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**REPORT ON LEGISLATION BY THE
ANIMAL LAW COMMITTEE**

H.R. 4148

Representative Moran

AN ACT to phase out cosmetic animal testing and the sale of cosmetics tested on animals.

Humane Cosmetics Act

THIS LEGISLATION IS APPROVED

SUMMARY OF THE PROPOSED LEGISLATION

House of Representatives Bill No. 4148, the Humane Cosmetics Act (the “Bill”), would prohibit any entity from conducting animal testing¹ in the United States for purposes of evaluating the safety or efficacy of a cosmetic² product, or contracting with another party to do so when the cosmetic testing affects interstate commerce. Additionally, the Bill would prohibit the sale, offer for sale, and transport of any cosmetic if the final product or any component thereof was developed or manufactured using cosmetic animal testing after the effective date of the Bill. Civil penalties for violations may be assessed up to \$10,000. Each violation for each separate animal and each day would constitute a separate offense. The prohibition on cosmetic animal testing would take effect one year after the date of enactment, and the prohibition on the sale of products manufactured using cosmetic testing would take effect three years after the date of enactment.

THE COMMITTEE SUPPORTS THE BILL

1. Background

As noted by the Bill’s sponsor, the Bill will “...bring the United States into the 21st Century and save countless animals from unnecessary cosmetics testing”³ by eliminating cosmetic animal testing in the United States.

¹ The term “cosmetic animal testing” is defined to mean the application or exposure of any cosmetic to the skin, eyes, or other body part of a live non-human vertebrate for purposes of evaluating the safety or efficacy of a cosmetic.”

² As used throughout, the term “cosmetic” is defined to have the same meaning as defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §321), at <http://www.law.cornell.edu/uscode/text/21/321>.

³ Press Release, HSUS, Federal Bill to End Cosmetics Testing on Animals Introduced in Congress (Mar. 5, 2014), available at

The U.S. Food and Drug Administration (FDA) has regulatory authority over cosmetics pursuant to the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Fair Packaging and Labeling Act (FPLA).⁴ The FD&C Act defines a cosmetic as something “intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance...[or] intended for use as a component of any such articles; except that such term shall not include soap.”⁵ While the FD&C Act requires manufacturers to ensure that cosmetic ingredients and the finished product are “safe” prior to being marketed,⁶ cosmetic animal testing is not required by the FDA for any cosmetic product or ingredient.⁷ Additionally, we note that no state law requires cosmetic animal testing. Moreover, as noted below, a number of states prohibit or limit cosmetic animal testing.

However, in practice many manufacturers have used animal testing to demonstrate cosmetic product safety. Most of these tests were developed in the twentieth century, including experiments such as the Draize eye and skin tests, which subjectively measure irritation caused by placing a substance in rabbits’ eyes or on their skin, and the LD50 test, which determines a substance’s toxicity from the dosage that kills half of animals who consume, breathe in or are injected with the substance.⁸ Although several organizations have deemed these tests inhumane,⁹ many companies continue to use the tests to substantiate their products’ safety, today.

2. Justification for the Bill

The Committee supports the Bill because it would (a) abolish practices that cause unnecessary pain and suffering to animals and are against public sentiment; (b) end tests which are not mandated by law and have been proven to be unreliable and inadequate to demonstrate

http://www.humanesociety.org/news/press_releases/2014/02/federal_bill_to_end_cosmetics_testing_introduced_in_Congress.html (last visited November 3, 2014).

⁴ FDA, *FDA Authority Over Cosmetics*, available at <http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074162.htm> (last visited November 3, 2014).

⁵ 21 U.S.C. §321.

⁶ *Id.*

⁷ FDA, *Cosmetics Safety Q&A: Animal Testing*, (“The Federal Food, Drug, and Cosmetic Act does not specifically require the use of animals in testing cosmetics for safety, nor does it subject cosmetics to FDA premarket approval”), available at <http://www.fda.gov/cosmetics/resourcesforyou/consumers/ucm167216.htm> (last visited November 3, 2014).

⁸ LD50 means “lethal dose 50 percent.” See NAVS, *The Use of Animals in Product Testing*, available at <http://www.navs.org/science/animals-in-product-testing#.Uzh3I6Kn9D0> (last visited November 9, 2014).

⁹ See generally NAVS, *Harm and Suffering*, available at <http://www.navs.org/science/animals-in-product-testing#.Uzh3I6Kn9D0> (last visited November 9, 2014). While the Animal Welfare Act (“AWA”) was specifically designed to regulate the treatment of animals used for testing purposes, it inherently recognizes that the animals will be used for testing, excludes certain animals such as mice and rats, mandates that inflicted pain be “minimized,” not eliminated. 21 U.S.C. §§2131, 2132(g), 2143(a)(3)(A).

effects on humans; and (c) follow state and international trends towards abolishing cosmetic animal testing.

- a. The Bill would abolish practices that cause unnecessary pain and suffering to animals and are against public sentiment.

Each year, thousands of animals, including rabbits, guinea pigs, rats and mice, are subjected to cosmetic testing in the United States.¹⁰ Animals subjected to these tests commonly experience significant pain over a protracted period of time and rarely receive pain relief.¹¹ Animals are commonly killed at the completion of the test,¹² “normally by asphyxiation, neck-breaking, or decapitation.”¹³ In the acute oral toxicity variation of the LD50 test, for example, a cosmetic product or ingredient is administered to rats and used to determine what amount of a particular substance when ingested, will cause half of animals to die within fourteen days of exposure.¹⁴ The substance is forcefully administered down the rat’s throat in a feeding tube, and commonly causes the animal to suffer from extreme and prolonged pain through convulsions, bleeding from the mouth, seizures, and paralysis.¹⁵ Another example is the Draize eye test, in which a cosmetic product or ingredient is administered into rabbits’ eyes and left untreated over a seven-day period or longer without anesthesia, resulting in bleeding, ulceration and, blindness.¹⁶ The rabbits’ eyes are often held open with clips at the lid, and the rabbits may break their necks or backs struggling to escape from the pain.¹⁷

While proponents of cosmetic animal testing believe that it helps ensure the product’s safety when used by humans, and further protects the company from liability,¹⁸ research continues to show strong public support for a ban on cosmetic animal testing. For example, a recent Lake Research poll commissioned by the Humane Society of the United States found that seventy-three percent (73%) of Americans would favor federal legislation that would phase out and ultimately end cosmetic animal testing, with fifty-five percent (55%) of those polled

¹⁰ HSUS, *Cosmetic Tests that Use Animals*, available at http://www.humanesociety.org/issues/cosmetic_testing/tips/common_cosmetics_tests_animals.html#.U11QvaKn9D0 (last visited November 9, 2014).

¹¹ *Id.*

¹² *Id.*

¹³ HSUS, *Fact Sheet: Cosmetic Testing*, Mar. 13, 2014, available at http://www.humanesociety.org/issues/cosmetic_testing/qa/questions_answers.html (last visited November 3, 2014).

¹⁴ *Id.*

¹⁵ *Id.* See also NEAVS, *Product Development and Drug Testing*, available at <http://www.neavs.org/research/testing> (last visited November 9, 2014).

¹⁶ *Id.* See also JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH, CENTER FOR ALTERNATIVES TO ANIMAL TESTING, available at <http://altweb.jhsph.edu/resources/faqs.html> (last visited November 3, 2014).

¹⁷ *Product Development and Drug Testing*, *supra* note 15. See also Katie C. Galanes, Detailed Discussion of Animal Testing in Commercial Products, Michigan State University College of Law (2010), available at <http://www.animallaw.info/articles/ddusanimaltesting.htm> (last visited November 3, 2014).

¹⁸ See *Cosmetics Safety Q&A: Animal Testing*, *supra* note 7; *The Use of Animals in Product Testing*, *supra* note 8.

favoring such legislation “strongly.”¹⁹ Three out of four voters said they would feel safer or just as safe if non-animal cosmetic testing was used.²⁰

- b. The Bill would end animal testing which is not mandated by law and has proven to be unreliable and inadequate to demonstrate effects on humans.

The Bill would end unnecessary cosmetic animal testing, as federal law does not require animal testing for cosmetics.²¹ Further, thousands of commonly used cosmetic ingredients have been historically deemed safe by the FDA for cosmetic use, and thus have no need for additional testing.²²

Additionally, cosmetic animal testing has failed to demonstrate true product safety due to its inherent unreliability and inaccuracy. Animal tests to show a cosmetic’s toxicity “have never been validated by a regulatory body,” and thus “represent an outdated science of techniques that are not adequate to predict human safety.”²³ Specifically, animal test results do not always predict human effects,²⁴ since animals and humans have “differences in absorption, distribution, metabolism, and excretion of chemicals.”²⁵ For example, the Draize eye test has been criticized because a rabbit eye’s cornea is structured differently than that of a human.²⁶ Rabbits also produce fewer tears than humans, which means chemicals linger longer and cause greater irritation than in a human eye.²⁷ Similarly, the Draize skin test has been criticized because animals have very different skin than that of humans.²⁸ Further, scientists’ subjective observations during the tests and the differences of reactions from animal to animal make it very difficult to routinely reproduce the Draize score for a product.²⁹

¹⁹ See Federal Bill to End Cosmetics Testing on Animals Introduced in Congress, *supra* note 3.

²⁰ *Id.*

²¹ *Cosmetics Safety Q&A: Animal Testing*, *supra* note 7.

²² See 21 CFR Part 182, Substances Generally Recognized as Safe, at <http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&sid=786bafc6f6343634fbf79fcdca7061e1&rgn=div5&view=text&node=21:3.0.1.1.13&idno=21>. These ingredients are currently used by more than five hundred cruelty-free companies. See Federal Bill to End Cosmetics Testing on Animals Introduced in Congress, *supra* note 3.

²³ Federal Bill to End Cosmetics Testing on Animals Introduced in Congress, *supra* note 3.

²⁴ Jim Moran & Paul A. Locke, *Beauty and the Beasts: The U.S. Should Ban Testing Cosmetics on Animals*, SCIENTIFIC AMERICAN, available at <http://www.scientificamerican.com/article/beauty-and-the-beasts-the-u-s-should-ban-testing-cosmetics-on-animals/> (last visited November 3, 2014).

²⁵ AAVS, *Blinded for Beauty: Rabbits Used in Animal Testing*, available at http://www.aavs.org/site/c.bkLTKfOSLhK6E/b.6457329/k.CCC6/Blinded_for_Beauty.htm#U1zyuqKn9D0 (last visited November 9, 2014).

²⁶ *Id.*

²⁷ *Id.*

²⁸ *Id.*

²⁹ *Id.*

Non-animal methods of product safety testing of cosmetics provide a superior alternative to animal tests.³⁰ These non-animal methods include computational or *in silico* models,³¹ which “are based on human biology and are more predictive of human reactions than animal tests”³² as well as *in vitro* models which use tissue and cells.³³ The FDA publicly supports the use and development of alternatives to animal testing, and has stated that it “will continue to be a strong advocate of methodologies for the refinement, reduction, and replacement of animal tests with alternative methodologies that do not employ the use of animals.”³⁴

c. The Bill would follow state and international trends towards abolishing cosmetic animal testing.

In response to public opposition to animal testing, a number of U.S. states including New York, California and New Jersey, have enacted laws limiting or prohibiting animal testing for cosmetic and household products where a recognized non-animal testing alternative exists.³⁵

Additionally, there have been recent international trends towards abolishing cosmetic animal testing. As of March 2013, the European Union banned cosmetic animal testing and the marketing of cosmetic products that were tested on animals.³⁶ Israel’s 2010 regulations banning cosmetic animal testing and the marketing of cosmetic products tested on animals, regulations modeled after those of the European Union, also went into effect in 2013.³⁷ India prohibited domestic cosmetic animal testing in 2014, and is contemplating a ban on importing and selling such items.³⁸ The Brazilian state of São Paulo also recently banned cosmetic testing, fining violators \$435,000 per animal in the event of non-compliance.³⁹ South Korea recently introduced a policy proposal recognizing non-animal testing for “functional” cosmetics, which traditionally

³⁰ *Blinded for Beauty: Rabbits Used in Animal Testing*, *supra* note 25.

³¹ *The Use of Animals in Product Testing*, *supra* note 8; see generally JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH, CENTER FOR ALTERNATIVES TO ANIMAL TESTING, *FAQs*, available at <http://altweb.jhsph.edu/resources/faqs.html#3> (last visited November 3, 2014).

³² Federal Bill to End Cosmetics Testing on Animals Introduced in Congress, *supra* note 3.

³³ JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH, CENTER FOR ALTERNATIVES TO ANIMAL TESTING, *supra* note 31.

³⁴ *Id.*

³⁵ See, e.g., N.Y. PUB. HEALTH LAW §505; CAL. CIV. CODE §1834.9; N.J.S.A. §4:22-49.

³⁶ EUROPEAN COMMISSION, *Health and Consumers: Ban on Animal Testing*, available at http://ec.europa.eu/consumers/sectors/cosmetics/animal-testing/index_en.htm (last visited November 3, 2014).

³⁷ Gabe Fisher. *Import ban on animal-tested products goes into effect*, THE TIMES OF ISRAEL, Jan. 1, 2013, available at <http://www.timesofisrael.com/import-ban-on-animal-tested-products-goes-into-effect/> (last visited November 3, 2014).

³⁸ Rupali Mukherjee. *Govt bans cosmetic companies from testing on animals*, THE TIMES OF INDIA, Jan. 23, 2014, available at <http://timesofindia.indiatimes.com/city/mumbai/Govt-bans-cosmetic-companies-from-testing-on-animals/articleshow/29225017.cms> (last visited November 3, 2014).

³⁹ *Brazil’s Sao Paulo state bans animal testing*, THE SUN DAILY, Jan. 24, 2014, available at <http://www.thesundaily.my/news/939145> (last visited November 3, 2014).

have required pre-market evaluation by the South Korea Ministry of Food and Drug Safety.⁴⁰ Currently, the New Zealand government is considering a cosmetic animal testing ban,⁴¹ and China, which has historically required animal testing, recently announced through its Food and Drug Administration that effective June 2014, it would “allow the sale of ‘non-specialized cosmetics’ manufactured in China, such as soap, shampoo and some skin products” to skip animal testing, if the company is able to perform non-animal tests validated by the European Union or demonstrate that safety data for the raw ingredients already exists.⁴² It is clear that around the globe, countries are realizing that cosmetic animal testing is outdated and further that more viable options exist to ensure the safety of cosmetic products.

CONCLUSION

For the reasons explained above, the Committee supports the Bill.

Animal Law Committee
Christine Mott, Chair

November 2014

⁴⁰ HSI INTERNATIONAL, *South Korea to Accept Non-Animal Tests for Functional Cosmetics*, Dec. 13, 2013, available at http://www.hsi.org/news/press_releases/2013/12/korea-cosmetics-testing-proposal-121313.html (last visited November 3, 2014).

⁴¹ HSI INTERNATIONAL, *New Zealand Could Ban Cosmetic Testing on Animals*, March 20, 2014, available at http://www.hsi.org/news/press_releases/2014/03/new-zealand-could-ban-animal-tested-cosmetics-032014.html (last visited November 3, 2014).

⁴² Shaojie Huang, *Interest Grows in Animal Testing Alternatives*, N.Y. TIMES, May 2, 2014, available at http://sinosphere.blogs.nytimes.com/2014/05/02/interest-grows-in-animal-testing-alternatives/?_php=true&_type=blogs&_r=0 (last visited November 3, 2014).