

# Statement

Pharmaceutical  
Manufacturers  
Association

STATEMENT BY THE  
PHARMACEUTICAL MANUFACTURERS ASSOCIATION

CONCERNING PENNSYLVANIA

HOUSE BILL 873

HOUSE COMMITTEE ON JUDICIARY

MAY 25, 1989

The Pharmaceutical Manufacturers Association (PMA) is a non-profit trade association representing some 100 companies that research and develop nearly all new drugs manufactured in this country. Six of these member companies are headquartered in Pennsylvania and several others have major facilities located in the Commonwealth. In total, PMA member companies employ over 30,000 Pennsylvania citizens.

We appreciate the opportunity to offer our comments and concerns about House Bill 873 which would further regulate facilities that use animals in preclinical trials for biomedical research. PMA opposes House Bill 873 because it would impose unnecessary state regulation on a system that is already uniformly regulated at the Federal level.

Animal research has played a key role in virtually every advance in medical science -- the development of important drugs such as antibiotics, vaccines, insulin and chemotherapy, and the development of life-saving procedures such as open heart surgery and organ transplants.

The use of animals will continue to make important contributions to medical research. Pharmaceutical manufacturers are required by the Food and Drug Administration (FDA) to conduct thorough studies with animals before testing them in humans. These studies are subject to a number of state and federal laws and regulations designed to ensure that laboratory animals are treated humanely. Foremost among them is the federal Animal Welfare Act of 1966, as amended in 1970, 1976, and 1985, which regulates the treatment, handling, housing, care and transportation of animals used for research purposes.

The U.S. government, through the Animal Welfare Act and its amendments, requires that the Department of Agriculture set minimum standards for the care of animals by dealers, exhibitors and researchers. Existing provisions require that:

- o Laboratory workers be properly trained and educated about animals and their habits and feeding and care requirements.
- o Dogs be exercised regularly.
- o Laboratories monitor the psychological health of monkeys and other non-human primates.
- o All research facilities have an institutional animal care and use committee.
- o The committees have a scientist, a veterinarian and at least one member who is not affiliated with the facility.
- o The institutional committees conduct periodic lab inspections, review the portions of research protocols that cover animals and write semi-annual reports.

In addition, the National Institutes of Health has policies, principles, and guidelines for its research grantees on the proper care and use of laboratory animals. The FDA, since 1979, has had regulations for good laboratory practices that require researchers and their companies to have proper facilities for the housing and care of animals.

Moreover, the treatment of animals is carefully monitored not only by the government, but also by private organizations. Several private and professional organizations establish standards and issue guidelines, educate and train lab workers, sponsor seminars and certify programs for humane animal treatment.

One of the best known organizations is the American Association for the Accreditation of Laboratory Animal Care (AAALAC). Affiliated institutions include most medical, veterinary and pharmacy schools, government and industry laboratories and hospitals. Almost all of the PMA member firm animal facilities are AAALAC accredited and conform to NIH guidelines.

In conclusion, the regulations governing the use of animals in preclinical trials for biomedical research are uniformly established and applied at the Federal level. PMA member companies comply with these federal requirements as well as those established by the National Institutes of Health and the AAALAC. House Bill 873 is therefore duplicative and unnecessary. We respectfully urge the Committee to reject this bill.