

2022

## The Heart of Animal Research and Testing Law: A Study of the Animal Welfare Act, the Health Research Extension Act, and Proposed Solutions Supporting the Three Rs, 55 UIC L. Rev. 1 (2022)

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THE HEART OF ANIMAL RESEARCH AND TESTING LAW: A STUDY OF THE ANIMAL WELFARE ACT, THE HEALTH RESEARCH EXTENSION ACT, AND PROPOSED SOLUTIONS SUPPORTING THE THREE RS

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The contents of this Article contain the author’s analysis and are not the views or analysis of the author’s client(s), associates, affiliates, or employers, past or present, nor should this Article be construed as legal advice.

This Article is dedicated to John F. Montanaro III (August 10, 1991-April 26, 2011). John F. Montanaro III is Lenore M. Montanaro’s brother. John passed away from acute lymphoblastic leukemia at the age of nineteen. While in active treatment for cancer, John focused his high school senior project on the topic of dogs and helping pets and people. Through his efforts, John was able to save over one dozen dogs from being unnecessarily euthanized due to owners’ financial difficulties to pay for their animals’ oncological treatments. John did this through Ocean State Veterinary Specialists (“OSVS”), located in East Greenwich, Rhode Island, and he raised the money himself as part of his high school senior project. After John passed away, OSVS created a garden vigil on its premises and named it the “John F. Montanaro III Memorial Garden” in recognition of John and his efforts to help pets and people.

The author thanks Jesse Carbonaro, Maria Conversa, Erin Murphy, and Brooke Payton for their edits and dedication to this Article and James F. Gesualdi for his mentorship and wisdom.

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## I. INTRODUCTION

When some people think of animal research and testing, they may visualize sterile and cold laboratories or complex equipment, wired crates without pans filled with animals, and electric machinery. They may envision dozens of animals experiencing profound suffering and torture. These conceptualizations are understandable, as history, books, and media, along with some individuals and organizations have put forth frightening information about animal research and testing methods or outcomes.<sup>1</sup> This does not mean, however, that the available or propounded information about the use of animals in research is untrue compared to how it is described or perceived. Rather, the use of animals in research and testing is often conceptualized and

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1. History reveals that an analysis of the moral rights of animals has occurred for decades and that the use of animals in research has long been a practice, including a practice of controversy. *See generally* ARTHUR SCHOPENHAUER, ON THE BASIS OF MORALITY (1903) (writing that animals have moral rights); ARTHUR SCHOPENHAUER, PARERGA AND PARALIPOMENA (1851) (expressing opposition to vivisection of animals); JEREMY BENTHAM, AN INTRODUCTION TO THE PRINCIPLES OF MORALS AND LEGISLATION (1823) (writing in support of the moral interests of animals); JEAN-JACQUES ROUSSEAU, DISCOURSE ON THE ORIGIN OF INEQUALITY (1755) (writing about the sentience of animals). Many books have featured animal research as a central theme or topic. *See generally* NEIL ABRAMSON, UNSAID (2011) (writing a fictional story of an attorney who is trying to save a chimpanzee who is intended to be used for research purposes). Movies and television have featured animal research as a central theme or topic: in *Legally Blonde 2*, Elle Woods “saves” her dog’s mother from a cosmetic testing laboratory; and *The Plague Dogs*; *Test Subjects*; *Pinky and the Brain*; and *Behind the Mask* are other examples of visual portrayals of animal research. Some non-profit organizations announce the ills of animal research in an attempt to solicit donations. *See* PETER SINGER, ETHICS INTO ACTION: HENRY SPIRA AND THE ANIMAL RIGHTS MOVEMENT, at 50 (1998) (quoting Henry Spira:

It didn’t make any sense to me, to put out a publication, to tell people about atrocities, and ask them to send money so we can tell you next month about more atrocities. Meanwhile, the atrocities keep increasing, the treasuries of the antivivisection groups keep increasing, and it doesn’t help one solitary animal. It defines common sense to me why people would be doing that.).

understood too generally. Research involving animals varies in terms of the type of species, method of use, duration of the experiment, and more.<sup>2</sup> Conversely, science and medicine often expect, even demand, other disciplines to accept what is done to animals as necessary, as though science and medicine ought to be trusted by the public without question and without fail. This misinformation, unquestioned reliance on the word of science and medicine, and lack of transparency are distracting and harmful to people, animals, and science.

Instead, the use of animals in research must be understood as a living, breathing, and dynamic process that exists on a multi-dimensional spectrum. This multi-dimensional spectrum is a metaphorical heartbeat. It requires many individuals, agencies, organizations, advocates, scientists, medical professionals, veterinarians, and attorneys to maintain its pulse, to carry a body of advances forward, for the betterment of people and animals.

It is important to understand the spectrum of outcomes for animal research and testing. Conceptually grouping animals who are used in research with minimal pain or on an outpatient basis (*e.g.*, into the same category as animals who are significantly researched or lose their lives during the research process) dishonors the lives of animals who experience profound suffering. In fact, some (although not nearly enough) research conducted today is as minimally invasive to animals as it can be and is done on animals who are able to engage in species-specific behavior and are free to live their lives, in homes, with families.<sup>3</sup> Certainly, this minimally invasive animal research is not what most opponents of animal research and testing resent or resist.<sup>4</sup> Rather, many opponents abhor the use of otherwise healthy or adoptable animals, especially cats and dogs,<sup>5</sup> into what they perceive as unjustified experiments

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2. See generally Courtney G. Lee, *The Animal Welfare Act at Fifty: Problems and Possibilities in Animal Testing Regulation*, 95 NEB. L. REV. 194 (2016) (writing about various methods of testing, differing species used, and alternatives to animal-based research methods).

3. With permission of animals' owners, clinical trials are performed on companion animals. See generally *A Pilot study to evaluate the effectiveness and safety of a new drug in the management of dogs with congestive heart failure caused by degenerative (myxomatous) mitral valve disease*, CUMMINGS VETERINARY MED. CTR. AT TUFTS UNIV., [www.trials.vet.tufts.edu/clinical\\_trials/a-pilot-study-to-evaluate-the-effectiveness-and-safety-of-a-new-drug-in-the-management-of-dogs-with-congestive-heart-failure-caused-by-degenerative-myxomatous-mitral-valve-disease/](http://www.trials.vet.tufts.edu/clinical_trials/a-pilot-study-to-evaluate-the-effectiveness-and-safety-of-a-new-drug-in-the-management-of-dogs-with-congestive-heart-failure-caused-by-degenerative-myxomatous-mitral-valve-disease/) [perma.cc/A3RJ-6XTG] (last visited Jan 9, 2022) (conducting a study about congestive heart failure in companion animal dogs).

4. *Brown University criticized for using live pigs in medical training*, CBS NEWS (Jan. 30, 2019), [www.cbsnews.com/news/brown-university-criticized-for-using-live-pigs-in-medical-training/](http://www.cbsnews.com/news/brown-university-criticized-for-using-live-pigs-in-medical-training/) [perma.cc/DC6G-VYT6] (establishing that some opponents of animal research resist invasive animal-based research methods).

5. There are countless reasons why people love companion animals ("pets").

that cost the animals their lives and wellbeing. This *is* true: many animals used in research and testing experience immense trauma and/or lose their lives.<sup>6</sup>

The emerging concept of “One Health” necessitates a unified approach to the health and well-being of people and animals.<sup>7</sup> This demonstrates that some research that is done to benefit dogs, for example, may have the added benefit of supporting scientific advances to benefit humans, and vice-versa.<sup>8</sup> However, deontological, utilitarian, virtue-based, or other philosophical perspectives about the benefits or detriments of the worthiness of animal research and testing is outside the scope of this Article. Moreover, this Article is not an advocacy piece. The author is not employed by an animal welfare, protection, or rights organization nor is the author writing from the lens of needing to generate or

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Pets provide emotional support, wellness, safety and protection, companionship, and love. Dogs and humans evolved together and share a reciprocal relationship. See Jeffery Kluger, *Why Dogs and Humans Love Each Other More Than Anyone Else*, TIME (July 20, 2018), [www.time.com/5342964/human-bond-dog-thoughts/](http://www.time.com/5342964/human-bond-dog-thoughts/) [perma.cc/5SQH-R6E6] (writing that dogs and humans have a “symbiotic” relationship and that humans and dogs “adore each other.”).

6. See generally John F. Van Vleet et al., *Cardiac Disease Induced By Chronic Adriamycin Administration In Dogs And An Evaluation Of Vitamin E And Selenium As Cardioprotectants*, 99 AM. J. PATHOL. 1 (1980) (stating that “[c]hronic adriamycin. . . intoxication was produced in three groups of beagle dogs [(six dogs per group)] by weekly intravenous injections . . . for [twenty] weeks” and all of the dogs developed cardiomyopathy; “death occurred in [eleven] dogs during [w]eeks 17-20”).

7. See generally *One Health*, CTRS. FOR DISEASE CONTROL & PREVENTION, [www.cdc.gov/onehealth/index.html](http://www.cdc.gov/onehealth/index.html) [perma.cc/BWF5-A7A4] (last visited Nov. 15, 2021) (noting that there is a connection between the health of people, animals, and the environment); *Healthy Pets, Healthy People*, CTRS. FOR DISEASE CONTROL & PREVENTION, [www.cdc.gov/healthypets/index.html](http://www.cdc.gov/healthypets/index.html) [perma.cc/3CKW-6EVT] (last visited Nov. 15, 2021) (establishing that there is a bond between people and pets).

8. *One Health: It’s for All of Us*, U.S. FOOD & DRUG ADMIN., [www.fda.gov/animal-veterinary/animal-health-literacy/one-health-its-all-us](http://www.fda.gov/animal-veterinary/animal-health-literacy/one-health-its-all-us) [perma.cc/46ZC-S73A] (last visited Nov. 15, 2021) (citing *Mission Statement, ONE HEALTH INITIATIVE*, [www.onehealthinitiative.com/mission-statement/](http://www.onehealthinitiative.com/mission-statement/) [perma.cc/W37W-RVFE] (last visited Nov. 15, 2021)) (quoting in part that

[m]edical advances in understanding and treating a disease in one species, such as heart disease in people, may be applied to other species. And a change in the environment can affect all living things, from people to animals to plants. The One Health Initiative recognizes this interconnectedness and advocates a comprehensive approach to health and environmental problems versus a piecemeal approach. By building bridges between physicians, veterinarians, environmental scientists, and public health professionals, the initiative aims to ‘promote, improve, and defend the health and well-being of all species.’);

see also Cummings, *supra* note 3 (conducting a study about congestive heart failure in companion animal dogs).

secure a “victory” to solicit public support or monetary donations.<sup>9</sup> Rather, this Article is solely focused on people, animals, and science, the current state of the law, and the incremental steps that can be taken *now* to advance the welfare of animals used in research and testing. An understanding of the multi-dimensional spectrum of the use of animals in research and testing is required to understand how people and animals can best be served and protected now and in the future.

Just as a heart contains ventricles and chambers, which contribute to a healthy circulatory system, so too is scientific research and testing like a heart contributing to a system that aims to keep the body of humanity well. For far too long, the heart of scientific research and testing has been tachycardiac<sup>10</sup> — racing, working hard, for more advances in the name of science, but not necessarily enabled to do what is best for science. In other words, scientific research and testing have been working harder, not smarter.

Please allow this Article to serve as an intentional slowdown of the pulse of animal-based scientific research and testing law. This intentional slowing begins with a solid introductory framework of the sub-areas of animal research while also noting the well-known and longstanding standards governing the animal research and testing arena.

Animal research and testing can be generally understood as an umbrella phrase encompassing specific categories of research. These categories can be identified as biomedical, chemical, and education/training. Biomedical animal research generally refers to research that is done to the body systems of animals, such as research that brings drugs into development.<sup>11</sup> Chemical animal research generally refers to research that is done to animals that involves components of or whole products, *i.e.*, chemicals, and that usually tests for the safety and efficacy of chemicals.<sup>12</sup>

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9. Singer, *supra* note 1, at 50. (quoting Henry Spira:

We did not want to build a tax-exempt charity to raise money in order to be able to raise more money. We wanted to adapt to the animal movement the traditions of struggle which had proven effective in the civil rights movement, the union movement and the women’s movement . . . The animal movement had been starved of victories.)

10. Tachycardic refers to tachycardia, which is a term used to describe a fast heart rate. See Tachycardia, CLEVELAND CLINIC, [www.my.clevelandclinic.org/health/diseases/22108-tachycardia](http://www.my.clevelandclinic.org/health/diseases/22108-tachycardia) [perma.cc/4Q4K-WNZU] (last visited Jan. 9, 2022) (stating that Tachycardia is when the “heart beats faster than it should”).

11. 21 U.S.C. § 355(b)(5)(B) (2022); see also 42 U.S.C. § 262 (2022) (requiring the regulation of the applications for and uses of biologic products).

12. See *generally* 15 U.S.C. § 2601 *et seq.* (2022) (referencing the Toxic Substances Control Act (“TSCA”), which governs the use of chemicals and animal testing, and does not require the use of animals for certain categories, such as cosmetics per 15 U.S.C. § 2602(2)(B)(vi) (2022)).

Education/training research generally refers to research that is done in a university, classroom, or educational setting and/or with an educational/training purpose.<sup>13</sup> Unlike other forms of research and testing, the use of animals in education/training research is not usually a U.S. federal government legal requirement to achieve a particular end within most education, although, if animals are used, local, state, and federal laws regarding the use of animals in education must be followed.<sup>14</sup>

Animal research and testing has a variety of uses and requirements within federal agencies including the Food and Drug Administration (“FDA”)<sup>15</sup> and the Environmental Protection Agency (“EPA”).<sup>16</sup> Current federal law requires, as another example, that the U.S. Health and Human Services issue guidance for applications for drug development, and further mandates that animal and clinical trials form the basis of a claim for drug development.<sup>17</sup> Current federal regulations require “well-controlled animal studies when the results of those studies establish that the drug product is reasonably likely to produce clinical benefit to humans.”<sup>18</sup>

The National Institute of Health’s (“NIH”) Office of Laboratory Animal Welfare (“OLAW”) recognizes and encourages

13. See generally 7 U.S.C. § 2132(e) (2022) (defining a research facility, in part, as an institution, but does not include all schools and even if some schools are included as a research facility, they can be exempt; also defining an exhibitor).

14. *What are the regulations for using animals in education programs?*, USDA, [www.nal.usda.gov/legacy/aglaw/what-are-regulations-using-animals-educational-programs](http://www.nal.usda.gov/legacy/aglaw/what-are-regulations-using-animals-educational-programs) [perma.cc/6E4R-E7TJ] (last visited Jan. 9, 2022); *Humane Education Laws by State*, ANIMAL WELFARE INST., [www.awionline.org/content/humane-education-laws-state](http://www.awionline.org/content/humane-education-laws-state) [perma.cc/EPA4-QB3W] (last visited Jan. 9, 2022).

15. *Development & Approval Process: Drugs*, U.S. FOOD & DRUG ADMIN, [www.fda.gov/drugs/development-approval-process-drugs](http://www.fda.gov/drugs/development-approval-process-drugs) [perma.cc/5KKG-V3JR] (last visited Nov. 15, 2021) (stating that

[b]efore a drug can be tested in people, the drug company or sponsor performs laboratory and animal tests to discover how the drug works and whether it’s likely to be safe and work well in humans. Next, a series of tests in people is begun to determine whether the drug is safe when used to treat a disease and whether it provides a real health benefit.).

16. On September 10, 2019, the former EPA Administrator announced that an aggressive pursuit in the reduction in animal testing stating that “[t]he EPA will reduce its requests for, and [its] funding of, mammal studies . . . by 30 percent by 2025 and eliminate all mammal study requests and funding by 2035.” *Administrator Memo Prioritizing Efforts to Reduce Animal Testing*, U.S. ENV’T PROT. AGENCY (Sep. 10, 2019), [www.epa.gov/research/administrator-memo-prioritizing-efforts-reduce-animal-testing-september-10-2019](http://www.epa.gov/research/administrator-memo-prioritizing-efforts-reduce-animal-testing-september-10-2019) [perma.cc/57DM-D32K].

17. 21 U.S.C. § 355(b)(5)(B) (2022); see also 42 U.S.C. § 262 (2022) (requiring the regulation of the applications for and uses of biologic products).

18. 21 C.F.R. § 314.610 (2022).

implementation of “The Three Rs,”<sup>19</sup> which are the (1) Replacement;<sup>20</sup> (2) Refinement;<sup>21</sup> and (3) Reduction<sup>22</sup> of animals used in research and testing. The consistent reach toward The Three Rs is our collective pillar; all involved in the research and testing of animals should work diligently to replace, refine, and reduce animals used in research and testing. OLAW’s *Guide* is an ideal starting place to understand The Three Rs more fully.<sup>23</sup>

This Article analyzes animal research that is done when an animal dealer is involved and/or within a research facility,<sup>24</sup>

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19. *Guide for the Care and Use of Laboratory Animals*, INST. FOR LAB. ANIMAL RSCH., 1, 4-5 (2011), [www.olaw.nih.gov/sites/default/files/Guide-for-the-Care-and-Use-of-Laboratory-Animals.pdf](http://www.olaw.nih.gov/sites/default/files/Guide-for-the-Care-and-Use-of-Laboratory-Animals.pdf) [perma.cc/EU7M-UJ9A] [hereinafter *Guide*] (stating that The Three Rs “represent a practical method” of implementing ethical use principles. Further stating that “[i]n 1959, W.M.S. Russell and R.L. Burch published a practical strategy of replacement, refinement, and reduction” which is now an “internationally accepted approach for researchers to apply when deciding to use animals in research and designing humane animal research studies”).

20. Replacement includes replacing the animals themselves. It also includes replacement of the processes used in research or questions that are asked in research. *See id.* at 5 (stating that “[r]eplacement refers to methods that avoid using animals. The term includes absolute replacements (*i.e.*, replacing animals with inanimate systems such as computer programs) as well as relative replacements (*i.e.*, replacing animals such as vertebrates with animals that are lower on the phylogenetic scale).”).

21. *Id.* (stating that

[r]efinement refers to modifications of husbandry or experimental procedures to enhance animal well-being and minimize or eliminate pain and distress. While institutions and investigators should take all reasonable measures to eliminate pain and distress through refinement, IACUCs should understand that with some types of studies there may be either unforeseen or intended experimental outcomes that produce pain. These outcomes may or may not be eliminated based on the goals of the study.).

22. *Id.* (stating that

[r]eduction involves strategies for obtaining comparable levels of information from the use of fewer animals or for maximizing the information obtained from a given number of animals (without increasing pain or distress) so that in the long run fewer animals are needed to acquire the same scientific information. This approach relies on an analysis of experimental design, applications of newer technologies, the use of appropriate statistical methods, and control of environmentally related variability in animal housing and study areas[.]).

23. *Guide*, *supra* note 19, at 1-9.

24. *See* 7 U.S.C. § 2132(e) (2022) (stating that a research facility

means any school (except an elementary or secondary school), institution, organization, or person that uses or intends to use live animals in research, tests, or experiments, and that (1) purchases or transports live animals in commerce, or (2) receives funds under a grant, award, loan, or contract from a department, agency, or instrumentality of the United States for the purpose of carrying out research, tests, or



whether that research is for biomedical research, chemical research, and/or education/training research. The goal of this Article is to discuss animal welfare law that is conducted pursuant to the Animal Welfare Act (“AWA”) and/or the Health Research Extension Act (“HREA”) and to identify possible solutions to further the longstanding goals of The Three Rs.

Animal research is, presumably, done in the name of science—but what is science? From a legal perspective, the U.S. Supreme Court described it best within the context of evidentiary law and animal testing law in the *Daubert v. Merrell Dow Pharmaceuticals, Inc.*<sup>25</sup> decision as follows:

Of course, it would be unreasonable to conclude that the subject of scientific testimony must be “known” to a certainty; arguably, there are no certainties in science. . . . (“Indeed, scientists do not assert that they know what is immutably ‘true’—they are committed to searching for new, temporary, theories to explain, as best they can, phenomena”); . . . (“Science is not an encyclopedic body of knowledge about the universe. Instead, it represents a *process* for proposing and refining theoretical explanations about the world that are subject to further testing and refinement.” (emphasis in original)).<sup>26</sup>

Therefore, because science itself is a process, it too, must evolve. The U.S. Supreme Court held in *Daubert* that, from an evidentiary perspective, an expert’s testimony must be based on “scientific knowledge” in order to be admissible in a federal trial:

The primary locus of this obligation is Rule 702, which clearly contemplates some degree of regulation of the subjects and theories about which an expert may testify. “*If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue*” an expert “may testify *thereto*.” (emphasis added.) The subject of an expert’s testimony must be “scientific . . . knowledge.”<sup>27</sup>

The Court in *Daubert* requires, therefore, that scientific

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experiments . . . ).

Further, the AWA permits the USDA to

exempt, by regulation, any such school, institution, organization, or person that does not use or intend to use live dogs or cats, except those schools, institutions, organizations, or persons, which use substantial numbers (as determined by the [USDA]) of live animals the principal function of which schools, institutions, organizations, or persons, is biomedical research or testing, when in the judgment of the [USDA], any such exemption does not vitiate the purpose of this chapter).

*See generally* AWA & AWA Regulations, *infra* note 30 (noting that some entities may not be considered to be dealers and/or research facilities per the definitions of dealer and/or research facility under the AWA and its Regulations).

25. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 590 (1993).

26. *Id.*

27. *Id.* at 588.

knowledge be reliable. It must be “derived by the scientific method”<sup>28</sup> as opposed an inference or assertion that is not grounded in the process of the scientific method:

But, in order to qualify as “scientific knowledge,” an inference or assertion must be derived by the scientific method. Proposed testimony must be supported by appropriate validation—*i.e.*, “good grounds,” based on what is known. In short, the requirement that an expert’s testimony pertain to “scientific knowledge” establishes a standard of evidentiary reliability.<sup>29</sup>

This Article summarizes some of the basic statutes, regulations, and case law involved in the research and testing of animals. Parts II and III offer a summary of the background and purpose, as applicable, as well as the current language and meaning of two basic United States federal laws, the AWA and the HREA, pertaining to research and testing. Part IV summarizes a small sample of relevant and basic prior legal challenges related to animal research and testing law. Part V identifies possible steps forward to further advance The Three Rs.

## II. ANIMAL WELFARE ACT & ITS REGULATIONS

The AWA,<sup>30</sup> enacted in 1966, is a federal law in the United States.<sup>31</sup> The Act and its associated regulations<sup>32</sup> provide minimum standards for the treatment of animals, including the treatment of some animals in some research and testing.<sup>33</sup> The United States Department of Agriculture (“USDA”), via its Animal and Plant Health Inspection Service (“APHIS”), has an Animal Care program that exists to “[e]nsure the humane treatment of animals covered by the Animal Welfare Act.”<sup>34</sup>

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28. *Id.* at 590.

29. *Id.*

30. The AWA is 7 U.S.C. §§ 2131 *et seq.* (2022). The AWA Regulations are 9 C.F.R. §§ 1.1-4.11 (2022).

31. 7 U.S.C. §§ 2131-2160 (2022).

32. 7 U.S.C. § 2151 (2022) states that the USDA may “promulgate such rules, regulations, and orders as he may deem necessary in order to effectuate the purposes” of the AWA.”

33. The AWA imposes other requirements not directly related to research and testing law or that are unnecessary for this discussion. These include, but are not limited to, a severability provision, an animal fighting provision, and also the prohibition on slaughter of dogs and cats for human consumption. 7 U.S.C. §§ 2152, 2156, 2160 (2022). While such requirements are useful to know, they are beyond the scope of this Article and are thus excluded from analysis in this Article.

34. See *Animal and Plant Health Inspection Service: About Animal Care*, U.S. DEPT. OF AGRIC. (June 2, 2020), [www.aphis.usda.gov/aphis/ourfocus/animalwelfare/usda-animal-care-overview](http://www.aphis.usda.gov/aphis/ourfocus/animalwelfare/usda-animal-care-overview) [perma.cc/CLW3-MURN] (providing information and resources to the public about the USDA and the APHIS).

### A. Background and Purpose

The AWA has its origins in laboratory animal law.<sup>35</sup> Prior to the introduction of the bill, which was later passed (with changes) and enacted as Public Law 89-544, H.R. 13881,<sup>36</sup> two articles, in two distinct magazine publications, told the story of animals used in research.<sup>37</sup> The first article, titled, *The Lost Pets That Stray to the Labs*, was published by Sports Illustrated.<sup>38</sup> The article, displayed on pages thirty-six to forty-nine of the thirty-five-cent publication, told the story of Pepper, a five-year-old Dalmatian who disappeared from the eighty-acre yard of a family in Lakavage, Pennsylvania.<sup>39</sup> The article stated that it was likely that “a dog thief simply stopped his car on the road in front of the Lakavage house, opened the door, invited Pepper to hop in, and then drove away with her.”<sup>40</sup> The article foreshadowed the eventual enactment of the Animal Welfare Act when it stated:

[w]hether or not the martyred Pepper will succeed in making a federal case out of dognapping is up to the men who make our nation’s laws, but there are two things that the legislative investigation of her death and disappearance have made quite clear: 1) many pet dogs are being stolen from the front lawns and sidewalks of this country, and 2) the thefts in large part are motivated by science’s constant and growing need for laboratory animals.<sup>41</sup>

A second article, titled, *Concentration Camps for Dogs*, was published by Life.<sup>42</sup> The article, displayed on pages twenty-one to

35. PUB. L. NO. 89-544, 80 Stat. 350 (1966), *supra* note 50.

36. Coles Phinzy, *The Lost Pets That Stray to the Labs*, SPORTS ILLUSTRATED 41 (Nov. 29, 1965) [www.vault.si.com/vault/1965/11/29/the-lost-pets-that-stray-to-the-labs](http://www.vault.si.com/vault/1965/11/29/the-lost-pets-that-stray-to-the-labs) [perma.cc/8NW7-2BMJ] (quoting Congressman Resnick stating,

‘I am not an antivivisectionist,’ he said, ‘and the issue of vivisection is nowhere involved in this legislation. Neither is the issue of animal care in the laboratory. This bill is concerned entirely with the theft of dogs and cats and, to a somewhat lesser degree, the indescribably filthy conditions in which they are kept by the dealer.’).

*See generally* Hearing Before the Committee on Commerce, 89th Cong. at 293 (1966), [www.awahistory.nal.usda.gov/search/5250786](http://www.awahistory.nal.usda.gov/search/5250786) [perma.cc/KC5V-AY3H] (noting that the legislative history materials provide information about the purposes and background of provisions of the AWA); see also *Concentration Camps for Dogs*, *infra* note 46 (writing about animals that were stolen and used in research).

37. Phinzy, *supra* note 36 at 41; *Concentration Camps for Dogs*, *infra* note 42 at 22-28.

38. Phinzy, *supra* note 36 at 41.

39. *Id.*

40. *Id.*

41. *Id.*

42. *Concentration Camps for Dogs*, LIFE MAG. 22-28 (Feb. 4, 1966), [www.flickr.com/photos/13476480@N07/albums/72157649635811481/](http://www.flickr.com/photos/13476480@N07/albums/72157649635811481/) [perma.cc/S2KP-F4AB].

twenty-nine of the aforementioned thirty-five-cent publication, discussed the story of Lucky, a “lemon-colored English pointer with a fine head and subtle signs of good, expensive breeding.”<sup>43</sup> The article described how Lucky was more than “lucky” (*i.e.*, blessed) when a woman bought him for three dollars, plus one dollar for his chain, at an auction.<sup>44</sup> She saved him from the fate of many of his canine counterparts in the United States.

Less than one year after the publication of the LIFE magazine article, the AWA, originally enacted as the Laboratory Animal Welfare Act of 1966, was born.<sup>45</sup> It “authorize[d] the Secretary of Agriculture to regulate the transportation, sale, and handling of dogs, cats, and certain other animals intended to be used for purposes of research or experimentation, and for other purposes.”<sup>46</sup> The Laboratory Animal Welfare Act of 1966, now the AWA, was enacted with three purposes: (1) to ensure that animals intended for use in research facilities, exhibition purposes, or for use as pets are provided humane care and treatment; (2) to assure the humane treatment of animals during transportation in commerce;<sup>47</sup> and (3) to protect the owners of animals from the theft of their animals by preventing the sale or use of animals which have been stolen.<sup>48</sup> Moreover, the law stated that Congress found it “essential to regulate . . . the transportation, purchase, sale, housing, care, handling, and treatment of animals by carriers or by persons or organizations engaged in using them for research or experimental purposes . . . .”<sup>49</sup>

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43. *Id.*

44. *Id.* (stating that

[u]nscrupulous dog ‘dealers’ taking advantage of the growing demand for dogs for vital medical research are running a lucrative and unsavory business. . . . To cash in on [the need for dogs in research] the dealers rove the country paying a buck or two to anyone who comes forward with a dog, and no questions asked).

45. PUB. L. NO. 89-544, 80 Stat. 350 (1966).

46. *Id.*

47. *See* 7 U.S.C. §§ 2132 (2022) (stating that commerce means

trade traffic, transportation, or other commerce . . . (1) between a place in a [s]tate and any place outside of such State, or between points within the same [s]tate but through any place outside thereof, or within any territory, possession, or the District of Columbia; (2) which affects trade, traffic, transportation, or other commerce described in paragraph (1)).

*See also* 7 U.S.C. § 2148 (2022) (prohibiting the importation of a live dog into the United States for the purposes of resale unless the dog is in good health; has vaccinations; and is at least six months of age; or unless a dog is imported for research purposes or veterinary treatment).

48. 7 U.S.C. § 2131 (2022).

49. *Id.*

## B. Requirements

The AWA and its associated regulations<sup>50</sup> have several requirements to effectuate their intended purposes.<sup>51</sup> These requirements include standards and policies around licensing and registration,<sup>52</sup> disposing of animals,<sup>53</sup> obtaining animals,<sup>54</sup> recordkeeping,<sup>55</sup> animal treatment,<sup>56</sup> Institutional Animal Care and Use Committee (“IACUC”) requirements,<sup>57</sup> training and information requirements,<sup>58</sup> and investigations, inspections, and penalties.<sup>59</sup> The AWA also imposes a principal-agent relationship upon persons or entities for acts, omissions, or failures under the AWA.<sup>60</sup>

Before one can understand the aforementioned requirements of the AWA, however, it is crucial to know how the AWA defines “animal.” The AWA does not actually cover all species of animals, or even all species in the Chordata Phylum.<sup>61</sup> Rather, the definition of animal under the AWA includes some species (“covered animals”) and excludes other species as follows:

The term “animal” means 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 excludes (1) birds, rats

50. 9 C.F.R. §§ 1.1-4.11 (2022).

51. *Id.*

52. 7 U.S.C. §§ 2133, 2134, 2136, 2142, 2149, 2153 (2022); 9 C.F.R. §§ 2.1-2.27; 9 C.F.R. §§ 2.30, 2.31 (2022).

53. 7 U.S.C. §§ 2135 (2022).

54. 7 U.S.C. §§ 2137, 2138, 2148, 2158 (2022); 9 C.F.R. § 2.60, 2.100-2.102 (2022).

55. 7 U.S.C. §§ 2140, 2142, 2146a (2022); 9 C.F.R. §§ 2.35, 2.75-2.80 (2022).

56. 7 U.S.C. §§ 2141, 2142, 2143, 2144 (2022); 9 C.F.R. §§ 2.33, 2.40 (2022).

57. 7 U.S.C. §§ 2143, 2144, 2157 (2022); 9 C.F.R. §§ 2.31, 2.37 (2022).

58. 7 U.S.C. §§ 2144, 2145 (2022); 9 C.F.R. § 2.32 (2022).

59. 7 U.S.C. §§ 2146, 2147, 2149 (2022).

60. 7 U.S.C. §§ 2139 (2022) (stating that

[w]hen construing or enforcing the provisions of [the AWA], the act, omission, or failure of any person acting for or employed by a research facility, a dealer, or an exhibitor[;] or a person licensed as a dealer or an exhibitor pursuant to [the requirement of § 2133 that no license be issued to dealers or exhibitors absent compliance of the USDA’s promulgated standards[;] or an operator of an auction sale [subject to § 2142 of this title], or an intermediate handler[;] or a carrier, within the scope of his employment or office, shall be deemed the act, omission, or failure of such research facility, dealer, exhibitor, licensee, operator of an auction sale, intermediate handler, or carrier, as well as of such person).

61. There are seven primary taxonomic ranks: kingdom, phylum, class, order, family, genus, and species. *Taxonomy – Glossary*, NAT’L PARKS SERV., [www.irma.nps.gov/content/help/taxonomy/Glossary.aspx#rank](http://www.irma.nps.gov/content/help/taxonomy/Glossary.aspx#rank) (last visited Jan 9, 2022).

of the genus *Rattus*, and mice of the genus *Mus*, bred for use in research, (2) horses not used for research purposes, and (3) other farm animals, such as, but not limited to livestock or poultry, used or intended for use as food or fiber, or livestock or poultry used or intended for use for improving animal nutrition, breeding, management, or production efficiency, or for improving the quality of food or fiber. With respect to a dog, the term means all dogs including those used for hunting, security, or breeding purposes.<sup>62</sup>

According to a 2019 USDA Annual Report, there were 18,270 cats, 58,511 dogs, 181,993 guinea pigs, 98,296 hamsters, 68,257 nonhuman primates, 50,777 pigs, 142,472 rabbits, 13,953 sheep, and 165,017 other species, totaling 797,546 *covered* animals, that were used in research.<sup>63</sup> Birds, rats of the genus *Rattus*, and mice of the genus *Mus*, are not considered to be animals with respect to animal research and testing. As such, legal requirements that are imposed upon research that is done to covered animals pursuant to the AWA are not imposed upon the excluded animals. However, if, pursuant to HREA, research is funded via the Public Health Service (“PHS”), then such research would follow the requirements of the *Guide*, which extends to vertebrates, too.<sup>64</sup>

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62. 7 U.S.C. § 2132(g) (2022). In 2002, Congress enacted the exception which excluded certain animals in research via the Farm Security and Rural Investment Act of 2002 (PUB. L. NO. 107-171, § 10301, 116 Stat. 134, 491).

63. *Animal & Plant Health Inspection Service: Annual Report Annual Usage by Fiscal Year: 2019*, U.S. DEPT. OF AGRICULTURE (Apr. 27, 2021), [www.aphis.usda.gov/animal\\_welfare/annual-reports/2019/fy19-summary-report-column-F.pdf](http://www.aphis.usda.gov/animal_welfare/annual-reports/2019/fy19-summary-report-column-F.pdf) [perma.cc/7AHJ-JBF7] (showing that “covered” includes animals that are not exempted by the reporting requirements of the AWA; non-covered animals include “birds, rats, and mice”).

64. See *Guide*, *supra* note 19 at 1-2 (noting that the *Guide* applies to vertebrate animals).

### 1. *Licensing and Registration*<sup>65</sup>

The AWA requires dealers<sup>66</sup> and exhibitors,<sup>67</sup> but not research facilities, to obtain a license.<sup>68</sup> The AWA requires that dealers and exhibitors demonstrate that their facilities are in compliance with the AWA regulations in order to obtain a license.<sup>69</sup> However, dealers or exhibitors with a *de minimis* business are not required to obtain a license.<sup>70</sup> If a person<sup>71</sup> does not qualify as a dealer or exhibitor under the Act, the person can demonstrate that their facilities are in compliance with the AWA regulations and agree, in writing, to comply with the requirements of the AWA and the associated regulations.<sup>72</sup>

The USDA issues Class A and Class B licenses.<sup>73</sup> The Class A

65. The AWA regulations governing licensing and registration requirements are located at 9 C.F.R. §§ 2.1-2.27, 2.30-2.38 (2022). *See also Licensing and Registration Under the Animal Welfare Act: Guidelines for Dealers, Exhibitors, Transporters, and Researchers*, UNITED STATES DEPT. OF AGRIC., [www.aphis.usda.gov/animal\\_welfare/downloads/aw/awlicreg\\_gray-book.pdf](http://www.aphis.usda.gov/animal_welfare/downloads/aw/awlicreg_gray-book.pdf) [perma.cc/9H86-QT9A] (last visited Nov. 15, 2021) (providing guidelines for licensing and registration requirements).

66. *See* 7 U.S.C. § 2132 (2022) (quoting that a dealer

means any person, who, in commerce, for compensation or profit, delivers for transportation, or transports, except as a carrier, buys, or sells, or negotiates the purchase or sale of, (1) any dog or other animal whether alive or dead for research, teaching, exhibition, or use as a pet, or (2) any dog for hunting, security, or breeding purposes . . .” and that [s]uch term does not include a retail pet store (other than a retail pet store which sells any animals to a research facility, an exhibitor, or another dealer)).

67. 7 U.S.C. § 2132 (2022).

68. 7 U.S.C. § 2133 (2022).

69. 7 U.S.C. § 2133 (2022); *see also* 7 U.S.C. § 2134 (2022) (quoting

[n]o dealer or exhibitor shall sell or offer to sell or transport or offer for transportation, in commerce, to any research facility or for exhibition or for use as a pet any animal, or buy, sell, offer to buy or sell, transport or offer for transportation, in commerce, to or from another dealer or exhibitor under this chapter any animals, unless and until such dealer or exhibitor shall have obtained a license from the Secretary and such license shall not have been suspended or revoked);

9 C.F.R. § 2.1(a)(3) (2022) (listing persons exempt from two sections of licensing requirements of the AWA).

70. 7 U.S.C. § 2133 (2022).

71. 7 U.S.C. § 2132 (2022) (quoting that a person includes “any individual, partnership, firm, joint stock company, corporation, association, trust, estate, or other legal entity.”).

72. 7 U.S.C. § 2133 (2022).

73. *See Animal and Plant Health Inspec. Serv.: Apply for a License or Registration*, U.S. DEPT. OF AGRIC. (Aug. 30, 2021), [www.aphis.usda.gov/aphis/ourfocus/animalwelfare/apply/licensing-and-registration-application-packets](http://www.aphis.usda.gov/aphis/ourfocus/animalwelfare/apply/licensing-and-registration-application-packets) [perma.cc/7JFM-T4NF] (providing information about and application forms for a license).

license is “issued to dealers who sell animals that are bred and raised at their facility in a closed or stable colony.”<sup>74</sup> For example, Tufts University Cummings School of Veterinary Medicine has a Class A license.<sup>75</sup> A Class B license is “issued to other dealers whose business includes the purchase and/or resale of warm-blooded animals.”<sup>76</sup> In 2013, the NIH announced that, effective fiscal year 2015, it would no longer fund research projects that use dogs obtained from a Class B dealer.<sup>77</sup> This is progress.

The AWA regulations detail requirements for obtaining a valid license.<sup>78</sup> For example, a person seeking a license must be at least eighteen years of age, complete an application form<sup>79</sup>, and pay a licensing fee.<sup>80</sup> The USDA Secretary must charge, assess, and cause to be collected reasonable fees for licenses issued.<sup>81</sup> The fees charged, assessed, and collected must be adjusted “on an equitable basis taking into consideration the type and nature of the operations to be licensed.”<sup>82</sup> The fees must be deposited and covered into the United States “Treasury as miscellaneous receipts.”<sup>83</sup> Also, the regulations prohibit a person from obtaining more than one license.<sup>84</sup> Finally, licensees or applicants for an initial license must not “interfere with, threaten, abuse (including verbal abuse) or harass any APHIS official in the course of carrying out his or her duties.”<sup>85</sup>

The AWA also regulates research facilities by requiring a

74. *Id.*

75. See *Animal and Plant Health Inspection Service: USDA Animal Care Public Search Tool*, U.S. DEPT. OF AGRICULTURE, [www.aphis-efile.force.com/PublicSearchTool/s/](http://www.aphis-efile.force.com/PublicSearchTool/s/) (last visited Nov. 15, 2021) (listing persons licensed or registered under the AWA).

76. *Id.* (providing examples of a Class B licensee: commercial dog-breeding facilities, animal brokers, and operators of auction sales).

77. Notice Regarding NIH Plan to Transition from Use of USDA Class B Dogs to Other Legal Sources, NAT. INST. OF HEALTH OFF. OF EXTRAMURAL RSCH. (Dec. 17, 2013), [www.grants.nih.gov/grants/guide/notice-files/NOT-OD-14-034.html](http://www.grants.nih.gov/grants/guide/notice-files/NOT-OD-14-034.html) [perma.cc/4S2M-2ZFE].

78. 9 C.F.R. § 2.1 (2022).

79. 9 C.F.R. §§ 2.1-2.2 (2022).

80. 9 C.F.R. § 2.1 (2022).

81. 7 U.S.C. § 2153 (2022); 9 C.F.R. § 2.1 (2022).

82. 7 U.S.C. § 2153 (2022)

83. See *id.* (requiring that Congress may appropriate no more than \$400,000.00 to the USDA, so that the USDA can enforce § 2156, which is for animal fighting).

84. See 9 C.F.R. § 2.1(b)(1) (2022) (stating that

[l]icenses are issued to specific persons, and are issued for specific activities, types and numbers of animals, and approved sites [and that a] new license must be obtained upon change of ownership, location, activities, or animals. A licensee shall notify Animal Care no fewer than 90 days and obtain a new license before any change in the name, address, substantial control or ownership of his business or operation, locations, activities, and number or type of animals . . . ).

85. 9 C.F.R. § 2.4 (2022).



research facility to register its business.<sup>86</sup> As noted above, the AWA does not require a research facility to obtain a license.<sup>87</sup> The AWA requires the registration with the USDA for several entities including every research facility,<sup>88</sup> every intermediate handler,<sup>89</sup> every carrier,<sup>90</sup> and every exhibitor not licensed under the AWA.<sup>91</sup> The AWA allows the USDA to require the licensing of operators of auction sales where any dogs or cats are sold, in commerce, under such conditions as the USDA may prescribe and upon the payment of a fee.<sup>92</sup>

The AWA regulations specify that licenses are generally valid and effective for three years, unless the license is revoked, suspended, voluntarily terminated, or expired.<sup>93</sup>

A person who has been or is an officer, agent, or employee of a licensee whose license has been suspended or revoked and who was responsible for or participated in the activity upon which the order of suspension or revocation was based will not be licensed, or registered as a carrier, intermediate handler, dealer, exhibitor, or research facility, within the period during which the order of suspension or revocation is in effect.<sup>94</sup>

The regulations also outline requirements regarding the denial of a license application,<sup>95</sup> termination of a license,<sup>96</sup> and the appeal of an inspection report.<sup>97</sup> Additionally, the regulations include provisions governing the requirements and procedures of

86. 7 U.S.C. § 2136 (2022).

87. 7 U.S.C. § 2133 (2022).

88. 7 U.S.C. § 2132 (2022).

89. *See* 7 U.S.C. § 2132 (2022) (quoting that an immediate handler

means any person including a department, agency, or instrumentality of the United States or of any [s]tate or local government (other than a dealer, research facility, exhibitor, any person excluded from the definition of a dealer, research facility, or exhibitor, an operator of an auction sale, or a carrier) who is engaged in any business in which he receives custody of animals in connection with their transportation in commerce.).

90. *See id.* (quoting that a carrier “means the operator of any airline, railroad, motor carrier, shipping line, or other enterprise, which is engaged in the business of transporting any animals for hire.”).

91. 7 U.S.C. § 2136 (2022).

92. 7 U.S.C. § 2142 (2022).

93. 9 C.F.R. § 2.5 (2022).

94. 9 C.F.R. § 2.9 (2022); *see also* 9 C.F.R. § 2.10 (2022) (quoting that “[n]o partnership, firm, corporation, or other legal entity in which any such person has a substantial interest, financial or otherwise, will be licensed or registered during that period” and that “[a]ny person whose license has been suspended for any reason may apply . . . , in writing, for reinstatement of his or her license or registration”).

95. 9 C.F.R. § 2.11 (2022).

96. 9 C.F.R. § 2.12 (2022).

97. 9 C.F.R. § 2.13 (2022).

registration.<sup>98</sup> Finally, the regulations provide requirements regarding the registration of research facilities.<sup>99</sup>

## 2. *Disposing of Animals*

The AWA states that a dealer or exhibitor must not sell or dispose of any dog or cat within five business days, or another time period as may be specified by the USDA, after acquiring the animal.<sup>100</sup>

## 3. *Obtaining Animals*

The AWA prohibits a research facility from purchasing a dog or cat unless the purchase is from an operator of an auction sale, a person with a valid license as a dealer or exhibitor, or a person exempt from obtaining a license.<sup>101</sup> Likewise, the AWA prohibits any department, agency, instrumentality of the United States which uses animals for research or experimentation or exhibition from purchasing a dog or cat unless the purchase is from an operator of an auction sale, a person with a valid license as a dealer or exhibitor, or a person exempt from obtaining a license.<sup>102</sup>

The AWA was intended to protect pets from becoming laboratory animals.<sup>103</sup> The AWA does not allow a dealer to sell, provide, or make available to any individual or entity a random source<sup>104</sup> dog or cat unless the dealer provides the recipient of the random source dog or cat with a valid certificate.<sup>105</sup> The certificate must contain a series of information: the name, address, and USDA license or registration number of the dealer (if it exists); the name, address, USDA license or registration number (if such number exists), the signature of the recipient of the dog or cat; and a description of the dog or cat.<sup>106</sup> The certificate must also include: the name and address of the person, pound, or shelter from which the dog or cat was purchased or otherwise acquired by the dealer,

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98. 9 C.F.R. § 2.25 (2022).

99. 9 C.F.R. § 2.30 (2022).

100. 7 U.S.C. § 2135 (2022) (noting that this requirement does not apply to operators of auction sales subject to 7 U.S.C. § 2142 (2022)).

101. 7 U.S.C. § 2137 (2022).

102. 7 U.S.C. § 2138 (2022).

103. 7 U.S.C. § 2131 (2022).

104. 9 C.F.R. § 1.1 (2022) (quoting that “[r]andom source means dogs and cats obtained from animal pounds or shelters, auction sales, or from any person who did not breed and raise them on his or her premises.”).

105. 7 U.S.C. § 2158(b)(1) (2022); *see also* U.S.C. § 2158(c) (2022) (requiring that a dealer who fails to comply or includes false information in the certification is subject to penalties).

106. *See* 7 U.S.C. § 2158(b)(2)(C) (2022) (requiring that the “description of the dog or cat” include “the species and breed or type of such; the sex of such; the date of birth (if known) of such; the color and any distinctive marking of such; and any other information that the [USDA] requires by regulation . . .”).

and an assurance that such person, pound, or shelter was notified that the dog or cat may be used for research or educational purposes; the date of the purchase of the acquisition; a statement by the pound or shelter (if that is where the animal was acquired); and any other information that the USDA requires.<sup>107</sup> The “original” certification must accompany the shipment of a dog or cat to be sold, provided, or otherwise made available by the dealer, and must be kept and maintained by the research facility for at least one year for enforcement purposes.<sup>108</sup> Also, the dealer must keep one copy of the certification for at least one year for enforcement purposes.<sup>109</sup>

The AWA does not prohibit certain entities<sup>110</sup> from selling animals for research.<sup>111</sup> In fact, it expressly allows the following entities to sell animals for research: a state, county, or city owned and operated pound or shelter; private entity established for the purpose of caring for animals, such as a humane society, or other organization that is under contract with a state, county, or city that operates as a pound or shelter and that releases animals on a voluntary basis; and each research facility licensed by the USDA.<sup>112</sup>

Some states may have a law that prohibits an entity, such as a municipality, from selling or transferring an animal to an animal dealer or research facility.<sup>113</sup> This kind of law is an antidote to “pound seizure” which is when a pound or shelter turns over its animals to animal research.<sup>114</sup> To provide an example, Massachusetts’s law on pound seizure reads, in part, as follows:

An animal control officer shall not be a licensed animal dealer registered with the United States Department of Agriculture. An animal control officer shall not give, sell or turn over any animal which may come into the officer's custody to a business or institution licensed or registered as a research facility or animal dealer with the United States Department of Agriculture either privately or in the course of carrying out the officer's official assignments as an agent for the officer's municipality. A municipality shall not give, sell or turn over an animal which may come into its custody to any business or institution licensed or registered as a research facility or animal

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107. 7 U.S.C. § 2158(b)(2) (2022); *see also* U.S.C. § 2158(b)(4) (2022) (requiring that a copy of the certificate must also be provided in instances where one research facility transfers animals to another research facility).

108. 7 U.S.C. § 2158(b)(3) (2022).

109. *Id.*

110. *See* 7 U.S.C. § 2158(a)(1) (2022) (stating that the entities must hold and care for a dog or cat for at least five days to enable the dog or cat to be recovered by the animal’s original owner or adopted by other individuals before being sold).

111. 7 U.S.C. § 2158(a) (2022).

112. 7 U.S.C. § 2158(a)(2) (2022).

113. *Pound Seizure*, AM. ANTI-VIVISECTION SOC’Y., [www.aavs.org/our-work/campaigns/pound-seizure/](http://www.aavs.org/our-work/campaigns/pound-seizure/) [perma.cc/K9ZQ-TLL3] (last visited Jan 9, 2022).

114. *Id.*

dealer with the United States Department of Agriculture. Whoever violates this subsection shall be punished by a fine of not more than \$1,000.<sup>115</sup>

The Commonwealth's statute prohibits an animal control officer ("ACO") from being a USDA dealer or from giving, selling, or turning over an animal to a research facility or animal dealer with the USDA.<sup>116</sup> It further prohibits a municipality from giving, selling or turning over an animal to a research facility or animal dealer with the USDA.<sup>117</sup>

Notably, the definition of "animal" in the Commonwealth is not necessarily limited like the definition under the AWA.<sup>118</sup> One primary difference between the two is that the AWA definition excludes certain species.<sup>119</sup> Therefore, an ACO or municipality would likely not be permitted to obtain a bird and then sell the bird to a research facility. Another takeaway is that Massachusetts's law on pound seizure does not expressly prohibit a private entity, such as a humane society or rescue organization, from giving, selling, or turning over an animal to a research facility.<sup>120</sup> There is no express requirement under the AWA that prohibits a state from enacting a law limiting the ability of animal welfare nonprofit organizations to give, sell, or turn over an animal to a research facility or animal dealer.<sup>121</sup> This means that it is important to be aware of who manages a humane society or rescue organization, who sits on the boards of such entities, and who donates to the entities. If possible, learn whether a particular humane society or rescue organization gives, sells, or turns over animals to research facilities. Also, the AWA's definitions of dealer and/or research facility do not necessarily — and in actuality — tell the true story of all of the masterminds or funders using or financing the use of animals in research. Essentially, a pharmaceutical company, for example, can pay for a research facility to conduct its research, thus complicating the transparency and extent of who is benefiting from, supporting, or backing the animal-based research.<sup>122</sup>

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115. MASS. GEN. LAWS ch. 140 § 151 (2022).

116. *Id.*

117. *Id.*

118. *Knox v. Mass. Soc'y for the Prevention of Cruelty to Animals*, 425 N.E.2d 393, 395 (Mass. App. Ct. 1981) (holding that an "animal" includes goldfish); *Commonwealth v. Turner*, 14 N.E. 130, 132 (1887) (holding that "animal" includes "wild and noxious animals"); *Coolidge v. Choate*, 11 Metcalf. 79, 83 (1846) (quoting that "[l]ife is the gift of God, not to man only, but to all animals, and it ought not to be taken away, except from necessity, or for some useful and proper purpose.").

119. 7 U.S.C. § 2132(g) (2022), *supra* note 62.

120. MASS. GEN. LAWS ch. 140 § 151 (2022).

121. 7 U.S.C. § 2158(a) (2022) (permitting humane societies to sell a dog or cat to a dealer).

122. [ClinicalTrials.gov](https://clinicaltrials.gov) provides the ability to conduct advanced searches about the funding of studies. A search of year 2019 reveals 1,975 results for studies that were funded by the NIH and/or another federal agency and 7,321

#### 4. Recordkeeping Requirements

The AWA requires the production and retention of records relating to animals.<sup>123</sup> Dealers and exhibitors must have records with respect to the purchase, sale, transportation, identification, and previous ownership of animals.<sup>124</sup> Research facilities must keep records with respect to the purchase, sale, transportation, identification, and previous ownership of live dogs and cats.<sup>125</sup> Research facilities must also maintain records for IACUCs, the acquisition of some animals, and more.<sup>126</sup> Also, if a regulatory agency of the federal government requires records to be maintained by intermediate handlers and carriers, the regulatory agency of the federal government must include information which the USDA requires to administer the AWA.<sup>127</sup> If a regulatory agency of the federal government does not prescribe requirements for any such forms, the intermediate handlers and carriers themselves must keep, for a reasonable period of time as the USDA requires, the records with respect to transporting, receiving, handling, and delivery of animals.<sup>128</sup> The Act further allows the USDA to promulgate “recordkeeping requirements” governing the purchase, handling, or sale of animals, in commerce, by dealers, research facilities, and exhibitors at auction sales and by the operators of such auction sales.<sup>129</sup>

On February 1, 2017, records were removed from the AWA website.<sup>130</sup> This removal meant that those seeking the records could not access them. However, the AWA now requires that the APHIS restore the lost contents and all content generated since then on its

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studies funded by “all others (individuals, universities, organizations)” listed.

123. 7 U.S.C. § 2140 (2022).

124. *Id.*

125. *Id.* (noting that dealers and exhibitors must make and retain records for all animals, but research facilities have a lessened requirement that requires records for live dogs and cats only).

126. 9 C.F.R. § 2.35 (2022).

127. 7 U.S.C. § 2140 (2022) (the records are with respect to the “transportation, receiving, handling, and delivery of animals”).

128. *Id.* (stating that “[s]uch records shall be made available at all reasonable times for inspection and copying by the [USDA]”; see generally, 9 C.F.R. § 2.3 (2022) (stating that each applicant for a license must demonstrate compliance)).

129. 7 U.S.C. § 2142 (2022).

130. Karin Brulliard, *USDA Abruptly Purges Animal Welfare Information From Its Website*, WASH. POST (Feb. 3, 2017), [www.washingtonpost.com/news/animalia/wp/2017/02/03/the-usda-abruptly-removes-animal-welfare-information-from-its-website/](http://www.washingtonpost.com/news/animalia/wp/2017/02/03/the-usda-abruptly-removes-animal-welfare-information-from-its-website/) [perma.cc/2Y7A-SX6D] (quoting that “[t]he U.S. Department of Agriculture . . . abruptly removed inspection reports and other information from its website about the treatment of animals at thousands of research laboratories, zoos, dog breeding operations and other facilities”).

searchable database.<sup>131</sup> The law further requires that the following records must be publicly available, for a period of three years, via a searchable database without redactions (except signatures): all final AWA inspection reports,<sup>132</sup> including all reports documenting all AWA non-compliances; all final AWA enforcement records; all reports or other materials documenting non-compliances; and all final AWA research facility annual reports, including their attachments with appropriate redactions for confidential business information.<sup>133</sup>

### 5. Treatment of Animals

The AWA governs some aspects of the treatment of animals, notably for covered animals.<sup>134</sup> However, it is important to note that the AWA does not limit an entity, such as a research facility, from extending more kindness, especially humane care and treatment, to animals. The AWA also does not limit an entity from treating non-covered animals under the AWA with the humane care and treatment that the entity is required to extend to covered animals.<sup>135</sup> The AWA requires that all animals delivered for transportation, transported, purchased, or sold — in commerce — by a dealer or exhibitor must be marked or identified during a time and in a humane manner as the USDA prescribes.<sup>136</sup> The law further states that only live dogs and cats must be marked or identified by a research facility.<sup>137</sup>

The AWA allows the USDA to promulgate “humane standards” governing the purchase, handling, or sale of animals in commerce, by dealers, research facilities, and exhibitors at auction sales and by the operators of such auction sales.<sup>138</sup> Although experts, including outside consultants, may be consulted by the USDA,<sup>139</sup> the USDA is not authorized to promulgate rules, regulations, or

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131. 7 U.S.C. § 2146a (2022). The USDA APHIS search tool can be found at [www.aphis.usda.gov/aphis/ourfocus/animalwelfare/SA\\_Access\\_Animal\\_Care\\_Search\\_Tool](http://www.aphis.usda.gov/aphis/ourfocus/animalwelfare/SA_Access_Animal_Care_Search_Tool) [perma.cc/5L2Z-5GXG].

132. 7 U.S.C. § 2146a(b)(1) (2022).

133. 7 U.S.C. § 2146a(b) (2022).

134. 7 U.S.C. § 2132(g) (2022).

135. See generally JAMES F. GESUALDI, ESQ., EXCELLENCE BEYOND COMPLIANCE (2014) (providing that individuals and entities can implement high standards for animals than those starting point standards legally required by law).

136. 7 U.S.C. § 2141 (2022).

137. *Id.*; see also 9 C.F.R. § 2.50-2.55 (2022) (outlining requirements regarding the identification of animals, including requirements about tags).

138. 7 U.S.C. § 2142 (2022); see also *id.* (permitting a state or political subdivision of a state to promulgate standards in addition to those standards promulgated by the USDA).

139. See 7 U.S.C. § 2143(a)(5) (2022) (stating that “[i]n promulgating and enforcing standards . . . the [USDA] is authorized and directed to consult experts, including outside consultants . . .”).

orders with regard to the “design, outlines, or guidelines of actual research or experimentation by a research facility as determined by [the] research facility” except that the USDA may require each research facility to comply with “acceptable standards governing the care, treatment, and use of animals” and thus must provide information, assurances, and an explanation for any deviations.<sup>140</sup>

The AWA prohibits the delivery or receipt of dogs, cats, or additional kinds or classes of animals without a valid veterinary certificate<sup>141</sup> issued by a veterinarian licensed to practice veterinary medicine.<sup>142</sup> The USDA may, however, provide exceptions to the certification requirement, namely for animals shipped to research facilities for purposes of research, testing, or experimentation requiring the animals to not be eligible for the certification.<sup>143</sup>

The AWA also prohibits the delivery of dogs, cats, or additional kinds or classes of animals before the animals are less than a certain age, as determined by the USDA.<sup>144</sup> Lastly, the AWA

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140. 7 U.S.C. § 2143(a)(6)(A)(i) (2022); *see also* 7 U.S.C. § 2143(a)(7) (stating that

The [USDA] shall require each research facility to show upon inspection, and to report at least annually, that the provisions of this chapter are being followed and that professionally acceptable standards governing the care, treatment, and use of animals are being followed by the research facility during actual research or experimentation [and that] such research facilities shall provide. . . . information on procedures likely to produce pain or distress in any animal and assurances demonstrating that the principal investigator considered alternatives to those procedures; . . . assurances satisfactory to the [USDA] that such facility is adhering to the standards described in this section; and. . . an explanation for any deviation from the standards promulgated under this section);

*see also* 9 C.F.R. § 2.36 (2022) (providing that a reporting facility must submit an annual report).

141. 7 U.S.C. § 2143(f) (2022) (requiring that the certificate must certify that the veterinarian inspected the animal on a specified date, which shall not be more than ten days before such delivery, and, when so inspected, the animal appeared free of any infectious disease or physical abnormality which would endanger the animal or animals or other animals or endanger public health).

142. *See* 7 U.S.C. § 2143(f) (2022) (stating that

[n]o dogs or cats, or additional kinds or classes of animals designated by regulation of the Secretary, shall be delivered by any dealer, research facility, exhibitor, operator of an auction sale, or department, agency, or instrumentality of the United States or of any State or local government, to any intermediate handler or carrier for transportation in commerce, or received by any such handler or carrier for such transportation from any such person, department, agency, or instrumentality).

143. 7 U.S.C. § 2143(f) (2022).

144. 7 U.S.C. § 2143(g) (2022) (stating that the USDA must “designate additional kinds and classes of animals and may prescribe different ages for particular kinds or classes of dogs, cats, or designated animals, . . . when [the USDA] determines that such action is necessary or adequate to assure their humane treatment in connection with their transportation in commerce.”).

generally prohibits cash-on-delivery arrangements of any animal in commerce.<sup>145</sup>

6. *Regulatory Standards Imposed on Dealers, Research Facilities, and Exhibitors*

The AWA requires the USDA to promulgate minimum standards “to govern the humane handling, care, treatment, and transportation of animals by dealers, research facilities, and exhibitors.”<sup>146</sup> Such minimum standards include “handling, housing, feeding, watering, sanitation, ventilation, shelter from extremes of weather and temperature, adequate veterinary care, and separation of species.”<sup>147</sup> Also, standards are required for the exercise of dogs and for a physical environment adequate to promote the psychological well-being of primates.<sup>148</sup>

7. *Additional Regulatory Standards Imposed on Research Facilities*

The AWA further provides for the promulgation of additional standards<sup>149</sup> on research facilities.<sup>150</sup> These additional requirements are for “animal care, treatment, and practices of experimental procedures to ensure that animal pain and distress are minimized, including adequate veterinary care<sup>151</sup> with the appropriate use of anesthetic, analgesic, tranquilizing drugs, or

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145. 7 U.S.C. § 2143(h) (2022) (stating that

[n]o intermediate handler or carrier involved in the transportation of any animal in commerce shall participate in any arrangement or engage in any practice under which the cost of such animal or the cost of the transportation of such animal is to be paid and collected upon delivery of the animal to the consignee, unless the consignor guarantees in writing the payment of transportation charges for any animal not claimed within a period of 48 hours after notice to the consignee of arrival of the animal, including, where necessary, both the return transportation charges and an amount sufficient to reimburse the carrier for all out-of-pocket expenses incurred for the care, feeding, and storage of such animals).

146. 7 U.S.C. § 2143(a)(1) (2022).

147. 7 U.S.C. § 2143(a)(2)(A) (2022).

148. 7 U.S.C. § 2143(a)(2)(B) (2022).

149. *See* 7 U.S.C. § 2143(a)(3)(E) (2022) (stating that there are exceptions to the required promulgated standards when specified by research protocol and that an exception must be detailed, explained in a report, and filed with the IACUC).

150. 7 U.S.C. § 2143(a)(3) (2022).

151. *See* 9 C.F.R. § 2.33 (2022) (requiring in part that each research facility must have an attending veterinarian who must provide adequate veterinary care and must establish and maintain programs of adequate veterinary care); *and see* 9 C.F.R. § 2.40 (2022) (implementing veterinary standards for dealers and exhibitors).



euthanasia. . . .”<sup>152</sup> The promulgated regulations must include a requirement that the “principal investigator considers alternatives to any procedure likely to produce pain to or distress in an experimental animal.”<sup>153</sup> The regulations must additionally include veterinary requirements in any practice which could cause pain to animals.<sup>154</sup> The AWA requires the promulgation of regulations which state that “no animal is used in more than one major operative experiment from which [the animal] is allow to recover” unless there is a “scientific necessity” or “special circumstances” as determined by the USDA.<sup>155</sup>

### 8. *Regulatory Standards Imposed on The Transportation of Animals in Commerce*

The AWA also requires the promulgation of standards to govern the transportation of animals in commerce, including the handling, care, and treatment of animals transported in commerce.<sup>156</sup>

### 9. *IACUC Requirements*

The AWA requires that every research facility<sup>157</sup> establish at least one IACUC to provide a crucial oversight role to ensure the humane treatment of animals<sup>158</sup> Each IACUC is appointed by the CEO of the research facility and must consist of three or more members.<sup>159</sup> The members of an IACUC must “possess sufficient ability to assess animal care, treatment, and practices in experimental research as determined by the needs of the research facility” and must “*represent society’s concerns regarding the welfare*

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152. 7 U.S.C. § 2143(a)(3)(A) (2022).

153. 7 U.S.C. § 2143(a)(3)(B) (2022).

154. 7 U.S.C. § 2143(a)(3)(C) (2022) (stating that for any practice which could cause pain to animals, the AWA requires that regulations include provisions that a veterinarian is consulted in the planning of such procedures; for the use of tranquilizers, analgesics, and anesthetics; for pre-surgical and post-surgical care by laboratory workers, in accordance with established veterinary medical and nursing procedures; against the use of paralytics without anesthesia; and that the withholding of tranquilizers, anesthesia, analgesia, or euthanasia when scientifically necessary shall continue for only the necessary period of time).

155. 7 U.S.C. § 2143(a)(3)(D) (2022).

156. 7 U.S.C. § 2143(a)(4) (2022).

157. 7 U.S.C. § 2132(e) (2022).

158. 7 U.S.C. § 2143(b)(1) (2022); *see also* 7 U.S.C. § 2143(b)(1)(C) (2022) (stating that if an IACUC consists of more than three members, no more than three of the members can be from the same administrative unit of the research facility); *see also* 9 C.F.R. § 2.31 (2022) (providing regulatory guidance about IACUCs).

159. 7 U.S.C. § 2143(b)(1) (2022).

of animal subjects used at such facility.”<sup>160</sup> The AWA requires that each IACUC must have at least one “doctor of veterinary medicine.”<sup>161</sup> Also, at least one member who is not otherwise affiliated with the facility must be a member.<sup>162</sup> Moreover, at least one member must not be an immediate family member who is affiliated with the research facility.<sup>163</sup> Finally, at least one member must provide “*representation for general community interests in the proper care and treatment of animals.*”<sup>164</sup>

Every IACUC<sup>165</sup> is required to have a quorum for all “formal actions” that it undertakes, including a quorum for its semiannual inspections<sup>166</sup> of all animal study areas and animal facilities of the research facility.<sup>167</sup> With each semiannual inspection, an IACUC must review the practices involving pain to animals<sup>168</sup> and the condition of animals in order to ensure compliance and to “minimize pain and distress to animals.”<sup>169</sup> If any deficiencies or deviations are discovered during the semiannual inspection, the IACUC must notify “the administrative representative of the research facility of any deficiencies or deviations.”<sup>170</sup>

If the deficiencies or deviations remain uncorrected after notification and opportunity to correct, the IACUC must notify APHIS and the funding federal agency.<sup>171</sup> If, after notice and an opportunity for correction, the federal agency which funds a research project determines that the conditions of animal care,

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160. *Id.* (emphasis added).

161. 7 U.S.C. § 2143(b)(1)(A) (2022).

162. 7 U.S.C. § 2143(b)(1)(B)(i) (2022).

163. 7 U.S.C. § 2143(b)(1)(B)(ii) (2022).

164. 7 U.S.C. § 2143(b)(1)(B)(iii) (2022) (emphasis added).

165. 7 U.S.C. § 2143(c) (quoting that federal research facilities must generally “have the same composition and responsibilities” as other research facilities); 7 U.S.C. § 2143(a)(6)(A)(i); *see also* 7 U.S.C. § 2143(a)(7) (providing guidance about requirements for annual standards); *see also* 7 U.S.C. § 2144 (quoting “[a]ny department, agency, or instrumentality of the United States having laboratory animal facilities shall comply with the standards and other requirements promulgated by the [USDA] for a research facility”).

166. There is no requirement in the AWA that prohibits an IACUC from conducting inspections on more than a semiannual basis. *See* 7 U.S.C. § 2143(b)(3) (2022) (providing that a semiannually inspect is generally required, but not providing a limit or restriction on the number of inspections that could occur).

167. 7 U.S.C. § 2143(b)(2-3) (2022).

168. 7 U.S.C. § 2143(b)(3)(A) (2022).

169. 7 U.S.C. § 2143(b)(3)(B) (2022).

170. 7 U.S.C. § 2143(b)(4)(C) (2022).

171. 7 U.S.C. § 2143(b)(4)(C) (2022) (noting that the funding federal agency which provided the funding of the project with respect to which such uncorrected deficiencies or deviations occurred must also be notified.). *See also* 7 U.S.C. § 2143(c) (2022) (noting that federal IACUCs must report deficiencies or deviations to the head of the federal agency conducting the research, rather than to APHIS and that the head of the federal agency conducting the research is responsible for all corrective action taken at the facility and the granting of all exceptions to the inspection protocol).

treatment, or practice have not complied with the promulgated standards, the federal agency must suspend or revoke federal support for the project.<sup>172</sup>

In addition to conducting an “at-least” semiannual inspection, an IACUC must file an inspection certification report<sup>173</sup> of each inspection at the research facility.<sup>174</sup> Each certification report must be signed by a majority of IACUC members involved in the inspection.<sup>175</sup> A certification report must include reports of any violation of promulgated standards or assurances required by the USDA.<sup>176</sup> A violation consists of “any deficient conditions of animal care or treatment, any deviations of research practices from originally approved proposals that adversely affect animal welfare, any notification to the facility regarding such conditions,” and any made corrections.<sup>177</sup> The AWA also requires that each certification report include any minority views<sup>178</sup> of the IACUC and any other information pertinent to the activities<sup>179</sup> of the IACUC.

The AWA prohibits a member of an IACUC from releasing any confidential information of a research facility, including any information that concerns or relates to the trade secrets, processes, operations, style of work, or apparatus; or the identity, confidential statistical data, amount of source of any income, profits, losses, or expenditures of the research facility.<sup>180</sup> Also, an IACUC member cannot use, nor attempt to use, to the member’s advantage or reveal to any other person any information which is confidential and entitled to protection.<sup>181</sup>

If an IACUC member violates any of the aforementioned trade secret violations, the member may be punished by removal from the

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172. See 7 U.S.C. § 2143(f) (2022) (stating that any research facility losing federal support as a result of such actions must have a right of appeal under sections 701 through 706 of title 5). See also 9 C.F.R. § 2.37 (2022) (stating that

[e]ach federal research facility shall establish an IACUC which shall have the same composition, duties, and responsibilities required of nonfederal research facilities by § 2.31 with the following exceptions:(a) The Committee shall report deficiencies to the head of the federal agency conducting the research rather than to APHIS; and (b) The head of the federal agency conducting the research shall be responsible for all corrective action to be taken at the facility and for the granting of all exceptions to inspection protocol).

173. See 7 U.S.C. § 2143(b)(4)(A-B) (2022) (stating that the research facility must keep each certification inspection report on file for at least three years at the research facility and must be available for inspection by the APHIS and any funding federal agency).

174. 7 U.S.C. § 2143(b)(4)(A) (2022).

175. 7 U.S.C. § 2143(b)(4)(A)(i) (2022).

176. 7 U.S.C. § 2143(b)(4)(A)(ii) (2022).

177. *Id.*

178. 7 U.S.C. § 2143(b)(4)(A)(iii) (2022).

179. 7 U.S.C. § 2143(b)(4)(A)(iv) (2022).

180. 7 U.S.C. § 2157(a) (2022).

181. 7 U.S.C. § 2157(b) (2022).

IACUC and a fine and imprisonment.<sup>182</sup> Further, if any person, including the research facility, is injured as a result of such a violation by an IACUC member, the member might be liable for actual and consequential damages, as well as a reasonable attorney's fee.<sup>183</sup>

### *10. Training, Information, and Inter-Agency Requirements*

Each research facility must provide training.<sup>184</sup> This training is required for scientists, animal technicians, and other personnel involved with animal care and treatment.<sup>185</sup> The training must include instruction on a variety of topics, such as the humane practice of animal maintenance and experimentation; research or testing methods that minimize or eliminate the use of animals or limit animal pain or distress; utilization of the information service at the National Agricultural Library; and methods whereby deficiencies in animal care and treatment should be reported.<sup>186</sup>

The AWA also requires that the USDA establish an "information service" at the National Agricultural Library which, in cooperation with the National Library of Medicine, provides specific information to the public.<sup>187</sup> This required information must be pertinent to employee training, which could prevent unintended duplication of animal experimentation<sup>188</sup> and on improved methods of animal experimentation. Improved methods could reduce or replace animal use and minimize pain and distress to animals, such as anesthetic and analgesic procedures.<sup>189</sup>

The AWA requires that the USDA "consult and cooperate with other federal departments, agencies, or instrumentalities concerned with the welfare of animals" used for research or experimentation or with regulating the transportation in commerce or the handling of the animals.<sup>190</sup> The law requires the USDA to "consult with the Secretary of Health and Human Services prior to the issuance of

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182. U.S.C. § 2157(c) (2022) (noting that if the violation is willful, it increases to \$10,000.00 from \$1000.00 and from prison of no more than one year to prison of no more than three years).

183. 7 U.S.C. § 2157(d) (2022).

184. 7 U.S.C. § 2143(d) (2022).

185. *Id.*

186. 7 U.S.C. § 2143(d)(1-4) (2022); *see also* 9 C.F.R. § 2.32 (2022) (stating, in part,

[i]t shall be the responsibility of the research facility to ensure that all scientists, research technicians, animal technicians, and other personnel involved in animal care, treatment, and use are qualified to perform their duties [and t]his responsibility shall be fulfilled in part through the provision of training and instruction to those personnel).

187. 7 U.S.C. § 2143(e) (2022).

188. 7 U.S.C. § 2143(e)(2) (2022).

189. 7 U.S.C. § 2143(e)(1-3) (2022).

190. 7 U.S.C. § 2145(a) (2022).

regulations.”<sup>191</sup> The law further requires the USDA to consult with the Secretary of Transportation<sup>192</sup> prior to promulgating any standard governing the air transport and handling of animals.<sup>193</sup> Also, the USDA may work with officials within various states<sup>194</sup> and “cooperate with the officials of the various [s]tates or political subdivisions . . . in carrying out the purposes of this chapter and of any [s]tate, local, or municipal legislation or ordinance on the same subject.”<sup>195</sup>

### 11. Investigations, Inspections, and Penalties

The AWA requires the USDA to make investigations or inspections<sup>196</sup> to determine whether a dealer, exhibitor, intermediate handler, carrier, research facility, or operator of an auction sale has violated the AWA or any of its regulations or standards.<sup>197</sup> The USDA has, at all *reasonable* times, access to the places of business, the facilities, the animals, and also, records<sup>198</sup> of any dealer, exhibitor, intermediate handler, carrier, research facility, or operator of an auction sale.

The AWA requires the USDA to inspect every research facility at least once per year.<sup>199</sup> If there are any “deficiencies or deviations from the standards promulgated” the USDA must conduct follow-up inspections until all of the deficiencies or deviations are corrected.<sup>200</sup> If an animal is found to be suffering as a result of a failure to comply with the AWA, its regulations, or standards, the USDA’s promulgated standards<sup>201</sup> permit inspectors to “confiscate

191. *Id.*

192. *See* 7 U.S.C. § 2145(a) (2022) (noting that the Secretary of Transportation has the “authority to disapprove any such standard if [the Secretary of Transportation] notifies the [USDA], within thirty days after such consultation, that changes in its provisions are necessary in the interest of flight safety”).

193. 7 U.S.C. § 2145(a) (2022).

194. 7 U.S.C. § 2145(b) (2022).

195. 7 U.S.C. § 2145(b) (2022) (emphasis added); *see also* U.S. Const. Amend. X (quoting “[t]he powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people”).

196. *See* 7 U.S.C. § 2147 (2022) (stating that the USDA must promulgate rules and regulations requiring dealers, exhibitors, research facilities, and operators of auction sales to permit inspection of their animals and records at reasonable hours upon request by legally constituted law enforcement agencies in search of lost animals).

197. 7 U.S.C. § 2146a (2022).

198. 7 U.S.C. §§ 2140; 2146(a) (2022).

199. 7 U.S.C. § 2146(a) (2022).

200. *Id.* (stating that the USDA may confiscate or destroy an animal that is suffering if the animal is held by a dealer, exhibitor, operator of an auction sale, intermediate handler, or carrier; or held by a research facility and no longer required by the research facility).

201. 9 C.F.R. §§ 1.1-4.11 (2022).

or destroy<sup>202</sup> the animal found to be suffering.<sup>203</sup> If someone forcibly assaults, resists, opposes, impedes, intimidates, or interferes with any person who is performing the required duties of inspections, the interfering person must be fined or imprisoned.<sup>204</sup>

The AWA provides for penalties related to licenses.<sup>205</sup> Specifically, the license of a dealer, exhibitor, or operator of an auction sale may have their license suspended on a temporary basis if the dealer, exhibitor, or operator violated or violates the AWA.<sup>206</sup> When this occurs, the dealer, exhibitor, or operator is entitled to have notice and an opportunity for a hearing.<sup>207</sup> At this point, the license could be suspended for an additional period of time, or the license could be revoked.<sup>208</sup>

Civil penalties are also possible for violations.<sup>209</sup> Specifically, a dealer, exhibitor, research facility, intermediate handler, carrier, or operator of an auction sale that violates the AWA, or any rule, regulation, or standard promulgated by the USDA may be assessed a civil penalty of no more than \$10,000.00 for each violation.<sup>210</sup> Also, with a violation, a cease and desist order<sup>211</sup> could be entered so that the violation stops.<sup>212</sup> Each violation and each day that a violation continues constitutes a separate offense.<sup>213</sup> An order that enters for penalty and/or for cease and desist is final unless an appeal<sup>214</sup> is filed to the U.S. Court of Appeals.<sup>215</sup> If the penalty remains final and unpaid, the USDA must request the U.S. Attorney General to institute a civil claim to collect the penalty.<sup>216</sup> If a cease and desist order is entered and the person fails to obey it, the USDA must subject the person to a civil penalty of \$1,500.00 for each offense

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202. 7 U.S.C. § 2146(a) (2022).

203. *Id.*

204. *See* 7 U.S.C. § 2146(b) (2022) (noting that if a deadly or dangerous weapon is used, the fine increases from up to \$5,000 to up to \$10,000, and/or from up to three years imprisonment to up to ten years imprisonment.).

205. 7 U.S.C. § 2133 (2022).

206. 7 U.S.C. § 2149(a) (2022).

207. *Id.*

208. *Id.*

209. *See* 7 U.S.C. § 2149(b) (2022) (stating that no penalty can be assessed unless notice and opportunity for hearing occurs); *see also* 7 U.S.C. § 2149(b) (2022) (stating that the USDA must consider the appropriateness of the penalty with respect to the size of the business of the person involved, the gravity of the violation, the person's good faith, and the history of previous violations).

210. 7 U.S.C. § 2149(b) (2022).

211. *See* 7 U.S.C. § 2149(b) (2022) (stating that no cease-and-desist order can be entered unless notice and opportunity for hearing occurs).

212. 7 U.S.C. § 2149(b) (2022).

213. *Id.*

214. *See* 7 U.S.C. § 2149(c) (2022) (stating that a dealer, exhibitor, research facility, intermediate handler, carrier, or operator of an auction sale may, within 60 days after an order is entered, seek review by the U.S. Court of Appeals).

215. 7 U.S.C. § 2149(b-c) (2022).

216. 7 U.S.C. § 2149(b) (2022).

and for each day during which the failure to obey occurs is a separate offense.<sup>217</sup>

Criminal penalties are also permissible.<sup>218</sup> A knowing violation of the AWA by a dealer, exhibitor, or operator of an auction sale must, upon conviction, be subject to not more than one year of prison or a fine of \$2,500.00, or both.<sup>219</sup>

Finally, the USDA must notify the Attorney General whenever the USDA has reason to believe that any dealer, carrier, exhibitor, or intermediate handler is dealing with stolen animals or is placing the health of any animal in serious danger.<sup>220</sup> This could result in a temporary restraining order or injunction against the dealer, carrier, exhibitor, or intermediate handler.<sup>221</sup>

### III. HEALTH RESEARCH EXTENSION ACT & PHS POLICY

The HREA, enacted in 1985, is a United States federal law.<sup>222</sup> It requires the U.S. Department of Health and Human Services, through the Director of the National Institutes of Health (“NIH”), to establish guidelines<sup>223</sup> about (1) the proper care of animals to be used in biomedical and behavioral research; (2) the proper treatment of animals while they are used in research; and (3) the organization and operation of animal care committees. These guidelines of the NIH,<sup>224</sup> via its OLAW, are the PHS Policy on Humane Care and Use of Laboratory Animals.<sup>225</sup> The guidelines also incorporate the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training (“Principles”).<sup>226</sup>

217. *Id.*

218. 7 U.S.C. § 2149(d) (2022).

219. *Id.*

220. 7 U.S.C. § 2159 (2022).

221. *Id.*

222. 42 U.S.C. § 289d (2022), PUB. LAW 99-158 § 495. (2022).

223. 42 U.S.C. § 289d(a)(2)(B) (2022) (stating that “[the] guidelines shall not be construed to prescribe methods of research”).

224. Who We Are, NAT’L INST. OF HEALTH (Jan. 10, 2022), [www.nih.gov/about-nih/who-we-are](http://www.nih.gov/about-nih/who-we-are) [perma.cc/PZE5-5LDW] (noting that NIH is within the U.S. Department of Health and Human Services).

225. *PHS Policy on Humane Care and Use of Laboratory Animals*, NAT. INST. OF HEALTH OFF. OF LAB. ANIMAL WELFARE, [www.olaw.nih.gov/policies-laws/phs-policy.htm](http://www.olaw.nih.gov/policies-laws/phs-policy.htm) [perma.cc/8V63-DCT3] (last visited Nov. 15, 2021).

226. *Id.* (noting that the Principles were

promulgated in 1985 by the Interagency Research Animal Committee and adopted by the U.S. Government agencies that either develop requirements for or sponsor procedures involving the use of vertebrate animals; the Principles were incorporated into the PHS Policy in 1986 and continue to provide a framework for conducting research in accordance with the Policy).

*See Guide, supra* note 19 at 1-2 (noting that the *Guide* applies to vertebrate animals).

In summary, the PHS Policy incorporates the U.S. Government Principles, the *Guide*,<sup>227</sup> and the AVMA Guidelines but does not override the requirements under the AWA. Rather, the PHS Policy requires that entities base their programs of animal care on the *Guide* and comply with the AWA and its applicable regulations. Compliance with the AWA regulations is an absolute requirement of PHS Policy.<sup>228</sup>

For the treatment of animals while they are used in research, the law requires that the guidelines must delineate the appropriate (1) use of tranquilizers, analgesics, anesthetics, paralytics, and euthanasia for animals and (2) pre-surgical and post-surgical veterinary medical and nursing care for animals.<sup>229</sup> HREA also states that the guidelines must require that an animal care committee which conducts biomedical and behavioral research and receives funds must be in compliance with the guidelines.<sup>230</sup>

HREA requires that each animal care committee must be appointed by the CEO of the entity for which the committee is established, shall not consist of fewer than three members, and must include at least one person who has no association with the entity and at least one veterinarian.<sup>231</sup> Each animal care committee must: review the care and treatment of animals in all study areas and facilities of the research entity at least semi-annually to evaluate compliance with the guidelines; keep appropriate records of the semi-annual reviews; and with each review that is conducted, file with the NIH, at least annually, a certification that the review has been conducted, and the reports of any violations of the guidelines or assurances required which were observed in the review.<sup>232</sup>

HREA also imposes a requirement that for each application of a grant, contract, or cooperative agreement involving research on animals which is administered by the NIH or any national research institute to include assurances “satisfactory to the Director of NIH that” the applicant meets the requirements of the guidelines and has an animal care committee.<sup>233</sup> Each application must also include assurances that scientists, animal technicians, and other personnel involved with animal care, treatment, and use by the applicant have instruction or training in the humane practice of animal maintenance and experimentation available to them.<sup>234</sup>

Finally, for each application of a grant, contract, or cooperative

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227. *Guide*, *supra* note 19 at 1-9.

228. *Id.*

229. PUB. LAW 99-158(a)(2) (2022).

230. 42 U.S.C. § 289d(b)(1) (2022).

231. 42 U.S.C. § 289d(b)(2) (2022).

232. *See* 42 U.S.C. § 289d(b)(3)(C) (2022) (stating that “[r]eports filed [must] include any minority views filed by members of the [IACUC]”).

233. 42 U.S.C. § 289d(c)(1)(A) (2022).

234. 42 U.S.C. § 289d(c)(1)(B) (2022).



agreement involving research on animals which is administered by the NIH or any national research institute must include a statement of the reasons for the use of animals in the research to be conducted with the funds provided under the grant or contract.<sup>235</sup>

The NIH must suspend or revoke a grant or contract “under such conditions as the [NIH] determines appropriate” if the following occurs: the conditions of animal care, treatment, or use in an entity which is receiving a grant, contract, or cooperative agreement involving research on animals do not meet the guidelines; the entity has been notified by the NIH of the determination and has been given a reasonable opportunity to take corrective action; and no action has been taken by the entity to correct such conditions.<sup>236</sup>

A research entity, however, is not required to disclose trade secrets that are privileged or confidential or commercial or financial information that is privileged or confidential.<sup>237</sup>

#### IV. CASE STUDIES

Since it was first enacted in 1966, the AWA has undergone several amendments.<sup>238</sup> Still, many entities and individuals have sought to challenge the AWA, extend its protections, or request further enforcement and greater transparency.<sup>239</sup> The following are three examples of challenges of and to the AWA, or cases related to animal research and testing.<sup>240</sup> The first case, *Taub v. State*,

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235. See 42 U.S.C. § 289d(c)(2) (2022) (stating also that notice and comment requirements must be followed).

236. 42 U.S.C. § 289d(d) (2022).

237. 42 U.S.C. § 289d(e) (2022).

238. The AWA was amended in 1970 (Pub. Law. 91-579), 1976 (Pub. Law 94-279), 2002 (Pub. Law. 107-171), 2007 (Pub. Law 110-22), and 2008 (Pub. Law 110-246), to name several.

239. Delcianna Winders, *Administrative Law Enforcement, Warnings, and Transparency*, 79 OHIO ST. L. J. 451, 493-99 (2018); Justin Marceau, *How the Animal Welfare Act Harms Animals*, 69 HASTINGS L.J. 925, 946-58 (2018); Leslie Rudloff, *Failure to Launch: The Lack of Implementation and Enforcement of the Animal Welfare Act*, 67 SYRACUSE L. REV. 173, 178-90 (2017); Pamela D. Frasc, *Gaps in US Animal Welfare Law for Laboratory Animals: Perspectives from an Animal Law Attorney*, 57 ILAR J., 3, 285-92 (2016); *Animals Used in Research*, ANIMAL LEGAL DEFENSE FUND, [www.aldf.org/focus\\_area/animals-used-in-research/](http://www.aldf.org/focus_area/animals-used-in-research/) [perma.cc/728N-GCJQ] (last visited Jan. 7, 2022).

240. There are additional cases to read for background and understanding, such as *Animal Legal Defense Fund v. Madigan*, 781 F. Supp 797, 798 (D.D.C.1992) (holding on appeal that none of the plaintiffs had standing); *Alt. Research & Dev. v. Glickman*, 101 F. Supp 2d 7, 9 (D.D.C. 2000); *Animal Legal Defense Fund, Inc. v. Epsy*, 29 F.3d 720, 720 (D.C. Cir. 1994); *Animal Legal Def. Fund v. Glickman*, 154 F.3d 426, 429 (D.C. Cir. 1998); *Animal Legal Defense Fund v. Veneman*, 469 F.3d 826, 830 (9th Cir. 2006); *PETA v. USDA*, 797 F.3d 1087, 1097 (D.C. Cir. 2015); *Medlock v. Bd. of Trustees of the Univ. of Mass.*, 31 Mass. App. Ct. 495, 495 (1991); *Day v. Veneman*, 315 F.3d 297, 298 (2003).

establishes that generally, animal research that is done pursuant to the AWA and the NIH is not considered to be state animal cruelty.<sup>241</sup> The second two cases, *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, and *General Elec. Co. v. Joiner*, provide an evidentiary law framework for expert scientific opinions about scientific research done with animal models.<sup>242</sup> There are countless court and tribunal decisions within animal research and testing law. As a primer, it is important to begin with the foundational cases summarized below. Later, this Article offers potential paths forward within the current landscape.

### A. *Taub v. State*

The Maryland Court of Appeals held, in *Taub v. State*, that Maryland's animal cruelty statute did not apply to research done on animals.<sup>243</sup> The issue in the case was whether Maryland's animal cruelty statute could be used to convict a scientist who was conducting research on non-human primates under a federal program.<sup>244</sup>

The pertinent factual background of the case is that Dr. Edward Taub ("Dr. Taub") operated a laboratory which was funded by the NIH "under a series of grants outlining the specific animal research to be done by the laboratory."<sup>245</sup> Dr. Taub, under an NIH grant, conducted research to gain information to help retrain human beings afflicted with a stroke.<sup>246</sup> In an effort to learn to retrain limbs damaged by a stroke, Dr. Taub surgically abolished all sensations in the limb of a monkey; following the surgery, experiments could be performed to retrain the limb.<sup>247</sup> With information furnished by a former employee of Dr. Taub's laboratory, the police investigated and seized monkeys pursuant to a court order.<sup>248</sup> Dr. Taub was then charged for animal cruelty under Maryland law and was found guilty for "failing to provide necessary veterinary care for six of the monkeys."<sup>249</sup>

An appeal to the circuit court was made, and Dr. Taub was then guilty of one charge for failing to provide necessary veterinary care for one monkey named Nero.<sup>250</sup> Then, a petition for certiorari was granted, wherein the court reversed the lower decisions because the higher court determined that the Maryland legislature

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241. *Taub*, 463 A.2d at 819, *infra* note 243.

242. *Daubert*, 509 U.S. at 579, *infra* note 253; *Joiner*, 522 U.S. at 136, *infra* note 269.

243. *Taub v. State*, 463 A.2d at 819 (Md. 1983).

244. *Id.*

245. *Id.* at 820.

246. *Id.*

247. *Id.*

248. *Id.*

249. *Id.*

250. *Id.*

was concerned with punishing *unnecessary or unjustifiable* pain or suffering.<sup>251</sup> Rather, “the [Maryland] legislature recognized that there are certain normal human activities to which the infliction of pain to an animal is purely incidental and unavoidable . . .” and that Dr. Taub’s research was done pursuant to the AWA and NIH grant. As a result, Dr. Taub’s conviction was reversed.<sup>252</sup> This case establishes that some work that is done using animals under the AWA may be lawful, even if outside of the AWA it might be unlawful.

### B. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*

In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, the U.S. Supreme Court rejected an earlier test, the *Frye* test, and instead determined that the Federal Rules of Evidence provide the appropriate standard for admitting expert scientific testimony in a federal trial, which means that the reliance on animal studies could not be used because it was not “relevant.”<sup>253</sup> The primary issue was whether, in a federal trial, the *Frye* “general acceptance” standard could be used to admit a scientific expert opinion into evidence.<sup>254</sup>

The pertinent factual background is as follows: two children were born with serious birth defects.<sup>255</sup> A lawsuit was filed in state court against a pharmaceutical company (“Respondent”), then removed to federal court, on their behalf, alleging that their birth defects were caused by their mother’s ingestion of a prescription anti-nausea drug named Bendectin.<sup>256</sup> After the discovery process, Respondent filed a dispositive motion, arguing that Bendectin did not cause birth defects in humans.<sup>257</sup>

To support its dispositive motion, Respondent submitted an affidavit of Dr. Steven Lamm, a physician and epidemiologist.<sup>258</sup> Dr. Lamm’s affidavit concluded that, based on his review of literature on Bendectin, including over thirty published studies involving over 130,000 patients, the maternal use of Bendectin within the first trimester of pregnancy had not been established as a risk factor for human birth defects.<sup>259</sup> The petitioners responded with the testimony of eight experts of their own who concluded that Bendectin could cause birth defects; their conclusions were based on in vitro and in vivo animal studies.<sup>260</sup>

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251. *Id.* at 821 (emphasis added).

252. *Id.* at 822.

253. *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 587 (1993).

254. *Id.*

255. *Id.* at 582.

256. *Id.*

257. *Id.*

258. *Id.*

259. *Id.*

260. *Id.* at 583.

The District Court granted Respondent's motion because it held that the petitioner's evidence did not meet the *Frye* standard.<sup>261</sup> It determined that the "animal-cell studies, live-animal studies, and chemical-structure analyses on which petitioners had relied could not raise by themselves a reasonably disputable jury issue regarding causation."<sup>262</sup> Relying on *Frye*, the U.S. District Court for the Ninth Circuit affirmed.<sup>263</sup>

The U.S. Supreme Court granted certiorari to resolve the issue about what was the proper standard to admit expert testimony.<sup>264</sup> It established what has come to be known as the *Daubert* standard, which relies upon the Federal Rules of Evidence<sup>265</sup> rather than the *Frye* standard.<sup>266</sup> The *Daubert* standard requires that prior to admitting a scientific expert opinion into evidence, a federal court must (1) determine whether the reasoning or methodology underlying the opinion is sufficiently reliable or trustworthy; and (2) determine whether the opinion is helpful to the trier of fact.<sup>267</sup> For prong two, several factors should be evaluated, including whether: the expert theory or methods can or have been tested; the theory or methods were previously engaged in a peer review and publication; there was a known or potential rate of error of the theory or method; and the theory or method are accepted in the scientific community.<sup>268</sup> This case establishes that animal-based science is not necessarily reliable or trustworthy for federal evidence expert opinion purposes.

### C. *General Elec. Co. v. Joiner*

Chief Justice William Rehnquist held in *General Elec. Co. v. Joiner*, that animal tests are too unreliable to be admitted as evidence under the *Daubert* rule.<sup>269</sup> The facts and travel of the case are as follows: a man ("Joiner" or "Respondent"), who was diagnosed with small-cell lung cancer, filed suit in state court, claiming that the disease was due to his workplace exposure to chemical PCBs and derivative "furans" and "dioxins" that were in materials manufactured by the petitioners.<sup>270</sup> The case was removed to federal

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261. *Id.*

262. *Id.* at 584.

263. *Id.*

264. *Id.* at 585.

265. FED. R. EVID., 402 401, 702, 104(a).

266. *Id.*

267. *Daubert*, 509 U.S. at 589-91.

268. *Id.* at 591-94.

269. *General Electric Co. v. Joiner*, 522 U.S. 136, 146 (1997) (holding that there was no evidence that an adult human had been exposed to polychlorinated biphenyls (PCBs) and that the testimony of experts failed to show a link between exposure to PCB and small cell cancer).

270. *Id.* at 136.

court and moved for summary judgment.<sup>271</sup> The lower court held for the petitioner because it held that Joiner's expert testimony "failed to show that there was a link between exposure to PCBs and small-cell lung cancer and was therefore inadmissible" as it did not rise beyond a subjective belief or unsupported speculation.<sup>272</sup> The Eleventh Circuit reversed this decision; it held that the lower court should not have excluded the expert testimony.<sup>273</sup>

The U.S. Supreme Court held that the lowest court was correct, and that it was proper to exclude the expert testimony.<sup>274</sup> The reason for this was because "[t]he animal studies cited by [R]espondent's experts were so dissimilar to the facts [of the case] as the studies involved infant mice . . . whereas Joiner was an adult human . . ." <sup>275</sup> Chief Justice questioned the reliability of the use of animals, because "Joiner was an adult human being whose alleged exposure to PCBs was far less than the exposure in the animal studies."<sup>276</sup> As a result, the animal studies failed to satisfy the requirement that expert evidence fits the facts of the case.<sup>277</sup> This case establishes that animal-based studies may be excluded as expert testimony because animal-based studies do not mirror the human experience.

## V. STEPS FORWARD

There are several steps that should be taken to ensure the proper welfare of animals in research. The primary theme among these proposed steps is that science is currently limited by the current limitations of law and policy. As such, current law and policy must be amended to allow science to have greater flexibility.

First, with respect to ensuring compliance with The Three Rs, especially "Reduction," it is important to understand the number of animals involved. As noted above, birds, rats of the genus *Rattus*, and mice of the genus *Mus*, are not considered to be animals with respect to animal research and testing.<sup>278</sup> Without knowing the current and accurate number of all animals used in research, how can scientists comply with The Three Rs, to actually reduce the number of species? Therefore, the AWA and its regulations should require at least an accurate and consistent reporting of the number of animals used in research, regardless of species. Second,

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<sup>271</sup> *Id.*

<sup>272</sup> *Id.*

<sup>273</sup> *Id.*

<sup>274</sup> *Id.* at 137.

<sup>275</sup> *Id.*

<sup>276</sup> *See id.* at 144 (quoting "[n]o study demonstrated that adult mice developed cancer after being exposed to PCBs. One of the experts admitted that no study had demonstrated that PCBs lead to cancer in any other species").

<sup>277</sup> *Id.*

<sup>278</sup> 7 U.S.C. § 2132(g) (2022).

proponents of animal welfare should be encouraged to join an IACUC, submit public comments, and reasonably and lawfully advocate<sup>279</sup> for the humane treatment of animals. Attorneys and others should not be intimidated by the complexity of the relevant statutes, regulations, and policy documents to enter the animal research and testing legal arena. Third, legal and policy guardrails exist which make it difficult, if not impossible, to limit the use of non-animal studies. These statutory, regulatory, and policy blocks should be eliminated or adjusted to allow science, not law, direct and enable solutions.

Between 92-96% of drugs that pass preclinical tests fail to proceed to the market.<sup>280</sup> The “default preclinical testing methods for the efficacy and safety of drugs have relied heavily on the use of animals.”<sup>281</sup> After preclinical animal-based tests are completed, and the FDA approves an Investigational New Drug application, the drug undergoes a series of clinical trials.<sup>282</sup> Half of the drugs that succeed in clinical trials and receive FDA marketing approval are later relabeled or withdrawn for serious or lethal adverse effects not detected during animal testing.<sup>283</sup>

Science is limited by federal law’s drug development process because the process generally requires animal-based models in drug development. This presents a major opportunity to advance The Three Rs within the drug development process. For example, as noted above, current federal law requires that *animal* and clinical trials form the basis of a claim for drug development.<sup>284</sup> If instead, the word “nonclinical” replaced the word “animal,” then entities could rely on science, not limited legal requirements, to govern its methods or advancements; science would be permitted to use animal and/or other nonclinical methods, rather than be stifled into

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279. See 18 U.S.C. § 43 (2022) (stating that the Animal Enterprise Terrorism Act prohibits any person from engaging in certain conduct “for the purpose of damaging or interfering with the operations of an animal enterprise . . .”).

280. Aysha Akhtar, *The Flaws and Human Harms of Animal Experimentation*, 24 CAMBRIDGE Q. OF HEALTHCARE ETHICS 410 (Oct. 2015) (citing John Pippin, M.D., *Animal Research in Medical Sciences: Seeking a Convergence of Science, Medicine, and Animal Law*, 54 S. TEX. L. REV. 469, 472 (2012)). Dr. Pippin is a former animal researcher and has experience as director of academic affairs for the Physicians Committee for Responsible Medicine, and he is board certified in internal medicine, cardiovascular disease, and nuclear cardiology. Dr. Pippin, MD, FACC, PHYSICIANS COMM. FOR RESPONSIBLE MED., [www.perm.org/about-us/staff/john-pippin](http://www.perm.org/about-us/staff/john-pippin) [perma.cc/FRM8-ATSX] (last visited Jan. 10, 2022). See also Pippin, at 498 (noting the failure rates of animal testing).

281. See Pippin, *supra* note 280, at 496 (noting the drug development process).

282. *Id.*

283. *Id.* at 498 (citing U.S. GEN. ACCOUNTING OFF., FDA DRUG REVIEW: POST-APPROVAL RISKS 1976-1985, 24 (1990)).

284. 21 U.S.C. § 355(b)(5)(B) (2022); see also 42 U.S.C. § 262 (2022) (requiring the regulation of the applications for and uses of biologic products).

the use of animal models only.

As stated earlier in this Article, the USDA is generally not authorized to promulgate rules, regulations, or orders with regard to the “design, outlines, or guidelines of actual research or experimentation by a research facility as determined by [the] research facility”<sup>285</sup>; yet *science is limited* by requiring the use of animal models above other models or methods. If this and other restrictions on the actual research were adjusted, then there is no question that brilliant scientific minds would continue to advance the process of research and scientific inquiry itself and the methods by which the processes unfold, with greater intention, deepened efficacy, and more compliance with The Three Rs.

There are several technological options that might greatly reduce, refine, and replace the use of animals in research and testing. These include the use of human cells, tissues, and organs; computer-based analysis; advanced imaging; and genetic studies.<sup>286</sup> Modern science and technology enable researchers to incorporate *in vitro* or *in silico* methods rather than relying on *in vivo* methods.<sup>287</sup> Micro-dosing “consists of the sub-pharmacologic administration of an investigational drug” although the industry does not appear to be taking full advantage” of it as a tool.<sup>288</sup> Chip technologies allow researchers to mirror the functions of human organs and whole body systems.<sup>289</sup> In addition to the creation of human-relevant methods to conduct research, medical research science should incorporate the promotion of lifestyle changes to reduce the occurrence of some preventative or reversible diseases.<sup>290</sup>

It is not unfeasible to enable scientific innovation by providing

285. See 7 U.S.C. § 2132 (2022) (defining a research facility).

286. *Alternatives to Animal Testing*, NAT. INST. OF ENV'T HEALTH SCI., [www.niehs.nih.gov/health/topics/science/sya-iccvam/index.cfm](http://www.niehs.nih.gov/health/topics/science/sya-iccvam/index.cfm) [perma.cc/SZ7V-GYQX] (last visited Nov. 15, 2021).

287. *Id.*

288. Graham Lappin, *The Expanding Utility Of Microdosing*, 4 CLINICAL PHARM. IN DRUG DEV. 6, 401-06 (2015), [www.accp1.onlinelibrary.wiley.com/doi/full/10.1002/cpdd.235](http://www.accp1.onlinelibrary.wiley.com/doi/full/10.1002/cpdd.235) [perma.cc/3G3J-RVYB]. See also Katy Taylor, *Animal Experimentation: Working Towards a Paradigm Change*, ANIMAL EXPERIMENTATION: WORKING TOWARDS A PARADIGM CHANGE 595, [www.brill.com/view/book/edcoll/9789004391192/BP000031.xml#R002082](http://www.brill.com/view/book/edcoll/9789004391192/BP000031.xml#R002082) [perma.cc/4XSC-NAKA] (explanatory parenthetical).

289. See Taylor, *supra* note 288, at 594 (quoting that

[a]nother development in toxicology that seeks to overcome the criticism that cell cultures are too simplistic, is the *lab on a chip* concept: body or *organ on a chip* models vary in size and complexity but essentially use engineering technology to combine small cultures of cells (e.g., liver, brain, and kidney) into a single, tiny device with fluid running between the compartments of each type of cell).

290. See generally DEAN ORNISH & ANNE ORNISH, UNDO IT! HOW SIMPLE LIFESTYLE CHANGES CAN REVERSE MOST CHRONIC DISEASES (2019) (providing steps to reverse many different diseases).

incentives to entities that choose to further comply with The Three Rs. One possible incentive could be to provide a financial voucher or credit program for entities that choose to engage in non-animal-based studies to allow such entities to bypass a step requiring animal-based research in the drug development process. Another incentive could be awarded to entities engaged in education/training to significantly reduce, refine, or replace the use of animals. The reduction, refinement, and replacement of animals in education/training requires a change of cultures; animal-based education and training should not be the default method of education and training, especially if the education/training causes or results in the suffering or death of an animal. Entities must be incentivized to reduce, refine, and replace.

It is time to focus less on AWA warnings, enforcement, and the punishment of actual and/or alleged bad actors and focus more on awarding good behavior and empowering science. This can be done by removing restrictions upon science requiring the use of animals and instead, by providing incentives to enable solutions that are in alignment with The Three Rs to reduce, refine, and replace.

## VI. CONCLUSION

Two basic U.S. federal laws, the AWA and the HREA provide minimal standards protecting some animals used in scientific research. Current law and policy strive to achieve The Three Rs to reduce animal suffering. Likewise, with the removal of some legal and policy roadblocks, science itself has a great opportunity to further advance its methods and outcomes for the betterment of people and animals. Incremental steps can be taken now to help people and animals today. Advocates for people, animals, and scientific advancement should learn the relevant animal research laws and identify lawful and creative solutions that are in alignment with The Three Rs.

Animal protection advocate Henry Spira, a non-attorney, stated: “What greater motivation can there be than doing whatever one possibly can to reduce pain and suffering?”<sup>291</sup> Science is ready to reduce the pain and suffering of animals. It’s up to all of us to enable science to do what it does best: evolve now.

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291. SINGER, *supra* note 1, at 186.