

# The Slow Path to Progress: Recent Public Policy the Use of ANIMAL for TESTING

By Sara Amundson

## Moving Mountains

For more than 50 years, primates, dogs, rabbits, rats, mice, and other species have been used to assess the safety and efficacy of certain chemicals and products used in our homes and environment. It will take nothing less than revolutionary changes in the test methods required to end the use of animals in toxicity testing.

We know that the predictivity of animal methods, such as the LD-50 — in which substances are force-fed to groups of animals numbering from 50 to 200 for each test, and the results are based on the point at which 50 percent of them die — is about as realistic as flipping a coin. We also know that existing animal-based test methods have not been scientifically validated. Validation is the relevance, reliability, and reproducibility of a test method used to predict a certain biological outcome. Now, however, the field of toxicology is faced with a new paradigm — one that is predicated on good science, challenging the wholesale use of animals and the inertia allowing the status quo.

Part of that paradigm is the continuing reluctance of federal regulators to embrace non-animal, alternative tests as good science. As long as regulators do not approve the non-animal methods, the industries will not use

them. While such tests are often time efficient, cheaper to administer in the long-term, and at least as predictive as their animal-based counterparts, these arguments will not sway an industry with one foot in with federal regulators and the other in with its lawyers.

## Using Industry Arguments to Win

Between the late 1980s and '90s, California State Assemblyman Jack O'Connell bravely took on the cosmetics and household products industries. He introduced a bill that would have banned the use of rabbits' skin and eyes in irritation tests on cosmetics and household products. The bill overwhelmingly passed three times, only to be vetoed by then California Governors George Deukmejian and Pete Wilson. The opposition from the regulated industries and federal regulators was that "there are no validated alternatives to replace the Draize."

Yet, the regulated industries have insisted that where there are validated alternatives, they will use them. This, however, is not the case. The institutionalized culture around animal testing has prevailed. Rich Ulmer, president of In Vitro International, which manufactures a non-animal test for skin corrosivity called Corrositex, states, "It is our collective observation, based on nearly

15 years of offering non-animal testing methods to industry, that even after validation has been removed as a barrier to using such methods, there is still quite a bit of reluctance within industry to using a 'new' method."

In 2000, Senator Jack O'Connell, sponsored a new bill (S.B. 2082) that stated where there are validated alternatives approved by federal regulators, the industry must use them. The bill covers a variety of substances, including industrial chemicals, cosmetics, household products, and pesticides. Despite massive opposition, the bill passed, and in September, 2000, Governor Gray Davis signed it into law. Although the new statute is a minuscule step in ending the use of animals in safety and efficacy testing, it sets a precedent for industry.

## Destroying the Double Standard

In December, 2000, President Clinton signed Public Law 106-545, the ICCVAM (Interagency Coordinating Committee for the Validation of Alternative Methods) Authorization Act. The law is another chip at the inertia associated with animal testing. It codifies ICCVAM and empowers it to require federal agencies to accept validated alternative test methods. The bill also destroys the

# Changes in ALS

“validation double standard” that requires non-animal alternatives to meet a high standard of validation, while new and revised animal tests are often simply incorporated into the federal regulatory mandates after a cursory review. The new law requires that for the first time all methods be validated, a standard most existing animal-based tests cannot meet.

To date, several alternative test methods have been assessed by the ICCVAM. Some of the alternative test methods are reduction and/or refinement methods, but the ICCVAM has also considered at least one actual replacement method. Federal regulatory agencies have begun to adopt ICCVAM recommendations on alternative tests. Unfortunately, some of these recommendations are often still conditional on the use of a single animal in a test to prohibit false test results. Non-animal, alternative tests are often far more sensitive than their counterparts, leading scientists to be concerned about accurate prediction of the endpoint to be measured.

Animal advocates have been both cautiously optimistic and sincerely concerned about the laborious path to permanently replace the LD-50 test. Significant modifications in the existing animal tests have reduced the numbers

of animals used to three or five for each chemical assessed, and delete death as the endpoint measured. However, the statistical relevance of the traditional LD-50 and its alternative counterparts, because of the reliance on interspecies extrapolation of the data, continues to be questioned by animal advocates. The most promising non-animal, alternative test method for measuring this endpoint is a human cell line that can directly measure death in actual human cells.

## Our Federal Taxpayer Dollars at Work for Animals

While 2000 was a banner year for new federal and state laws to promote the integration of alternative test methods in regulations and with the regulated industry, 2001 demonstrated congressional commitment to funding the science. For the first time ever, the U.S. Congress earmarked \$4 million in the Environmental Protection Agency's (EPA) budget for the research, development and validation of non-animal, alternative test methods. In addition, Congress acknowledged the importance of ICCVAM activities by specifically addressing it in the Labor, Health and Human Services and Education Appropriations bill. This is the first time animal advocates have seen their taxpayer dollars at work in the United

States to actually fund the necessary science to replace animal tests.

## Fourth World Congress on the Use of Animals in the Life Sciences

Converging on New Orleans in August were more than 400 scientists, international and federal regulators, and animal protection advocates, intent on continuing the dialogue on the status of alternatives to using animals in research, testing and education. While the dearth of federal regulators from the United States was of particular note, animal advocates made significant contributions to the scientific presentations and subsequent discussions. Of consequence are the difficulties we are having in ensuring that the EPA and the regulated chemical industry abide by the “thoughtful toxicology” required by the October 14, 1999, agreement for the High Production Volume Program struck with animal protection advocates. In several cases, companies sponsoring chemicals that are well-characterized are submitting plans calling for additional, unnecessary testing. In addition, a round of presentations and discussions directly addressed the concerns animal advocates and scientists have regarding the proposed Endocrine Disruptor Screening Program.

One prominent announcement made at the close of the World Congress is the ICCVAM recommendation that an additional three alternative tests are approved for assessing the corrosivity endpoint. They are Episkin, a human collagen assay; EpiDerm, a human skin cell-based test; and a Rat Skin TER assay, which consists of pieces of rat skin. Corrositex, is a non-animal test, was originally approved in 1993 by the Department of Transportation and subsequently recommended by ICCVAM to other federal agencies that measure the endpoint.

Unfortunately, a false negative result with the three newly-approved alternatives still requires the use of an animal as a back-up method. This strategy has infuriated animal protection advocates.

An industry toxicologist once told me that the only way some companies will embrace non-

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households. As a consumer, every time you purchase a shampoo or laundry soap you have the opportunity to make a choice for animals. Whether it's laundry detergent from Seventh Generation or a basket of bath products from The Body Shop, we urge you to purchase gifts with compassion during this holiday season.

For further information on the Corporate Standard and International Logo, please contact [www.leapingbunny.org](http://www.leapingbunny.org) or (888) 546-CCIC.



Photo credit: Trevor Pearson

animal test methods is if they are forced to – and state and federal laws

can accomplish this. However, some

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## Finally! All Chimpanzees and Monkeys from Now-Defunct Coulston Facility Get to Go to Sanctuary.

By Liz Clancy Lyons

Animal advocates are celebrating the news that The Coulston Foundation, the country's most notorious primate laboratory, closed its doors in September and retired all 266 of its chimpanzees to The Center for Captive Chimpanzee Care. The unprecedented move comes after more than a decade of scathing government reports, declining business and pressure from DDAL and other animal advocates. DDAL and its members have long supported The Center, a Florida based sanctuary renown for its innovative approach to chimpanzee care and rehabilitation.

Like most of the sanctuary's original residents, 16 of the 266 chimpanzees were previously owned by the Air Force. DDAL played a crucial role in helping The Center obtain custody of its original inhabitants through a multi-year battle that started when the government announced it would give its 144-strong chimpanzee colony either to a researcher or sanctuary. Despite Congressional concern



Photo Credit: Carole Noon

over the laboratory's animal care record and failing financial wellbeing, the Air Force awarded most of its chimpanzees to The Coulston Foundation. Undaunted, The Center and DDAL, with the *pro bono* services of Washington, D.C. law firm Spriggs & Hollingsworth, took the battle over the "forgotten veterans" (as they became known) to the courts. Ultimately, The Center obtained 21 of the chimpanzees given to Coulston. Now it has taken custody of the rest, plus dozens more in Coulston's hands when the lab went under. However, until sufficient funds can be raised to enlarge the Florida sanctuary, the chimpanzees and monkeys will stay at the old Coulston facilities, albeit under much improved care.

DDAL has committed more than \$100,000 in funds and resources to The Center's efforts. The sanctuary's primary funder, The Arcus Foundation, has issued a challenge grant to match any donation made through 2003. Donations should be sent to CCCC, P.O. Box 12220 Ft. Pierce, FL 34979. Or donate on-line via The Center's website at [www.savethechimps.org](http://www.savethechimps.org).

Please watch for more about The Center and its newest residents in an upcoming issue of the *Animal Guardian*.



we get letters

I read the article about the boy with the BB gun and a reader's response with guilt over his past. I, too, am haunted by the days as an early teen-ager, that I randomly, and with disregard for animal life, shot sparrows at a friend's family farm during the summer. Their privet hedges in Iowa were visited by hundreds of sparrows each day and we took the opportunity to use them as target practice. There is never a day that goes by that I am not haunted by my stupidity. My father was an avid hunter who I accompanied on quail, pheasant, duck, squirrel and dove hunting trips. The result was, at least, that whatever was killed was used for food. This does not excuse the slaughters but at least puts it into perspective. We ate what we killed. I stopped hunting with my father after an incident in a duck blind when a duck was winged and a member of the 'party' snapped its neck in order to kill it.

To say that I am remorseful would be an understatement. How very sorry I am for the wanton slaughter of creatures I did as a young man. No one told me otherwise. Regretfully.

Curtis Haugeborg  
Sacramento, CA

*Doris Day, continued from page 2*

Khouri for her courage and independence. I know working in the entertainment industry is not easy, and being a woman in Hollywood creates even more challenges. Her commitment to animal welfare in the big stakes world of motion pictures is a great example for today's and tomorrow's filmmakers, and demonstrates, once again, what one person can do.

Callie's protection of elephants hit home with me because my own awareness and actions on behalf of animal welfare were accelerated with my own "Hollywood story."

The year was 1955, and I was hesitant about the next proposed project. Alfred Hitchcock had long been promising that he and I would team for a film called, "The Man Who Knew Too Much." Hitchcock was going to film most of the picture in London and Marrakesh, Morocco, and I had never been outside of the United States. Between leaving my two dogs and having to fly, I was reluctant to accept the role. I was also not too excited about what I thought was the "kiddie song" written for me for the film, "Que Sera, Sera." I did decide to make the film and sing the song, and many of you have seen and heard the results.

I had a difficult time in Marrakesh. I had never imagined such poverty and starvation existed. It was clear that a few rich people had everything they needed; and the

rest – and notably the animals – had nothing. I had never seen such pitiful creatures.

It was dire, and prompted me to do something extreme. It was one of the only times during my years in Hollywood that I "pulled rank."

I announced that I would not appear in any scenes with animals unless they were properly fed. I wouldn't get in the keop and allow the horses to pull me unless they were fed. I was very clear about what had to be done.

To my relief, the company set up a feeding station where all the goats, lambs, horses, cows, dogs, cats, burros and other animals were brought to be fed. I couldn't feed the whole country; but, at least, I made sure we had succeeded in helping the animals used in the picture by the time we left Marrakesh.

Ironically, my co-star in "The Man Who Knew Too Much," also became known for his association with animals. The actor, of course, was Jimmy Stewart, and his role in "Harvey" is one of the most-loved and best-remembered in film history. Always a pal, he even appeared at a press conference in Hollywood in the early 1990s to show support for rabbits and the end to some of the horrible product tests done on bunnies.

To Callie Khouri, I say, "Thank you." It wasn't easy for me in 1955, and I know it couldn't have been easy in 2001, to take such a stand for the animals.

It's a good lesson for other filmmakers that it can be done. I can't think of anyone who would choose animals suffering over staying 100 percent true to a novel. Hollywood, are you listening? 🐾

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public health advocates, environmentalists, and toxicologists insist that animal tests are still simply "the best we have." Sound science demands that, as with every other scientific discipline, significant advances in toxicology must create a new paradigm. And animal activists must insist on good science that involves radical changes in the field of toxicology in order to end the use of animals in safety and efficacy testing.

Sara Amundson is the Deputy Director and Legislative Director for the Doris Day Animal League. She led the lobbying efforts to make Corrositex the first non-animal test method accepted by the Federal Government, for passage of the ICCVAM Authorization Act and, with Western Regional Director Beverlee McGrath, the California statute. Sara also lobbied to secure the first congressional earmark in the EPA's budget for non-animal, alternative tests. Sections of this article were originally printed in The Animals' Agenda and A Primer on Animal Rights: Leading Experts Write About Animal Cruelty and Exploitation. 🐾