DEATH: THE PRICE OF BEAUTY: ANIMAL TESTING AND THE COSMETICS INDUSTRY By Kelly Renz McNeal

Millions of nonhuman animals are poisoned and killed each year in barbaric tests.¹ These tests were crudely developed as long ago as the 1920s to evaluate the toxicity of consumer products and their ingredients.² The safety testing of chemicals and consumer products probably accounts for only 10 to 20 percent of the use of animals in laboratories.³ This equates to approximately 2 to 4 million animals in the United States per year.⁴ In 1999, cosmetic companies netted over \$89 billion in profit.⁵ The use of animal testing in cosmetics⁶ raises issues such as:

- (1) the ethics and humaneness of deliberately poisoning animals;
- (2) the propriety of harming animals for the sake of marketing a new cosmetic or

household product;

- (3) the applicability of animal data to humans; and
- (4) the possibility of sparing millions of animals by developing alternatives to a

handful of widely used procedures.⁷

Our task must be to free ourselves...

by widening our circle of compassion

⁴ Id.

¹ Product Testing: Toxic and Tragic. http://www.peta.org/mc/factsheet_display.asp?ID=91 (last accessed April 21, 2005)

 $^{^{2}}$ Id.

³ Overview of Animal Testing Issues. http://www.hsus.org/web-

files/PDF/ARI/ARIS_An_Overview_Of_Animal_Testing_Issues.pdf (last accessed April 20, 2005)

⁵ Wages and Wage Determination, September 2000.

⁶ The term "cosmetic" means (1) articles intended to be poured, rubbed, 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, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap. Federal Food, Drug, and Cosmetic Act, §201. ⁷ *Overview of Animal Testing Issues*. http://www.hsus.org/web-

files/PDF/ARI/ARIS_An_Overview_Of_Animal_Testing_Issues.pdf (last accessed April 20, 2005)

to embrace all living creatures

in the whole of nature and its beauty. -Albert Einstein.

The practice of testing cosmetics on animals began in 1933, soon after a woman applied mascara⁸ and went blind.⁹ The Food and Drug Administration (FDA) passed the Federal Food, Drug, and Cosmetic Act (FDCA)¹⁰ in 1938 to protect the public from unsafe cosmetics.¹¹ The FDA's legal authority over cosmetics is different from other products regulated by the agency, such as drugs, biologics, and medical devices.¹² Cosmetic products and ingredients are not subject to FDA pre-market approval authority, with the exception of color additives.¹³

In the United States, manufacturers bear responsibility to ensure their products are safe for consumer use.¹⁴ In fact, cosmetic products that have not been adequately tested for safety must have a warning statement on the front label which reads, "WARNING – The safety of this product has not been determined."¹⁵ Although the FDA does not explicitly require animal testing for cosmetics products or ingredients, the agency has historically used animal toxicity data as its de facto gold standard to settle safety issues.¹⁶ The FDA "urges cosmetic manufacturers to conduct whatever tests are appropriate to establish that their cosmetics are safe", but "does not specifically mandate animal testing

 $^{11}_{12}$ Id.

¹³ Id.

⁸ Animal Testing Alternatives, All for Animals Newsletter, March 1998, Issue #1

⁹ Id.

¹⁰ 21 U.S.C.S §301-394.

¹² U.S. Food and Drug Administration, Center for Safety and Applied Nutrition, Office of Cosmetics and Colors, March 3, 2005

 ¹⁴ "Animal Testing," U.S. Food and Drug Administration, Office of Cosmetics and Colors Factsheet, Center for Food Safety and Applied Nutrition, Revised May 3, 1999.
¹⁵ Id.

¹⁶ Overview of Animal Testing Issues. http://www.hsus.org/web-

files/PDF/ARI/ARIS_An_Overview_Of_Animal_Testing_Issues.pdf (last accessed April 20, 2005)

for cosmetic safety"¹⁷ In contradiction, the FDA has stated that "animal testing by manufacturers seeking to market new products is often necessary to establish product safety."¹⁸

"The greatness of a nation and its moral progress

can be judged by the way its animals are treated." -- Mohandas K. Gandhi

The Animal Welfare Act (AWA), enacted by Congress, authorizes the Secretary of Agriculture to promulgate standards and other requirements governing the humane handling, housing, care, treatment, and transportation of certain animals by dealers, research facilities, exhibitors, carriers, and intermediate handlers.¹⁹ The AWA specifically prohibits the United States Department of Agriculture (USDA) from dictating what research is done.²⁰ If research is done using species covered by the AWA, the research facility must comply with the AWA and its regulations.²¹ The AWA defines animal to mean "any live or dead dog, cat, monkey (nonhuman primate mammal), guinea pig, hamster, rabbit, or such other warm-blooded animal, as the Secretary may determine is being used, or is intended for use, for research, testing, experimentation, or exhibition purposes, or as a pet; but such term <u>excludes</u> (1) birds, rats of the genus Rattus, and mice of the genus Mus, bred for use in research.²² Further, the regulations exempt from licensing any person who sells fewer than 25 dogs, and/or cats per year for research,

¹⁷ "Animal Testing," U.S. Food and Drug Administration, Office of Cosmetics and Colors Factsheet, Center for Food Safety and Applied Nutrition, Revised May 3, 1999.

¹⁸ *Position Paper*, U.S Food and Drug Administration, October 1992.

¹⁹ 7 U.S.C. §2131 *et seq*.

²⁰ 7 U.S.C. §2131

²¹ Animal Welfare; Inspection, Licensing, and Procurement of Animals, 69, Fed. Reg. 42089-42099 (July 14, 2004)

 $^{^{22}}$ 7 U.S.C. §2132(g). Black's Law Dictionary defines animal as "Non-human, animate being which is endowed with the power of voluntary motion". (6th Ed. 1990)

teaching, or testing purposes, if the dogs and cats were born and raised on the person's premises.²³

In fiscal year 2002, a total of 68,253 dogs and 24,222 cats from all sources were used in registered research facilities.²⁴ While reliable data on the specific number of rabbits used for cosmetic testing is difficult to find, it is estimated that 258,574 rabbits were used in some form of testing in 2000.²⁵ According to the Animal Welfare Report published by the USDA, research facilities are not required to report the number of rats, mice, or birds that are used in laboratories.²⁶ Ironically, this group of animals represents an estimated 90% of the laboratory animal population.²⁷ The U.S. significantly lags behind European Countries where rats, mice, and birds are not excluded.²⁸In an effort to include rats, mice, and birds under the protection of the AWA, the Alternative Research and Development Foundation filed a petition requesting that the definition of "animal" be amended.²⁹ The USDA and Alternative Research entered into a stipulation that provides that the USDA will amend the AWA regulation.³⁰ The USDA agreed to initiate and complete a rulemaking on the regulation within a reasonable time.³¹ This case was

²³ Animal Welfare; Inspection, Licensing, and Procurement of Animals, 69, Fed. Reg. 42089-42099 (July 14, 2004)

²⁴ Id.

²⁵ The dreaded Draize test: Harming the eye of the beholder. Crystal Miller. AV Magazine, Summer 2002.

²⁶ Science and Conscience: The Animal Experimentation Controversy.

http://www.humaneteen.org/science/pdf/Science and Conscience1.pdf (last accessed April 26, 2005) ²⁷ Id.

²⁸ "Member Action Vital-Project Animal Welfare Act". Anti-Vivisection Newsletter. Winter 1999.

²⁹ Alternative Research and Development Foundation, et al v. Veneman, et al, 347 U.S. App. D.C 296, (U.S. App. D.C. 2001).

³⁰ Id. ³¹ Id.

decided on September 7, 2001.³² Almost four years later, the definition of "animal" in the AWA still excludes rats, mice, and birds.³³

"Atrocities are not less atrocities when they occur in laboratories and are called medical research" -- George Bernard Shaw.

Cosmetic testing on animals includes <u>all</u> of the following practices: (1) testing a finished cosmetic product on animals; (2) testing individual ingredients of cosmetic products on animals; (3) testing any combination of ingredients on animals; (4) contracting a third-party company to perform any of the above tests; or (5) using a subsidiary or third-party company to perform any of the above tests in countries were animal testing is not banned.³⁴ Some cosmetic companies may claim that their products are not tested on animals, despite using one or more of the aforementioned practices.³⁵

Many companies test their products on animals for the obvious reasons.³⁶ They claim dangerous accidents could occur if their product gets into the eyes or are ingested by humans.³⁷ Many of these companies have their products tested by various laboratory companies, or perform the animal testing themselves.³⁸ Some of the tests conducted on animals include eye irritancy tests (Draize), acute toxicity tests (LD50), and skin irritancy tests.

"The question is not, Can they reason? nor, Can they talk? But rather, Can they suffer? -- Jeremy Bentham

³² Id.

³³ Animal Welfare; Inspection, Licensing, and Procurement of Animals, 69, Fed. Reg. 42089-42099 (July 14, 2004)

³⁴ Animal Testing, http://en.wikipedia.org/wiki/Animal_testing (last accessed April 21, 2005)

³⁵ Id.

³⁶ Haugen, David M. (Ed). Animal Experimentation. San Diego: Greenhaven Press Inc., 2000

³⁷ Id.

³⁸ Id.

During the Second World War, animal based protocols were developed to assess the effects of chemical warfare agents on eye irritancy.³⁹ In 1944, John Draize developed a scoring system to grade eye damage.⁴⁰ Since the war, the Draize test has become the standard procedure for estimating the eye irritancy potential of a wide variety of products, including shampoo, hairspray, deodorant, detergents, drugs, and pesticides.⁴¹ In the Draize test, a liquid, flake, granule, or powdered substance is dropped into one eve⁴² of a group of albino rabbits.⁴³ The other eve is used as a control.⁴⁴

Rabbits are most commonly used in this experiment, because they have insufficient tear ducts.⁴⁵ They usually receive no anesthesia during the tests.⁴⁶ Irritation levels are observed over several days.⁴⁷ Damage to the cornea, conjunctiva, and iris, as well as discharge, are recorded and combined into a single score.⁴⁸ The maximum score possible is 110, which usually means destruction of the eve.⁴⁹ The tests sometimes last from 72 hours to 7 to 18 days.⁵⁰

⁴⁹ Id.

³⁹ Overview of Animal Testing Issues. http://www.hsus.org/web-

files/PDF/ARI/ARIS An Overview Of Animal Testing Issues.pdf (last accessed April 20, 2005) ⁴⁰ Id. ⁴¹ Id.

⁴² To fully understand the absolute horrors of the sensitivity tests carried out on rabbits, it is necessary to consider and realize how sensitive eves are, and how painful it is to get even a tiny grain of sand or a drop of grapefruit juice in them. Much more toxic substances than grapefruit juice are put into the eyes of

rabbits used in Draize test experiments.

⁴³ Vivisecion, http://www.islamicconcern.com/vivisection.asp (last accessed April 21, 2005), Animal Experimentation, http://voiceforallanimals.utep.edu/experimentation.htm (last accessed April 20, 2005) ⁴⁴ Overview of Animal Testing Issues. http://www.hsus.org/web-

files/PDF/ARI/ARIS An Overview Of Animal Testing Issues.pdf (last accessed April 20, 2005) ⁴⁵ Safety testing of products for Human Use: Irrefutable necessity or morally indefensible false sense of security? Buyukmihci, Nedim C. Association of Veterinarians for Animal Rights. http://www.avar.org/safety testing.html (last accessed April 21, 2005)

⁴⁶ Vivisecion, http://www.islamicconcern.com/vivisection.asp (last accessed April 21, 2005), Animal Experimentation, http://voiceforallanimals.utep.edu/experimentation.htm (last accessed April 20, 2005) ⁴⁷ Overview of Animal Testing Issues. http://www.hsus.org/web-

files/PDF/ARI/ARIS An Overview Of Animal Testing Issues.pdf (last accessed April 20, 2005) ⁴⁸ Id

⁵⁰ Vivisecion, http://www.islamicconcern.com/vivisection.asp (last accessed April 21, 2005), Animal Experimentation, http://voiceforallanimals.utep.edu/experimentation.htm (last accessed April 20, 2005)

Reactions to the substances include swollen evelids, ulceration, bleeding, swollen or inflammation of the iris, hemorrhaging, massive deterioration, and blindness.⁵¹ In the worst situation, the cornea may ulcerate and perforate 52 . Since the cornea is one of the most sensitive tissues in the body, irritation and ulceration produces considerable amounts of pain.⁵³

During the tests, rabbits are often confined in a restraining device, or stock, with only their heads protruding.⁵⁴ Their eyelids are usually held open with clips.⁵⁵ Since the rabbits are restrained, they are unable to rub their eyes.⁵⁶ Therefore, they cannot in any way mitigate the discomfort or the pain produced.⁵⁷ Pain relieving drugs usually are not administered because experimenters claim their use would interfere with the test results.⁵⁸ As a result of these factors, many animals will break their necks or backs in an effort to escape.59

"There is no fundamental difference between man and the higher animals and their mental faculties... the lower animals, like man, manifestly feel pleasure and pain,

happiness, and misery." -- Charles Darwin.

⁵² Id. ⁵³ Id.

⁵⁴ Pain Free Shopping, Submitted by Judith Holman, Advocacy Committee, Ottawa Humane Society

⁵¹ Id. See also Safety testing of products for Human Use: Irrefutable necessity or morally indefensible false sense of security? Buyukmihci, Nedim C. Association of Veterinarians for Animal Rights. http://www.avar.org/safety_testing.html (last accessed April 21, 2005)

⁵⁵ Vivisecion, http://www.islamicconcern.com/vivisection.asp (last accessed April 21, 2005), Animal Experimentation, http://voiceforallanimals.utep.edu/experimentation.htm (last accessed April 20, 2005) ⁵⁶ Safety testing of products for Human Use: Irrefutable necessity or morally indefensible false sense of

security? Buyukmihci, Nedim C. Association of Veterinarians for Animal Rights. http://www.avar.org/safety_testing.html (last accessed April 21, 2005)

⁵⁷ Id. ⁵⁸ Id.

⁵⁹ Id. See also *Pain Free Shopping*, Submitted by Judith Holman, Advocacy Committee, Ottawa Humane Society.

Skin irritancy tests, such as the Draize 24-hour Patch Test and Dermal Toxicity tests also use immobilized animals, mostly rabbits and guinea pigs.⁶⁰ The process involves placing chemicals on the animals' raw, shaved skin and covering the skin with adhesive plaster.⁶¹ Laboratory technicians then record the damage at specific intervals for hours or days.⁶² Animals may suffer irritated or inflamed skin, bleeding, or bloody scabs.⁶³

"All the arguments to prove man's superiority cannot shatter this hard fact: in suffering, the animals are our equals." -- Peter Singer.

The LD50 test was originally developed to standardize batches of powerful biological medicines such as digitalis.⁶⁴ Because each batch of the drug varied in potency, it was important have a method to help ensure that new preparations were of uniform potency.⁶⁵ The LD50 test was used as a means of gauging potency.⁶⁶ The LD50 later became one of the first toxicity tests to be conducted on any chemical or product.⁶⁷ The LD50 value is the dose that kills 50% of a group of animals (usually rats or mice) to which it is administered, hence the term lethal dose 50%, or LD50.⁶⁸ The dose is usually

⁶⁰ Product Testing: Toxic and Tragic. http://www.peta.org/mc/factsheet_display.asp?ID=91 (last accessed April 21, 2005).

⁶¹*Hidden Ingredient: Animal Suffering*. http://www.idausa.org/facts/costesting.html (last accessed April 20, 2005).

⁶² Product Testing: Toxic and Tragic. http://www.peta.org/mc/factsheet_display.asp?ID=91 (last accessed April 21, 2005).

⁶³ Id.

⁶⁴ Trevan, J. (1927). The error of determination of toxicity. *Proceedings of the Royal Society*, Section B, 101: 483-514.

⁶⁵ Id. ⁶⁶ Id

⁶⁷ Overview of Animal Testing Issues. http://www.hsus.org/web-

files/PDF/ARI/ARIS_An_Overview_Of Animal Testing Issues.pdf (last accessed April 20, 2005) ⁶⁸ Id.

administered by mouth, but dermal, inhalation, and intravenous methods can also be used.⁶⁹

Sometimes the material is not very toxic, but the animals die from the volume of the material forced into their stomachs.⁷⁰ Depending on the material being tested, the animals may have severe abdominal pain, muscle cramps, convulsions, vomiting, diarrhea, gastrointestinal ulcers with bleeding, loss of kidney functioning, and other painful or distressing conditions.⁷¹ The animals are observed for up to 14 days.⁷² Those who will survive are euthanized, and the tissues of all the animals, including those who die, are examined pathologically.⁷³

"To insult someone we call him 'bestial'. For deliberate cruelty and nature, 'human' might be the greater insult." – Isaac Asimov.

There are several problems with all of these tests. There is a great deal of controversy over animal testing to determine the safety of cosmetic products to human consumers.⁷⁴ One study found that the Draize test "grossly over-predicted the effects that could be seen in the human eye," and on other concluded that the test "does not reflect the eye irritation hazard for man."⁷⁵ Another study found that the Draize eye irritancy test yields results that are inherently unreliable in predicting human toxicity.⁷⁶

⁶⁹ Id.

⁷⁰ Singer, Peter. Animal Liberation. New York: A New York Review Book, 1975.

⁷¹ Id. Conditions include convulsions, shock, paralysis, and bleeding from the mouth, nose, and anus. *Protest, Progress, and Product Tests: A Short history of animal tests.* http://www.sniksnak.com/aavs4.html (last accessed April 21, 2005)

⁷² Overview of Animal Testing Issues. http://www.hsus.org/web-

files/PDF/ARI/ARIS_An_Overview_Of_Animal_Testing_Issues.pdf (last accessed April 20, 2005) ⁷³ Id.

⁷⁴ Animal Testing, http://en.wikipedia.org/wiki/Animal_testing (last accessed April 21, 2005)

⁷⁵ R. Roggenband *et al.*, "Eye Irritation Responses in Rabbit and Man After Single Applications of Equal

Volumes of Undiluted Model Liquid Detergent Products," *Food and Chemical Toxicology*, 38 (2000): 727-734.

⁷⁶ Sharpe, R. *The Draize test—motivations for change*. Food and Chemical Toxicology, 1985, <u>23</u>, 139-143.

Humans and rabbits differ in the structure of their eyelids and corneas as well as their abilities to produce tears. ⁷⁷ When comparing a rabbit to human data on duration of eye inflammation after exposure to 14 household products, they differed by a factor of 18 to 250.⁷⁸ A battery of in vitro tests would be less expensive and likely more accurate than the Draize test.⁷⁹ Further, a clinical skin patch test conducted on human volunteers has been shown to produce skin irritation data that are "inherently superior to that given by a surrogate model, such as a rabbit."⁸⁰ Animal studies can neither confirm nor refute hypotheses about human physiology or pathology; human clinical investigation is the only way such hypotheses can be tested.⁸¹ However, the FDA maintains: "The Draize eye and skin irritancy tests continue to be considered among the most reliable methods currently available for evaluating the safety of a substance introduced into or around the eye or placed on the skin."⁸²

"If a man aspires towards a righteous life, his first act of abstinence is from injury to animals" -- Albert Einstein.

It has also been determined that the LD50 value should not be regarded as a biological constant, because so many factors -- including the animals' species and strain, age, gender, diet, bedding, ambient temperature, caging conditions, in time of day -- can all effect the LD50 value obtained.⁸³ The LD50 changes drastically from one species to

⁷⁷ A critical look at animal experimentation, Medical Research Modernization Committee 2002, http://www.mrmcmed.org/Critical Look.pdf (last accessed April 22, 2005)

⁷⁸ Id.

⁷⁹ Id.

⁸⁰ "Validity and Ethics of the Human 4-h Patch Test as an Alternative Method to Assess Acute Skin Irritation Potential," *Contact Dermatitis*, 45 (2001): 1-12.

⁸¹ A critical look at animal experimentation, Medical Research Modernization Committee 2002, http://www.mrmcmed.org/Critical_Look.pdf (last accessed April 22, 2005)

⁸² *Position Paper*, U.S Food and Drug Administration, October 1992.

⁸³ Morrison, J.R., Quinton and H. Reinert. 1968. The purpose and value of LD50 determinations. Pp -17 in *Modern Trends in Toxicology* (Eds. E. Boyland and R. Goulding). London: Butterworths. See also

another or even from one strain to another of the same species.⁸⁴ The LD50 of a substance in rabbits or rats in no way is an indicator of the acute toxicity of the same substance in humans.⁸⁵ Charles R. Magel, PhD, Emeritus Professor of Philosophy and Ethics at Moorhead State University, explains it best: "Ask the experimenters why they experiment on animals, and the answer is: "because the animals are like us." Ask the experimenters why it is morally okay to experiment on animals, and the answer is: "because the animals, and the answer is: "because the animals are like us." Ask the experimenters why it is morally okay to experiment on animals, and the answer is: "because the animals and the answer is: "because the animals are logical contradiction."⁸⁶

"An infallible characteristic of meanness is cruelty. Men who have practiced tortures on animals without pity, relating to them without shame,

how can they still hold their heads among human beings?" -- Samuel Johnson.

The Council of Europe, which comprises more than 42 European countries, has five conventions covering animal welfare, one of which is the European Convention for the Protection of Vertebrate Animals Used for Experimentation and other Scientific Purposes.⁸⁷ On January 15, 2003, the European Parliament and the Council of Europe amended Council Directive 76/768/EEC.⁸⁸ Article 4(a)(1)(a) prohibits "the marketing of cosmetic products, where the final formulation... has been the subject of animal testing using a method other than an alternative method after such alternative method has been

Balcombe, JP, Barnard, ND, Sandusky, C (2004). Laboratory routines cause animal stress. <u>Contemporary</u> <u>Topics in Laboratory Animal Science</u>, 43 (6), 42-51. This study held that "routine handling, venipuncture, and orogastic gavage lead to elevations of heart rate, blood pressure, and glucocorticoid concentrations... suggesting that despite their routine use in laboratory studies, these procedures are acutely stressful for animals." The

⁸⁴ Singer, Peter. Animal Liberation. New York: A New York Review Book, 1975.

⁸⁵ Singer, Peter. Animal Liberation. New York: A New York Review Book, 1975.

⁸⁶ The world history of Animal Rights and Vegetarianism Quotes. http://all-creation.franciscananglican.com/quotes.htm (last accessed April 19, 2005).

⁸⁷ Council of Europe. http://worldanimal.net/cos-existing.html (last accessed April 18, 2005).

⁸⁸ Directive 2003/15/EC of the European Parliament and of the Council of 27 February 2003.

validated and adopted...⁸⁹ Article 4(a)(1)(b) prohibits "the marketing of cosmetic products containing ingredients or combination of ingredients which ... have been the subject of animal testing using a method other than an alternative method after such alternative method has been validated...⁹⁰ Further, for tests concerning repeated dose toxicity, reproductive toxicity, and toxicokinetics, for which there are no alternatives yet under consideration, the period for implementation of the sections above shall be limited to a maximum of 10 years after entry into force.⁹¹

"Anything that can feel pain should not be put to pain." --R.M. Dolgin.

The Conciliation Agreement between Parliament and Counsel states that a testing ban will come into effect six years after the entry into force of the Directive, i.e. 2009, for the large majority of tests.⁹² As of 2009, even if there are no alternative methods, it will be prohibited to carry out tests on animals and to sell products which have been tested or whose ingredients have been tested on animals.⁹³ For those three tests for which there are no alternatives under consideration, a marketing ban shall come into effect within 10 years after entry into force, i.e. 2013.⁹⁴ The agreement means that the ban on animal testing and sales would start immediately, where alternative non-animal tests are

⁹¹ Id.

⁸⁹ Id.

⁹⁰ Id.

⁹² Report on the joint text of by the conciliation committee for a European Parliament and Council directive of the European Parliament and of the Council amending Council directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic product. Dagman Roth-Behrendt (Pes, D). (2003). As early as 1995, other countries within the European Union had bans on animal experimentation. Eight countries (Italy, Greece, Belgium, Ireland, Sweden, Finland, Luxembourg, and Germany) reported that cosmetic products had not been tested on animals in their territory. Six countries (Greece, the Netherlands, Ireland, Sweden, Finland, and Luxembourg) reported that cosmetic ingredients has not been tested on animals in their territory. See National Legislation Relating to Cosmetic Testing, http://worldanimal.net/cos-existing.html

⁹³ Directive 2003/15/EC of the European Parliament and of the Council of 27 February 2003.

⁹⁴ Report on the joint text of by the conciliation committee for a European Parliament and Council directive of the European Parliament and of the Council amending Council directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic product. Dagman Roth-Behrendt (Pes, D). (2003).

available.⁹⁵ This will be followed by a complete ban six years after the directive enters into force.⁹⁶ This will end the use of animals in the testing of cosmetic products, but without jeopardizing consumer safety, since alternative ways of testing will have to be developed in the transition period to replace animal testing.⁹⁷

France has challenged the Directive on the grounds that it violates World Trade Organization (WTO) agreements.⁹⁸ To comply with international law, the proposed amendment prohibits the performance of tests on animals on the territory of the Member States, but not the marketing of products which have been tested on animals.⁹⁹ Therefore, the prohibition cannot be challenged under WTO rules.¹⁰⁰ This response has been supported by responses to questions submitted to the Commission by members of the European Parliament.¹⁰¹

⁹⁵ Id.

⁹⁶ Id.

⁹⁷ Id.

 100 Id at p. 4.

iù ai p.

¹⁰¹ See, for example, written question E-0949/98 by Mark Watts (PSE) to the Commission (30 March 1998) on the subject of animal protection in GATT/WTO. The answer was given by Sir Leon Brittan on behalf of the Commission (7 May 1998) in the following terms:

It is correct that the Community's obligations under the World Trade Organisation (WTO) agreement are among the elements which must be taken into account when developing any policies which may affect trade, including those mentioned by the Honourable Member. However, as the Honourable Member indicates the General agreement on tariffs and trade (GATT)/WTO does not prevent the introduction of measures which are considered to be necessary for the protection of animals on the territory of the Community.

It is the Commission's view that it cannot unilaterally impose the Community's welfare-based production standards on third countries. For example, WTO rules do not permit the Community to prohibit imports of cosmetic products on the sole ground that they have been tested on animals, even if the Community imposes such an animal-testing ban for marketing of Community products. Rather than proceeding to an import ban of such products, the Community should focus on the creation of multilateral standards for animal welfare. The Community should first try to convince its trading partners to modify their policies in the direction it thinks appropriate. Consumers in Europe should, moreover, be in a position to make an informed choice

 ⁹⁸ France Tries To Overturn EU Animal Testing Ban. http://www.buzzle.com/editorials/8-26-2003-44645.asp (last accessed April 22, 2005).
⁹⁹ COM (2000) 189 final, p. 2.

The U.S. Government has expressed concern that the entry into force of the ban could restrict trans-Atlantic trade as certain U.S. products tested on animals could be prohibited from sale in the European Union (EU), while EU products not tested on animals could be prohibited for sale in the United States.¹⁰² The National Foreign Trade Council states that the EU "has effectively banned U.S. and other non-EU exports of products deemed hazardous, stifled scientific and industrial innovation and advancement and, in the process, has ignored a basic reality, namely that a certain amount of risk is unavoidable in every day life.²¹⁰³ It is incumbent on the U.S. and the EU to try to harmonize the many differences among the WTO membership into a unified, workable, and fluid mechanism that facilitates rather than impedes the flow of international trade.¹⁰⁴

To minimize trade disruption, the U.S. Government and European Commission have agreed to pursue a project on harmonized alternative testing methods.¹⁰⁵ The project will involve cooperation between the U.S. interagency expert group (ICCVAM¹⁰⁶) and the EU expert group (ECVAM¹⁰⁷).¹⁰⁸ The aim will be to develop mutually acceptable alternatives to animal testing that would then be submitted to the OECD¹⁰⁹ for

about the animal welfare aspects of the products they buy, for example through labelling schemes.

¹⁰² European Union Non Tariff Barriers to Trade according to the USTR 2003 National Trade Estimate Report on Foreign Trade Barriers. http://www.gtwassociates.com/alerts/EUStandards2003.html (last accessed April 22, 2005)

¹⁰³ "Looking behind the Curtain: The Growth of Trade Barriers that Ignore Sound Science". National Foreign Trade Council, Inc. May 2003.

¹⁰⁴ Id. ¹⁰⁵ Id.

¹⁰⁶ The Interagency Coordinating Committee on the Validation of Alternative Methods

¹⁰⁷ European Centre for the Validation of Alternative Methods

¹⁰⁸ European Union Non Tariff Barriers to Trade according to the USTR 2003 National Trade Estimate Report on Foreign Trade Barriers. http://www.gtwassociates.com/alerts/EUStandards2003.html (last accessed April 22, 2005).

¹⁰⁹ Organisation for Economic Co-operation and Development

international validation.¹¹⁰ This would likely result in internationally validated alternatives, which the FDA could accept for most cosmetics.¹¹¹ Ultimately, it is important to reconcile the different approaches of the U.S and the EU if the cause of trade liberalization is to advance.¹¹² However, a logical conclusion flows from all of this...if the EU can eliminate the use of testing cosmetics on unsuspecting, helpless animals, while still maintaining safety for humans, when will the United States also come to the realization that the European Union's approach is the correct, moral, approach to pursue?¹¹³

"The soul is the same in all living creatures, although the body of each is

different" -- Hippocrates

It is important to note that results from animal tests are not transferable between species, and therefore cannot guarantee product safety for humans. In reality, these tests do not provide protection for consumers from unsafe products, but rather they are used to protect corporations from legal liability.¹¹⁴ Many companies continue to perform these tests and because they are in the habit, and because their legal departments and insurance companies suggest they do it to cover themselves if they are sued.¹¹⁵ Corporate products

¹¹⁰ European Union Non Tariff Barriers to Trade according to the USTR 2003 National Trade Estimate Report on Foreign Trade Barriers. http://www.gtwassociates.com/alerts/EUStandards2003.html (last accessed April 22, 2005).

¹¹¹ Id. ¹¹² "Looking behind the Curtain: The Growth of Trade Barriers that Ignore Sound Science". National

¹¹³ A Commentary provides "An Act to Prohibit Animal Testing for Cosmetic Manufacturing", http://www.animallaw.com/cosmetic.cfm (last accessed April 18, 2005). This regulation states: "Except as specifically required by federal law or regulation, no cosmetic manufacturer shall conduct or have any other person conduct on its behalf, any tests which involves the placing of a cosmetic and in animals eve or on an animal's skin to measure its irritating effects, nor use any other traditional animal test method for which an appropriate industry accepted alternative test method exists."

¹¹⁴ Herbert Gundersheimer, M.D., member, Physicians Committee for Responsible Medicine. http://www.walklightly.org/experimentation.htm (last accessed April 20, 2005)

¹¹⁵ Singer, Peter. Animal Liberation. New York: A New York Review Book, 1975. A LEXIS search for products liability suits surrounding the use of animals in cosmetic testing provided no case law (i.e. there

liability lawyers and insurance companies continue to endorse the use of animal tests.¹¹⁶ The FDA's 2003 Annual Report of Consumer Complaints about cosmetic products lays out the type of product used, and the problem reported.¹¹⁷ An examination of the brands specified for fragrance preparations, hair preparations, hair coloring preparations, and make-up preparations revealed 50 total complaints.¹¹⁸ Comparing these 50 complaints¹¹⁹ with a list of companies that do and do not test on animals¹²⁰, a total of 20 of the 50 complaints (40%) came from companies that test on animals.¹²¹ This evidence begs the question…why are countless animals being tortured and sacrificed for use in cosmetics testing, to supposedly protect humans, when the success rate is this minute?

"If, as we know, are creatures with fur, feathers or fins are our brothers in a lower stage

of development, then their very weakness and inability to protest demands that man

should refrain from torturing them for the mere possibility of obtaining some knowledge

which he believes may be to his own interests." -- Luther Burbank

were no cases against companies that test on animals, nor any against companies that do not test on animals). See also *Pain Free Shopping*, Submitted by Judith Holman, Advocacy Committee, Ottawa Humane Society ("While those companies which do animal testing have not been immune from reports of personal injury to consumers using their products, the cosmetic company "Beauty Without Cruelty", which does not perform animal testing states that it has had no reports of consumer injuries during its 27 year history").

¹¹⁶ "Vanity, Cruelty, Regulatory Inertia: The Search for Alternatives to Cosmetic Testing". By John McArdle, Ph.D. Anti-Vivisection Magazine. Winter 1999.

 ¹¹⁷ "Consumer Complaints about Cosmetic Products. 2003 Annual Report". U.S. Food and Drug Administration, Office of Cosmetics and Colors, Center for Food Safety and Applied Nutrition.
¹¹⁸ Id.

¹¹⁹ The FDA lists the complaints by the type of product, the company that manufactures the product, the brand of the product, and the complaint received. The FDA notes that the reporting is voluntary and the information is "as reported" by the complainant.

¹²⁰ Companies that do/ do not test on animals. http://www.caringconsumer.com/searchcompany.asp (last accessed April 22, 2005)

¹²¹ Reasons for the complaints varied as follows: Respitory system reactions (choking, coughing, shortness of breath, sneezing, and wheezing), Tissue damage (dryness, peeling, cracking, ulcerations), Dermatitis (rash, redness, swelling, blisters, inflammation, irritation), and Pain (itching, burning, soreness),

As early as 1957, individuals were looking for ways in which inhumanity toward animals used in testing could be diminished or removed.¹²² At this time, the concept of animal testing alternatives was known as the "Three R's": Refinement, Reduction, and Replacement.¹²³ This concept still exists today.¹²⁴ Replacement means the substitution of insentient material for conscious living higher animals.¹²⁵ Reduction means reduction in the numbers of animals used to obtain information of a given amount and precision.¹²⁶ Refinement means any decrease in the incidence or severity of inhumane procedures applied to those animals which still have to be used.¹²⁷ However, the only viable choice is the replacement of animals used in tests; refinement and reduction still allow countless animals to suffer.¹²⁸ Hundreds of cosmetic companies have turned their backs on animal testing and are taking advantage of the many sophisticated non-animal test methods available today.¹²⁹

"I am in favour of animal rights as well as human rights. That is the only way of a whole

human being." – Abraham Lincoln

The most common types of alternative methods available today include in-vitro

tests, computer software, databases of tests already done (to avoid duplication), and even

 ¹²² Russell, W. M. S. (1957). The Increase of Humanity in Experimentation: Replacement, Reduction and Refinement. Paper read at UFAW Symposium on Humane Technique in the Laboratory, May, 1957, London; Abstract in Coll. Papers Lab. Animals Bur., 6: 23-5.
¹²³ Id.

¹²⁴ Overview of Animal Testing Issues. http://www.hsus.org/web-

files/PDF/ARI/ARIS_An_Overview_Of_Animal_Testing_Issues.pdf (last accessed April 20, 2005)¹²⁵ Russell, W. M. S. (1957). The Increase of Humanity in Experimentation: Replacement, Reduction and Refinement. Paper read at UFAW Symposium on Humane Technique in the Laboratory, May, 1957, London; Abstract in Coll. Papers Lab. Animals Bur., 6: 23-5.

¹²⁶ Id. ¹²⁷ Id.

¹²⁸ Animal Testing Alternatives. http://www.allforanimals.com/alternatives1.htm (last accessed April 22, 2005)

¹²⁹ Product Testing: Toxic and Tragic. http://www.peta.org/mc/factsheet_display.asp?ID=91 (last accessed April 21, 2005)

human "clinical trial" tests.¹³⁰ The search for alternatives to the rabbit eye irritancy test began in 1981 with the creation of the Johns Hopkins Center for Alternatives to Animal Testing (CAAT).¹³¹ The mission of the CAAT embodies a scientific approach to the use of alternatives and the development and safety evaluation of products, including those that are FDA regulated.¹³² The FDA has stated that it values the leadership taken by the CAAT to encourage research, development, and validation of alternative methods.¹³³ One alternative to the Draize eye irritancy test is Eytex.¹³⁴ Eytex is an in vitro (test tube) procedure that measures eye irritancy via a protein alteration system.¹³⁵ A vegetable protein from the jack bean mimics the reaction of the human cornea to an alien substance.¹³⁶ The test is simple, fast, and relatively cheap, and a number of companies and government laboratories claim to have produced good results.¹³⁷ Also, the Eytex is much cheaper than the Draize test.¹³⁸ The testing kits can test three concentrations of a chemical for about \$99.50; a Draize test of comparable range would cost more than \$1000.¹³⁹ This alternative is used by Avon.¹⁴⁰ The SkinEthic Human Corneal Epithelial Model (HCE) forms a corneal epithelial tissue resembling a corneal epithelium of the

¹³⁰ Id.

¹³¹ Overview of Animal Testing Issues. http://www.hsus.org/web-

files/PDF/ARI/ARIS_An_Overview_Of_Animal_Testing_Issues.pdf (last accessed April 20, 2005) ¹³² U.S Food and Drug Administration, B.A. Schwetz and N.L. Wilcox. CAAT Newsletter, Vol 14, No. 1, Fall 1996.

¹³³ Id.

¹³⁴ Overview of Animal Testing Issues. http://www.hsus.org/web-

files/PDF/ARI/ARIS_An_Overview_Of_Animal_Testing_Issues.pdf (last accessed April 20, 2005) ¹³⁵ Animal Testing Alternatives. http://www.allforanimals.com/alternatives1.htm (last accessed April 22, 2005)

¹³⁶ Id.

¹³⁷ Overview of Animal Testing Issues. http://www.hsus.org/web-

files/PDF/ARI/ARIS_An_Overview_Of_Animal_Testing_Issues.pdf (last accessed April 20, 2005) ¹³⁸ Barnaby J. Feder, *Beyond white rats and rabbits*, The New York Times. Feb. 28, 1988, at 4. ¹³⁹ Id

¹⁴⁰ Animal Testing Alternatives. http://www.allforanimals.com/alternatives1.htm (last accessed April 22, 2005)

human eye.¹⁴¹ This model is used to assess the ocular irritation potential of test substances following topical application.¹⁴²

Other alternatives to the use of animals are sophisticated computer systems¹⁴³ and human corneas from eye banks.¹⁴⁴ Mathematical models using human clinical data are another source of information that is more reliable than data derived from animal studies.¹⁴⁵

"The belief that nonhuman animals are somehow made for us lies at the root of what the

law says we can do to them today. "-Steven Wise

Several companies have developed artificial skin systems that can be used to

assess the irritancy potential of tests agents.¹⁴⁶ An alternative to the Draize skin irritancy

tests is Skintex.¹⁴⁷ This is an in vitro method to assess irritancy that uses pumpkin rinds

to mimic the reaction of a foreign substance on the human skin.¹⁴⁸ Both Eytex and

Skintex can measure 5,000 different materials.¹⁴⁹ Similarly, Episkin and EpiDerm, multi-

layered skin models made up of cultures of human skin cells, have been scientifically

validated and accepted around the world as total replacements for rabbit skin corrosion

¹⁴⁶ Overview of Animal Testing Issues. http://www.hsus.org/web-

¹⁴¹ Skin Irritancy Tests Using Human Skin Models,

http://www.safepharm.co.uk/Services/Toxicology/Alternatives/skin-irritancy.html (last accessed April 21, 2005).

¹⁴² Id.

¹⁴³ Opponents say computer models can always be used as substitutes. They are wrong. Animal research is the only way to obtain absolutely essential information. Humans build computers. No human knows enough to make a computer that can duplicate a living creature, its diseases, its response to medications, or the side effects that medications might cause. There are only two choices for gaining this information: test new medications on animals or on human. American Academy of Neurology Foundation,

http://www.thebrainmatters.org/index.cfm?key=0.4.3 (last accessed April 22, 2005)

¹⁴⁴ Cosmetic Animal Testing, http://www.clearleadinc.com/site/cosmetic-animal.html (last accessed April 22, 2005)

¹⁴⁵ A critical look at animal experimentation, Medical Research Modernization Committee 2002, http://www.mrmcmed.org/Critical_Look.pdf (last accessed April 22, 2005)

files/PDF/ARI/ARIS_An_Overview_Of_Animal_Testing_Issues.pdf (last accessed April 20, 2005) ¹⁴⁷ Animal Testing Alternatives. http://www.allforanimals.com/alternatives1.htm (last accessed April 22,

²⁰⁰⁵⁾

¹⁴⁸ Id.

¹⁴⁹ Id.

studies.¹⁵⁰ Further, Epipak uses cloned human tissue to test potentially harmful substances.¹⁵¹ Finally, Testskin uses human skin grown in a sterile plastic bag to test for irritancy.¹⁵² This method is used by Avon, Amway, and Estée Lauder.¹⁵³

A major advantage of these truly in vitro models is that the test substance can be applied directly (topically) to the culture surface, thereby closely mimicking dermal exposure in humans.¹⁵⁴ The models are therefore particularly appropriate for irritancy testing of products intended for topical exposure in humans, such as treatments for skin conditions, cosmetics, and wound dressings.¹⁵⁵

Alternatives to the LD50 test include the Fixed Dose Procedure, the Acute Toxic Class Method, and the Up and Down Procedure.¹⁵⁶ However, all of these tests still use animals as subjects.¹⁵⁷ For these alternatives, reduction, not replacement, is utilized.¹⁵⁸ Further, in the Acute Toxic Class Method and the Up and Down Procedure, death is still the endpoint.¹⁵⁹

"As a practicing physician who is board-certified in internal medicine and oncology, I can find no evidence that the Draize test, LD 50 test, or any other tests

¹⁵⁰ National Toxicology Program, Episkin, EpiDerm, and Rat Skin Transcutaneous Electrical Resistance (TER), In Vitro Test Methods for Assessing the Dermal Corrosivity Potential of Chemicals, National Institute of Environmental Health Sciences, Aug. 2001. TER is technically a replacement alternative because it replaces the use of animals as test subjects. Unfortunately, the test does involve killing animals to obtain a precious skin cells. See also Overview of Animal Testing Issues. http://www.hsus.org/webfiles/PDF/ARI/ARIS An Overview Of Animal Testing Issues.pdf (last accessed April 20, 2005) ¹⁵¹ Animal Testing Alternatives. http://www.allforanimals.com/alternatives1.htm (last accessed April 22,

²⁰⁰⁵⁾

¹⁵² Id. ¹⁵³ Id.

¹⁵⁴ Skin Irritancy Tests Using Human Skin Models,

http://www.safepharm.co.uk/Services/Toxicology/Alternatives/skin-irritancy.html (last accessed April 21, 2005).

¹⁵⁵ Id.

¹⁵⁶ Overview of Animal Testing Issues. http://www.hsus.org/web-

files/PDF/ARI/ARIS An Overview Of Animal Testing Issues.pdf (last accessed April 20, 2005) ¹⁵⁷ Id.

¹⁵⁸ Id.

¹⁵⁹ Id.

using animals to support the 'safety' of chemicals and cosmetics have any relevance to the human species..." --Donald C. Doll, M.D.

It is extremely important that testing protocols be harmonized internationally to reflect the latest developments in alternative methods.¹⁶⁰ However, individuals seeking to implement alternatives to particular animal tests face formidable obstacles, even though the alternatives may perform as well, or better than, the animal test.¹⁶¹ Ideally, the alternative and animal tests should be assessed according to an independent standard.¹⁶² However, there is limited clinical testing on humans; therefore good quality human data is often lacking.¹⁶³ Consequently, the animal test itself is typically used to as the default standard against which the alternative test is judged.¹⁶⁴ In other words, the lack of a true gold standard means that in vitro tests are judged according to how well they accord with animal data, not human data.¹⁶⁵

"Science...has established a new set of values, which amounts to the pitiless exploitation of the rest of nature for the physical benefit of man." –John Vyvyan

The general public has been led to believe that animals rarely suffer in laboratories.¹⁶⁶ The value of the animal experimentation has been grossly exaggerated by those with a vested economic interest in its preservation.¹⁶⁷ Millions of animals are studied in research labs each year in order to test the effects of experimental treatments

files/PDF/ARI/ARIS_An_Overview_Of_Animal_Testing_Issues.pdf (last accessed April 20, 2005) ¹⁶¹ Overview of Animal Testing Issues. http://www.hsus.org/web-

¹⁶⁰ Overview of Animal Testing Issues. http://www.hsus.org/web-

files/PDF/ARI/ARIS_An_Overview_Of_Animal_Testing_Issues.pdf (last accessed April 20, 2005) ¹⁶² Id.

 $^{^{163}}$ Id.

¹⁶⁴ Id.

¹⁶⁵ Id.

 ¹⁶⁶ A critical look at animal experimentation, Medical Research Modernization Committee 2002, http://www.mrmcmed.org/Critical_Look.pdf (last accessed April 22, 2005)
¹⁶⁷ Id.

that ethical issues prevent from being tested on humans...¹⁶⁸ It seems unethical that the "user species" would impose the fear, pain, and health consequences of the testing to an unwitting, unwilling, unconsenting¹⁶⁹ species.¹⁷⁰

The main disadvantages to animal testing are animal discomfort, death, species extrapolation problems, excessive time, excessive expense, and most importantly, the inhumane treatment of animals.¹⁷¹ Animals, as sentient beings, deserve equality and to be protected from these types of atrocities. The fundamental form of equality is *equal consideration of interests*, and it is this that we should extend beyond the boundaries of our own species.¹⁷² Essentially this means that if an animal feels pain, the pain matters as much as it does when a human feels pain.¹⁷³ How bad pain and suffering are does not depend on the species of being that experiences it.¹⁷⁴

"Compassion for animals is intimately connected with goodness of character; and

it may be confidently asserted that he who is cruel to animals cannot be a good man." –

Arthur Schopenhauer

There are points on which any reasonable compassionate person, animal advocate or not, would agree.¹⁷⁵ There needs to be a call for an immediate end to animal testing for trivial, unnecessary, and ethically questionable purposes, a ban that would save the

¹⁶⁸ Kimmel, Allan J. Ethical Issues in Behavioral Research. Cambridge: Blackwell Publishers, 1996.

¹⁶⁹ In order for humans to participate in experiments, they <u>must</u> give consent. The Committee of Ministers of the Council of Europe (1990) provides, in Principle 3: "No medical research may be carried out without informed, free, express and specific consent of the person undergoing it." The U.S. has similar provisions. ¹⁷⁰ *Episode 96: "Manimal and the cosmetics testing laboratory"*.

http://www.grinningplantet.com/2004/10-12/cosmetics-animal-testing-article.htm (last accessed April 10, 2005).

¹⁷¹ Animal Testing Alternatives. http://www.allforanimals.com/alternatives1.htm (last accessed April 22, 2005).

¹⁷² Animal Rights, A letter from Peter Singer to Richard A. Posner.

http://slate.msn.com/default.aspx?id=110101&entry=110109 (last accessed April 22, 2005) ¹⁷³ Id.

¹⁷⁴ Id.

¹⁷⁵ Animal Testing, Isn't it a choice between kids and rats?

http://www.dawnwatch.com/animal_testing.htm (last accessed April 15, 2005).

majority of laboratory animals, millions per year.¹⁷⁶ Through the promotion of validated methods for testing therapeutic drugs that are more predictive of health effects compared to current standards, the health and well-being of both humans and animals are better protected.¹⁷⁷ We owe it to ourselves and to nonhuman animals to create not merely a body of rules and regulations to govern our conduct but a level of sensibility that makes us care, deeply and constructively, about the entire planet and all of its varied inhabitants.¹⁷⁸ If we can accomplish this, then perhaps, some far off day, those who follow us down the track of the generations will be able to dwell in relative harmony with all of the creatures of the earth, human and nonhuman.¹⁷⁹

Progress toward the widespread use of alternatives to animal testing will continue to gain strength as awareness of the current inhumane testing methodologies, and awareness and support for already-developed and developing alternatives, are made known.¹⁸⁰ The billions of dollars invested annually in animal research would be put to much more efficient, effective, and humane use if redirected to clinical and epidemiological research and public health programs.¹⁸¹ If we apply the principle of equal consideration to animals, then we must extend to animals the one basic right that we extend to all human beings: the right not to be treated as things.¹⁸²

¹⁷⁶ Animal Testing, Isn't it a choice between kids and rats?

http://www.dawnwatch.com/animal_testing.htm (last accessed April 15, 2005).

¹⁷⁷ U.S Food and Drug Administration, B.A. Schwetz and N.L. Wilcox. CAAT Newsletter, Vol 14, No. 1, Fall 1996.

 ¹⁷⁸ Francione, Gary. Animals, Property, and the Law. Temple University Press, 1995.
¹⁷⁹ Id.

¹⁸⁰ Animal Testing Alternatives. http://www.allforanimals.com/alternatives1.htm (last accessed April 22, 2005)

¹⁸¹ *A critical look at animal experimentation*, Medical Research Modernization Committee 2002, http://www.mrmcmed.org/Critical_Look.pdf (last accessed April 22, 2005)

¹⁸² Francione, Gary. Introduction to Animal Rights: Your child or the dog. Temple University Press, 2000.

"Lots of people talk to animals...Not very many listen, though...That's the problem" -

Benjamin Hoff