

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

**H.R. 816**

**Representative Ken Calvert**

To amend the ICCVAM Authorization Act of 2000 to improve reporting about animal testing and alternative test method use by Federal agencies, and for other purposes.

**Federal Accountability in Chemical Testing Act (FACT Act)**

**THIS LEGISLATION IS APPROVED**

**I. SUMMARY OF PROPOSED LEGISLATION**

The proposed legislation, H.R. 816 (the FACT Act), would require public reports on the federal government’s use of animals in toxicological testing and the government’s progress on the use of alternative toxicological testing methods. The purpose of toxicological tests is to protect human safety by measuring the effects of a substance on laboratory animals, such as a substance’s ability to cause cancer, birth defects, changes in genetic material, and the ability to damage cells.<sup>1</sup>

Specifically, the FACT Act would amend the ICCVAM Authorization Act of 2000, 42 USC § 2851-3, which established requirements concerning the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM). ICCVAM’s purpose is in part to “reduce, refine, or replace the use of animals in testing, where feasible.”<sup>2</sup> Under current law, the ICCVAM is required to make biennial reports on its progress to the public.<sup>3</sup> But there is no requirement that federal agencies report on the number and species of animals used in their toxicological tests. Hence the public has incomplete information on how its tax dollars may be used to experiment on animals.

The FACT Act would require the ICCVAM to include in its biennial reports data on the use of animals for toxicological tests and the use of alternative test methods by 15

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<sup>1</sup> JOANNE ZURLO ET AL., ANIMALS AND ALTERNATIVES IN TESTING: HISTORY, SCIENCE, AND ETHICS 9 (1994), [http://caat.jhsph.edu/publications/animal\\_alternatives/chapter3.html](http://caat.jhsph.edu/publications/animal_alternatives/chapter3.html).

<sup>2</sup> 42 USCS § 2851-3(b)(5).

<sup>3</sup> 42 USCS § 2851-3(e)(7).

or more federal agencies,<sup>4</sup> including the Department of Agriculture (USDA), Food and Drug Administration, and Department of Defense.<sup>5</sup>

## II. ARGUMENT

Since 1920, the United States has used toxicological testing to ensure that products are safe for humans.<sup>6</sup> But the accuracy of such tests on animals is limited because humans and laboratory animals are different.<sup>7</sup> In addition, public support of animal testing has been declining in the United States due to concerns about animal welfare.<sup>8</sup> Public opinion in the United States reflects opinion in many other countries: for example, the European Union recognizes the “intrinsic value” and sentience of animals used in laboratories and limit their use,<sup>9</sup> and other countries such as New Zealand,<sup>10</sup> Israel,<sup>11</sup> and India<sup>12</sup> restrict or ban cosmetic testing on animals.

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<sup>4</sup> The legislation adds the underlined text to the following requirement in 42 USC § 2851-3(e)(7):

The ICCVAM shall, consistent with the purposes described in subsection (b), carry out the following functions. . . (7) Prepare reports to be made available to the public on its progress under this Act. The first report shall be completed not later than 12 months after the date of the enactment of this Act and subsequent reports shall be completed biennially thereafter, to include a description of the progress on the development, validation, acceptance, and utilization of alternative test methods (including animal use data by species, number, and test type) for toxicological testing conducted, supported, or required by, or submitted to, each Federal agency listed in subsection (c) during the reporting period.

<sup>5</sup> The other agencies are: Agency for Toxic Substances and Disease Registry, Consumer Product Safety Commission, Department of Energy, Department of the Interior, Department of Transportation, Environmental Protection Agency, National Institute for Occupational Safety and Health, National Institutes of Health, National Cancer Institute, National Institute of Environmental Health Sciences, National Library of Medicine, and the Occupational Safety and Health Administration, and “[a]ny other agency that develops, or employs tests or test data using animals, or regulates on the basis of the use of animals in toxicity testing.” (42 USC § 2851-3(c)).

<sup>6</sup> E.g., S. Parasuraman, *Toxicological Screening*, J. of Pharmacology & Pharmacotherapeutics 74 (Apr. – June 2011), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3127354/>.

<sup>7</sup> E.g., Thomas Hartung, *Food for Thought ... on Animal Tests*, ALTEX 4 (2008) (correlation between humans and laboratory animals is about 60% depending on the animal; even a substance found to be safe in monkeys caused multiple organ failure in human subjects within hours), [http://www.altex.ch/resources/altex\\_2008\\_1\\_3\\_9\\_FFT\\_HartungE.pdf](http://www.altex.ch/resources/altex_2008_1_3_9_FFT_HartungE.pdf).

<sup>8</sup> PEW RESEARCH CENTER, AMERICANS, POLITICS AND SCIENCE ISSUES 141-44 (July 1, 2015), [http://assets.pewresearch.org/wp-content/uploads/sites/14/2015/07/2015-07-01\\_science-and-politics\\_FINAL-1.pdf](http://assets.pewresearch.org/wp-content/uploads/sites/14/2015/07/2015-07-01_science-and-politics_FINAL-1.pdf).

<sup>9</sup> Directive 2010/63/EU of the European Parliament and of the Council ¶ 12 (Sept. 22, 2010), provides:

Animals have an intrinsic value which must be respected. There are also the ethical concerns of the general public as regards the use of animals in procedures. Therefore, animals should always be treated as sentient creatures and their use in procedures should be restricted to areas which may ultimately benefit human or animal health, or the environment. The use of animals for scientific or educational purposes should therefore only be considered where a non-animal alternative is unavailable. Use of animals for scientific procedures in other areas under the competence of the Union should be prohibited.

Toxicological tests on animals involve pain, suffering, and often death. For example, in the Draize rabbit eye test, 100 microliters of a test substance is introduced into a restrained rabbit's eye and then the effects are observed for as long as 21 days.<sup>13</sup> The effects can be severe and painful, including ulceration, hemorrhaging, and blindness.<sup>14</sup> After the test, the rabbits may be euthanized if the eyes are severely damaged.<sup>15</sup> As another example, in the 50% lethal dose (LD50) test, a substance is administered at different dose levels to large numbers of animals, and the effect is observed for 14 days.<sup>16</sup> The mortality rate is high.<sup>17</sup>

Since the ICCVAM was established by the United States in 2000 to promote the development of alternative tests that replace, refine, or reduce the use of animals in toxicological tests, the federal government has made substantial progress in developing new tests. Over 70 alternative test methods for toxicity tests required by federal regulations are currently listed on the ICCVAM website.<sup>18</sup>

Yet it is estimated that federal agencies still spend millions or billions of dollars per year on animal experiments.<sup>19</sup> The Animal Law Committee has previously expressed its concern about inhumane tests secretly conducted by the USDA Meat Animal Research

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<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32010L0063>.

<sup>10</sup> New Zealand Animal Welfare Amendment Act (No 2) 2015 § 84(A), <http://www.legislation.govt.nz/act/public/2015/0049/latest/DLM6432504.html>.

<sup>11</sup> Johns Hopkins Bloomberg School of Public Health, Center for Alternatives to Animal Testing, *Import Ban on Animal-tested Products Goes into Effect in Israel*, [http://altweb.jhsph.edu/news/2012/Israel\\_bans\\_testing.html](http://altweb.jhsph.edu/news/2012/Israel_bans_testing.html).

<sup>12</sup> Vishwa Mohan, *India bans import of cosmetics tested on animals*, THE TIMES OF INDIA (Oct. 14, 2014), <http://timesofindia.indiatimes.com/india/India-bans-import-of-cosmetics-tested-on-animals/articleshow/44814398.cms>.

<sup>13</sup> ICCVAM, ICCVAM SUMMARY REVIEW DOCUMENT: THE LOW VOLUME EYE TEST B-15 (2010), [https://ntp.niehs.nih.gov/iccvam/docs/ocutox\\_docs/lvet/appb-srd.pdf](https://ntp.niehs.nih.gov/iccvam/docs/ocutox_docs/lvet/appb-srd.pdf).

<sup>14</sup> S. Parasuraman, *supra* note 6, at 76.

<sup>15</sup> Samantha L. Wilson, *et al.*, *An Overview of Current Techniques for Ocular Toxicity Testing*, TOXICOLOGY 33 (2015), [http://ac.els-cdn.com/S0300483X14002157/1-s2.0-S0300483X14002157-main.pdf?\\_tid=54b3d9fc-0907-11e7-bb5d-00000aab0f6c&acdnat=1489531454\\_cabb522c4742aafab5a62e720adda59b](http://ac.els-cdn.com/S0300483X14002157/1-s2.0-S0300483X14002157-main.pdf?_tid=54b3d9fc-0907-11e7-bb5d-00000aab0f6c&acdnat=1489531454_cabb522c4742aafab5a62e720adda59b).

<sup>16</sup> Parasuraman, *supra* note 6, at 75.

<sup>17</sup> *Id.*

<sup>18</sup> U.S. Dept. of Health & Human Svcs., Nat'l Toxicity Program, *Alternative Methods Accepted by US Agencies*, <https://ntp.niehs.nih.gov/pubhealth/evalatm/iccvam/acceptance-of-alternative-methods/index.html>.

<sup>19</sup> *E.g.*, Nikki Schwab, *Beagles 'Lobby' Against Taxpayer-Funded Animal Experiments*, US NEWS & WORLD REPORT (July 9, 2014), <https://www.usnews.com/news/blogs/washington-whispers/2014/07/09/beagles-lobby-against-taxpayer-funded-animal-experiments>; Thomas Hartung, *Toxicology for the Twenty-First Century*, NATURE 208 (2009), <http://www.animalexperiments.info/resources/Studies/Alternatives/Tox--overall.-Hartung-2009./Toxicity-Hartung-2009-Nature.pdf>.

Center that were uncovered by a *New York Times* exposé in 2015.<sup>20</sup> One of these tests involved injecting testosterone into pregnant sows at such high levels that it “began to deform their babies’ genitals, making urination difficult.”<sup>21</sup> And in 2014, the Food and Drug Administration, National Center for Toxicological Research, awarded funding for tests involving the exposure of nicotine on adolescent squirrel monkeys.<sup>22</sup>

Little is known about the details of most toxicological tests on animals funded by federal tax dollars, such as the cost or the number of animals used. In 2016, thirteen members of Congress asked the Government Accountability Office to conduct a review of animal research at federal agencies stating that, “it is impossible to determine what federal animal research programs currently entail, what they cost and if they meet federal standards because of the limited and decentralized information available publicly.”<sup>23</sup> The letter notes that federal agencies are not currently required to report their total use of animals in research.<sup>24</sup>

Data about toxicological tests on animals is critical for ensuring that tax dollars are used efficiently, that animals are not being used unnecessarily, and that animal welfare standards are maintained when they are used. For example, as a result of the *New York Times* exposé referred to above and the ensuing public outcry, the USDA was audited and the Meat Animal Research Center has been forced to make efforts to improve animal welfare.<sup>25</sup> The animal welfare improvements would likely not have occurred if the public had remained in the dark about tests that its tax dollars were funding.

### III. OPPOSITION

Opposition to sharing information about animal experimentation with the public appears to be concern about threats of violence against scientists engaged in animal testing.<sup>26</sup> But the information required under the FACT Act would not require the

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<sup>20</sup> ANIMAL LAW COMMITTEE, REPORT ON THE ANIMAL WELFARE IN AGRICULTURAL RESEARCH ENDEAVORS ACT (March 2016), <http://www2.nycbar.org/pdf/report/uploads/20073061-AnActtoamendtheAnimalWelfareActANIMALS32216.pdf>.

<sup>21</sup> Michael Moss, *U.S. Research Lab Lets Livestock Suffer in Quest for Profit*, N.Y. TIMES (Jan. 29, 2015), <http://www.nytimes.com/2015/01/20/dining/animal-welfare-at-risk-in-experiments-for-meat-industry.html>.

<sup>22</sup> U.S. Dept. of Health & Human Svcs., Aspects of Nicotine Self-Administration in a Nonhuman Primate, <https://www.fda.gov/TobaccoProducts/PublicHealthScienceResearch/Research/ucm483304.htm>.

<sup>23</sup> Letter from Representative Ken Calvert et al., to Gene L. Dodaro, Comptroller General of the U.S. 1 (Dec. 8, 2016), [https://www.scribd.com/document/334235428/Congress-GAO-Animal-Testing-Request#from\\_embed](https://www.scribd.com/document/334235428/Congress-GAO-Animal-Testing-Request#from_embed).

<sup>24</sup> *Id.*

<sup>25</sup> Patrick Farrell, *U.S. Animal Research Center Needs More Oversight, Audit Says*, N.Y. TIMES (Dec. 20, 2016), [https://www.nytimes.com/2016/12/20/dining/us-meat-animal-research-center-audit.html?\\_r=0](https://www.nytimes.com/2016/12/20/dining/us-meat-animal-research-center-audit.html?_r=0).

<sup>26</sup> See, e.g., Memo from Chavonda Jacobs-Young, Administrator, USDA, to Gil H. Harden, Assistant Inspector General for Audit, Office of the Inspector General, USDA re: United States Meat Animal Research Center Review 5 (Sept. 22, 2016) (explaining that since the *New York Times* exposé, employees received threats), <https://www.usda.gov/oig/webdocs/02007-0001-31.pdf>.

disclosure of the names of employees involved in testing or other sensitive details,<sup>27</sup> and steps may be taken by agencies to mitigate the possibility of violent threats.<sup>28</sup>

#### **IV. CLOSING SUMMARY**

For the reasons explained above, the Animal Law Committee approves the FACT Act.

Lori Barrett  
Chair, Animal Law Committee

May 2017

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<sup>27</sup> See footnote 4, *supra*.

<sup>28</sup> See, e.g., U.S.D.A. OFFICE OF THE INSPECTOR GENERAL, U.S. MEAT ANIMAL RESEARCH CENTER REVIEW AUDIT REPORT 02007-0001-31, 11 (Sept. 30, 2016) (suggesting a few ways to ensure safety of employees while providing increased transparency about animal experimentation to the public), <https://www.usda.gov/oig/webdocs/02007-0001-31.pdf>.