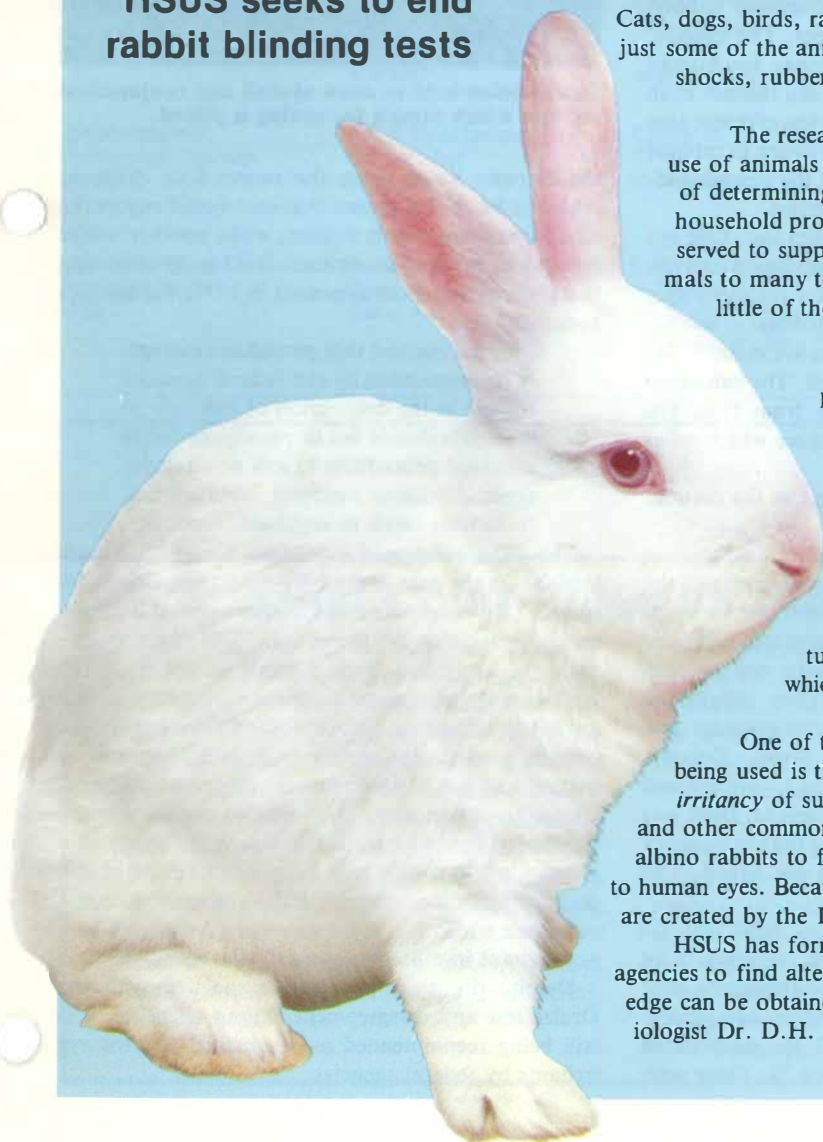

OF THE UNITED STATES

THE Humane Society

CLOSE-UP REPORT

ANIMALS ARE SUFFERING

**HSUS seeks to end
rabbit blinding tests**



Annually, 65 to 100 million animals are being used as test subjects in the laboratories of cosmetic companies, drug manufacturers, university and commercial research centers, and producers of household products. The Humane Society of the United States has taken the position that much of this testing is not only unreliable, but also results in unnecessary pain and death.

Cats, dogs, birds, rats, mice, monkeys, and rabbits are just some of the animals routinely subjected to electric shocks, rubber riot control bullets, huge doses of radiation, and chemical solutions.

The research industry has long held that the use of animals is the only "reliable" way we have of determining the safety of a cosmetic, drug, or household product. Over the years this belief has served to support scientists as they subjected animals to many tests. The American public has seen little of the massive animal suffering that has taken place in the research labs.

Today, a new debate is taking place. People from all walks of life are asking if all the suffering and death is worth it. Many research scientists have joined the ranks of those who are questioning the scientific and ethical foundation of using animals for research subjects. Scientists have developed new techniques utilizing tissue cultures, computer models, and bacteria which can be used to test the safety of substances.

One of the most outrageous tests currently being used is the Draize test to determine the *eye irritancy* of substances. Drops of soap, perfume, and other common products are put into the eyes of albino rabbits to find out if these things are harmful to human eyes. Because of the pain and suffering which are created by the Draize test which is unreliable, The

HSUS has formally asked government regulatory agencies to find alternatives to the test. "Some knowledge can be obtained at too high a price," says physiologist Dr. D.H. Smyth in his book, *Alternatives to Animal Experiments*.

What is the Draize Test?

More than 35 years ago, Dr. J.H. Draize and several of his colleagues at the Food and Drug Administration (FDA) developed a test to assess the eye irritancy of chemicals and mixtures of chemicals. This Draize test is now routinely used on albino rabbits to test cosmetics, toiletries, pesticides, drugs, and other chemicals before they are put on the market.

The Draize test involves, or can involve, a great deal of pain. It provides crude information on whether or not a substance will irritate human eyes. Because of the animal suffering involved and the poor quality of the information obtained, The Humane Society of the United States along with a coalition of more than 300 local animal welfare groups has asked FDA, other agencies, and the cosmetic industry to devote time and money to the development of an alternative to the Draize test which does not involve the use of animals.

Federal regulations specify that albino rabbits *must* be used in eye irritancy studies. The rabbits' eyes are by no means ideal substitutes for human eyes. The corneas of rabbits' eyes are thinner than human corneas and rabbits have far less efficient tear glands. Although the nictitating membrane in rabbits' eyes may compensate for the lack of the cleansing effect of tears, this is by no means certain.

Six to nine rabbits are used for each test. One eye of each rabbit is left untreated to serve as a control, while the test substance is forced into the other eye. The rabbits may or may not be restrained in stocks, as shown in the photo. Observations are made 1, 24, 48, 72, and 168 hours after treatment. The substance is then scored on a scale ranging from 0 to 110 developed by Draize and his colleagues which relies on the following features:

- (a) the development of opaqueness in the cornea,
- (b) inflammation in the iris,
- (c) inflammation of the conjunctivae.

The total score is meant to give some measure of the irritancy potential of the test substance.

Twenty-seven years after the Draize test had been developed, two American toxicologists conducted a major survey of its reliability. They distributed twelve compounds to twenty-four government and industrial laboratories, including Avon, Colgate-Palmolive, General Foods, American Cyanamid and the Food and Drug Directorate in Canada. Each was to follow a set procedure in assessing the eye irritancy of each compound. The Draize test was found to be unreliable.

Three of the substances were so mild that no laboratory reported them as irritants. However, there was wide variation on each of the remaining nine substances. For example, after 24 hours, one laboratory reported a median score of 7 for ethoxylated lauryl alcohol while another gave it a 79. These were



Rabbit being held to show eyeball and conjunctival sac into which sample for testing is placed.

the extreme scores from the twenty-four different laboratories; but it means that one would report the alcohol as being highly irritant, while another would report it as being a non-irritant. It is hardly surprising that, when the report appeared in 1971, the authors concluded that:

"Rabbit eye and skin procedures currently recommended by the federal agencies for use in the delineation of irritancy of materials should not be recommended as standard procedures in any new regulations. Without careful reeducation, these tests result in unreliable results."

The FDA conducted a follow-up study and concluded that the data in the 1971 report was essentially correct. However, the FDA authors placed a different interpretation on the results. They argued that the 1971 study had made the mistake of using the Draize test to attempt to discriminate between different grades of irritants. Instead, the Draize test should only be used to distinguish an irritant from a non-irritant and not to determine the *degree* of irritancy. Using this caveat, the FDA scientists argued that the Draize test could be used to evaluate the safety of a substance in a simple pass-fail manner. Even in this pass-fail situation, there is still no guarantee that a substance which is a non-irritant in a rabbit will be a non-irritant in a human eye and vice versa.

Despite the clear problems associated with the Draize test and disagreement among scientists, it is still being recommended as a standard test for eye irritants by federal agencies.

The HSUS has sent detailed arguments to the government agencies involved, outlining why the Draize test should be dropped and asking them to immediately fund research into alternatives. As part of the arguments, The HSUS pointed out that there are three interlocking elements which lead to the inevitable conclusion that the Draize test can no longer be justified as a routine test for eye irritancy.

(1) The test will cause suffering and, in some cases, a great deal of suffering to the rabbits being used. Many toxicological technicians have expressed strong feelings against the test, especially in those instances where the rabbits scream when the test substance is introduced into the eye.

(2) The information produced by the test is crude at best and totally unreliable at worst. Where routine testing is carried out, a test should be highly reproducible, especially when many different laboratories are involved.

(3) The prospects for developing an alternative to the Draize test are very good. However, time and money are required, and no government agency or commercial organization has yet devoted sufficient time, money, or energy to the task. The techniques

are available, but the will to select the best one and to validate it has, so far, been lacking.

What are the Alternatives?

In April, 1978, a contract research organization in England reported on the results of some preliminary work to develop a cell culture alternative to the Draize test. Three shampoos of known irritancy (low, moderate, and high) were tested. In all cases, the cell system distinguished between shampoos of high and low irritancy. The cell test did not reliably distinguish between the moderately irritant shampoo and the other two. The organization stressed that the results are preliminary and the discriminatory powers of the test need to be improved. They concluded there is "a basis for an in vitro system for the screening of severe irritants as an alternative to the Draize test." Partly as a result of this work and of consumer pressure, several cosmetic companies in England have collaborated to support further research by a single scientist on tissue culture tests for screening irritants.

The Results Aren't Pretty!



The above photographs show four grades of rabbit eye reaction to irritants. The first picture on the left shows a normal eye. The second picture shows an eye with maximum marks (3) for redness. The third picture demonstrates what is meant by the development of opacity. This eye achieves maximum marks (4) for

opacity. The final picture shows an eye which achieves maximum marks (4) for cbemosis (swelling of conjunctivae due to fluid collection in cells and between cells). As one might imagine, any substance which produces a reaction this severe is also likely to cause a lot of pain.

The Cosmetic Industry and the Draize Test

The cosmetic and toiletries industry is currently estimated at a \$10 billion per annum market. About 4,000 companies manufacture and sell cosmetics. However, only ten companies control approximately three-fifths of the total market with Avon, Bristol Myers, Revlon, and Proctor & Gamble leading the industry in 1977, followed by Colgate-Palmolive, Gillette, and Chesebrough-Ponds, according to a market survey by Frost & Sullivan.

Some companies do *no* animal testing and yet market safe products. The reasons for this lack of animal testing differ. For example, Yardley claims to do no animal testing, but this is because their product lines have been on the market for a long time and they have developed no new products which would

require additional testing. If they were to develop new products, they probably *would* test on animals. Some companies do no animal testing because of their ethical stand against the use of animals or animal products. However, companies which take an ethical stand against animal testing are tiny when compared to the industry giants and their products are difficult to obtain except in health food stores.

The cosmetic industry as a whole should be urged to make a positive commitment to deal with the problem of animal testing by developing and validating adequate alternatives. There have been a number of initiatives to pressure the industry into making a positive commitment to "alternatives" but, so far, without success. The most recent and probably most

detailed effort was launched by the Coalition to Stop Draize Rabbit Blinding Tests. After a number of efforts to interest Revlon to seek alternatives, HSUS's Dr. Rowan and Mr. Spira of the Coalition met with the Revlon Vice-President of Public Affairs. As a result of that meeting, the Coalition was invited to put forward a proposal for Revlon's consideration.

The proposal pointed out the scientific and ethical problems of the Draize test. It asked Revlon, as one of the leaders of the cosmetic industry, to approach the Cosmetic, Toiletry and Fragrance Association with a proposal that the CTFA should organize a collaborative effort by the industry to develop an alternative to the Draize test which does not involve the use of live animals. As part of the proposal, it was suggested that Revlon should allocate *one hundredth of one percent* of its gross annual sales to the project as an indication of good faith.

Revlon referred the proposal to the CTFA's Committee on Pharmacology and Toxicology for consideration by a subcommittee which had been established to review short-term testing procedures for the industry. Part of Revlon's response to the Coalition's proposal reads as follows: *"Neither Revlon, nor any other single company, can give any assurances as to what action, if any, this committee, or any other committee of the CTFA, may take on this matter, except to say that it will receive consideration."* Neither the Coalition nor HSUS consider this to be an adequate response. If Revlon had committed funds to the idea of developing an alternative prior to refer-

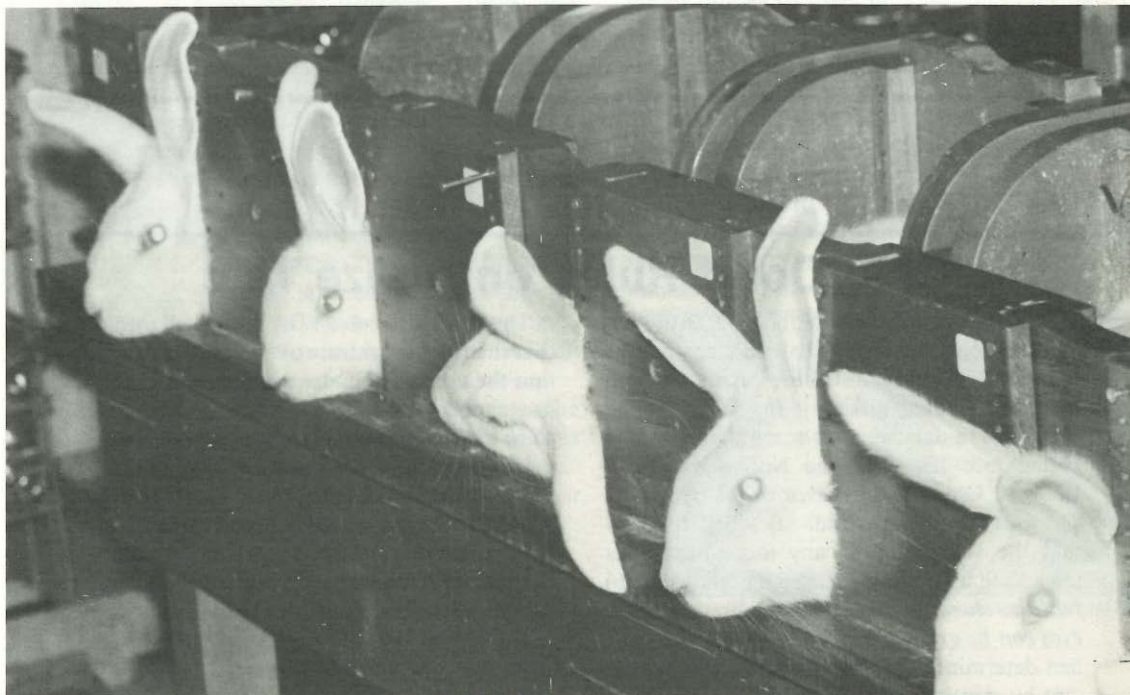
ring the proposal to the CTFA, it might have stood a better chance of acceptance. Without Revlon's support, the outcome looks bleak.

Humane Groups form Coalition to Abolish Draize Test

The creation of Henry Spira, a New York City teacher, the Coalition is sponsored by The HSUS and other national groups. Several HSUS staff members, including Dr. Andrew Rowan of the Institute for the Study of Animal Problems and HSUS President John A. Hoyt, are working closely with Mr. Spira, who is serving as coordinator. More than 300 local animal welfare groups have added their support to the Coalition in response to a national appeal.

A number of steps have already been taken by the Coalition. These initiatives include letters to federal agencies, an approach to the Cosmetic, Toiletry and Fragrance Association, and a specific proposal to Revlon to help with the development of an alternative to the Draize test.

Unless the company gives some early indication that it will actively support the development of an alternative to the Draize test, the Coalition is prepared to consider other measures, including the possibility of enlisting consumer buying power by requesting concerned humanitarians to stop buying Revlon products.



An old type of stock used for restraining rabbits for experimental purposes. One rabbit is struggling to free itself.

The Bureaucratic Maze and the Draize

There are several federal agencies which require eye irritancy testing—either explicitly or implicitly. These include the Consumer Product Safety Commission, the Food and Drug Administration, and the Environmental Protection Agency. The chart outlines their areas of responsibility and the enabling legislation leading to Draize eye testing.

Both EPA and CPSC have based their eye irritancy test requirements on the Draize method in which the albino rabbit *must* be used. With regard to cosmetics, the FDA has no authority to require test data prior to marketing of a new product, but each new product must either be “adequately substantiated for safety” or bear a warning statement that “the safety of this product has not been determined.”

Agency	Enabling Legislation	Address	Chemicals Covered
Consumer Product Safety Commission (CPSC)	Federal Hazardous Substances Act	Associate Executive Director Hazardous Substances Identification and Analysis (CPSC) Washington, D.C. 20207	Includes general household products and consumer items consisting of mixtures of chemicals
Environmental Protection Agency (EPA)	Federal Insecticide Fungicide and Rodenticide Act (FIFRA)	Office of Pesticide Programs EPA Washington, D.C. 20460	Pesticides
Environmental Protection Agency (EPA)	Toxic Substances Control Act (TOSCA)	Office of Toxic Substances EPA Washington, D.C. 20460	Chemicals not covered by other three acts
Food and Drug Administration (FDA)	Federal Food, Drug and Cosmetic Act	Division of Cosmetics Technology FDA, 200 C Street, S.W. Washington, D.C. 20024	Includes cosmetics, ophthalmic products and other therapeutic agents.

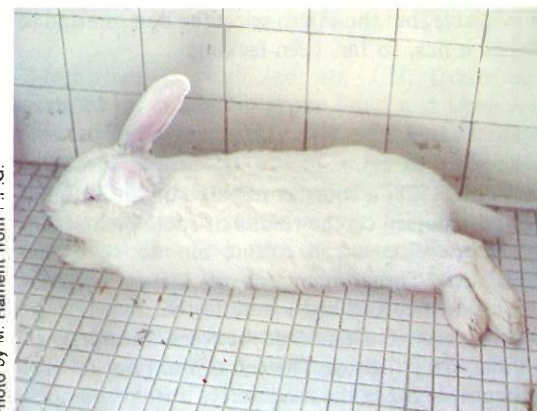
Ohio Court Rules on Draize Test

In January, 1974, the Food and Drug Administration (FDA) went to court against the producers of Beacon Castile Shampoo with Lanolin. A young girl using the shampoo had suffered eye damage after some shampoo had gotten into her eye. The Northern District Court of Ohio ruled in favor of the company. The court said FDA had: (a) failed to show that the shampoo was any more hazardous than similar products on the market, and (b) failed to show that the results of tests on rabbit eyes can be extrapolated to humans. The FDA had determined that the shampoo was an irritant by means of the Draize test.

The court also ruled FDA had failed to show that the full concentrate of shampoo might get into the user's eye under normal conditions of use and that the user would *not ordinarily flush* the shampoo out of the eye immediately.

In a memorandum dated February 6, 1974, the FDA legal counsel argued that the FDA should, in the future, have sound evidence and a consistent medical and scientific rationale for charging potential injury to health. The implications of this argument are that the Draize test does not provide sound evidence for the court; and, therefore, it is arguable whether the test provides evidence to establish the safety of a product.

Photo by M. Hamment from F.P.G.



Support HSUS Efforts To Stop the Use of The Draize Test

It causes *pain* and it's *unreliable*, yet government agencies and cosmetic companies are still using the Draize test. Why? Because they haven't chosen to explore potential alternative techniques. The economic incentive to find a new test for eye irritancy is not present. It's fairly inexpensive to use the rabbits. Alternatives may cost less but the difference is not enough to spur action.

Reason has not worked. Economic, social, and political pressure are the tools we must employ to end the use of this cruel test. The federal agencies and the cosmetic companies must be convinced of our determination to end the pain and suffering to defenseless creatures.

Your support is urgently needed for a victory on the Draize test.

Your individual action is important, but equally important is the united action of the Draize Coalition and The HSUS. Funds are needed to continue to carry on personal contacts, letter writing campaigns, and scholarly research required to make the research community employ alternative testing methods.

Send your tax-deductible contribution to The HSUS today. Join forces with The HSUS in this essential movement to protect our fellow creatures.

Remember, just saying you like animals is not enough!



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Additional copies of this report are available upon request at 10¢ each.

What You Can Do

✓ Buy cosmetics which have been on the market for a long time. Usually, well-established or well-known fragrances, lipsticks, powders, etc., which have been marketed for some time have not been tested on animals.

✓ Make an effort to find out if the products you regularly use have been tested on animals. Ask sales clerks, write to the companies, read the labels.

✓ Write to the **Cosmetic, Toiletry and Fragrance Association, 1133-15th Street, N.W. Washington, D.C. 20005**, stating your objection to the Draize test. Ask that they orchestrate a collaborative effort by the industry to develop alternatives. They may send you a pamphlet entitled: “Animal Testing: What are the Choices?” This pamphlet is directed to the whole field of animal testing and not just the Draize test.

React to the pamphlet! Write back and explain the results on the 1971 survey which revealed the unreliability of the Draize test. Tell them about the Ohio court case. Send copies of letters and replies to The HSUS.

✓ Write to the Food and Drug Administration stating your objection to the Draize test. Ask that FDA begin the search for an alternative now!

✓ Write to the cosmetics companies themselves. Urge them to support the search for alternatives. Ask them to allocate one-hundredth of one percent of gross annual sales to finding an alternative as suggested by the Coalition. Stress your objections to the use of rabbits by them or companies they have contracted with for research. Remember, every letter is valuable. Some companies will initiate action after receiving very few letters.

✓ Use the elements of this *Close-Up Report* to write a letter to the editor of your local newspaper. Send copies to HSUS.

✓ Write letters to the editors of magazines you read, especially magazines which carry cosmetic advertising. Your letter might be printed. Or, better yet, you may give an editorial person an idea for a story.



You can buy cosmetics that have not been tested on animals.

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