

Testing for Toxicity: Trends in Animal Testing Regulation

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Environmental laws in the United States have long sought to protect human health and the natural environment.¹ These laws tend to focus not only on the preservation and allocation of resources, but also on the ethical and moral concerns involved in protecting health and the use of valuable resources.² Animal testing has been routinely used for more than sixty years to ensure that cosmetic products pose no threat to this ideal of human health.³ Though the FDA does not require cosmetic premarket testing and approval, it is up to the cosmetic company to guarantee product safety, or else label each product with a warning.⁴ There are obvious ethical concerns with regard to how animals used for the testing of potentially toxic chemicals are treated. The treatment of these animals has historically received little legislative attention.⁵ However, recent trends across the globe and at the state level have shown a mounting concern for animal welfare, along with a movement toward legislative enforcement of alternative testing methods.⁶

The Animal Welfare Act of 1966 still stands as the only federal law prescribing the minimum standards for the use and treatment of research animals.⁷ The definition of “animal” within the Act explicitly removes birds, rats, mice, and cold-blooded animals

¹ *About EPA*, U.S. ENVTL. PROT. AGENCY, <http://www.epa.gov/aboutepa/index.html> (last updated Oct. 29, 2010).

² *Id.*

³ Azalea P. Rosholt, *An Unnecessary Measure to a Necessary End—Possible Legal Challenges to Directive*, 60 FOOD & DRUG L.J. 421, 421 (2005).

⁴ *FDA Authority Over Cosmetics*, U.S. DEP'T OF HEALTH & HUMAN SERVS. (March 3, 2005), <http://www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/ucm074162.htm>.

⁵ *Animal Welfare Act*, U.S. DEP'T OF AGRIC., http://awic.nal.usda.gov/nal_display/index.php?info_center=3&tax_level=3&tax_subject=182&topic_id=1118&level3_id=6735&level4_id=0&level5_id=0&placement_default=0 (last modified Nov. 4, 2010).

⁶ Rosholt, *supra* note 3, at 421-422.

⁷ U.S. DEP'T OF AGRIC., *supra* note 5.

from its protection.⁸ These animals account for over ninety-five percent of the animals used for scientific research and testing.⁹ For the small number of animals that are protected under the Act, the Act holds that they are to receive, “humane care and treatment.”¹⁰ While the Act fails to specify exactly what this humane care and treatment is, it does specify that humane care and treatment does not apply to the procedures used for animal testing.¹¹ Many believe that differences in human and animal physiology cause the validity of such testing to be questionable, rendering pointless the thousands of animal lives given in the pursuit of knowledge for human safety.¹² Recent efforts by the United States and the European Union seem to acknowledge this problem.¹³

In 2003, the European Union enacted the seventh amendment to the Cosmetics Directive.¹⁴ The enactment came into full force in 2009, holding that the makers of cosmetic products in European Union member states will no longer be able to test for toxicity using animal research, where there are other validated methods of testing.¹⁵ For those methods of testing in which an alternative method is yet to be determined, the deadline is extended to 2013.¹⁶ Companies that are in violation of the amendment will be forced to comply, or else be subject to fines and injunction.¹⁷ Since the ban not only prohibits the testing of cosmetics on animals, but also the sale of products tested on animals, some foresee issues due to the inconsistency of such laws in commercially

⁸ 7 U.S.C. § 2131 (1999).

⁹ Stephanie J. Engelsman, “World Leader” – At What Price? A Look at Lagging American Animal Protection Laws, 22 PACE ENVTL. L. REV. 329, 333 (2005).

¹⁰ 7 U.S.C. § 2131 (1999).

¹¹ Stacy E. Gillespie, *Animal Testing A Cover-Girl Face Does Not Have to Begin With Animal Cruelty: Chapter 476 Gives Legal Force to Alternative Testing Methods*, 32 MCGEORGE L. REV. 461, 469 (2001).

¹² *Id.* at 464.

¹³ *Id.* at 462-463.

¹⁴ Laura Donnellan, *Animal Testing in Cosmetics: Recent Developments in the European Union and the United States*, 13 ANIMAL L. 251, 257 (2007).

¹⁵ *Id.* at 267.

¹⁶ *Id.*

¹⁷ *Id.*

connected countries such as the United States.¹⁸ Others have scrutinized the amendment for being unrealistic in its aim to abolish the use of animals in cosmetic testing over a mere period of 10 years.¹⁹ Regardless of these issues, the amendment is a huge step in the right direction for proponents of increased animal protection under the law.²⁰

These European sentiments seem to be reaching into America at the Federal level, starting with a report by the National Research Council (NRC).²¹ In 2007, the NRC provided a futuristic outlook on animal research entitled, “Toxicity Testing in the 21st Century: A vision and a strategy.”²² The report proposed a collaboration in order to reduce animal testing, and depend more on *in vitro* testing of toxicity; testing based on human cells.²³ In a 2008 effort to help realize this vision, two National Institutes of Health (NIH) and the Environmental Protection Agency (EPA) announced a toxicity testing agreement.²⁴ The agreement planned to reduce reliance on animal toxicity testing through the use of automated screening robots.²⁵ The robots would employ “cells and isolated molecular targets instead of laboratory animals.”²⁶ The purpose of the alliance was to be able not only to move away from animal testing, but also to gather data more relevant to humans.²⁷

At the state level, California has long been the leader in animal testing reform. In 2000, California adopted Chapter 476 (later to become California Civil Code § 1834.9)

¹⁸ *Id.* at 269.

¹⁹ *Id.*

²⁰ *Id.* at 270.

²¹ *NIH Collaborates with EPA to Improve the Safety Testing of Chemicals—New Strategy Aims to Reduce Reliance on Animal Testing*, U.S. ENVTL. PROT. AGENCY (Feb. 15, 2008), <http://yosemite.epa.gov/opa/admpress.nsf/d0cf6618525a9efb85257359003fb69d/35995a22ceb67467852573f0006559de!OpenDocument>.

²² *Id.*

²³ *Id.*

²⁴ *Id.*

²⁵ *Id.*

²⁶ U.S. ENVTL. PROT. AGENCY, *supra* note 21.

²⁷ *Id.*

prohibiting the use of animals in tests where there are accepted alternative testing methods.²⁸ The law came about as a response to two approved alternative testing methods researched and released by The Inter-Agency Coordinating Committee on the Validation of Alternative Methods (ICCVAM).²⁹ The first of these tests, called the Murine Local Lymph Node Assay (LLNA), uses a smaller number of mice instead of a larger number of guinea pigs to test chemicals that cause contact dermatitis.³⁰ In the original test, the guinea pigs would be painted with the chemicals and then injected with the chemicals to speed up the negative effects.³¹ The LLNA on the other hand, tests the effects of the chemicals by a reaction in the lymph nodes of the mice after the chemicals are painted on the ears of the animal.³² It does not depend on the mice developing a disease, and is purportedly less painful, costly, and time consuming.³³ The second alternative avoids the use of animals altogether by replacing the traditional rabbit skin test with the use of a “skin-like protein barrier.”³⁴ To enforce the new regulation, California put the power in the hands of government officials only, based on the assumption that animal advocate groups would instigate unnecessary litigation, and use Chapter 476 to harass the cosmetics industry.³⁵ Violators of the regulation are subject to injunctive relief and fines not to exceed \$5000.³⁶

While the concepts behind the Seventh Amendment to the Cosmetics Directive and California Civil Code §1834.9 are like-minded, the scope of California Civil Code

²⁸ Gillespie, *supra* note 8, at 470.

²⁹ *Id.*

³⁰ *Id.* at 468.

³¹ *Id.*

³² *Id.*

³³ Gillespie, *supra* note 8, at 468.

³⁴ *Id.*

³⁵ *Id.* at 471.

³⁶ *Id.* at 470.

expands past that of the Directive to include the testing of pesticides and household products along with cosmetics.³⁷ The two regulations also diverge in their means of redress, the Directive being less focused on a maximum amount of punitive damages, but rather a compliance with the alternative methods available.³⁸

A number of other states have also taken similar European/Californian routes in seeking to avoid needless toxicity testing on animals. In 2007, New Jersey adopted Chapter 210, prescribing that no testing method was to be used where there was an acceptable alternative prescribed by the ICCVAM.³⁹ In 2008, New York added §505 to the public health law, in a similar amendment titled, “Animal Irritancy Tests Prohibited.”⁴⁰ These additions to the law come especially welcome to the many adversaries of the infamous Draize Test. Developed in the heat of an “injurious consumer climate,” the test is performed exclusively on albino rabbits.⁴¹ The rabbits are placed into holding devices with only the head exposed in order to prevent them from scratching their eyes out after cosmetic products or household cleaners are applied.⁴² These tests can last upwards of seventy-two hours, and in most cases the rabbit is not anesthetized during the test and is killed after the test has been completed.⁴³ Though the adoption of the testing regulations in California, New York, and New Jersey do not specifically criminalize the use of these tests, they do provide alternative testing methods to be used where applicable.⁴⁴

³⁷ Donnellan, *supra* note 10, at 276.

³⁸ *Id.*

³⁹ N.J. STAT. ANN. § 4:22-59 (West 2010).

⁴⁰ N.Y. PUB. HEALTH LAW §505 (Gould 2010).

⁴¹ Donnellan, *supra* note 10, at 271.

⁴² *Id.*

⁴³ *Id.*

⁴⁴ *Id.* at 274.

It appears that the “Three R’s” developed in the 1990s amongst the scientific community may just now be getting some legal backup: Replacement through cell cultures, reduction of the number of animals used, and refinement of procedures in order to reduce animal pain.⁴⁵ Absent legal incentive, the treatment of animals used for testing and the use of painful and antiquated tests will likely be kept in place for some time. Fortunately for animals subjected to such testing, recent trends suggest a glimmer of hope toward the adoption of more humane protection under the law. These trends suggest a possible increase in litigation, and more public awareness to the behind-the-scenes act of animal testing. The combination of federally funded research by the EPA and the legislative recognition of alternatives at the state level points to animal testing reform in the United States as an issue that is subject to widespread positive change in the near future.

⁴⁵ *Id.* at 279.