DORIS DAY ANIMAL LEAGUE

Testimony in Support of H.B. 873

Before the Pennsylvania House Judiciary Committee

Holly E. Hazard
May 25, 1989

Suite 200 • 111 Massachusetts Avenue, N.W., Washington, D.C. 20001 • 202/842/3325

Holly Hazard

Mr. Chairman and members of this Committee, thank you for this opportunity to present the views of the Doris Day Animal League in support of H.B. 873. The Doris Day Animal League is an animal protection organization focusing on legislative issues with over 300,000 members nationwide and 28,863 members and supporters in the State of Pennsylvania.

This Bill touches on several areas of concern to those of us interested in increasing the protections afforded animals. Because of the limited time available I will concentrate on areas in which I have some expertise and leave other issues, although of equal importance, to those on the panel who may be in a better position to evaluate them.

I. Search Warrants.

The search warrant issue strikes at the very core of the enforcement capability of the anti-cruelty statute. Despite contentions that this will slow down or obstruct research in some way, it is important to note that the search warrant provision in the statute is no different than the search warrants currently available to law enforcement officials in virtually every other area of criminal enforcement within the State of Pennsylvania and virtually every other state in the Union.

The search warrant provision will not grant a special right to those charged with enforcement of the anti-cruelty code, but will simply present them with the same tools afforded law

enforcement officers in other areas to effectively bring those choosing to violate the statutes to courts of law. Search warrants may only be issued under the same restrictions and guidelines that are set out under current law. Without probable cause no search warrant would be issued. If probable cause exists that cruelty is taking place within a research facility in the State of Pennsylvania, then law enforcement officials should be given the tools necessary to correct this wrong.

The disruption to a research facility will be no greater than the disruption to any other form of enterprise for which probable cause to suspect criminal evidence exists. The mere accusation of criminal activity by law enforcement personnel is not enough to obtain a warrant. A search warrant can only be issued if an impartial and unbiased judicial officer concurs with law enforcement personnel that probable cause exists that criminal activity is taking place. The purpose of this check is to protect citizens from overzealous law enforcement officials. Animal research officials should have no greater constitutional rights than others. If they violate the criminal code, our government needs to have the enforcement tools necessary to prosecute them. If only legitimate research is taking place in a facility within the confines of the law as set forth by the State and Federal government, then no disruption will take place. If that is not the case, then research facilities have no cause to complain that their activities are being disrupted.

In the only criminal prosecution of a research laboratory to

date in the United States, the case of State of Maryland v. Institute for Behavioral Research, the use of search warrants was an integral part of the prosecution. In that case, the seizure of documents, biological samples, pharmaceuticals and seventeen macaques presented the prosecutor with the evidence necessary to convict Dr. Taub of cruelty to animals under the state anti-cruelty statute. This research, never questioned by the U.S. Department of Agriculture or the National Institutes of Health previous to the prosecution of Dr. Taub, was later found to be flawed and funding for the experiments was stopped. It is ludicrous for the research community to condemn attempts at obtaining search warrants for research which is of no value to humans and is cruel to the animals on the grounds that this kind of research may be disrupted.

The research community claims that appropriate monitoring of research is currently being conducted by the federal government and specifically by the National Institutes of Health and the Department of Agriculture. History, however, shows us that these programs have been largely ineffective in stemming even the most flagrant animal abuses in research and testing facilities. In one of the most notorious cases in the history of the animal rights movement, the University of Pennsylvania was allowed to operate for over a decade with the tacit approval of the National Institutes of Health and the U.S. Department of Agriculture's Animal Welfare Inspection Program. It was only through the illegal acquisition of tapes filmed by research scientists at this facility that that facility was seriously investigated and eventually closed by the

Secretary of Health and Human Services. This research, clearly deserving of significant disruption, would have continued unabated had animal rights activists not called the status quo into question. Had animal activists had the ability to obtain a search warrant, then significantly less disruption would have occurred at the laboratory.

In the most recent case brought to light in Pennsylvania, a firm known as Biosearch, Inc., which tests commercial, household, and other products for a number of nationally known product manufacturers, was inspected for compliance with FDA's good laboratory practice on no fewer than six occasions spanning the years 1979 through 1986. If the allegations brought forward with reference to this case are born out, then significant violations of federal and state law have occurred. Yet, no provision exists under the Pennsylvania anti-cruelty statute to allow law enforcement officials within the State the opportunity to obtain the evidence necessary to adequately enforce the State anti-cruelty statute.

Without the mechanisms necessary for adequate and appropriate prosecution of individuals choosing to violate the State anti-cruelty statutes, the law itself is a sham. Prosecutors are no less in need of material evidence when prosecuting anti-cruelty cases than they are in the area of drugs, theft or any other criminal provision of the Pennsylvania criminal code. I urge this Committee to support this responsible and needed section of House Bill 1554.

II. Institutional Care Committees.

The federal Animal Welfare Act requires that each institutional care committee have one member who is a doctor of veterinary medicine and at least one member not affiliated in any way with the facility and who can provide representation for general community interests in the proper care and treatment of animals. The federal legislation states that the committee shall be comprised of at least three members. The Pennsylvania Bill would require that each committee have a member who is a representative of the animal care staff of the facility, a member who is a state enforcement agent, and a member who is a representative of an incorporated humane or animal welfare organization. These two sections are complimentary. The federal Act authorizes the Secretary to cooperate with the officials of Pennsylvania or other states in carrying out the purpose of the federal legislation and of any state legislation on the same subject. Because the requirements of these committees are not in conflict and the federal Animal Welfare Act encourages state action in this area, the state law would not be preempted and would ensure strict compliance with the intent of the federal legislature.

This section of the Pennsylvania Bill will close a loophole in the federal legislation that has been abused in several instances by research facilities throughout the United States. Numerous examples have come to light that evidence a need to define at least one outside member of the animal care committee as being from a humane organization. University after university has abused

the discretion allotted by Congress in the 1985 amendments to the federal Animal Welfare Act by allowing individuals closely associated with university research or other research facilities to serve as the outside member. If these committees are to work effectively, then it is imperative that individuals from all perspectives on the use of animals come together to discuss the research on animals taking place at each facility. The Pennsylvania law goes a long way toward ensuring that the clear intent of Congress to bring an outside member to these committees is indeed carried out by the research facilities themselves.

III. Prohibited Tests: LD-50 toxicity and Draize eye irritancy test.

The most important fact that can be taken from this hearing is that these tests, relied on for the past sixty years by industry for the purposes of premarket evaluation of their products, are flawed on scientific grounds. As any reputable scientist will concur, the results of these tests are subjective and have been found to vary significantly from laboratory to laboratory. The tests correlate poorly with data on irritancy for humans exposed to many of these products. For example, the rabbit's eye differs significantly from the human eye both in its structure and in its tearing mechanism. Rats do not react to toxins in the same manner as humans. These differences should lead to significant questions regarding the justification for continued use of this test regardless of the humane concerns brought forth by the animal protection community.

You will hear three arguments in support of the continued use

of the Draize Eye Irritancy and other animal tests. Industry will claim the tests are required by law, they are required for safety and they are necessary until other tests can be validated. None of these arguments can be justified when weighed against the facts.

1. Regulatory Requirements. The first line of defense for the manufacturers of cosmetic and household products when questioned as to their continued use of these outmoded tests is that the federal government requires that these tests be performed in order to comply with federal regulatory requirements. This is not true.

The federal government encourages animal testing, the federal government accepts the results of animal testing, but the federal government does not require these tests for the purposes of assessing premarketing safety of a product. At a hearing this month of a Task Force set up by Governor Schaefer in Maryland to review the issue, a spokesperson for the FDA reiterated its position as follows:

> As commonly noted by opponents of animal testing, current law administered by the Food & Drug Administration (FDA) does not require the use of animal tests for cosmetics.[1]

In a letter dated September 22, 1988 to the Honorable Barbara Boxer of the U.S. House of Representatives, the FDA stated as follows:

> The Federal Food, Drug and Cosmetic Act does not give FDA the authority to require cosmetics manufacturers and

---

[1] U.S. Food & Drug Administration statement to the Maryland Governor's Task Force to study animal testing - April 17, 1989.

> distributors to test their cosmetic products or ingredients for safety or make such data available to FDA if tests have been conducted.

With reference to the Consumer Product Safety Commission which has jurisdiction over some household washing, cleaning and laundry products, the Commission stated as early as 1984 in a Federal Register Notice that:

> It is important to keep in mind that neither the FHSA [Federal Hazardous Substances Act] nor the Commission's regulations require any firm to perform animal tests. The statute and its implementing regulations only require that a product be labeled to reflect the hazards associated with that product.

The FDA and the CPSC are the only agencies with jurisdiction over the product lines in question. They have stated clearly and concisely that they do not require these tests. As further evidence of lack of government jurisdiction in this area, Avon Products, Inc., the largest selling brand of beauty products in the world, announced on April 5th that it has validated a laboratory test for eye irritancy as a replacement for the Draize test and would cease reliance on the Draize test immediately. Avon has also announced that it intends to stop all animal testing by the end of May.

Given the statements made by the federal government as to its lack of jurisdiction to require testing and the recent conversion of Avon to more humane testing procedures, it is unconscionable that corporations would continue to fight progress in this area by opposing this legislation.

2. The Safety Argument. The second argument used by manufacturers interested in continuing to use animal testing methodology is that these tests are necessary for the purposes of protecting human health and safety prior to making decisions on the marketing of these products. This is a specious argument. All any of us need do is to look under the sinks in our kitchens or in our bathrooms to find products clearly dangerous if used inappropriately, but which have been marketed despite their toxic levels for animals or for that matter for our children.

Companies do not make decisions not to market cosmetics or household products based on their relative toxicity to animals. Rather, companies use animal test data as a crutch to justify the introduction of their products on the market regardless of the results of the animal test. As evidence of this marketing practice I would like to give you just a few examples.

The first is a case described in the December 1988 issue of the Journal of the American Medical Association. In this case a product called Super Nail Nailoff was marketed as a cosmetic for the purposes of removing sculptured nails. This product has caused the death of at least one 16 month old boy after accidental ingestion. A second child, a two year old boy, experienced signs of severe cyanide poisoning after he accidentally spilled the product on himself in bed. In the same article describing the injuries to these children, the authors described the medium lethal dose of the product for guinea pigs, the toxic level for both oral dose and for skin absorption in rats, and also information on

premarketing clinical tests on humans. Thousands of animals are dead, two kids are dead or injured, and this product is still on the market. The safety of consumers was not protected by those animal tests.

A second example is in the court case of Harris v Belton. The plaintiff sued a company over a cosmetic promised to bring a "lighter lovelier skin beauty for you...". Unfortunately, the product caused the plaintiff's skin to be burned, scarred and darkened.

When she brought suit against the manufacturer in California she learned that the law does not protect a consumer from unsafe products. Rather the law requires the manufacturer to warn if the product is unsafe. Because the product she used was labeled as potentially damaging, the Court ruled that the company was not responsible for damages to the plaintiff. The premarket animal tests did not keep this product off the market. In fact, even evidence of serious damage to a human did not cause the company to reevaluate its responsibility to consumers.

In another case on this issue a United States District Court for the Northern District of Ohio found that the government could not sustain its burden by reliance on Draize Eye Irritancy data in a case involving shampoo accidentally spilled in a consumer's eye. In that case the government relied on the corneal epithelial damage to the eye of rabbits as evidence that the shampoo in question was dangerous and should be banned as adulterated under the Food, Drug & Cosmetic Act. The Court found that the tests done by a

toxicologist on rabbits were unpersuasive in meeting the government's burden. The Judge described the lack of the rabbit's capacity to tear and the long anesthetic effect of the substance on rabbits that showed that the doctor's reports "can not be extrapolated to apply to humans...." The studies on rabbits did not protect the user of the shampoo and did not keep the product off the market.

3. Validation. The third argument used by the opponents of this Bill is the question of validation. Unlike other areas of controversy with regard to animal testing our opponents do not state that there is no alternative but that the alternatives that do exist to the Draize test have not been "validated."

At a meeting last year in Washington, D.C., industry toxicologists discussed the validation procedures currently being monitored of at least 14 non-animal alternatives to the Draize test. One irony of discussing validation at all is that the Draize test itself was never validated. However, valid alternatives to the Draize do exist. As mentioned before, Avon has recently announced its successful "validation" project with the Eytex System. The Eytex alternative to the Draize involves a chemical protein study that has been tested on products in every segment of american industry and the U.S. military.

In another recent announcement, Noxell Corporation unveiled its alternative to the Draize test. This alternative, the Agarose-Diffusion method, has been found to have a 100% correlation with the Draize. However, the Noxell Corporation has not taken the

final step in announcing a complete switch to this alternative but rather has preferred to describe its use as a "pre-screen" to the Draize test. The Agarose-Diffusion method unveiled by Noxell is cited in scientific literature as far back as 1965. Yet in 1989 Noxell continues on its "validation" track. If one looks at the alternatives available and the effort put forth by industry to combat the problem it is obvious that industry's efforts in this regard have been for the most part a superficial public relations ploy. The Cosmetics, Toiletries & Fragrances Association has stated that it is working on validation and has invested between $5-8 million on the validation of alternatives to the Draize test. But if we compare this amount of money to the amount of money corporations spent on advertising in this amount of time, we can see that it is a pittance.

For example, Proctor & Gamble spent about $1 billion in advertising this past year. Bristol Myers Corporation spent $990 million. When we compare that kind of money to $5 million spent on alternatives in the past five to eight years by the entire industry, it is easy to understand the frustration of those of us who are concerned with the thousands of animals dying annually in the name of consumer safety.

The validation argument is nothing more than an economic argument. When the economics of validation are transposed with the figures on the cost expended by industry in areas related to their marketing interests, one can clearly see that industry has been disingenuous in its repeated assertions that it is working towards

alternatives to animal testing.

As Avon has so clearly pointed out in the last month, "validation" of alternatives is possible, the safety of consumers is not a justification for continuing with animal tests, and the change from animal testing methodology to more humane testing techniques does not mean that products will cease to be approved for marketing by the federal government.

In conclusion, no federal regulations prohibit U.S. companies from switching to more technologically advanced methodologies. Animal tests are not used to protect consumer safety, but rather as a crutch for industry in case of consumer injury. Validation of alternatives is not only possible but has, in fact, occurred for Avon as well as hundreds of other product manufacturers that have chosen to become cruelty free.

The Draize eye rabbit test and the LD-50 test should be eliminated from all product protocols as inhumane and unecessary to assess product safety.

The Doris Day Animal League urges this Committee to vote House Bill 873 favorably out of this body. Thank You.