Changing Laws to Change Toxicology

By Sara Amundson,
Deputy Director and Legislative Director,
Doris Day Animal League

Chipping away at the many uses of animals in toxicological testing is daunting. 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 used to assess skin corrosivity, skin irritation, ocular irritation, and a host of other endpoints to end the use of animals in toxicity testing.

We know that the predictability of animal methods, such as the Lethal Dose-50 (LD50)—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 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 faster to run, cheaper to administer in the long run, 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 Senator 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, such as the Draize eye and skin irritancy tests, commonly used protocols to determine product safety. The bill overwhelmingly passed three times, only to be vetoed. 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 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 O'Connell's new bill (S.B. 2082) stated that where there are validated alternatives approved by federal regulators, 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 Governor Gray Davis signed it into law. Although the new statute is a miniscule step in ending the use of animals in safety and efficacy testing, it sets a precedent for industry.

Now, Assemblyman Pete Grannis (R-NY) has introduced the same legislation in New York, A. 6254. The bill has the support of animal protection organizations and the Soap and Detergent Association. For updated information, please check the Doris Day Animal League website at www.ddal.org.

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 bureaucratic and industry 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 '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 ICCVAM Authorization Act requires for the first time that all methods be validated, a standard that most existing animal-based tests cannot meet.

To date, several alternative test methods have been assessed by the ICCVAM and its peer review committees. 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, through their recommendations, requirements, or regulations, alternatives for measuring allergic contact dermatitis and skin corrosivity on the basis of ICCVAM recommendations.

Animal advocates are also cautiously optimistic about the path to permanently replace the LD50 test. Significant modifications in the existing animal tests have reduced the numbers of animals used to three or five for each chemical assessed and deleted death as the endpoint measured. However, the statistical relevance of the traditional LD50 and its alternative counterparts, because of the continued 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. It is imperative that animal advocates move the ICCVAM and individual federal agencies toward funding and supporting any steps to be taken to integrate validated, non-animal, alternative test methods into federal requirements and regulations.

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. The U.S. Congress, for the first time ever, earmarked $4 million in the Environmental Protection Agency's Office of Research and Development 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 the agency in the Labor, Health, and Human Services and Education Appropriations bill. This is the first opportunity animal advocates in the United States have had to see their taxpayer dollars at work and actually funding the necessary science to replace animal tests.

An industry toxicologist once told me that the only way some companies will embrace non-animal test methods is if they are forced to—and state and federal laws can accomplish this. After efforts in the 1980s to ban the Draize test in several states, fewer cosmetics and household product companies still use this horrific test. The intense focus by animal activists on testing for vanity products prompted an international dialogue among activists, toxicologists, federal regulators, and manufacturers to expand the research funding, validation, and regulatory acceptance of non-animal alternative tests. However, some public health advocates, environmentalists, and toxicologists insist that animal tests are 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 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 on both the ICCVAM Authorization Act and the California statute. Sara also crafted language and lobbied to secure the first Congressional earmark in the Environmental Protection Agency's budget for research, development, and validation of non-animal, alternative test methods.

This article was published in the Animals' Agenda *in an earlier format.*