE BILL NO. 873
by Frederick G. Ferguson
May 25, 1989

Mr. Chairman, Members of the Committee, my name is Frederick Ferguson. I am a Professor of Veterinary Science and Director of Laboratory Animal Resources at the University Park Campus of The Pennsylvania State University. My statement this morning is the result of my concern about the potential impact of House Bill No. 873 on the research environment in the Commonwealth of Pennsylvania and my concern about the poor cost/benefit ratio of this legislation in light of other existing and pending regulations and laws.

The use of animals in the advancement of scientific knowledge has provided many important contributions of which we are all the beneficiaries. A prime example of this is the fact that the majority of the significant research advances made by the Nobel Laureates in medicine and physiology in the last 88 years have depended to some degree on the use of animals. I suspect that each of us can easily identify some of these contributions, such as the development of polio vaccine or definition of the genetic complex associated with tissue transplantation, that have positively impacted on our lives.

The use of vertebrate animals in research is a complex societal issue which through the years has required public assurance that animals used for these purposes are provided proper care and handling. Since the early 1960's in the United States, the need for this assurance has resulted in considerable legislative and regulatory activity which has impacted on the use of animals. An eminent danger of this activity is that future research, which would improve the health and well-being of both animals and man, may be seriously impeded by excessive regulation.

House Bill 873, amending Title 18 (Crimes and Offenses) of the Pennsylvania Consolidated Statutes regulating animal research; and providing penalties, has the potential to have a significant negative impact on research throughout the Commonwealth of Pennsylvania.

● <u>CONCERNS</u>

(1) This Bill duplicates existing comprehensive Federal statutes, regulations, and guidelines pertaining to the care and use of animals for research purposes. As a result, it would require unnecessary expenditures of both money and labor by research organizations within the Commonwealth and the Pennsylvania Department of Agriculture. The economic impact would be considerable and should be carefully evaluated before passage.

(2) If the purpose of this Bill is to license those organizations not covered by existing Federal laws and regulations, this should be clearly stated. Persons or organizations covered by related Federal laws and regulations should be excluded from the provisions of House Bill No. 873.

(3) As proposed, the Bill presents no support for improvement of the Commonwealth research environment. In contrast, a Bill which would support funding to upgrade existing animal research programs would be well received. Funds could be effectively and constructively used for improving existing programs and facilities, for primary animal housing,

and for training of personnel involved with animal care and use throughout the Commonwealth.

I shall address the issues related to the duplication and licensure concerns.

● DUPLICATION

Similar to House Bill No. 873, already existing laws and pending regulations cover:

Licensure or Registration
Humane Handling, Treatment and Care
Inspection - Announced and Unannounced
Training of Researchers, Technicians and Attendants
Institutional Animal Care and Use Committees

Specific existing or pending laws and regulations are described in the following.

Animal Welfare Act

The Laboratory Animal Welfare Act of 1966 (P.L. 89-544) and the following amendments already are in effect.

Animal Welfare Act of 1970 (P.L. 91-579)
Animal Welfare Act of 1976 (P.L. 94-279)
Animal Welfare Act of 1985 (P.L. 99-198)

In 1966 the Federal government became involved with animal use in research with passage of the Laboratory Animal Welfare Act. Any institution that used dogs and cats in research had to be registered with the United States Department of Agriculture (USDA), which had the responsibility for administering the law. In 1970 and 1976 the U.S. Congress amended and expanded the scope of the USDA's activities and the animals covered. Research institutions had to be registered with USDA if any warm-blooded animals were used in biomedical research. Other organizations such as zoos, roadside exhibitions, and circuses, also, had to be registered with USDA. In 1985 an additional series of amendments to the Food Security Act were adopted, which were directed at biomedical research. In 1987 the USDA published the proposed regulations for administration of the 1985 amendments and received approximately 7857 responses from the public which resulted in almost 100 pages of comments by USDA. In March of this year the USDA published in the Federal Register Parts I (Definitions) and II (Regulations) and proposed regulations for Part III (Standards). Parts I and Part II were published again in a proposed form with comments limited to their interrelationships with Part III. May 15 was the deadline for comments on Parts I and II. Parts I and II are expected to be finalized 90 days after March 15, 1989. Briefly, the regulations state that institutions using animals covered by the Animal Welfare Act must have an institutional animal care and use committee, consisting of three members. One member must be a veterinarian and a second member a non-institutional affiliated person who is able to represent the public and the community. The committee must review all protocols involving the use of animals and make semi-annual inspections

of all animal care and use locations. It must provide a report to the Chief Executive Officer responsible for animal care. Items of non-compliance must be reported to the USDA.

The Health Research Extension Act of 1985

In 1985, this act incorporated changes in the Public Health Service Act as published in the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals. These changes included: (1) Application of the Policy to intramural PHS research. (2) Appointment of an Institutional Animal Care and Use Committee (IACUC) by the Chief Executive Officer of the Institution. (3) The institution's Assurance to PHS must include an explanation of the training or instruction available to scientists, animal technicians, and other personnel involved with animal care, treatment or use. Training must include information on humane practices and methods that minimize the numbers of animals and animal distress. (4) The IACUC must evaluate the institutions programs and facilities for activities involving animals at least twice each year. (5) The IACUC is responsible for reporting requirements.

Protocols must be prepared for each research project using animals and submitted for review by the IACUC. The protocol and its review address for example:

Detailed Description of the Proposed Use of Animals
Identification of Species, Strain, Age, Sex, and
Numbers of Animals
Justification of the Use of Animals.
Veterinary Care
Housing Conditions
Training and Qualifications of Personnel
Description of Use of Analgesics, Anesthetics, Tranquilizers
or Restraint
Methods of Euthanasia

Guide For the Care and Use of Laboratory Animals
(NIH PUBLICATION NO. 85-23)

The Guide for the Care and Use of Laboratory Animals was first published in 1963 and subsequently has been revised in 1965, 1968, 1972, 1978, and 1985. The purpose of the Guide is to provide a basis for institutions and organizations to assure provision of quality research animal care and use programs. In the Guide, which is 83 pages long, there are provisions which address specific details which relate to the many aspects of the humane care and use of animals in research including institutional policies, laboratory animal husbandry, veterinary care, physical plant, and special considerations.

Other Legal and Regulatory Provisions

In addition to these laws and regulations, there are other laws which do not address animal welfare directly, but are related to protection of animals

used in research or to assurance of the quality of testing procedures. They include:

The Endangered Species Act
Marine Mammal Protection Act
Good Laboratory Practice Regulations

The Food and Drug Agency (FDA), PHS, USDA, and other Federal agencies are working together to enforce these laws and regulations. These interagency activities cover the majority of the animals used for research purposes in the Commonwealth.

Enforcement and Implementation

Animal and Plant Health Inspection Service
Public Health Service
Other Federal Agencies
American Association for Accreditation of
Laboratory Animal Care
Pennsylvania Department of Agriculture

Unannounced inspections by the Animal and Plant Health Inspection Service (APHIS) of the USDA occur at least annually under the provisions of the Animal Welfare Act. Each research facility must show upon inspection and report at least annually that it is in compliance with the Animal Welfare Act and that professionally acceptable standards governing the care, treatment and use of animals are being followed. It also requires these facilities to provide information, explanation, and assurance concerning painful procedures. With the provisions of the Policy on Humane Care and Use of Laboratory Animals, PHS has initiated a program of unannounced inspections of research animal care and use programs. Granting agency review teams frequently examine animal care and use programs at the time of institutional site visits. Under the Good Laboratory Practice regulations, the FDA and other Federal agencies carry out inspections and evaluations. In addition, many institutions and organizations are participants in an independent accreditation process through the auspices of the American Association for the Accreditation of Laboratory Animal Care (AAALAC). AAALAC uses the PHS Guide and the Animal Welfare Act as primary reference documents for its on-site peer evaluation process. Finally, within Pennsylvania under Act 225, the Dog Law, research facilities using dogs are inspected by a representative of the Pennsylvania Department of Agriculture, Bureau of Dog Law Enforcement.

● LICENSURE

There is one other part of this Bill that I would like to comment on, that is the licensure provision. Section 2(a) relates to who is to be licensed by the Pennsylvania Secretary of Agriculture and who is to be licensed under the Federal Laboratory Animal Welfare Act (P.L. 89-544). Are persons, partnerships, associations or corporations or schools licensed under the Federal Act excluded from state licensure? Are the same, thereby, excluded from the provisions of House Bill No. 873? This is not clear and the Bill's ambiguity could affect resultant regulations and subsequent enforcement.

SUMMARY

It has been over 35 years since the work with monkey and human kidneys enabled the growth of polio virus in cell culture which subsequently resulted in development of a polio vaccine. Today we are confronted by important diseases, such as AIDS and Lyme Disease. We and those to follow us, including the animal populations, will undoubtedly be dependent on the special benefits provided by the use of animal and human surrogates to improve the quality of life. We are obligated to protect the privilege of using animals in research; however, we must carefully protect resultant benefits by not over-regulating research in the Commonwealth of Pennsylvania.

The significant question (when one carefully considers other existing laws and regulations that are in place or pending) is should the research organizations and the Department of Agriculture in the Commonwealth of Pennsylvania be subjected to additional, unnecessary expenditure of money and labor for duplicative efforts.