P.L.A.N.
Pennsylvania Legislative Animal Network

P.O. Box 2432

Harrisburg, PA 17105

Dear House Judiciary Committee:

The Pennsylvania Legislative Animal Network is pleased to provide you with this information on HB 873. After receiving this package and listening to the proponent witnesses, we hope you will give your full support to this measure.

This is a moderate bill. It is not anti-science or anti-research. It is only an attempt to improve the conditions of thousands of laboratory animals in Pa. and save thousands more from needless suffering. The specific tests banned under this legislation pertain only to household products and cosmetics.

As our testimony shows, the Food and Drug Administration does not require animal testing for cosmetics and household products.

We have also included a copy of a videotape, since most of us never go beyond the laboratory door. Although it is extremely graphic, we do not apologize; it depicts the suffering inflicted on animals in Pa. labs.

The head injury lab scenes of this video have been shown to members of Congress, other federal officials and on national networks.

We believe there are many responsible laboratories in Pa. doing valuable research. But this legislation would enable the Commonwealth to ban needless non-medical research and improve conditions in those labs that show little regard for animal life.

Sincerely,

The Pennsylvania Legislative Animal Network

P.L.A.N.

Pennsylvania Legislative Animal Network

P.O. Box 2432

Harrisburg, PA 17105

Animal Care and Welfare, Inc. SPCA	Pittsburgh
Animal Friends, Inc.	Pittsburgh
Because You Care	McKean
Butler County Humane Society	Butler
Central Penn Spay/Neuter Fund, Inc.	Harrisburg
Humane Society of Lebanon County	Myerstown
Lehigh County Humane Society	Allentown
Lehigh Valley Animal Rights Coalition	Allentown
Mobilization for Animals, PA, Inc.	Pittsburgh
Morris Animal Refuge	Philadelphia
Northwest PA Humane Society	Erie
Pennsylvania Animal Protectors Assoc.	Pottsville
Pennsylvania Animal Welfare Society	Philadelphia
Pity Not Cruelty	Villanova
Trans-Species, Unlimited	Williamsport
Woman's Humane Society	Philadelphia

Representing more than 36,000 Pennsylvanians across the state working for animal protection!

Mary Kay cuts off animal testing

By JOE SIMNACHER 5/20/89
Dallas Morning News

DALLAS — Mary Kay Cosmetics Inc. of Dallas on Wednesday announced a moratorium on the use of laboratory animals for consumer product safety testing — an industry first.

"Our research shows that there is a great deal of consumer concern and confusion about the use of animals for safety testing for cosmetic toiletries, household products, all the way through medical research," said Mary Kay president Richard C. Bartlett.

Mr. Bartlett said he recently became aware of an apparent scientific breakthrough that would allow non-animal testing. He decided to put a moratorium on his company's laboratory animal testing while the viability of new tests using tissue cultures is verified.

Mary Kay executives made the announcement Wednesday at an industry workshop at the Johns Hopkins Center for Alternatives to Animal Testing in Baltimore.

"Since 1981, we have actively participated in the development of alternative testing methods," Mr. Bartlett said. "Apparent advances in this methodology allow us not to pause and evaluate the potential of recently announced non-animal testing methods."

Mary Kay's animal testing has generated negative publicity in recent months. In the comic strip "Bloom County," cartoonist Berke Breathed poked merciless fun at Dallas company founder Mary Kay Ash. Earlier, "Bloom County" strips had satirized the

Please see **TEST** *on* **9A**

TEST: No more animal research

Continued from 8A 5/20/89

use of animals in Mary Kay's cosmetics-testing laboratories.

"I'm delighted that progress is being made; this was a tough nut to crack," Mr. Breathed said Wednesday.

The 1987 Pulitzer Prize-winning cartoonist said he had received mail from many of Mary Kay's 185,000 independent sales force members indicating that they did not know their company was involved in animal testing.

"It wouldn't be up to me to decide what kind of effect that might have had on it," Mr. Breathed said. "I know that the combined efforts of all the animal rights organizations, and with a little nudge from (comic strip character) Opus, no doubt helped the Mary Kay corporation see the light."

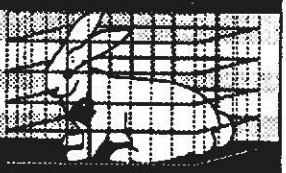
In a telephone interview, Mr. Bartlett said the Dallas company is the first in the industry to put animal testing on hold. He called for the formation of a blue-ribbon panel of industry and academic scientists to address the issue.

"It is our hope that we can share and examine data and develop new safety testing methods to the satisfaction of the scientific community, regulatory agencies and, more importantly, the American public."

Animal Testing*

Total animals tested in 1987, by method used

Testing methods:	
Painful, without anesthesia	3,696
Painful, with anesthesia	18,068
Not painful	71,249
Total number of animals tested	94,345



Reported testing in U.S. companies in 1987

Company	Dogs	Cats	Rabbits	Guinea pigs	Hamsters	Primates	Wild animals	Total	Rank
Amer. Home Prod.	10,411	199	5,792	13,301	5,542	199	114	38,033	4th
Avon Products	0	0	477	1,323	0	0	0	1,800	77th
Bristol-Myers	704	9	1,466	1,474	195	142	839	4,865	47th
Colgate-Palmolive	88	40	3,686	808	503	0	0	5,115	45th
Gillette	0	0	155	155	111	0	0	421	--
Greyhound	0	0	167	70	0	0	0	237	--
Johnson & Johnson	3,239	0	7,589	10,175	1,379	149	0	22,541	8th
U.S. Surgical	1,171	3	0	0	0	0	0	1,174	98th
Schering-Plough	947	96	2,900	11,220	4,126	496	482	20,182	9th

*Excludes rats, mice and animals used at contract laboratories
--Not in top 100

Source: USDA

AP/Alonita P. Hernandez

While animal rights groups also picketed Mary Kay's annual sales meeting in Dallas, Mr. Bartlett said he did not think the company had been singled out as a target by such organizations.

Until Wednesday, Mary Kay had used a three-tier procedure for verifying the safety of its products. The first tier was a search of literature on the toxicity of ingredients, followed by rodent testing and finally testing on humans.

The new testing method would replace laboratory rats and mice with in-vitro test methods — cell-culture technology developed at the Baltimore center, Mr. Bartlett said.

"The moratorium on animal testing may require us to reschedule the launch of several products," he said. "However, it is hoped that the shift to alternative testing methods will eventually result in accelerated product development capabilities."

The Mary Kay announcement came at a workshop sponsored by the Dallas company with the Environmental Protection Agency, Procter and Gamble Co. and F. Hoffmann-LaRoche & Co.

500 animal-rights activists rally outside testing lab in Kensington

By Jodi Enda
Inquirer Staff Writer

About 500 animal-rights activists from several states marched through the streets of Kensington yesterday in an effort to shut down a laboratory that they contend abuses and kills animals while testing cosmetics and household products.

Waving signs with messages such as "Rabbits don't wear makeup" and "Shame," the chanting protesters rallied in front of the red-brick building that houses Biosearch Inc., in the 3400 block of B Street.

Dressed in black from head to toe and carrying a straw wreath strung with black flowers, Virginia Wolfe of Allentown said she was "in mourning for all the animals that die here, that suffer here, that are tortured here."

"We were just horrified when we heard what was happening here," said Wolfe, who is president of the Lehigh Valley Animal Rights Coalition.

The nation's largest animal-rights group, People for the Ethical Treatment of Animals, said earlier this year that it documented more than 100 violations of state and federal animal-cruelty and consumer-fraud laws by Biosearch. Representatives of that group and the American Anti-Vivisection Society, a Jenkintown-based organization that co-sponsored the rally, said District Attorney Ronald D. Castille is investigating the alleged violations.

Spokesmen for Castille and for Biosearch could not be reached for comment yesterday. The company was closed during the peaceful demonstration, which included a 2½-mile march and numerous speeches from the back of a flatbed truck parked on B Street.

Sponsors dubbed Biosearch the "Nightmare on B Street."

Leaders of the demonstration said the manufacturers of cosmetics, toiletries and other household products are not required to test their products on animals but did so to protect themselves from lawsuits. To avoid publicity, the companies contract with laboratories like Biosearch to do the tests for them, the animal-rights activists said.

"We're hoping to draw attention to the terrible things that go on inside the Biosearch lab without any regard to pain and suffering," said Harold Hovel of Westchester County, N.Y., whose "grim-reaper" costume drew a few stares. Hovel wore a black cape and hood, covered his face with a skeleton mask and carried a plastic scythe, a plastic knife and a rope.

On the other end of the rope was the neck of Laura Schneiderman, who was dressed as a rabbit in pink and white.

"Everything that goes into that lab is killed after they do experiments on it," said Schneiderman, who, along with Hovel, is a member of the Animal Welfare Alliance in Westchester County. "Many of them die in agony."

Group accuses testing lab of animal cruelty and fraud

By Jim Detjen
Inquirer Staff Writer

A national animal-rights group said yesterday that it has documented more than 100 violations of state and federal animal-cruelty and consumer-fraud laws by Biosearch Inc., a Philadelphia products-testing laboratory.

A spokeswoman for Biosearch, which is in the 3400 block of B Street in Kensington, declined to discuss the allegations. "We have no comment whatsoever," said the spokeswoman, who refused to give her name and then hung up the telephone. Efforts to reach other company officials were unsuccessful.

Ingrid Newkirk, national director of People for the Ethical Treatment of Animals, the nation's largest animal-rights group, said during a news conference that the alleged violations were documented by two former Biosearch employees.

The first employee, Cheryl Baker of Philadelphia, worked there from October 1987 until this month. Baker said she contacted the animal-rights group in December because she was appalled by what she had seen. The second employee worked undercover at Biosearch from February to June to verify Baker's findings, Newkirk said.

The alleged violations include falsification of records and test results; the subjecting of unanesthetized animals to painful and unnecessary procedures; the cutting open of animals while they are still alive, and the failure to provide adequate food, water and veterinary care for lab animals.

"Biosearch is an abominable example of animal cruelty," said Newkirk, who said that the company used 13,800 mice, rats, guinea pigs, rabbits and cats in 1987.

Biosearch conducts product tests on people and animals for nearly 200 clients, including such major cosmetic and consumer products concerns as Revlon, Benetton Cosmetics Corp., Colgate-Palmolive, Procter & Gamble, Estee Lauder, L'Oreal, Mennon, Noxell, Alberto-Culver, Bristol-Myers, Chesebrough-Pond's Inc., Mary Kay and A.H. Robins, the animal-rights group said.

Newkirk said that records, photographs and videotapes documenting the alleged violations have been turned over to the Philadelphia District Attorney's Office, the U.S. Department of Agriculture's Animal and Plant Health Inspection Service and members of Congress.

Terry Williamson, a spokesman for the District Attorney's Office, said the office has just begun reading the group's documents. "It's under review, but I can't say whether it will require an investigation or not," he said.

According to Newkirk, many cosmetics firms say they have stopped conducting procedures known as the Draize test, in which chemical substances are placed in rabbits' eyes, and the LD50 test, in which animals are exposed to chemicals until at least half of the animals have died. Both tests are performed to determine whether products are safe for people.

But she said firms are now contracting with Biosearch or other product-testing firms to conduct these controversial studies.

Baker said she witnessed company employees falsifying test data almost daily.

Baker said that in an April test of a liquid makeup made by the Noxell Corp., a company employee signed a form saying that 53 participants had been examined, even though they had not been.

Carroll Bodie, a vice president and general counsel of Noxell, said yesterday that the firm has employed Biosearch for 10 years and has always found its work to be accurate. "Because of the substantial additional testing that goes into our products we are certain that the safety and claims made for our products are soundly documented," he said.

The investigator who worked undercover at Biosearch said she witnessed numerous cases of animal cruelty at the facility. "I saw animals dissected while they were still alive, mice drowned in cooking oil and rabbits screaming in pain when products were dripped into their eyes," said the woman, who declined to give her name because she is involved in other investigations for the animal-rights group.

According to the animal-rights group, Biosearch employs about 30 people and is one of the state's largest independent product-testing laboratories.

People for the Ethical Treatment of Animals, which is based in Washington, a $5 million annual budget and 60 full-time employees.

HHS Secretary Suspends Funding Of Pa. Brain-Trauma Experiments

Animal Rights Advocates End Sit-In at NIH Offices in Bethesda

By Mark Katches
Washington Post Staff Writer

Health and Human Services Secretary Margaret M. Heckler ordered the National Institutes of Health yesterday to suspend funding for brain-trauma experiments on monkeys at a University of Pennsylvania head injury clinic, prompting more than 60 animal rights activists to claim "complete victory" and end their four-day sit-in at NIH offices in Bethesda.

Heckler ordered a halt to research at the Pennsylvania Head Injury Laboratory until the "serious concerns" raised about procedures used at the laboratory are answered.

Heckler took the action yesterday after receiving a preliminary report from NIH investigators reviewing work at the Pennsylvania clinic. The report was scheduled for completion today, but was expedited because of the sit-in at the offices of the National Institute of Neurological and Communicative Diseases and Stroke, according to NIH spokesman Storm Whaley.

In a prepared statement, Heckler said: "The use of animals must occur under protected and humane conditions, and only for scientifically necessary purposes . . . . I have been informed that serious concerns have been raised about procedures used by the University of Pennsylvania in the use of primates to study head injury . . . .

Until all questions about the use of primates in these head-injury experiments have been satisfactorily resolved, I have instructed NIH to suspend the use of federal funds for primate research on head injury at the University of Pennsylvania."

NIH Director Dr. James Wyngaarden later issued a statement saying he had complied with Heckler's order. He said the investigators' preliminary report "indicates material failure to comply with the Public Health Service policy for the care and use of laboratory animals."

Wyngaarden said he will decide whether to end the project after the university responds to the report.

University of Pennsylvania spokesman Virgil Renzulli said officials there had not yet received a copy of the report, but a statement by University President Sheldon Hackney and Provost Thomas Ehrlich said that "any fault in research will be corrected."

About 65 demonstrat
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fices ended their protes
afternoon after hearing c
ments by Heckler and W
The sit-in began Mond
and lasted more than 77

The demonstrators, m
bers of People for t
Treatment of Animals,
sang and cried as the
united with friends, re
other animal-rights act
held signs and applaude
through the front doors.

"This is a complete vi
Gary Francione, a law
group. "It couldn't have
any better."

But Frank Martin, p
the Pennsylvania chapte
tional Head Injury
which represents victin
damage, expressed ange
ler's decision, saying th

Scenes from the University of Pennsylvania Head Injury Lab

(Experimenter #1): The animal's down for a second lateral bang. That's him waving *(experimenter waves monkey's arm).* As you can see, the monkey is awake, moving all extremities *(experimenter throws monkey's limbs around on the table — both men laugh).* Ah, that's his trainer who taught him how to do those tricks *(laughter.)*

(Experimenter #2): You might want to mention that this monkey has already been banged once.

(#1): I said that — a second bang.

(#2): Did you say that?

(#1): I said this is the animal's second bang. He was banged once at a 680 G-force and quickly recovered. Cheerleading over in the corner, we have B-10 *(camera pans to disabled monkey strapped to a chair in the corner — experimenters laugh).* ...B-10 wishes his counterpart well. As you can see, B-10 is alive... B-10 is watching and hoping for a good result *(camera pans back to monkey awaiting injury on table.)* ... Future B-17 over here *(laughter).*

An experimenter lops off a portion of a baboon's ear with a hammer.

(Experimenter #1): Looks like I left a little ear behind. Eeeeh. *(The experimenter then ties this brain-injured, conscious baboon to the operating table.)* Oh, have some axonal brain damage there, monkey, or else we'll have wasted five hundred dollars worth of HRP on you, you sucker! Get him closer. The monkey is (unintelligible). Don't be shy now, sir. Nothing to be afraid of *(laughter).* Oh, what's going on here, tsk, tsk, tsk, tsk. Look, there she goes, there she goes; she's on TV *(laughter)* holding her monkey. Look! Yeah! Go! Go! Ta Da! Just like a cat! Here kitty, kitty, kitty, kitty — look at the cat commercial. Say, over here, say 'cheese.' Looks like he's gonna fall over. You better hope the, uh, the, uh, anti-vivisection people don't get a hold of this film.

(Experimenter #2): The who?

(#1): The anti-vivisection people. They got a nice shot of you. They got Larry's name...in the picture. And Karen. There, look at that part of his head *(laughter).* Hum, that's some part you've got there. He has the, uh, the punk look.

(#2): The punk look, is that what you said? *(laughter)*

(#1): Friends! Romans! Countrymen! *(laughter).* Look, he wants to shake hands. Come on. Oh, not again. Put your head down *(much laughter).* He says, 'You're gonna rescue me from this, aren't you? Aren't you?'

Congress of the United States
House of Representatives
Washington, D.C. 20515

May 17, 1985

Dear House Judiciary Committee
The video provided to you contains excerpts from the tape discussed below

The Honorable Margaret M. Heckler
Secretary of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Mrs. Secretary:

We are writing to you regarding the funding provided through the Department of Health and Human Services for the University of Pennsylvania Head Injury Clinic. As you know, a video tape has been circulating which provides shocking and disturbing information about some of the procedures followed by the Clinic in its research using primates.

On the basis of the evidence provided by this film, it is obvious that the quality of the research being done at the University of Pennsylvania's Head Injury Clinic is open to very serious question on scientific grounds. It is absolutely clear that federal funding of such research is inappropriate and provides information of dubious scientific value if this film reflects the caliber of work performed there.

For this reason, we urge you to suspend any further funding of the University of Pennsylvania Head Injury Clinic until an independent investigation conducted by recognized and disinterested scientists can be carried out. In a period when funds for medical research are scarce and many worthy projects cannot be funded, it would be irresponsible to continue funding this research without conducting such an independent inquiry.

Sincerely,

Tom Lantos
Tom Lantos, M.C.

Claudine Schneider
Claudine Schneider, M.C.

Pat Schroeder
Pat Schroeder, M.C.

Rod Chandler
Rod Chandler, M.C.

Sander M. Levin
Sander Levin, M.C.

Barbara Boxer
Barbara Boxer, M.C.

Sala Burton, M.C.

Robert J. Mrazek, M.C.

Charles Hayes, M.C.

Harry M. Reid, M.C.

Jim Jeffords, M.C.

Jim Moody, M.C.

Bill Archer, M.C.

Claude Pepper, M.C.

Robert A. Roe, M.C.

Ronald V. Dellums, M.C.

DANIEL P. MOYNIHAN
NEW YORK

United States Senate

WASHINGTON, D.C. 20510

April 8, 1985

Dear Dr. Wyngaarden:

Over recent weeks, I have received letters from many of my constituents regarding animal experimentation at the University of Pennsylvania's Head Injury Clinic. A videotape synopsis of experimentation conducted at the Clinic, prepared and distributed by the Animal Liberation Front and People for the Ethical Treatment of Animals, shows baboons subjected to severe head injuries without proper sedation, the animals' open wounds cauterized, once again without proper sedation, and other improper practices.

I am writing to request that the National Institutes of Health conduct an immediate investigation of the Head Injury Clinic, and report its findings to me as soon as possible. I also am eager to learn whether efforts have been made by the Clinic to reduce reliance on animal experimentation, by using computer models and cell cultures.

My constituents argue that the Head Injury Clinic should not receive Federal support if its researchers are not abiding by current laboratory standards for animal experimentation. I concur.

I look forward to hearing from you on this matter.

Sincerely,

Daniel Patrick Moynihan

Dr. James B. Wyngaarden
Building 1, Room 124
National Institutes of Health
Bethesda, Maryland 20205

In Defense of the Animals

We have become far too careless, self-indulgent and cruel in the pain we inflict on these creatures

I might as well come right out with it: contrary to some of my most cherished prejudices, the animal-rights people have begun to get to me. I think that in some part of what they say they are right.

I never thought it would come to this. As distinct from the old-style animal rescue, protection and shelter organizations, the more aggressive newcomers, with their "liberation" of laboratory animals and periodic championship of the claims of animal well-being over human well-being when a choice must be made, have earned a reputation in the world I live in as fanatics and just plain kooks. And even with my own recently (relatively) raised consciousness, there remains a good deal in both their critique and their prescription for the virtuous life that I reject, being not just a practicing carnivore, a wearer of shoe leather and so forth, but also a supporter of certain indisputably agonizing procedures visited upon innocent animals in the furtherance of human welfare, especially experiments undertaken to improve human health.

So, viewed from the pure position, I am probably only marginally better than the worst of my kind, if that: I don't buy the complete "speciesist" analysis or even the fundamental language of animal "rights" and continue to find a large part of what is done in the name of that cause harmful and extreme. But I also think, patronizing as it must sound, that the zealots are required early on in any movement if it is to succeed in altering the sensibility of the leaden masses, such as me. Eventually they get your attention. And eventually you at least feel obliged to weigh their arguments and think about whether there may not be something there.

It is true that this end has often been achieved—as in my case—by means of vivid, cringe-inducing photographs, not by an appeal to reason or values so much as by an assault on squeamishness. From the famous 1970s photo of the newly skinned baby seal to the videos of animals being raised in the most dark, miserable, stunting environment as they are readied for their life's sole fulfillment as frozen patties and cutlets, these sights have had their effect. But we live in a world where the animal protein we eat comes discreetly prebutchered and prepacked so the original beast and his slaughtering are remote from our consideration, just as our furs come on coat hangers in salons, not on their original proprietors; and I see nothing wrong with our having to contemplate the often unsettling reality of how we came by the animal products we make use of. Then we can choose what we want to do.

The objection to our being confronted with these dramatic, disturbing pictures is first that they tend to provoke a misplaced, uncritical and highly emotional concern for animal life at the direct expense of a more suitable concern for human suffering. What goes into the animals' account, the reasoning goes, necessarily comes out of ours. But I think it is possible to remain stalwart in your view that the human claim comes first and in your acceptance of the use of animals for human betterment and *still* to believe that there are some human interests that should not take precedence. For we have become far too self-indulgent, hardened, careless and cruel in the pain we routinely inflict upon these creatures for the most frivolous, unworthy purposes. And I also think that the more justifiable purposes, such as medical research, are shamelessly used as cover for other activities that are wanton.

For instance, not all of the painful and crippling experimentation that is undertaken in the lab is being conducted for the sake of medical knowledge or other purposes related to basic human well-being and health. Much of it is being conducted for the sake of superrefinements in the cosmetic and other frill industries, the noble goal being to contrive yet another fragrance or hair tint or commercially competitive variation on all the daft, fizzy, multicolored "personal care" products for the medicine cabinet and dressing table, a firmer-holding hair spray, that sort of thing. In other words, the conscripted, immobilized rabbits and other terrified creatures, who have been locked in boxes from the neck down, only their heads on view, are being sprayed in the eyes with different burning, stinging substances for the sake of adding to our already obscene store of luxuries and utterly superfluous vanity items.

Phony kinship: Oddly, we tend to be very sentimental about animals in their idealized, fictional form, and largely indifferent to them in realms where our lives actually touch. From time immemorial, humans have romantically attributed to animals their own sensibilities—from Balaam's Biblical ass who providently could speak and who got his owner out of harm's way right down to Lassie and the other Hollywood pups who would invariably tip off the good guys that the bad guys were up to something. So we simulate phony cross-species kinship, pretty well drown in the cuteness of it all—Mickey and Minnie and Porky—and ignore, if we don't actually countenance, the brutish things done in the name of Almighty Hair Spray.

This strikes me as decadent. My problem is that it also causes me to reach a position that is, on its face philosophically vulnerable, if not absurd—the muddled, middling, inconsistent place where finally you are saying it's all right to kill them for some purposes, but not to hurt them gratuitously in doing it or to make them suffer horribly for one's own trivial whims.

I would feel more humiliated to have fetched up on this exposed rock, if I didn't suspect I had so much company. When you see pictures of people laboriously trying to clean the Exxon gunk off of sea otters even knowing that they will only be able to help out a very few, you see this same outlook in action. And I think it *can* be defended. For to me the biggest cop-out is the one that says that if you don't buy the whole absolutist, extreme position it is pointless and even hypocritical to concern yourself with lesser mercies and ameliorations. The pressure of the animal-protection groups has already had some impact in improving the way various creatures are treated by researchers, trainers and food producers. There is much more in this vein to be done. We are talking about rejecting wanton, pointless cruelty here. The position may be philosophically absurd, but the outcome is the right one.

Paul Harvey

When 'Science' Becomes Sadism, It's Shameful

Paul Harvey's comment has tried to be fair and still will.

Despite my personal empathy for suffering animals I have consistently defended the medical necessity for some laboratory experiments involving animals.

But some lab scientists are now an intolerable embarrassment to their longtime supporters.

As one for-instance, the redundant, repetitive experiments in the Gennarelli Laboratory at the University of Pennsylvania are hideously remindful of Auschwitz, Dachau and Buchenwald.

There, too, torture tests and agony-unto-death were defended in the name of "science."

Your taxes are paying for some monstrous medical experiments which you are supposed neither to see nor know about.

Indeed, when a committee of the Congress contemplated this subject, even the committee was not allowed to see videotapes of this Pennsylvania laboratory.

Both the Department of Agriculture and the Department of Health decreed that the film must not be shown on Capitol Hill.

While many medical laboratories are torturing animals, from this one videotaped evidence is available.

If you wish more graphic detail than I am willing to relate, you can secure same from PETA — People for the Ethical Treatment of Animals — P.O. Box 42516, Washington, D.C. 20015.

Twenty million rats, rabbits, cats, dogs, mice and monkeys are killed each year in the name of science. And the number has quadrupled in recent years.

While many experiments result in benefits to man, most have become experiments with no benefits beyond the abstract accumulation of knowledge and some experimenters don't even profess that purpose anymore.

Researchers are under no legal obligation even to use anesthetics. Dogs are driven insane with electric shock. Monkeys are attached to electrodes to see how much pain they can take before they die.

Primates are restrained for months in steel chairs, the heads encased in concrete, while researchers make jokes about the spilling of acid on a helpless baboon. Yes, the PETA recordings will document the jokes, also.

And some of what they do to kittens I cannot bring myself to describe.

I am now taking sides. Our family has created a foundation the specific purpose of which is to encourage however the humane treatment of animals.

As 150 living creatures are sacrificed every minute, at a cost of $7 billion a year, and two-thirds of that money is YOUR TAX MONEY.

Some lab attendants hear so many screams either they can't hear anymore or can't take anymore.

There is an ongoing holocaust which somebody must hear and heed and resist.

Los Angeles Times Syndicate — May 1, 1985

PETA FACTSHEET

COSMETIC TESTING: TOXIC AND TRAGIC

Animal Experiments #4

Every year, an estimated 14 million animals suffer and die in painful tests to determine the "safety" of cosmetics and household products.(1) Substances ranging from eye shadow and soap to furniture polish and oven cleaner are tested on rabbits, dogs, and other animals, despite the fact that the test results do not help prevent or treat human illness or injury.

The Draize Test

Since 1944, the Draize Eye Irritancy Test has been the standard test of substances that might get into the human eye.(2) In this test, a liquid, flake, granule or powdered substance is dropped into the eyes of a group of albino rabbits. The animals are immobilized in stocks from which only their heads protrude. They usually receive no anesthesia during the tests.

After placing the substance in the rabbits' eyes, technicians record the damage to the eye tissue at specific intervals for a 72-hour period. Reactions to the substances include swollen eyelids, inflamed irises, ulceration, bleeding, massive deterioration, and blindness.

During the tests, the rabbits' eyelids are held open with clips, and their ineffective tear ducts prevent them from blinking or washing away the test substance. Many animals break their necks as they struggle to escape. Technicians performing the Draize test do not attempt to treat the rabbits or seek antidotes to the test substance, so the test does not help prevent or treat potential human injuries.

Acute Toxicity Tests

Acute toxicity tests, commonly called lethal dose or poisoning tests, determine the amount of a substance that will kill part of a group of test animals.

In these tests, a substance is forced by tube into the animals' stomachs or through holes cut into their throats. It may be injected under the skin, into a vein, or into the lining of the abdomen; mixed into lab chow; inhaled through a gas mask; or applied into the eyes, rectum, or vagina.

Experimenters observe the animals' reactions, which can include convulsions, labored breathing, diarrhea, constipation, emaciation, skin eruptions, abnormal posture, and bleeding from the eyes, nose, or mouth.(3)

The widely used Lethal Dose 50 (LD-50) test was developed in 1927. The LD-50 testing period continues until 50 percent of the animals die, usually in two to four weeks.

Alternatives To Animal Tests

Non-animal testing methods have proven to be more reliable and less expensive than animal tests. Alternatives include the use of cell cultures; corneal and skin tissue cultures; chicken egg membranes; corneas from eye banks; and sophisticated computer and mathematical models. Companies also have the option of making products using the many ingredients or combinations of ingredients already included on the FDA's "Generally Recognized As Safe" (GRAS) list.

Lethal But Legal

Cosmetic and product tests on animals are not required by law. The Food and Drug Administration (FDA) only requires that each ingredient in a cosmetic be "adequately substantiated for safety" prior to marketing, or the product must carry a warning on the label that its safety has not been determined. The FDA does not have the authority to require any particular product test. Testing methods are determined by the cosmetic and household product manufacturers, and the test data are used only to defend the companies against consumer lawsuits.

Compassion In Action

A growing number of socially responsible manufacturers have recognized the cruelty of animal testing. More than 100 firms now offer safe and effective cosmetics, personal care and household products that are not tested on animals. By buying only "cruelty-free" products and by voicing their complaints to those who still use animal tests, consumers play a vital role in eliminating cruel test methods.

(1) Rowan, A.N., Of Mice, Models, & Men: A Critical Evaluation of Animal Research, (Albany) State University of New York Press, 1984.

(2) Pratt, D., Alternatives to Pain In Experiments On Animals, Argus Archives, 1980.

(3) Ibid.

PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS
P O B O X 4 2 5 1 6
WASHINGTON DC 20015
(2 0 2) 7 2 6 - 0 1 5 6

FACT SHEET ON PENNSYLVANIA HOUSE BILL 873
A BILL TO REGULATE ANIMAL RESEARCH

Intent:

To address inadequacies in federal regulations and inspections concerning the care and use of animals in research and to affirm the right of students not to participate in animal experimentation.

Why is state licensing and inspection of research facilities needed? Why should lab animals receive protection? 5511 (1) and 5511.1 (a)

According to the United States General Accounting Office, federal inspections by the United States Department of Agriculture (USDA) are infrequent and inadequate. The USDA has a poor record of uncovering animal abuse in research facilities. Federal regulations do not address the **use** of animals in research.

Aren't people who conduct animal experiments required to complete formal training in animal physiology and handling? 5511.1 (b) and (c)

No. Laboratory workers with no formal training can perform surgical and other invasive procedures on animals.

What is wrong with using animal lethal dose and Draize eye irritancy tests to test cosmetics and household products? 5511.1 (d)

The tests do not assure product safety (corrosive and toxic products remain marketed), have no clinical value in the treatment of accidental poisonings (the test animals are never given antidotes or otherwise treated for injury) and are a senseless waste of animal lives.

Are these tests required by law?

No. The two federal agencies that regulate cosmetic and household product safety, the Food and Drug Administration and the Consumer Product Safety Commission (CPSC) do not require animal tests.

Can students refuse to experiment on animals? 5511.1 (e)

No. We need legal provisions similar to those in Florida and California which affirm students' rights not to participate in animal experimentation.

PRINTER'S NO. 991

THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 873 Session of 1989

INTRODUCED BY MURPHY, O'DONNELL, KUKOVICH, ROBINSON, MICOZZIE, FOX, ITKIN, MICHLOVIC, TRELLO, BELARDI, CAWLEY, SAURMAN, RYBAK, KOSINSKI, McVERRY, MAYERNIK, FREEMAN, RITTER AND DeLUCA, APRIL 3, 1989

REFERRED TO COMMITTEE ON JUDICIARY, APRIL 3, 1989

AN ACT

Amending Title 18 (Crimes and Offenses) of the Pennsylvania Consolidated Statutes, regulating animal research; and providing penalties.

The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows:

Section 1. Section 5511(1) of Title 18 of the Pennsylvania Consolidated Statutes is amended to read:

§ 5511. Cruelty to animals.

* * *

(1) Search warrants.--Where a violation of this section is alleged, any issuing authority may, in compliance with the applicable provisions of the Pennsylvania Rules of Criminal Procedure, issue to any police officer or any agent of any society or association for the prevention of cruelty to animals duly incorporated under the laws of this Commonwealth a search warrant authorizing the search of any building or any enclosure in which any violation of this section is occurring or has

standards for issuing a license and prescribe a fee therefor.

(b) Regulations.--The secretary shall promulgate regulations to govern humane handling, treatment and care by research facilities and shall employ agents with authority to inspect research facilities at reasonable hours, with or without prior notice of inspection. The secretary shall require certification of formal training for researchers, technicians and attendants who directly handle live animals.

(c) Institutional care committee.--Each research facility shall form an Institutional Animal Care Committee which shall include representatives of the facility, including not less than one member of the animal care staff, one member who is a State enforcement agent responsible for inspection, and not less than one member who is a representative of an incorporated humane or animal welfare organization. The committee shall ensure that animal care and facilities conform to Federal and State laws and regulations, before, during and after their use.

(d) Prohibited tests.--A person may not subject a live animal to an eye irritancy test, including the Draize eye irritancy test, or use a live animal in an acute toxicity test, including the L.D. 50 test, for purposes of testing cosmetics or household products.

(e) Refusal to participate in experimentation.--No employee or student who refuses to participate in experimentation, research, or teaching methods involving dissection or vivisection shall be penalized for refusal to participate based upon the individuals fundamental beliefs.

(f) Penalty.--

(1) If the secretary has reason to believe that any person licensed by this section has violated any provision of

"Research facility." Any individual, institution, organization, elementary, secondary or postsecondary school that uses or intends to use live animals in research tests or experiments, purchases or transports live animals in commerce or receives State funding, directly or indirectly, for research or facility operations.

"Secretary." The Secretary of Agriculture of the Commonwealth.

Section 3. Within 60 days of enactment of the provisions of this act, the Governor shall appoint a review committee consisting of representatives of research and humane organizations, to review existing and proposed regulations. The Secretary of Agriculture shall act as chairman of the committee. Regulations shall be developed by the committee designed to minimize the duplication of research, the use of live animals in teaching, testing and research and to ensure humane treatment of animals maintained in research, teaching and other facilities in Pennsylvania.

Section 4. This act shall take effect as follows:

(1) Section 2 (Section 5511.1(d)) shall take effect one year from the date of enactment.

(2) The remainder of this act shall take effect in 60 days.

Pr

Beyond the Draize Test

World-War-II-Era Test is Cruel, Obsolete

Alternative to the Draize: CAM test uses egg membrane to show chemical irritancy. *Photo courtesy Colgate-Palmolive and American Fund for Alternatives to Animal Research.*

Studies Show Draize is Unreliable

One of the most commonly criticized toxicity tests in use today is the Draize test. The test was introduced in 1944 by FDA toxicologist John H. Draize. Draize was particularly interested in the toxic effects of industrial chemicals, and published methods of assessing the toxicity to skin and membranes. In the eye test, a drop of the test compound—from floor wax to toothpaste to mascara—is put into the eyes of conscious rabbits. The damage to the eye is judged by observers, a procedure that has been noted to be highly subjective and unreliable. The test is in common use at cosmetic companies and toxicology testing laboratories.

The eye test was developed by Draize as one method of assessing the effect of substances on mucous membranes. Draize wrote:

"Irritation of mucous membranes is measured on the rabbit's eye and penis. In the case of the penile mucosa the preparation is applied so that thorough wetting is attained."

Tissue damage was rated by Draize on a numerical scale, with 4 being the most severe damage.

"If a preparation is found sufficiently irritating to cause necrosis and sloughing of the mucosa, the agent is reapplied in sufficient dilution so that the resulting injuries total a score of 4 or less. In the measure of injury to the eye...0.1 ml is instilled in the conjunctival sac [behind the lower lid]. Readings are usually made at 1, 24, and 48 hours after instillation of the agent into the eye.... Readings are also made after 96 hours if residual injury is present." [1]

Cont. on page 10

Stephen Kaufman, M.D. on Eye Irritancy Testing

As an ophthalmologist in the New York University Department of Ophthalmology, I find it surprising that, in this day of advanced tissue cultures and in vitro models, the Draize eye irritation test is done at all. I have never used Draize data to assist in the care of a patient, and I know of no case in which another ophthalmologist found Draize data useful.

Rabbits are the traditional animal used in this test because they are inexpensive, have large eyes, and are easy to handle. Nevertheless, they are very poor models for human ocular damage. Among the many significant differences between the human and rabbit eye are the following:

Cont. on page 10

INSIDE

Cell Culture Packs Available

The Clonetics Corporation reports that its *Epi-Packs*, containing cultured human cells, are now in wide use as an alternative or adjunct to the Draize test. In the cell culture test, developed by Dr. Charles Shopsis, human cells are exposed to various dilutions of the agent to be tested. The effect of the test substance on the cells can be measured. According to Clonetics:

> **Use of the protocol has given correlation coefficients of .85 and .88 as compared to Draize test data for a series of eight surfactant-based substances used in an interlaboratory study. Studies of individual surfactants and alcohols also correlated well with published ocular irritancy data. The experimental protocol gives** reproducible results under varying cell densities and growth rates.

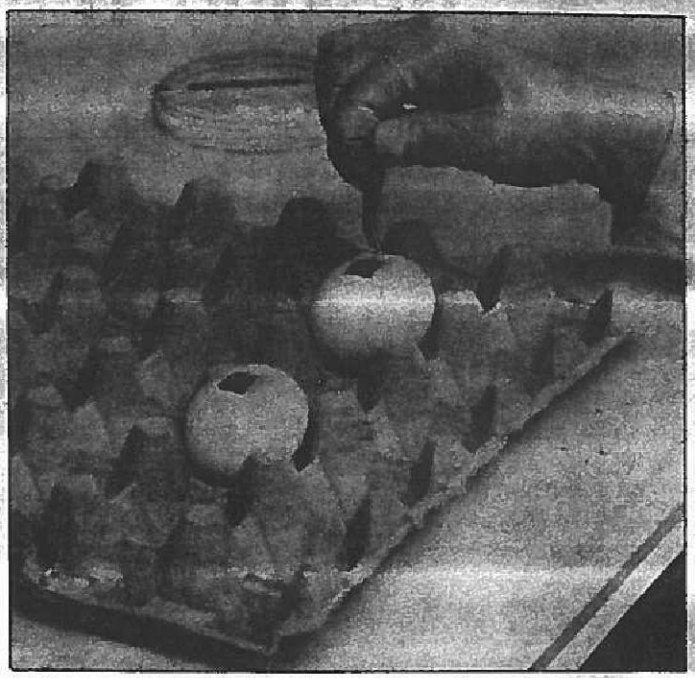
According to Pam K. Logemann of Clonetics, their human cell Epi-Packs are in use at many companies. While, for now, many use them side-by-side with the Draize test, she anticipates that as the cell culture method shows its value, companies will phase out the Draize.

Reference: Shopsis, C. and B. Eng. 1985. Rapid cytotoxicity testing using a semi-automated protein determination on cultured cells. *Toxicology Letters* 28:1.

Computer Model for Toxicity

In its February, 1987 *Toxicology Newsletter,* Health Designs, Inc. (HDI), announced a new computer model for toxicity prediction:

> HDI is proud to announce the availability of TOPKAT, a software package for the prediction of toxicity endpoints from the structure of chemicals. TOPKAT is intended to be used as a personal tool by toxicologists, pharmacologists, synthetic and medicinal chemists, regulators, and industrial hygienists, among others. TOPKAT is fully menu-driven and does not require computer programming or training.
>
> TOXICITY ENDPOINTS. TOPKAT implements the structure-activity equations (SAR) which HDI has developed over the past several years and, as initially delivered, can predict the following endpoints:
>
> Rat oral LD50
> Probability of mutagenicity (Ames)
> Probability of carcinogenicity (two-year assays)
> Teratogenicity (frank malformations)
> Rabbit skin irritation (Draize)
> Rabbit eye irritation
>
> Other endpoints will be available as SAR equations for them are developed. For more information, contact: HDI, 183 East Main St., Rochester, NY 14604, (716) 546-1464.



CAM test at Colgate-Palmolive. *Courtesy Colgate-Palmolive and American Fund for Alternatives to Animal Research.*

The CAM Test

A test developed by Dr. Joseph Leighton of the Medical College of Pennsylvania uses the chorioallantoic membrane (CAM) of the chicken egg. The membrane is a thin sheet of cells and blood vessels just under the shell. It functions as a respiratory organ for the chick embryo, but contains no nerve fibers and is in use by the chick for only about two weeks.

In the CAM test, a small amount of fluid is withdrawn from the egg so that part of the membrane falls away from the shell. A window is then cut in the shell with a dental tool and covered with clear tape. After an incubation period, a small ring is brought through the window and laid on top of the membrane. A drop of the substance to be tested is then placed into the ring. Later, the membrane is checked for changes in color, texture, blood vessel configuration and other variables.

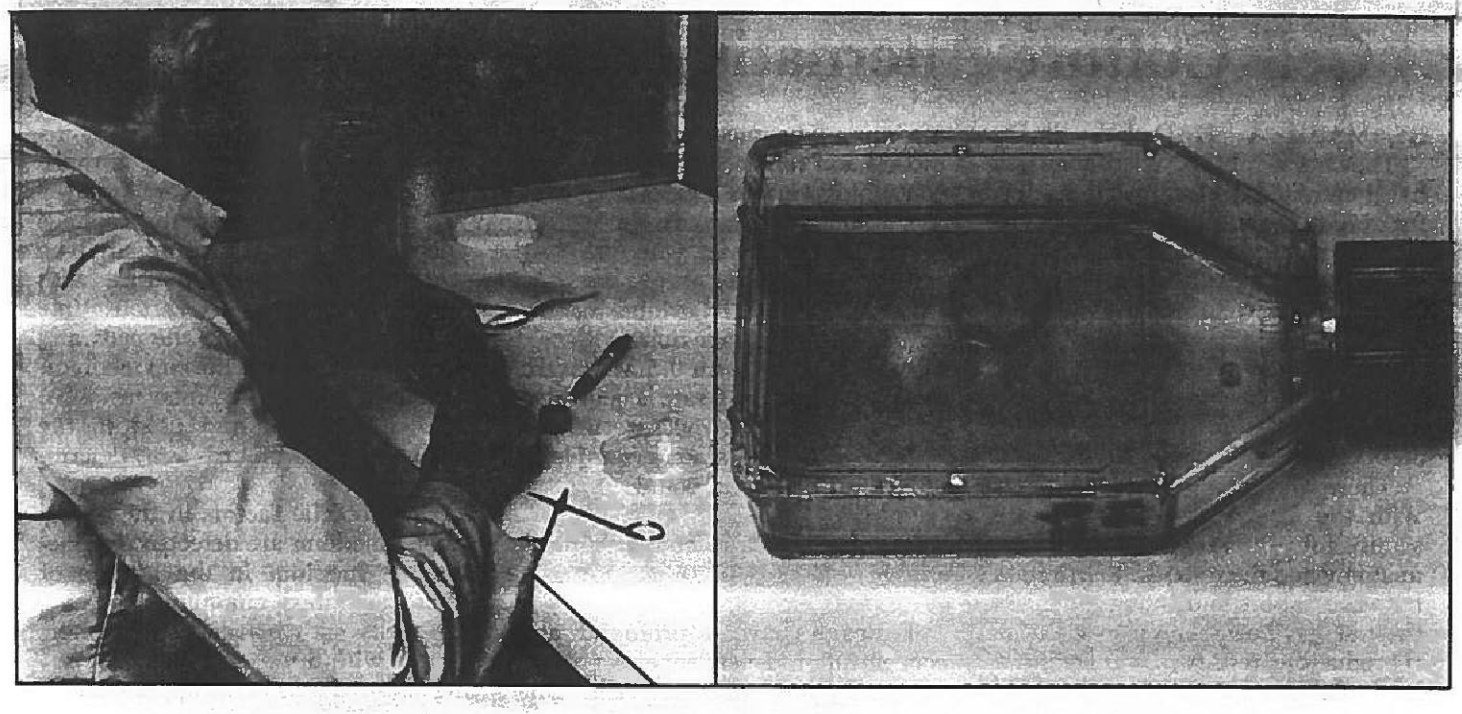
Tests comparing the CAM and the Draize have been favorable. Validation studies conducted by Colgate Palmolive showed a high correlation between results of the CAM test and the Draize on 12 test substances.

The Eytex System

The National Testing Corporation, 888 Research Drive, Palm Springs, CA 92262, has developed the Eytex system, a chemical method which can replace the Draize eye irritancy test. According to Christopher Kelly, Ph.D.:

"The Eytex system is particularly appropriate in several applications such as the screening of new ingredients for drugs, household and cosmetic products, the monitoring of production batches to assure safety, and the testing for product stability."

In late 1987 and early 1988, the system was tested using over 500 compounds and demonstrated excellent predictive capability for eye irritancy.



NOXELL'S ALTERNATIVE:

The Agarose Diffusion Method

The Noxell Corporation, makers of Noxzema, Cover Girl, and other cosmetic products has announced its acceptance of an alternative to the Draize test. In validation trials, the agarose diffusion method has compared very favorably to the Draize test, leading Noxell to adopt this test as an alternative to the Draize.

The agarose diffusion test has long been established for testing the safety of plastics and other synthetic materials in medical devices which come in contact with human tissues. Heart valves, intravenous lines, artificial joints and other products have been tested for irritancy with this method for about 25 years. The method was adapted for testing cosmetic products by Richard F. Wallin and R. Douglas Hume of North American Science Associates in Northwood, Ohio, and Edward M. Jackson of Noxell. The test is included in the U.S. Pharmacopeia, an indication of its official acceptance.

In the test, a thin layer of cells is placed along the bottom of a flask. Small amounts of the materials to be tested are placed on top of the cell layer. A thin cushion of agarose, a polysaccharide derivative of the sea plant agar, allows the test material to be held near the cells without crushing them. If the test material is an irritant, a zone of killed cells will be seen around it.

In their 1987 report, Wallin, Hume and Jackson found an 81 percent correlation between the agarose diffusion method and the Draize test for 16 products. The discrepancy was that the agarose method was slightly more sensitive than the Draize: two substances which passed the Draize showed some potential for danger on the agarose method. In addition, one chemical which failed the Draize appeared to be non-irritating on the agarose method.

In their next report, the authors tested 22 cosmetic products and found a 100 percent correlation with the Draize. The two tests agreed in every case. The researchers stated:

"The most impressive result...is the 100% correlation between in vivo and in vitro test results. The agarose diffusion test correctly identified every test material, whether it was postive or negative in previously conducted Draize tests."

Regarding the broad applicability of the test, they stated:

"To date, we have tested virtually every type of aqueous and nonaqueous cosmetic product formulation type by using actual finished cosmetic products as test materials. These products were emulsions (oil/water and water/oil; pigmented and nonpigmented), solutions, suspensions (both water-based and hydrocarbon-based), gels, and physical mixtures (both powder and wax mixtures)."

Specifically, they tested several mascaras, gel and paste oral hygiene products, powders, nail glaze and polish, lipstick, and facial cleansers.

The new method costs less than the Draize. The agarose diffusion test costs $50-$100 per product compared to $500-$700 per product for the Draize. The agarose diffusion test can be run in 24 hours, in contrast to the Draize, which must be read at 1, 2, and 3 days and again at days 7, 14, and 21 for products causing continuing irritation. Furthermore, the test can be run in any microbiology laboratory. It does not require tissue culture capabilities or other laboratory modifications or special technician training.

The test uses cells which originally came from mice. However, these cells are now available in commercially available cultured immortal cell lines, so no further animals are required.

References:

Wallin, R.F., Hume, R.D., Jackson, E.M., The Agarose diffusion method for ocular irritancy screening: cosmetic products, part I. J Toxicol.-Cut. & Ocular Toxicol. 6(4), 239-250, 1987.

Jackson, E.M., Hume, R.D., Wallin, R.F., The Agarose diffusion method for ocular irritancy screening: cosmetic products, part II. J. Toxicol.-Cut. & Ocular Toxicol. 7(3), 187-194, 1988.

Cell Culture Alternatives to the Draize Test

BY MARK A. HADLEY, Ph.D.

The Draize rabbit eye irritancy test has dominated ocular toxicity testing for over 40 years. The test attempts to predict the human ocular irritancy of a wide variety of substances designed for industrial, pharmaceutical, and cosmetic use.

In a typical Draize test, a test substance is introduced in one eye of each rabbit, and the response is observed at 24, 48, and 72 hours.[1]

There are a number of problems with the Draize test: 1) there are significant differences in both the anatomy and the response to irritation between rabbit and human eyes; 2) the test has been shown to yield irreproducible results[2]; 3) there have been sharp criticisms from animal welfare proponents[1].

The inadequacies of the Draize test have led to efforts in several laboratories to develop and validate alternatives. Because multiple mechanisms are involved in the process of ocular irritation[1] it is likely that a combination of in vitro tests will be required to effectively predict human ocular irritancy.[2]

Numerous in vitro tests have been developed to reduce or replace the Draize test[1]. A promising alternative is a series of cell culture assays designed by Shopsis, Borenfreund, Walberg, and Stark at the Rockefeller University. Each of these in vitro cytotoxicity assays has an excellent correlation coefficient when compared with the Draize test, and used together as a test battery, their accuracy would appear superior to the Draize test. The methodologies of these assays are briefly summarized below.

Uridine uptake inhibition assay[3]

Uridine uptake by cultured cells occurs through rapid membrane-transport and a subsequent rate-limiting phosphorylation step. Toxicants that damage cell membranes, reduce the levels of high-energy phosphorylated intermediates, or cause growth stasis will reduce the rate of uridine uptake. Cell membrane damage and metabolic disruption are the likely sequelae of exposure of tissue to irritants.

The procedure used in this assay is as follows: Balb/c 3T3 cells are cultured for 48 hours in a defined medium. The medium is then removed and replaced with a medium containing various concentrations of test agents. Four hours later, this medium is removed, the cells are washed with buffer three times, incubated with (3H) uridine for 15 minutes, washed three times with cold buffer and lysed with 0.5 M NaOH. One portion of the lysate is neutralized and counted to measure uridine uptake, and the second sample is analysed for protein count.

Cytological and colony inhibition assay[4]

Toxicants have a profound and concentration-dependent effect on the morphology of cultured cells. The changes include vacuolization, enlargement and flattening of the cells. Colony inhibition assays provide quantitative correlation of the cytological assay.

In this assay, cells are cultured for 24 hours at semi-confluence in 96-well plates. The medium is then removed and replaced with test media containing a range of concentrations of test agents. After a 24-hour incubation, cells are examined under a microscope and scored for morphological alteration. The highest concentration of test reagent which does not cause an observable morphological alteration in cells, as compared with controls, is called the highest tolerated dose (HTD).

Inhibition of colony formation is determined by placing cells at 250 cells/35mm dish. After a 24-hour incubation, the medium is replaced with test media containing various concentrations of toxicants, and the dishes are incubated for an additional 24 hours. The cells are then washed and allowed to grow in normal media for seven days. Colonies are fixed, counted and plotted as a percentage of untreated controls. In these studies the HTD corresponds to the amount of toxicant required to reduce colony formation by 50 percent.

Macrophage chemotaxis[5]

An important aspect of the inflammatory response is the chemotactic migration of macrophages to the site of inflammation. This migration, in response to substances released by cells which have been damaged by irritants, can be quantified in vitro using a chemotaxis chamber.

Cell culture media for macrophage chemotaxis testing are prepared by treating 3T3 cells in culture with potential irritants for various time periods, then washing the cells and refeeding them with normal medium. This medium (conditioned medium) is then collected and used in the macrophage chemotaxis assay described below.

Chemotactic factors in the conditioned medium are detected by placing the medium in the bottom of microchemotaxis chambers, covering the wells with polycarbonate filters (filters with 5 um pores), and layering cultured cells in the upper well for 4 hours. The membrane is then stained and the number of microphages that have migrated through the pores in response to the conditioned medium are counted.

There is clearly a need for toxicity testing methods which do not involve the use of large-scale animal studies. The need is based not only on the ethical and moral issues surrounding experimentation with animals, but also on the practical need for dependable, rapid, reproducible and inexpensive methods for determining cytotoxicity of chemical agents. One such method might be the development of specialized human cell lines. Toxicity tests using a human corneal cell hybridoma, "tailored" to maintain particular differentiated functions, should certainly yield results that are more physiologically relevant to the human eye than those obtained using animal cells.

References:

1. Swanston, D.W. Eye irritancy testing. *Animals and Alternatives in Toxicity Testing*. Academic Press, London, 1983, p. 337.

2. Shopsis, C., Borenfreund, E., Walberg, J., Stark, D.M. A battery of potential alternatives to the Draize test: uridine uptake inhibition, morphological cytotoxicity, macrophage chemotaxis, and exfoliative cytology. *Fd Chem Toxic* 23:259, 1985.

3. Shopsis, C., and Sathe, S. Uridine uptake inhibition as a cytotoxicity test: correlations with the Draize test. *Toxicology* 29:195, 1985.

4. Borenfreund, E., and Borrero, O. In vitro cytotoxicity assay: potential alternatives to the Draize ocular irritancy test. *Cell Biol Toxicol* 1:55, 1984.

5. Stark, D.M., Shopsis, C., Borenfreund, E., Walberg, J. Alternative approach to the Draize assay: chemotaxis, cytology, differentiation, and membrane transport studies. *Product Safety Evaluation*, ed. A.M. Goldberg, Mary Anne Liebert Inc., New York, 1983, p. 179.

Many large companies do not use animal tests. Among these are Nexxus, Paul Mitchell, Elizabeth Taylor, Tom's of Maine, and many other firms. Benetton recently stopped using animal tests for its cosmetics line.

Responsible Manufacturers

A number of companies have abandoned or have never used animal tests, choosing instead to use only ingredients whose safety is already known.

Nexxus and Paul Mitchell haircare products and Elizabeth Taylor's Passion perfume have all been marketed with no animal testing. Each of these companies uses formulations whose safety is known in advance, rendering animal tests unnecessary and promoting consumer safety as well.

Mitchell reports that the policy has enhanced his company's sales. Kate Chappell of Tom's of Maine, another manufacturer which never uses animal tests, said, "You can have a business that's socially responsible as well as successful. The FDA keeps lists of components which are recognized as safe—the GRAS lists, for 'Generally Recognized as Safe.' It's really unnecessary to keep testing and retesting."

If known safe ingredients are added together in new combinations, will there be dangerous interactions? Chappell responds, "Not only are the individual components well-accepted, but we make products from basic formulations which have a long history of safe use." Each ingredient is known to be safe, and the combinations are well-established as well.

An Ophthalmologist's Viewpoint

Marvin F. Kraushar, M.D., F.I.C.S. is Medical Director of the Retina Center of New Jersey, Clinical Professor of Ophthalmology at the University of Medicine and Dentistry of New Jersey, and Clinical Associate Professor of Ophthalmology at Mount Sinai Medical School.

As an ophthalmologist, I routinely prescribe eyedrops. It is important that these products be safe for use in the eye. However, I have never considered nor have I ever inquired into the results of Draize testing of a particular preparation prior to prescribing for my patients. The Draize test is a poor scientific model and has little redeeming application to the development of preparations intended for use in the human eye, because animal results cannot be predictably extrapolated to humans. For the same reason, it is equally inappropriate to use the resul of Draize testing for household products or for cosmetics which may reach the eye accidentally.

I have heard researchers suggest that banning Draize testing will be the first step in a domino process whereby all animal research is eventually banned. This argument is neither germane nor accurate. In fact, the Draize test gives a public relations "black eye" to animal research in general. Rationalization of the Draize test by saying it is "better than nothing" is worth no more than the test itself. The Draize test has not saved one human life and it probably never will.

Marvin F. Kraushar, M.D.

Draize Test is Done to Limit Liability

Not to Insure Safety

Many have asked why the Draize test is done at all. Obviously, many companies market products which have been shown to be irritants in the Draize test. Other companies never use the Draize and have no difficulty marketing products. It is clear that the Draize is used for reasons related to legal liability rather than scientific testing.

In 1968, the court case of Harris vs Belton illustrated the use of testing from a liability standpoint. The plaintiff was a black woman who used a skin-lightening cream. Artra Skin Tone Cream promised a "lighter, lovelier skin beauty for you...a complexion fresh and bright as springtime."

Unfortunately, the product caused the plaintiff's skin to be burned, scarred, and darkened. She sued for damages. A small but significant number of other users of the product also had adverse reactions.

The court ruled that the law does not prohibit the manufacture and sale of dangerous products, but simply provides that the customer be warned of potential adverse effects. The Artra product was labeled as potentially damaging for some users, and, on that basis, the court ruled that the company was not responsible for damages to the plaintiff.

The Draize appears to be used mainly as a method to decide when to label. Obviously, all cosmetic and household products should be appropriately labeled based on the knowledge of the potential effects of their ingredients. Draize testing is certainly not necessary in order to establish potential risk.

It appears that Draize testing is part of the process by which manufacturers avoid legal liability for damages caused by their products. It is not a medical or scientific necessity.

INTERPRETING THE DRAIZE TEST

When does a Draize test indicate potential danger? In a typical test, six rabbits are used. If two or more of the rabbits show eye irritation, the test substance is considered an irritant. However, if only one of the six shows signs of irritation, the substance is considered non-irritating.

The problems with such a standard are obvious: If a substance were to injure one out of every six people using a product, it is obviously not safe. Nonetheless, passing a Draize test simply means that no more than one out of six rabbits showed signs of injury.

Clairol Shows That Draize Tests Do Not Keep Dangerous Chemicals Off Market

New data from the cosmetics industry show that safety is not the reason that the Draize test is used. If it were, then products that were Draize-tested and appeared to be unsafe would not be marketed. But the test is not used that way. Numerous products fail the test and are marketed anyway, as Clairol recently revealed.

In response to new federal guidelines, Clairol recently released information on the safety of its products to beauticians who use them regularly. Many are clearly eye irritants. Some can cause permanent eye damage.

Clairol's notice regarding its permanent (oxidation) hair colors reads as follows: "CAUTION. Eye irritants. When oxidation haircolors are mixed with developers (hydrogen peroxide), the mixture may cause severe irritation and possible permanent eye injury."

The notice for Clairol's semipermanent hair color simply states: "CAUTION, eye irritants."

Clairol's bleach powders: "CAUTION. Eye irritant. When the bleach powders are mixed with hydrogen peroxide, the mixture may cause severe irritation and possible permanent eye injury...Flush with plenty of water immediately. Remove contact lenses if used. Get medical attention IMMEDIATELY."

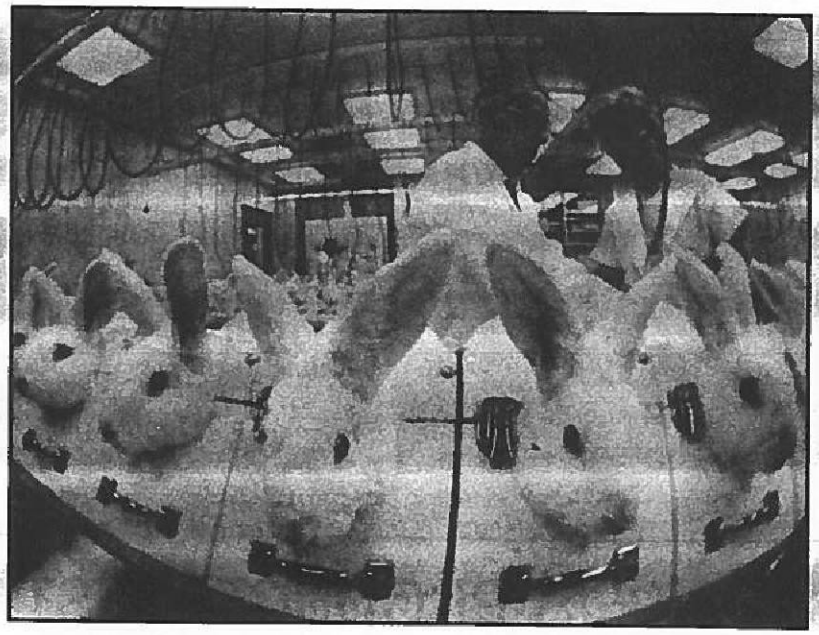
Clairol's Metalex hair dye remover is called an "eye irritant" and Clairol's aerosol hair sprays are described as "potential eye irritants."

The Draize test is not used to determine how best to treat the eye injuries that result. The animals are simply killed after the test, or are used in subsequent tests.

One must ask, if all these products were Draize-tested, and all were found to be irritants, and all were marketed anyway, what is the purpose of the Draize test? Labeling is an insufficient reason for animal testing. All such products should be kept out of the eye and should be labeled appropriately. A similar general-purpose label can be found on over-the-counter medications: "Keep this and all medications out of the reach of children." Animal tests are not required for this purpose.

Rabbit Test Misses Dangerous Chemicals

In 1948, the Draize test was four years old. In that year, researchers found that a concentrated solution of histamine phosphate caused only a slight and transient reaction in the rabbit eye, which failed to predict the harsh reaction of even much more dilute solutions in the human eye. A 1:200 dilution caused only a slight and brief reaction in the rabbit eye, while even a 1:50,000 dilution had a potent effect in the human eye. This was one of the early failures of the Draize test. But there have been many more.



In the Draize test, the rabbit's lower eyelid is pulled forward and the substance to be tested is placed in the rabbit's eye. The rabbit may remain in a stock for the duration of the test, which typically lasts two to three days. Products tested can range from toothpaste to floor wax to detergent to mascara—in sort, any cosmetic or household product.

0.5% selenium sulfide caused no reaction in the Draize test. But in humans it caused irritation and inflammation of the eye. 2.5% cresol caused only a mild reaction in rabbits, but in the human can cause swelling of the eye, opacification of the cornea, and congestion of the conjunctivae. Certain detergents caused no reactions in the rabbit eye, even at high concentrations. In humans, these same detergents caused pain and altered vision. A male hairdressing formulation passed the Draize test, only to cause numerous reports of irritation to the human eye. A 5% soap solution produced almost no effect in rabbits, but caused corneal damage in humans. Ozone at levels of 2-37 ppm were not injurious to rabbits but did cause irritation in the human eye.

Why so many differences between the rabbit test and human experience? There are many structural differences between the rabbit eye and the human eye. The pH of human tears (7.1 to 7.3) is much lower than that of rabbits (8.2). A one-point difference on the pH scale means a ten-fold difference in the acidity of tears. The rabbit's cornea is about 30 percent thinner than the human cornea. The "third eyelid" (nictitating membrane) which rabbits have (and humans do not) may change the animal's response to substances by clearing them away, or perhaps by trapping them against the cornea. Rabbits blink and tear at rates very different from the human. All these affect the way different species react to substances.

Reference:
McDonald, T.O.; Shadduck, J.A.: Eye Irritation, in Advances in Modern Toxicology, vol. 4, dermatotoxicology and pharmacology. Marzulli, F.N. and Maibach, H.I., Eds. Washington: Hemisphere Publishing Corp., 1977.

Ruy Tchao, Ph.D. On Alternatives to the Draize Eye Irritancy Test

As an Associate Professor of Pathology at the Medical College of Pennsylvania and a Visiting Professor at the Philadelphia College of Pharmacy and Science in the Department of Pharmacology and Toxicology, my research is in the area of developing alternatives to the Draize Test. I would like to give my answer to the three most frequently asked questions:

First, does the Food and Drug Administration (FDA) require animal tests such as the Draize test for consumer household products?

The FDA does not require any specific test for household products. According to Dr. Gary Flamm, Director of Toxicology, Food and Drug Administration, companies can submit test protocols for approval by the FDA.

Second, are there alternatives to the Draize eye irritancy test?

There are many alternatives to the Draize test. Recently the Soap and Detergent Association organized a panel of coded compounds to be tested by several alternative methods. The results showed that at least three methods ranked these compounds in the same order as the Draize test. One of the methods was the CAM assay developed by Dr. Joseph Leighton and myself. Two laboratories, at the Medical College of Pennsylvania and Colgate Palmolive Co., using this assay independently, obtained similar results on this series of compounds. Therefore, by using batteries of alternatives, the Draize test can be replaced.

Third, are the alternatives as safe as the Draize?

The Draize test itself has not been a good indicator of product safety in humans. The alternatives have the potential to yield much more information about a product than can the Draize test; therefore these alternatives are more useful to industries than the Draize test. The validation of the alternatives to the Draize test is a continuous process. As more compounds are tested in the alternative methods, one would learn the capabilities and the limits of each of the tests. As technology advances, new alternative methods will be developed, and the existing methods will be modified and improved.

Dr. Tchao's work has contributed to the development of the CAM test, in which chicken eggs substitute for the Draize test. In addition, Dr. Tchao has shown that toxicity of substances can be assessed by applying them to cell cultures and checking for changes in the cells' appearance and their ability to adhere to one another. He has shown that these methods correlate well with Draize tests.

Doctors Call for Ban on Draize

"As an ophthalmologist, I have a particular interest in the product-testing issue, as the Draize test on rabbit eyes is one of the major testing methods used. This test is n very reliable. In view of the fact that more mode testing methods are available, such as the chorioallantoi embrane test and cell culture methods, the Draize test and LD50 test should be considered obsolete."

Jay B. Lavine, M.D.
Phoenix, Arizona

"The results of these tests cannot be used to predict toxicity or to guide therapy in human exposure. As a board-certified emergency medicine physician with over 17 years of experience in the treatment of accidental poisonings and toxic exposures, I know of no instance in which an emergency physician has used Draize test data to aid in the management of an eye injury. I have never used results from animal tests to manage accidental poisonings. Emergency physicians rely on case reports, clinical experience and experimental data from clinical trials in humans when determining the optimal course of treatment for their patients."

Christopher D. Smith, M.D.
Long Beach, California

"Results of animal tests are not transferrable between species, and therefore, cannot guarantee product safety for humans. Data from animal tests are never used to treat cases of accidental poisonings, because products that are not toxic to animals can be toxic to humans and vice versa. In reality, these tests do not provide protection for consumers from unsafe products, but rather are used to protect corporations from legal liability."

Herbert Gundersheimer, M.D.
Baltimore, Maryland

"My evaluation of the scientific literature has led me to the opinion that these tests have outlived their usefulness and that more humane and scientifically accepted alternatives are available."

Kenneth Solomon, M.D.
Baltimore, Maryland

"I have been a physician for 29 years and have never in that time known the Draize test or the LD50 test to have any clinical usefulness or relevance. They are very crude and extremely cruel tests, and their performance on household products and cosmetics should be prohibited by law."

Phyllis A. Huene, M.D.
Annandale, Virginia

"As a physician concerned both with the safety of my patients and with methods of testing products commonly found in households, I support federal legislation to eliminate the Draize eye irritancy and LD50 tests from product-safety testing practices. I have long been familiar with the Draize and LD50 tests and can say with certainty that these tests do not promote consumer safety. Moreover, the data produced by these tests do not keep harmful products from being sold and are most certainly not helpful once a poisoning or exposure needs to be medically treated."

Ellen Michael, M.D.
Beverly Shores, Indiana

"Legislation to modernize consumer product testing methods is long overdue. Current safety testing procedures on animals are not only out-of-date and extremely cruel, but they are also inadequate to protect consumers from unsafe products."

Leslie Iffy, M.D.
Summit, New Jersey

"As members of the medical community, we are well aware of the advanced technology available in numerous in-vitro testing techniques.... When alternatives are alrea y well developed and widely available, how can we justify brutally cruel tests such as the Draize and the anachronistic LD50?"

Mark Silidker, M.D. and
Helen Silidker, R.N.
W. Orange, New Jersey

"Viable alternatives to animal testing are available.... In fifteen years of medical practice, I have never used the results of these tests to diagnose or treat patients. I find no justification for the continued use of these cruel tests."

Walter Nowak, M.D.
Worcester, Massachusetts

"As an ophthalmologist, I find the Draize test particularly outdated. It has little relevancy to human sensitivity to unknown products. It is cruel and wasteful of animal lives. Less expensive alternatives are already available."

James R. Lee, M.D.
Winthrop, Massachusetts

"As a board-certified emergency medicine physician who has been practicing for ten years, I have never found data from acute toxicity or eye irritancy tests on animals to be useful in treating patients. I would not rely on these data to treat patients, and I know of no physician who does. Legislation which prohibits these obsolete and irrelevant test procedures can play a very positive role in stimulating the use of modern tests which are better able to meet the needs of clinicians and to protect consumers."

Neill S. Barber, M.D.
Marshfield Hills, Massachusetts

"The Draize test and the LD50 acute toxicity test are as useless to the protection and treatment of humans as they are barbaric. They should be eliminated and replaced with alternative tests which are already in existence."

Beverly Greenwold, M.D.
Newtonville, Massachusetts

"...There is, to my knowledge, no area of science outside of commercial toxicology in which so many important decisions are based on data derived from tests which are so crude and imprecise.... The Draize and LD50 tests only provide the public with the illusion of safety. They quite simply cannot do the job they are supposed to do, and banning them, far from endangering public safety, would actually promote it."

Carlo Buonomo, M.D.
Baltimore, Maryland

Draize Test is Unreliable; from page 1

Unreliability

The Draize has made many serious errors. These are termed "false negatives," that is, substances that appear safe in the Draize test, only to prove dangerous in humans.

Several antihistimine drugs were classified as nonirritating in the Draize test, only to prove so painful in the human eye that they were unusable. Certain detergents showed no apparent effect in the Draize test, but have caused pain and blurred vision in people. Concentrations of ozone that have no effect on the rabbit eye cause significant irritation to the human eye. Numerous other chemicals have also passed the rabbit test, only to injure humans. [2]

A hairdressing product for men appeared to be safe in Draize testing, but in humans led to numerous complaints of eye irritation. In particular, visual blurring was a common complaint. The problem was resolved by altering the product to a more sensible formulation that omitted the offending ingredient. Companies which use only formulations with established safety avoid the problems caused by false negatives in animal testing. [3]

Even Draize noted problems with his tests. Sometimes chemicals had quite different effects on humans than the test results on animals. "The correlation between animals and man is not complete since we find that there is an occasional reversal."

Carrol S. Weil and Robert A. Scala (1971) of Carnegie-Mellon University and Esso Research and Engineering Company were concerned about the reliability of the test. They distributed test substances to 24 different laboratories for Draize testing. Government, consulting, food, chemical, and cosmetic and toiletries labs participated. Wide variations in test results were found:

"Certain laboratories consistently recorded unusually severe scores...for the materials tested.... Other laboratories reported consistently nonirritating scores... Certain materials were rated as the most irritating tested by some laboratories and, contrariwise, as the least irritating by others.... Thus, the tests which have been used for over 20 years to decide the degree of eye or skin irritation produce quite variable results among the various laboratories as well as within certain laboratories. To use these tests, or minor variations of them, to obtain consistency in classifying the material as an eye or skin irritant or nonirritant, therefore, is not deemed practical."

> *The Draize has made many serious errors. "The correlation between animals and man is not complete since we find that there is an occasional reversal."*
>
> John H. Draize

Why were the test results so different? *"The primary reason for differences was in the reading of reactions, as opposed to variation in interpretation and performance of the procedures. The latter, however, was also a component of the interlaboratory variability."*

Unless intensive and frequent instruction of lab personnel was begun, the authors wrote:

"...it is suggested that the rabbit eye and skin procedures currently recommended by the Federal agencies for use in delineation of irritancy of materials should not be recommended as standard procedures in any new regulations." [4]

References:

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Kaufman, from page 1

The rabbit's threshold of pain in the eye is much higher than that of humans, so irritating substances are not washed away as readily.

Unlike people, rabbits have a nictitating membrane (a third eyelid), which has an uncertain effect on a chemical's contact with the eye.

Humans develop corneal epithelial vacuoles in response to some toxic substances, but rabbits do not.

Bowman's membrane, important for the structural integrity of the eye, is six times thicker in the human cornea.

The cornea represents 25 percent of the rabbit eye surface, but only 7 percent of the surface area in man.

Thus, Dr. W. Morton Grant, author of Toxicology of the Eye[1], writes of the Draize test:

"For the purpose of deciding whether a substance is safe enough for human beings to use in their shampoos, cosmetics, and a great variety of household items...the testing problem is difficult, and is yet to be satisfactorily solved. One difficulty is in suspected differences between human beings and animals in the response of their eyes to contact with the chemicals."

On scientific grounds, we should abandon the outdated and inadequate test.

Reference:

1. W. Morton Grant, *Toxicology of the Eye*, 3rd Ed. (Springfield, IL: Chas C. Thomas, Publ.) 1986.