



2016

## The Animal Welfare Act at Fifty: Problems and Possibilities in Animal Testing Regulation

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Courtney G. Lee\*

## The Animal Welfare Act at Fifty: Problems and Possibilities in Animal Testing Regulation

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I. INTRODUCTION

Fifty years ago, lawmakers enacted what was to become the Federal Animal Welfare Act (AWA) with the noble intentions of providing a fundamental groundwork of minimum protections for nonhuman animals used in various contexts, including the focus of this Article—laboratory testing.<sup>1</sup> Over that half-century, however, those basic protections have eroded or otherwise proven ineffective. For instance, the species that comprise over 90% of laboratory subjects now are omitted completely from the very definition of “animal” in the statute.<sup>2</sup> Further, the law and various paradigms under which many research facilities operate do not reflect current understanding concerning the sentience of those omitted species and their qualifications for protection. The AWA also does not comport with scientific and technological developments that render much of present laboratory testing in the United States unnecessary—testing that many other countries already have enacted laws to prohibit. Also out of step with other countries’ laws, the AWA gives no consideration to the futures of living, otherwise adoptable, laboratory animals when they no longer are of use to their research facilities.

There are compelling arguments in favor of animal testing. My mother, herself a proponent of animal welfare, lost a horrible battle with cancer in 2012. Though the medicine she took ultimately was not successful in allowing her to stay here with us, from the many drugs she used initially to fight the disease to the morphine that helped ease her pain at the end, we were grateful for whatever assistance and added time those treatments could provide. Without knowing precisely the procedures involved in licensing those prescriptions, I assume animal testing was involved at least to some extent. Two years later, I

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1. *Animal Welfare Act*, U.S. DEP’T OF AGRIC. NAT’L AGRIC. LIBR. ANIMAL WELFARE INFO. CTR., <http://awic.nal.usda.gov/government-and-professional-resources/federal-laws/animal-welfare-act> [https://perma.unl.edu/SP2N-3GKT].

2. 7 U.S.C. § 2132(g) (2012); NAT’L ASS’N FOR BIOMEDICAL RESEARCH, MICE & RATS: THE ESSENTIAL NEED FOR ANIMALS IN MEDICAL RESEARCH 1 (2015), <http://www.nabr.org/wp-content/uploads/2015/05/Mice-Rats-In-Biomedical-Research-NABR.pdf> [https://perma.unl.edu/4AZY-PAW4].

took a bicycle ride only to wake up a week later with no recollection of the crash that nearly took my life or the days I spent in the ER, where I also likely benefitted from drugs and procedures that had been tested on animals at some point.

As a result, I do not engage in examination and criticism of the AWA and animal testing lightly. Still, the protections afforded by the AWA are just basic, minimum standards of care and treatment. Why are there such drastic distinctions drawn between species as well as other stark limitations in the statute's protections? How necessary and effective is the type of experimentation it endorses in light of today's scientific advancements? Fifty years after enactment, is it time to reevaluate the AWA and make a significant change?

This Article considers these questions and more in the context of animal experimentation under the AWA. Part II summarizes the background of the law, its enactment, and its amendments; Part III discusses the species covered, or not covered, by the AWA; Part IV considers the effectiveness and necessity of current animal testing procedures in light of growing technological advancements; Part V compares laboratory testing in other countries; Part VI explores the fates of laboratory animals no longer needed by their facilities; and Part VII offers some recommendations for improvements to the AWA.

## II. BACKGROUND OF THE ANIMAL WELFARE ACT

### A. Enactment and Evolution

In the 1960s, *Sports Illustrated* and *Life* magazines published disturbing stories documenting a trend whereby people with questionable morals would steal companion animals<sup>3</sup> and sell them to scientific research laboratories where the animals not only were subject to painful, often life-ending experiments but were transported and kept in appalling conditions until reaching the laboratory and possibly after.<sup>4</sup> In response to the ensuing public outcry, Congress enacted the Labo-

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3. Hereafter the term "animals" refers to nonhuman animals.

4. Benjamin Adams & Jean Larson, *Legislative History of the Animal Welfare Act: Introduction*, U.S. DEP'T OF AGRIC. NAT'L AGRIC. LIBR. ANIMAL WELFARE INFO. CTR., <http://awic.nal.usda.gov/legislative-history-animal-welfare-act/intro> [<https://perma.unl.edu/4FTC-SF6Z>] (summarizing the 1966 *Life* article, "Concentration Camp for Dogs," which described neglectful conditions at a dog dealer's farm); Coles Phinzy, *The Lost Pets That Stray To The Labs*, *SPORTS ILLUSTRATED*, Nov. 29, 1965, at 36, <http://www.si.com/vault/1965/11/29/612645/the-lost-pets-that-stray-to-the-labs> [<https://perma.unl.edu/9SG2-JC79>] (telling the story of Pepper, a five-year-old female Dalmatian stolen from a family in Pennsylvania, who was used in cardiology research in New York, and cremated after dying in an experiment nine days after the theft).

ratory Animal Welfare Act in 1966, now known simply as the Animal Welfare Act (AWA).<sup>5</sup>

This original version of the AWA focused mainly on dogs and cats<sup>6</sup> but attempted to regulate animal dealers and research laboratories also handling hamsters, guinea pigs, rabbits, and nonhuman primates.<sup>7</sup> Its protections only applied after those entities became licensed or registered, however,<sup>8</sup> and they only were required to obtain such certification if they used government funding (research facilities) and engaged in business across state lines (research facilities and dealers).<sup>9</sup> If a dealer or research entity operated entirely within state lines, used exclusively nongovernment funds or both, this expanded application of the AWA did not apply.<sup>10</sup>

Further, the government body tasked with oversight of AWA compliance, the United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) Animal Care program<sup>11</sup> had very little authority under the original Act to monitor and regulate the treatment of animals once they reached the laboratories.<sup>12</sup> As a previous Deputy Director of APHIS described it, “We only went up to the laboratory door, so to speak.”<sup>13</sup>

## B. Early Amendments

The AWA has been subject to multiple amendments to try to address these and other deficiencies over the fifty years since its enactment—some more comprehensive than others.<sup>14</sup> For example, the 1970 Congress updated the AWA’s definitions of general terms like “animal,” which changed from a specific (though brief) list of species to include all warm-blooded animals used in research except farm ani-

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5. Darian M. Ibrahim, *Reduce, Refine, Replace: The Failure of the Three R’s and the Future of Animal Experimentation* 200 (Ariz. Legal Studies, Discussion Paper No. 06-17, 2006); see Adams & Larson, *supra* note 4 (noting that the *Concentration Camp for Dogs* article generated more letters from the public to *Life* at that time than stories covering Vietnam or civil rights).

6. Adams & Larson, *supra* note 4.

7. *The Animal Welfare Act: A Legislative and Regulatory History*, ANIMAL & PLANT HEALTH INSPECTION SERV., U.S. DEP’T OF AGRIC. [http://www.aphis.usda.gov/animal\\_welfare/downloads/awa\\_leg\\_history.pdf](http://www.aphis.usda.gov/animal_welfare/downloads/awa_leg_history.pdf) [<https://perma.unl.edu/4E73-UCDH>].

8. Dale Schwindaman, Remarks at U.S.D.A. Symposium, Animal Welfare Act 1966–1996: Historical Perspectives and Future Directions 31 (Sept. 12, 1996) (transcript available at <https://ia800303.us.archive.org/19/items/CAT10860535/CAT10860535.pdf> [<https://perma.unl.edu/Y8RH-PPHF>]).

9. *Id.*; Adams & Larson, *supra* note 4.

10. Schwindaman, *supra* note 8.

11. TADLOCK COWAN, CONG. RESEARCH SERV., RS22493, THE ANIMAL WELFARE ACT: BACKGROUND AND SELECTED ANIMAL WELFARE LEGISLATION 3 (2013).

12. Schwindaman, *supra* note 8.

13. *Id.*

14. See Adams & Larson, *supra* note 4.

mals.<sup>15</sup> Congress later excepted other particular species used in research.<sup>16</sup> The 1970 amendments also added exhibitors to the group of regulated entities—with specific activities such as rodeos and purebred dog and cat shows excluded<sup>17</sup>—and increased the authority of the USDA Secretary to conduct inspections and require recordkeeping of those entities subject to AWA regulation.<sup>18</sup>

Importantly, these amendments authorized the Secretary to promulgate regulations concerning the humane use and treatment of animals by “dealers, research facilities, and exhibitors,” including the “appropriate” use of pain relieving medications during experimentation when determined to be proper by attending veterinarians.<sup>19</sup> The Secretary’s power was far from absolute, however, and the language deferred substantially to the laboratories, stating that the Secretary could not create regulations regarding “design, outlines, guidelines, or performance of actual research or experimentation by a research facility as determined by such research facility.”<sup>20</sup> The language did not include explanations of exactly what terms like “performance of actual research or experimentation” mean in this context, allowing for liberal interpretation.<sup>21</sup> Although generalized statutory terms can benefit proponents arguing either side of an issue, these exceptions commonly are understood to have granted discretion to research facilities.<sup>22</sup> Certain matters are placed outside the regulatory authority of the Secretary when facilities exercise this level of statutory discretion.

### C. Improved Standards for Laboratory Animals Act of 1985

In 1976, Congress added animal commerce and transport provisions and addressed the growing problem of organized animal fighting.<sup>23</sup> But just under a decade later came some of the most significant research-related amendments to date: the 1985 Improved Standards

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15. Animal Welfare Act of 1970, Pub. L. No. 91-579, § 3(3), 84 Stat. 1560 (codified as amended at 7 U.S.C. § 2132(g) (2012)).

16. Farm Security and Rural Investment Act of 2002, Pub. L. No. 107-171, § 10301, 116 Stat. 134, 491 (codified as amended at 7 U.S.C. § 2132(g) (2012)); *see infra* section III.A.

17. Animal Welfare Act of 1970 § 3(3).

18. *Id.* §§ 11, 13, 17.

19. *Id.* § 14.

20. *Id.*

21. *See id.*

22. *See* Andrew D. Cardon, Matthew R. Bailey, & B. Taylor Bennett, *The Animal Welfare Act: From Enactment to Enforcement*, 51 J. AM. ASS’N LABORATORY ANIMAL SCI. 301, 301–02 (2012) (“The determination of when actual research was being conducted was still left to the discretion of the research facility itself[.]”).

23. *See* Animal Welfare Act Amendments of 1976, Pub. L. No. 94-279, 90 Stat. 417 (codified as amended at 7 U.S.C. § 2132(g) (2012)).

for Laboratory Animals Act (ISLAA).<sup>24</sup> ISLAA generated cautious optimism among animal-welfare advocates and vitriol among research scientists participating in animal testing, who feared that the government's intrusion would hamper their progress.<sup>25</sup> It seems as if much of this worry was unnecessary, however; while the premise behind ISLAA, and even its title, gave the impression that it would make great strides in enhancing the humane treatment of animals used in laboratory testing—and, indeed, it took a step in that direction—the amendments created exceptions and loopholes that continued to grant deference to research facilities.<sup>26</sup> Congress certainly was not ready to support the idea that live-animal research was unnecessary or that it did not contribute significantly to the health and welfare of humans—a view still shared today by many respected and influential individuals and groups.<sup>27</sup> Although the new language acknowledged the need for more stringent monitoring, reporting, and adherence to humane protocols, the AWA's subsequent effectiveness in truly enhancing research animal welfare remains subject to debate.<sup>28</sup>

Still, the enactment of ISLAA signaled a shift: a formalized, governmental recognition that animals can feel pain, are worthy of con-

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24. See Improved Standards for Laboratory Animals Act, Pub. L. No. 99-198, §§ 1751–59, 90 Stat. 1354, 1645–50 (1985) (codified as amended at 7 U.S.C. § 2143 (2012)).
  25. Robert J. Masonis, *The Improved Standards for Laboratory Animals Act and the Proposed Regulations: A Glimmer of Home in the Battle Against Abusive Animal Research*, 16 B.C. ENVTL. AFF. L. REV. 149, 163–67 (1988).
  26. See 7 U.S.C. § 2143(a)(6)(A)(i) (2012) (preventing the Secretary from establishing and enforcing rules regarding “design, outlines, or guidelines of actual research or experimentation . . . as determined by [the] research facility”); Animals and Animal Products, 9 C.F.R. § 2.31(d)(1)(iv)(A) (2015) (permitting research facilities to withhold pain relief, conduct multiple major operations on the same animal, and not comport with humane euthanasia regulations if “justified for scientific reasons” in writing); see *infra* section II.B. & Part III (regarding the species excluded from the AWA definition of the term “animal”).
  27. Improved Standards for Laboratory Animals Act § 1751(1) (“[T]he use of animals is instrumental in certain research and education for advancing knowledge of cures and treatment for diseases and injuries which afflict both humans and animals[.]”); *About NABR*, NAT’L ASS’N FOR BIOMEDICAL RESEARCH, <http://www.nabr.org/about/> [<https://perma.unl.edu/8FKW-LNDG>] (“[T]he study of whole, living organisms is an indispensable element of biomedicine that is beneficial to both veterinary and human health.”); *About, SPEAKING OF RESEARCH*, <http://speakingofresearch.com/about/> [<https://perma.unl.edu/W9SY-XYGP>] (stating this organization “aims to change the tide of the controversial animal rights debate in the United States by encouraging students and scientists to speak out in favor of the lifesaving medical research developed with animals”).
  28. See John F. Lauerman, *Animal Research*, HARV. MAG., January-February 1999, at 48, <https://harvardmagazine.com/1999/01/mice.html> [<https://perma.unl.edu/YRB9-CWEQ>] (noting that despite AWA protections, even many in the scientific community agree that current research methods need improvement, and that reduction or elimination of the use of animals would be beneficial both financially and scientifically); *supra* note 26 and accompanying text.

sideration, and should be treated in a manner reflecting this at all stages, from dealer's cage to laboratory table.<sup>29</sup> Echoing this acknowledgment, ISLAA incorporated into its language a policy known as the "Three R's" to try to increase the humaneness of laboratory testing.<sup>30</sup> The Three R's were conceived by scientists back in 1959 to address this concern,<sup>31</sup> and require researchers to attempt to (1) reduce the number of live animals used in their testing, (2) refine experiments and procedures that inflict pain and suffering to diminish it, and (3) replace live animals with alternative subjects and methods of testing if possible while maintaining the scientific integrity of the study.<sup>32</sup>

Though certainly an improvement in protective standards over the original AWA provisions, some argue that the Three R's are insufficient to guarantee laboratory animal welfare.<sup>33</sup> In fact, ISLAA's language does include some substantial exceptions.<sup>34</sup> For instance, the principal investigator of the experiment in question must only "consider" alternatives to experimentation likely to cause pain and distress and may withhold pain-relieving drugs "when scientifically necessary," but there is no explanation of what those terms mean.<sup>35</sup> Does the word "consider" equate to consulting with outside veterinarians, conducting research regarding emerging technology, reviewing the work of other laboratories researching in the same area both domestically and abroad, etc.? Or does it mean talking about the project with a colleague at the same institution and concluding that the regulation has been satisfied? Furthermore, what does "likely to cause pain and distress" mean? What about "scientifically necessary"? It seems quite likely that a scientist's definition would differ substantially from that of an animal welfare activist.<sup>36</sup> Who decides?

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29. Masonis, *supra* note 25, at 158.

30. Ibrahim, *supra* note 5, at 201.

31. *Id.* at 193; see W.M.S. RUSSELL & R. L. BURCH, *THE PRINCIPLES OF HUMANE EXPERIMENTAL TECHNIQUE* (1959).

32. 7 U.S.C. § 2143(a)(3)(A)-(C) (2012); Ibrahim, *supra* note 5, at 192, 193-97.

33. See Ibrahim, *supra* note 5, at 205-24 (arguing that the Three R's do not allow for challenges to the purposes of animal experimentation in the first place; that loopholes built into the AWA's language allow researchers not to adhere to the regulations in practice; and that the Three R's do not apply to new technological alternatives to live-animal testing).

34. 7 U.S.C. § 2143(a)(3)(B), (C)(i), (C)(iv), (D)-(E).

35. See *id.* § 2143(a)(3)(B), (C)(v). Section 2143(a)(1) does require the Secretary generally to "promulgate standards to govern the humane handling, care, treatment, and transportation of animals by . . . research facilities," and hopefully laboratories use those general standards as guidance. Further, the standards include only "minimum requirements," allowing each specific facility to build upon them if desired.

36. See, e.g., Masonis, *supra* note 25, at 162-67 (explaining the disparate reactions of the research community versus the animal welfare community to proposed regulations under ISLAA).



#### D. Institutional Animal Care and Use Committees

Thankfully the AWA sets itself forth as instituting only the “minimum requirements” of humane treatment, permitting—though not compelling—those under its jurisdiction to establish more rigorous standards if they so choose.<sup>37</sup> Additionally, Title 9 of the Code of Federal Regulations (Regulations) codifies and institutes parameters under the AWA, expanding upon certain terms and standards.<sup>38</sup> Its provisions tried to address potential issues like those noted above, concerning the interpretation of undefined terms, by requiring research facilities to establish internal review groups called Institutional Animal Care and Use Committees (IACUCs).<sup>39</sup> Under the Regulations, the Chief Executive Officer of each covered research facility must appoint an IACUC to review regularly—at least every six months—and report annually upon that facility’s use of animals, assessing the facility’s adherence to requirements such as minimizing or avoiding pain and discomfort, considering whether test procedures are duplicative and if alternative procedures are available, providing appropriate living conditions, and employing the humane use of euthanasia.<sup>40</sup>

Again, whether a facility carries out many of these requirements depends upon whether an offending practice is “justified for scientific reasons,”<sup>41</sup> and the Regulations begin with the reminder that the IACUC does not have authority to regulate “the design, performance, or conduct of actual research or experimentation by a research facility.”<sup>42</sup> Moreover, the head of the facility itself—and not a neutral party—appoints the IACUC.<sup>43</sup> To counter suggestions of biased committees, the Regulations provide that at least one member cannot be affiliated at all with the research facility, intending for that member to represent the interests of the general community regarding laboratory animal welfare.<sup>44</sup> However, the Regulations only require three

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37. 7 U.S.C. § 2143(a)(2). For example, some research institutions also choose to pursue accreditation from outside organizations that may increase these standards, such as the Association for Assessment and Accreditation of Laboratory Animal Care International [hereinafter AAALAC], which boasts accrediting “[m]ore than 950 companies, universities, hospitals, government agencies and other research institutions in 41 countries,” including several major U.S. health organizations, such as St. Jude Children’s Research Hospital and the National Institutes of Health. *About AAALAC*, AAALAC INT’L (2015), <http://www.aaalac.org/about/index.cfm> [<https://perma.unl.edu/WU98-67KU>].

38. *See* Animal and Animal Products, 9 C.F.R. §§ 1.1–4.11 (2015).

39. *Id.* § 2.31(a).

40. *Id.* § 2.31(a), (e)(1)–(2), (d)(1)(i)–(xi).

41. *Id.* § 2.31(d)(1), (1)(iv)(A), (1)(x)(A), (1)(xi).

42. *Id.* § 2.31(a).

43. *Id.*

44. *Id.* § 2.31(b)(3)(ii).

total committee members.<sup>45</sup> If the committee is larger, no more than three members may be from the same administrative unit, suggesting that a facility could appoint a four-member IACUC where three members are from the same department and one is unaffiliated but might be paid for his or her participation.<sup>46</sup> Minority views do have to be included in any reports and committee members wishing to participate may not be excluded, but procedure approval or suspension is accomplished after consideration of a majority vote of a quorum of the committee.<sup>47</sup>

Other guidelines that build upon these minimum standards do exist, although they do not carry the weight of federal law.<sup>48</sup> Not all research facilities subscribe to them, but some do.<sup>49</sup> If a facility wishes to receive funding grants from the National Institutes of Health's Public Health Service (PHS), for example, a more extensive policy applies, including the requirement that each IACUC be comprised of no fewer than five members.<sup>50</sup> The same policy also expands the definition of "animal" and increases an IACUC's reporting obligations and other duties.<sup>51</sup>

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45. *Id.* § 2.31(b)(2)–(3) (requiring one chairperson, one veterinarian with responsibilities for animals used at the facility, and one unaffiliated member). *But see* COMM. FOR THE UPDATE OF THE GUIDE FOR THE CARE AND USE OF LAB. ANIMALS, NAT'L RESEARCH COUNCIL, GUIDE FOR THE CARE AND USE OF LABORATORY ANIMALS 24 (8th ed. 2011) [hereinafter NRC GUIDE] (noting the requirements of IACUC membership); NAT'L INST. OF HEALTH OFFICE OF LAB. ANIMAL WELFARE, U.S. DEP'T OF HEALTH AND HUMAN SERVS., PUBLIC HEALTH SERVICE POLICY ON HUMANE CARE AND USE OF LABORATORY ANIMALS 11 (2015) [hereinafter PHS POLICY] (stating that IACUCs at institutions supported by PHS funds must consist of at least five members).

46. *See* NRC GUIDE, *supra* note 45, at 24–25 (noting that the amount may not be so large that it constitutes a substantial source of income).

47. Animals and Animal Products, 9 C.F.R. § 2.31(c)(3), (d)(2), (d)(6) (2015).

48. *See* NRC GUIDE, *supra* note 45, at 1; PHS POLICY, *supra* note 45, at 7 (acknowledging that these documents do not supersede the AWA); Richard E. Fish, *How to Work with Your Institutional Animal Care and Use Committee (IACUC)*, U.S. DEP'T OF HEALTH & HUMAN SERVS. OFFICE OF RESEARCH INTEGRITY (2004), <https://ori.hhs.gov/education/products/ncstate/iacuc.htm> [<https://perma.unl.edu/HRC7-63YZ>] (noting that the AWA applies to almost all research facilities, but that other guidelines such as the PHS POLICY and NRC GUIDE (which is referenced within the PHS POLICY) apply to those facilities funded by PHS agencies).

49. *See* NRC GUIDE, *supra* note 45, at 4 (“[T]he *Guide* is used by a diverse group of national and international institutions and organizations, many of which are covered by neither the Animal Welfare Act nor the PHS Policy.”).

50. PHS POLICY, *supra* note 45, at 11 (stating that each IACUC must contain not only a chairperson, veterinarian with program responsibility, and unaffiliated member of the public as mandated by the AWA, but also a practicing scientist experienced in animal research, and a person whose “primary concerns are in a nonscientific area (e.g., ethicist, lawyer, and member of the clergy)”).

51. *Id.* at 8, 12–15.

### E. IACUC Effectiveness

Prior to enactment of ISLAA in 1985, one of the biggest faults of the AWA was its lack of enforcement.<sup>52</sup> APHIS's Animal Care unit, the USDA branch tasked with overseeing administration of the AWA, did not have adequate funding, training, or motivation to carry out its charge.<sup>53</sup> ISLAA and its establishment of IACUCs sought to remedy that fault and make AWA enforcement more efficient.<sup>54</sup> Though some argue that this was successful, others, both researchers and animal advocates, disagree.<sup>55</sup> While some IACUCs might be conscientious and carry out the intent of ISLAA,<sup>56</sup> many others do not.<sup>57</sup> This may not be entirely the fault of the IACUCs themselves; the generalized language they are forced to decipher could be at least partially to blame.<sup>58</sup> Although such language may allow the Regulations to apply more broadly between specialized research facilities, it also requires each facility to interpret exactly what those Regulations mean for them.<sup>59</sup> Thus, it seems that enforcement remains one of the AWA's biggest challenges.

While IACUCs must routinely review their research facilities' programs and procedures, the USDA also reviews APHIS oversight of the

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52. See Masonis, *supra* note 25, at 155–57.

53. *Id.* at 157–58 (noting that the USDA decreased funds allotted to the Animal Welfare Program in the 1980s, even requesting to eliminate it entirely at one point and generally demonstrated a negative attitude concerning the program).

54. *Id.* at 158–60.

55. Fish, *supra* note 48 (noting that “IACUCs are sometimes criticized within their institution[s] for inconsistency and over-interpretation of the regulations,” and also that “IACUCs are often criticized by animal rights activists for under-interpretation of the regulations and generally inadequate oversight”).

56. See *Animals in Research: IACUC Oversight*, SCIENTOPIA: DRUGMONKEY (Aug. 10, 2008), <http://drugmonkey.scientopia.org/2008/08/10/animals-in-research-iacuc-oversight/> [<https://perma.unl.edu/P4S8-QQR6>] (describing the author's experience with semiannual IACUC reviews as “serious business” where “anything goes,” from opening drawers and examining records to observing the animals and asking questions about current procedures, “[a]s they are supposed to [do]”).

57. See OFFICE OF INSPECTOR GEN., U.S. DEP'T OF AGRIC., ANIMAL AND PLANT HEALTH INSPECTION SERVICES OVERSIGHT OF RESEARCH FACILITIES AUDIT REPORT 33601-001-41 3, 30–38 (2014) [hereinafter *OIG AUDIT*] (summarizing hundreds of AWA violations related to poor IACUC monitoring over the course of two years).

58. See Fish, *supra* note 48 (describing the difficulty in evaluating what constitutes pain, distress, and “so-called humane endpoints (e.g., limits on size of tumors in cancer studies)”).

59. See *id.* (noting that IACUCs must themselves determine whether research personnel are sufficiently qualified, if the number of animals used in a program is appropriate, if the principal researcher gave adequate consideration to alternative testing methods, etc.); see also *Animals and Animal Products*, 9 C.F.R. § 2.31(c)(3), (d)(1), (d)(3) (2015) (stating that IACUCs determine how to conduct reviews and whether proposed research activities meet requirements like the Three R's, which themselves are stated in general terms, although the IACUCs may invite consultants to assist them in those determinations).

IACUCs.<sup>60</sup> In the most recent audit, covering fiscal years 2009–2011, the USDA Office of the Inspector General (OIG) encountered a multitude of issues, finding that IACUCs “are not always adequately monitoring experimental procedures on animals. As a result, [APHIS Animal Care] has reduced assurance that protocols are properly completed, approved, and adhered to and that animals are always receiving basic humane care and treatment.”<sup>61</sup> Specifically, OIG cited 531 of the 1,117 facilities registered at that time for 1,379 violations regarding lack of IACUC oversight, concluding that “animals are not always receiving basic humane care and treatment and, in some cases, pain and distress are not minimized during and after experimental procedures.”<sup>62</sup> OIG also found 727 violations related to unsuitable IACUC monitoring of research activities attributed to a lack of proper training or simply not making the monitoring a priority, frequently occurring in the areas of veterinary care, inspections and reviews, and protocol deviations.<sup>63</sup> These IACUCs did not provide veterinary care consistent with established procedures, either did not conduct program and facility reviews at all or did so in an untimely or incomplete manner, or both, and disregarded protocol deviations “from doubling the number of implants in an animal to using more animals than authorized.”<sup>64</sup>

OIG discovered that many facilities, in fact, did not report accurate numbers of animals used in their research or quantified the animals’ pain levels incorrectly.<sup>65</sup> OIG also found that many facilities received reduced violation penalties without merit or were issued a smaller number of violations than they actually committed.<sup>66</sup> Further, despite a 2,000-case backlog, OIG determined that APHIS Animal Care failed to close “at least 59 cases that involved grave or repeated welfare violations.”<sup>67</sup> “Grave” violations are defined as “those that undermine the purposes of the [AWA] (i.e., refusing to allow inspection, intimidating APHIS officials, falsifying documents) or that directly harm animals (i.e., animal escape or handling resulting in trauma or death, physically abusing animals, lack of attending veterinarian with sick, dead, and dying animals).”<sup>68</sup>

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60. See *News Releases and Reports*, OFFICE OF INSPECTOR GEN., U.S. DEP’T OF AGRIC., <http://www.usda.gov/oig/rptsauditsaphis.htm> [https://perma.unl.edu/EU2N-PTXT].

61. OIG AUDIT, *supra* note 57, at i. The *OIG Audit* shows that IACUC reviews do occur, but that those reviews may not be effective or complete. *Id.* at 28–35.

62. *Id.* at 28.

63. *Id.* at 30.

64. *Id.*

65. *Id.* at 32.

66. *Id.* at 23.

67. *Id.* at 13.

68. *Id.* at 13 n.27.

OIG presented several formal recommendations to APHIS as a result of this audit, including increasing training and guidance for research facilities,<sup>69</sup> reassessing penalty procedures,<sup>70</sup> updating written inspection instructions and reporting protocols,<sup>71</sup> and increasing IACUC review requirements.<sup>72</sup> APHIS agreed with these recommendations, at least generally, and set compliance deadlines in summer and fall 2015.<sup>73</sup> As part of its audit, OIG revisited recommendations it presented to APHIS in previous years, concluding that “some problems still persist,” such as lacking IACUC facility and program reviews, improperly reduced penalties for violations, and deficient IACUC monitoring.<sup>74</sup> Time will tell if the newest updates and adjustments will result in lasting changes and increased IACUC—and AWA—effectiveness.

### III. COVERAGE OF THE AWA

#### A. What Is an “Animal” under the AWA?

One particular aspect of the AWA that sparks a great deal of controversy is what species qualify—or do not qualify—as “animals.”<sup>75</sup> One of the most impactful changes to this description occurred in 2002 when Congress officially adopted a definition that excludes specific species from coverage.<sup>76</sup> Currently, the AWA defines “animal” as:

any live or dead dog, cat, monkey (nonhuman primate mammal), guinea pig, hamster, rabbit, or such other warm-blooded animal, as the [USDA] 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 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 im-

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69. *Id.* at 11–12.

70. *Id.* at 21, 26–27.

71. *Id.* at 33–35.

72. *Id.* at 34.

73. *Id.* at 11–12, 21, 26–27, 33–35. APHIS noted in several of its responses to the recommendations that pursuing “non-regulatory” changes—i.e., not pursuing the lengthy process to submit updates to formal written documents for agency voting and incorporation—would result in faster implementation of OIG’s recommendations. Although likely true and best at least in the short run, this means that the formal documents may not include the suggested updates that could help reduce violations in future years.

74. *Id.* at 37.

75. *See* Animal Welfare Act, Pub. L. No. 89-544, § 2(h), 80 Stat. 350, 351 (codified as amended at 7 U.S.C. § 2132(g) (2012)) (originally defining the term “animal” to mean only “live dogs, cats, monkeys (nonhuman primate mammals), guinea pigs, hamsters, and rabbits”).

76. Farm Security and Rural Investment Act of 2002, Pub. L. No. 107-171, § 10301, 116 Stat. 134, 491 (codified as amended at 7 U.S.C. § 2132(g) (2012)).

proving 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>77</sup>

As with many components of the AWA, this definition paints in broad strokes, and its exclusions cover more than just animals used in experimental research, which constitute the main focus of this Article. It is included in its entirety here to provide a more complete picture of this wide-sweeping statutory modification. For a statute originally enacted to address public concern about the mistreatment of animals used in laboratory testing,<sup>78</sup> this protective language omits a substantial number of species subject to what many consider invasive or even abusive procedures,<sup>79</sup> including the vast majority of animals actually used in scientific research.<sup>80</sup> Not covered are the specifically cited birds, rats, and mice, but also invertebrates such as insects and fish, which are used in greater quantities in research than one might initially assume.<sup>81</sup>

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77. 7 U.S.C. § 2132(g) (2012).

78. See Ibrahim, *supra* note 5, at 200. Granted, this public concern was inspired by the easily accessible, clearly heartbreaking issue of stolen common companion animals like dogs and cats, but see *infra* section III.C., discussing the sentience of laboratory animals like mice, rats, birds, and farm animals.

79. See Michael Moss, *U.S. Research Lab Lets Livestock Suffer in Quest for Profit*, N.Y. TIMES (Jan. 19, 2015), [http://www.nytimes.com/2015/01/20/dining/animal-welfare-at-risk-in-experiments-for-meat-industry.html?\\_r=0](http://www.nytimes.com/2015/01/20/dining/animal-welfare-at-risk-in-experiments-for-meat-industry.html?_r=0) (describing experiments at a Nebraska research center designed “to re-engineer the farm animal to fit the needs of the 21st-century meat industry,” resulting in “horrible” pain and death for cows, pigs, sheep, and other livestock exempted from AWA protection); *Animals in Research: Harm and Suffering*, NEW ENG. ANTI-VIVISECTION SOC’Y, <http://www.neavs.org/research/harm-suffering> [https://perma.unl.edu/N2B8-G5Y9]; *Examples of Severe Animal Suffering in Laboratories*, HUMANE SOC’Y OF THE U.S., [http://www.humanesociety.org/issues/pain\\_distress/tips/campus\\_policy\\_suffering\\_examples.html](http://www.humanesociety.org/issues/pain_distress/tips/campus_policy_suffering_examples.html) (last visited March 30, 2016). The Moss article reminded the public that farm animals are subject to scientific experimentation and are not protected by the AWA, but local authorities disputed the severity of its claims. See, e.g., Nicholas Bergin, *Meat Animal Research Center Says It Has Addressed Animal Care Concerns*, LINCOLN J. STAR (June 16, 2015), [http://journalstar.com/business/agriculture/meat-animal-research-center-says-it-has-addressed-animal-care/article\\_da4f96d8-4383-55da-b40b-af27719bf827.html](http://journalstar.com/business/agriculture/meat-animal-research-center-says-it-has-addressed-animal-care/article_da4f96d8-4383-55da-b40b-af27719bf827.html) [https://perma.unl.edu/Y83D-7G2K] (stating that the *New York Times* study focused on dated projects that were not ongoing and that the facility “has addressed all the recommendations of an independent review of its animal care practices”).

80. Kathy Hessler, *The Legal Framework of Animal Testing: Challenges and Opportunities*, Remarks at Symposium: Ethical Implications of the Commercial Use of Animals (Nov. 2012), 54 S. TEX. L. REV. 587, 588 (2013) (noting that only two to five percent of animals used in research are covered by the AWA).

81. *Id.*; see USE OF FISHES IN RESEARCH COMM., AMERICAN FISHERIES SOC’Y, GUIDELINES FOR THE USE OF FISHES IN RESEARCH 1 (2014) (describing the value of fish to scientific research); *A to Z of Animals*, UNDERSTANDING ANIMAL RESEARCH, <http://www.understandinganimalresearch.org.uk/animals/a-z-animals/> [https://perma.unl.edu/YN4T-4XGE] (claiming that fish are the third most common research subjects after mice and rats).

Rats and mice in particular, explicitly excluded from AWA protection, account for roughly 95% of the species used in laboratory testing.<sup>82</sup> That equates to a tremendous number of animals, as the total number of those used in research may reach from one million to up to 200 million used per year.<sup>83</sup> That number is approximate, since there is little reporting required of the use of animals not covered by the AWA.<sup>84</sup> So what reasoning lies behind federal law denying minimum protections to the most commonly used laboratory mammals?

## B. Legislative Background of the Definition

Legislative action concerning the matter was, and continues to be, affected by substantial lobbying efforts on both sides of the issue.<sup>85</sup> Both advocates for animal welfare and those favoring deference to scientific research concur that cost and ease of maintenance are contributing factors to the popularity of using mice and rats in laboratory testing, though the groups vary regarding degree. The research community claims it is one of many valid justifications, while those opposed to animal testing claim monetary motivation is the only real reason.<sup>86</sup> These rodents obviously are quite small, which makes them much less expensive to breed, purchase, and house plus easier to manage in terms of both numbers and physical handling during experi-

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82. *Laboratory Animals Species in Research*, NAT'L ASS'N FOR BIOMEDICAL RES., <http://www.nabr.org/biomedical-research/laboratory-animals/species-in-research/> [<https://perma.unl.edu/56XN-V8K7>].

83. Hessler, *supra* note 80, at 587–88; ANIMAL & PLANT HEALTH INSPECTION SERV., U.S. DEPT OF AGRIC., ANNUAL REPORT ANIMAL USAGE BY FISCAL YEAR (2015), [https://www.aphis.usda.gov/animal\\_welfare/downloads/7023/Animals%20Used%20In%20Research%202014.pdf](https://www.aphis.usda.gov/animal_welfare/downloads/7023/Animals%20Used%20In%20Research%202014.pdf) [<https://perma.unl.edu/K5HF-WD37>] (measuring the number of animals used in research in fiscal year 2014 at 834,453—but that number does not include birds, rats, and mice).

84. *See* Hessler, *supra* note 80, at 587–88.

85. *See* Coco Ballantyne, *The Lobbying Landscape and Beyond: 15 Groups to Know*, 14 NATURE MED. 1002 (2008) (summarizing fifteen organizations dedicated to lobbying in favor of medical research); *Animal Bill of Rights*, ANIMAL LEGAL DEF. FUND, <http://animalbillofrights.aldf.org> [<https://perma.unl.edu/D65N-Z5XT>] (sharing a petition to U.S. Congress asking for stronger standards of animal welfare, including for mice and rats under the AWA). Most other larger welfare organizations' websites also advertise their individual current lobbying efforts. *See, e.g., About Us*, HUMANE SOC'Y LEGIS. FUND, <http://www.hslf.org/about-hslf/> [<https://perma.unl.edu/28AM-9TJJP>]; *Advocacy Center*, ASPCA, <https://www.aspc.org/fight-cruelty/advocacy-center> [<https://perma.unl.edu/A3T6-RP6Y>].

86. *Laboratory Animals Species in Research*, *supra* note 82; *see* D. Smith, *Rats, Mice and Birds Excluded from Animal Welfare Act*, MONITOR ON PSYCHOL., July/Aug. 2002, at 14, <http://www.apa.org/monitor/julaug02/rats.aspx> (summarizing research groups' arguments that regulating rodents and birds under the AWA would raise care and maintenance costs prohibitively); *Rats, Mice & Birds*, ANIMAL WELFARE INST., <https://awionline.org/content/rats-mice-birds> [<https://perma.unl.edu/XG6E-RQUD>] (representing the view that rats, mice, and birds only are popular in laboratories due to financial considerations).

mentation than, say, nonhuman primates. The small size also eases expenses when their smaller bodies require lesser amounts of drugs and other ingested or implanted compounds to reach the desired effects and when more individuals can be exposed to the same tests to confirm results.<sup>87</sup>

The research community further asserts that, extending beyond these financial concerns, rodents are very similar to humans in their physiological and genetic makeup, making them ideal test subjects for the advancement of human health initiatives in areas like cancer, Alzheimer's, diabetes, cardiovascular diseases, and others.<sup>88</sup> Those advocating for higher standards of animal welfare may cite the same argument, however; if rats and mice are so like humans, do they not deserve the most basic federally mandated minimums of humane care and treatment?<sup>89</sup> This point does not suggest that all testing on them should cease—although some support that outcome<sup>90</sup>—but just that they receive consistently provided, base-level humane housing and necessary veterinary care and that researchers use them in accordance with the AWA's other low standards.<sup>91</sup>

If the 2002 Congress heard this theory, it was not convinced. Two years earlier, an organization devoted to discovery and adoption of non-animal research methods sued the Secretary of Agriculture specifically to include birds, mice, and rats under the AWA umbrella.<sup>92</sup> This action resulted in a settlement whereby the USDA agreed to consider these updates.<sup>93</sup> That is where the progress ended, however; even though some influential organizations that conduct animal test-

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87. *Laboratory Animals Species in Research*, *supra* note 82; *Rats, Mice & Birds*, *supra* note 86 (contending that when testing on mice and rats, “[a] few animals more or less do not make a big difference in the budget, so care is not taken to address all of the details that would make the research methodology sound and scientifically reliable with fewer animals; the investigator simply ‘uses’ more research subjects to overcome variables and thereby obtain statistically significant results”). Recall that the Three R's only apply to “animals” under the AWA, so scientists are not federally required to endeavor to reduce the numbers of rats and mice their laboratories use.

88. NAT'L ASS'N FOR BIOMEDICAL RESEARCH, *supra* note 2.

89. Hessler, *supra* note 80, at 589.

90. *See Ibrahim*, *supra* note 5, at 224–25 (“Animal advocates should . . . seek to abolish animal experimentation on moral grounds, rather than ceding the practice and attempting to regulate it.”).

91. 7 U.S.C. § 2143(a)(2)(A) (2012).

92. *Alts. Research & Dev. Found. v. Glickman*, 101 F. Supp. 2d 7 (D.D.C. 2000) (denying defendants' motion to dismiss, holding that plaintiffs had standing that the issue was subject to judicial review); *see About ARDF*, ALTERNATIVES RESEARCH & DEV. FOUND., <http://www.ardf-online.org/about.html> [<https://perma.unl.edu/FW4M-8C4C>] (explaining the general purpose of the plaintiff-organization).

93. Smith, *supra* note 86; *see Animal Welfare Act May Not Protect All Critters*, USA TODAY (May 7, 2002), <http://usatoday30.usatoday.com/news/nation/2002/05/07/animal-welfare.htm> [<https://perma.unl.edu/638F-DZAE>].



ing supported the additions,<sup>94</sup> one legislator immediately blocked the action for a year, giving another time to propose an ultimately successful amendment to the 2002 Farm Bill that led to the current, discriminative AWA definition.<sup>95</sup>

Those opposed to the animal welfare movement's pursuit of the issue are quick to remind that all "live, vertebrate" animals used in laboratories are protected under other guidelines to which many research facilities voluntarily adhere in order to receive funding, such as the policy propagated by the PHS.<sup>96</sup> They contend, in fact, that a large percentage of the current laboratory animals not covered by the AWA are already protected by these guidelines and those mandated by other accrediting organizations, and therefore increasing the application of the AWA would not result in meaningful improvements to their welfare.<sup>97</sup> Once again, however, this argument may turn to favor the other side: If such changes to the statute would not considerably alter things at most research facilities, why oppose the statutory modification so strenuously?<sup>98</sup>

Moreover, the AWA not only carries more legal authority and reaches more facilities than guidelines like those used by the PHS, but it also provides for services not found in those other documents, such as governmental review of welfare-related complaints by the public, and the systematic collection and reporting of accurate statistics, such as those concerning what and how many animals a facility uses in its experiments.<sup>99</sup> For example, IACUC monitoring and reporting deficiencies like those discussed in the OIG audit mentioned above did not even consider the use of birds, rats, and mice,<sup>100</sup> so one can only speculate as to how those problems might have expanded if it did include those most-common laboratory subjects. Plus, the public continues to grow more and more interested in such information, which in turn affects companies' marketing and product-labeling efforts.<sup>101</sup>

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94. *Animal Welfare Act May Not Protect All Critters*, *supra* note 93 ("Colgate-Palmolive and Procter & Gamble wrote to senators to argue there was no basis to exclude rats, birds and mice.").

95. *Id.*; Smith, *supra* note 86.

96. *See* PHS POLICY, *supra* note 45, at 8.

97. Smith, *supra* note 86.

98. *See id.* (discussing the costs associated with eliminating the AWA's species exclusions). The rebuttal usually turns once again to finances, and the allegedly dramatic increase in expense that would be associated with licensure, review, and reporting upon the use of more animals previously not included in such procedures. But if so many facilities already follow more stringent regulations anyway, would the difference really be so great?

99. F. Barbara Orlans, *The Injustice of Excluding Laboratory Rats, Mice, and Birds from the Animal Welfare Act*, 10 KENNEDY INST. ETHICS J. 229, 236–37 (2000).

100. OIG AUDIT, *supra* note 57, at 1.

101. *See Leaping Bunny Approved Brands*, LEAPING BUNNY PROGRAM, <http://www.leapingbunny.org/guide/brands> [<https://perma.unl.edu/8NUM-8B5A>] (listing

### C. Sentience of Unprotected Species

“The more we do experiments like this, the more we wonder if we should do experiments like this.”<sup>102</sup> This public concern increases as research animals and the labs in which they are used receive more media attention. Today more than ever, such information is readily accessible to just about anyone via the Internet and social media campaigns, and ranges from animal rights propaganda, to mainstream news exposés, and even to reports from scientific researchers themselves, many of whom care about the humane treatment of creatures in their charges or who left laboratories where programs did not align with these views, or both.<sup>103</sup>

Perhaps because they look and behave so similarly to humans, it has long been accepted that nonhuman primates are able to compose complex thoughts and to feel pain, fear, and despair.<sup>104</sup> In fact, highly

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over 600 U.S., Canadian, and European cosmetics, personal care, and household product companies that do not test on animals and voluntarily apply for and earn designation as “cruelty-free” by the Coalition for Consumer Information on Cosmetics).

102. Virginia Morell, *Rats See the Pain in Other Rats’ Faces*, SCIENCE (Mar. 31, 2015, 7:15 PM), <http://news.sciencemag.org/biology/2015/03/rats-see-pain-other-rats-faces> [https://perma.unl.edu/GS6W-3TAX] (quoting Jeffrey Mogil, neuroscientist at McGill University in Montreal, Canada, where researchers deliberately inflicted pain on mice to test whether other mice responded with empathy). Mogil went on to state that “there is no alternative” to using animals in pain and pain treatment research since “[t]issue cultures and computer simulations won’t work.” *Id.*
103. *See* *Alts. Research & Dev. Found. v. Glickman*, 101 F. Supp. 2d 7, 11 (D.D.C. 2000) (noting one plaintiff was a college science student who opposed the inhumane treatment of rats used in the school’s laboratory experiments); Roscoe G. Bartlett, Opinion, *Stop Using Chimps as Guinea Pigs*, N.Y. TIMES (Aug. 10, 2011), [http://www.nytimes.com/2011/08/11/opinion/stop-using-chimps-as-guinea-pigs.html?\\_r=3](http://www.nytimes.com/2011/08/11/opinion/stop-using-chimps-as-guinea-pigs.html?_r=3) (presenting arguments of an ex-scientist opposed to testing on nonhuman primates who states, “At the time, I believed such research was worth the pain inflicted on the animals. But in the years since, our understanding of its effect on primates, as well as alternatives to it, have made great strides, to the point where I no longer believe such experiments make sense—scientifically, financially or ethically.”); Moss, *supra* note 79 (exposing alleged inhumane research practices in the *New York Times*); Kelly Walton, *Why I am a Laboratory Animal Veterinarian*, SPEAKING OF RESEARCH (Jan. 21, 2013), <http://speakingofresearch.com/2013/01/21/why-i-am-a-laboratory-animal-veterinarian/> [https://perma.unl.edu/3HPG-ZAUJ] (sharing a laboratory veterinarian’s lifelong love for animals, and her views that animal testing is vital for society and that positions like hers ensure humane treatment in such experimentation).
104. *See* Lisa Myers & Diane Beasley, *A Question of Freedom for Chimpanzees Who Spend Lives in Research Labs*, NBC NEWS (Jan. 27, 2012, 11:17 AM), [http://rockcenter.nbcnews.com/\\_news/2012/01/27/10251519-a-question-of-freedom-for-chimpanzees-who-spend-lives-in-research-labs?lite](http://rockcenter.nbcnews.com/_news/2012/01/27/10251519-a-question-of-freedom-for-chimpanzees-who-spend-lives-in-research-labs?lite) [https://perma.unl.edu/4PG7-RLT2] (describing the experiences of chimps at the Texas Biomedical Research Institute where they are used in testing or kept confined just in case they are needed in the future).

publicized legal actions have been, and continue to be, filed and fought to earn them legal personhood so that lawsuits challenging mistreatment or unjustified confinement may be brought on their behalves.<sup>105</sup> But what about the species that look and act less like humans and are excepted from basic protections by the AWA? Is the exception of birds, mice, rats, livestock, and cold-blooded animals like fish from the statutory definition of “animal” based upon the fact that they lack the sentience of other beings?

In a word, no; but how humans interact with and use animals affects how they view those animals, and hence what treatment many feel is or is not justified.<sup>106</sup> For instance, whether a person sees a rabbit as a pet in the home, a product for meat consumption, a wild beast that eats gardens and landscaping, or as a subject of laboratory experiments affects the person’s view of the rabbit.<sup>107</sup> The human is far more likely to become upset and take corrective action if she sees the rabbit in discomfort if it is her pet as opposed to if it is soon to be her dinner, if it is damaging her property, or if it is her scientific research subject, and public concern varies even more depending on whether that research is for cosmetic or medical purposes.<sup>108</sup> None of these situations changes how the rabbit perceives and reacts to its environment, however.<sup>109</sup> For instance, it feels pain if it injures its eye accidentally in the wild the same way as it feels pain when confined and subjected to the notorious Draize eye-irritation test.<sup>110</sup>

Not only are research animals capable of feeling pain—otherwise why would they try to escape and need to be restrained during painful

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105. See *Court Cases*, NONHUMAN RIGHTS PROJECT, <http://www.nonhumanrightsproject.org/category/courtfilings/> [<https://perma.unl.edu/V3YT-TXYV>] (summarizing and providing links to commentary and legal documents filed since 2013).

106. Donald M. Broom, *Cognitive Ability and Awareness in Domestic Animals and Decisions About Obligations to Animals*, 126 APPLIED ANIMAL BEHAV. SCI. 1, 8 (2010).

107. *Id.*

108. *Id.*; Kirk R. Wilhelmus, *The Draize Eye Test*, 45 SURV. OPHTHALMOLOGY 493, 503 (2001).

109. Broom, *supra* note 106.

110. See *id.*; Wilhelmus, *supra* note 108, at 498–99, 504 (describing the design of the Draize test and some of the ethical opposition to its use); *Do Cosmetics Companies Still Test on Live Animals?*, SCI. AM. (Aug. 6, 2009), <http://www.scientificamerican.com/article/cosmetics-animal-testing/> [<https://perma.unl.edu/L2GY-LMNB>] (noting that the Draize test still is used today, although “many companies are moving away from” the practice). Of course this example depends on degree, and the main difference is that the wild rabbit can remove itself from the painful situation and reach its eye to rub it or otherwise attempt to remove any irritants, and the injury is less likely to be repeated; in the Draize test, the rabbit is not permitted to move or access its eyes for at least several hours—usually days—and it may be subjected to multiple irritant applications.

experiments like the Draize test?<sup>111</sup>—but they also are quite intelligent and capable of experiencing the emotional agony that accompanies many procedures, much as humans experience stress when anticipating and enduring painful medical treatments; but the animals are unable to know why, when, or how the experiments will occur so they can prepare accordingly, nor, of course, can they elect to participate voluntarily.<sup>112</sup>

Mice and rats demonstrate a high degree of sentience. For example, they feel and express empathy.<sup>113</sup> In a 2011 study from the University of Chicago, rats deliberately and expeditiously liberated cage-mates from restraints, even when given the choice between freeing the cage-mate and engaging in a pleasurable activity like eating chocolate.<sup>114</sup> Another study showed that rats also recognize pain in their companions' faces, experiencing discomfort themselves when they see a familiar mouse suffering.<sup>115</sup> Mice are perceptive enough to tell the difference between artists, distinguishing between artistic style and even between paintings by the same artist.<sup>116</sup> Mice also have been found to sing various songs to attract potential mates.<sup>117</sup> Addition-

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111. See Ibrahim, *supra* note 5, at 214 (noting that rabbits have been known to break their backs attempting to escape during painful Draize tests); M. Lynne Kesel, *Handling, Restraint, and Common Sampling and Administration Techniques in Laboratory Species*, in *THE EXPERIMENTAL ANIMAL IN BIOMEDICAL RESEARCH VOL. I: A SURVEY OF SCIENTIFIC AND ETHICAL ISSUES FOR INVESTIGATORS* 337 (Bernard E. Rollin ed., 1990) (describing ways to handle mice, rats, and other laboratory animals to minimize stress, escape, and biting during experimentation).
112. See Joseph Vining, *The Least of the Sentient Beings* 84 (Univ. of Mich. Law Sch. Pub. Law Legal Theory Working Paper Series, Working Paper No. 128, 2008) (“[P]eople working with animals today frequently say that animals, unlike humans, cannot give or withhold their consent, and that this in a way puts a greater burden on animal researchers.”); Marc Bekoff, *Empathic Rats and Ravishing Ravens*, *PSYCH. TODAY: ANIMAL EMOTIONS* (Dec. 8, 2011), <https://www.psychologytoday.com/blog/animal-emotions/201112/empathic-rats-and-ravishing-ravens> [<https://perma.unl.edu/KPG7-5LLE>] (noting that modern discoveries concerning non-primate species, including mice, rats, and birds prove that their cognitive and emotional capacities are more similar to those of primates than previously assumed).
113. Bekoff, *supra* note 112.
114. Inbal Ben-Ami Bartal, Jean Decety, & Peggy Mason, *Empathy and Pro-Social Behavior in Rats*, 334 *SCIENCE* 1427 (2011); see Bekoff, *supra* note 112 (quoting researchers that rats are “motivated by something internal” to continue trying to open the cage door, and that “[the rat] can hog the entire chocolate stash if he wanted to, and he does not. We were shocked”).
115. Dale J. Langford et al., *Social Modulation of Pain as Evidence for Empathy in Mice*, 312 *SCIENCE* 1967 (2006).
116. Shigeru Watanabe, *Preference for and Discrimination of Paintings by Mice*, 8 *PLoS ONE*, no. 6, June 2013, at 1 (using paintings by Renoir, Picasso, Kandinsky, and Mondrian).
117. Jonathan Chabout et al., *Male Mice Song Syntax Depends on Social Contexts and Influences Female Preferences*, 9 *FRONTIERS IN BEHAV. NEUROSCIENCE*, art. 76, Apr. 2015, at 1.

ally, due to their expressive personalities and affectionate natures, they are increasingly common household pets.<sup>118</sup>

Mice and rats are not the only animals excluded by the AWA that possess significant cognitive abilities. Birds also are more cognitively complex than initially believed, demonstrating skills previously thought to be possessed only by primates.<sup>119</sup> Crows, for example, are able to use tools to suit their needs.<sup>120</sup> Several fowl species communicate using intricate patterns that show understanding of a current situation—as opposed to just stimulus response—as well as comprehension of social order, deception, and the attentive state of others.<sup>121</sup> Studies suggest that chickens are as intelligent as human toddlers, recognizing their names and performing tasks such as transitive inference—meaning a chicken can determine that if A is greater than B and B is greater than C, then A is greater than C.<sup>122</sup> They even can perform basic math beginning from a very young age.<sup>123</sup> They also behave surprisingly like more traditional companion animals when treated as such, demonstrating multifaceted, individual personalities.<sup>124</sup>

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118. *See Pet Mice and Rats*, CANADIAN FED'N OF HUMANE SOCIETIES, [http://cfhs.ca/at-home/pets\\_mice\\_and\\_rats/](http://cfhs.ca/at-home/pets_mice_and_rats/) [<https://perma.unl.edu/VK27-D3WL>]; *Keeping Pet Rats: A Short Guide*, NAT'L FANCY RAT SOC'Y, <http://www.nfrs.org/shortinfo.html> [<https://perma.unl.edu/KZ2W-5DG7>].
119. Carolynn L. Smith & Jane Johnson, *The Chicken Challenge: What Contemporary Studies of Fowl Mean for Science and Ethics*, 15 *BETWEEN SPECIES* 75, 76–82 (2012) (summarizing studies which found that fowl display complex behaviors thought exclusive to primate species, like using tools, solving problems, and employing complicated communication techniques).
120. Jolyon Troscianko & Christian Rutz, *Activity Profiles and Hook-Tool Use of New Caledonian Crows Recorded by Bird-Borne Video Cameras*, *ROYAL SOC'Y PUB. BIOLOGY LETTERS*, Dec. 2015, at 1 (noting that wild crows engage in sophisticated tool usage previously observed in captive crows, such as manufacturing and using complex hooked stick tools); Christopher David Bird & Nathan John Emery, *Rooks Use Stones to Raise the Water Level to Reach a Floating Worm*, 19 *CURRENT BIOLOGY* 1410 (2009) (describing a study in which captive rooks used stones to raise the water level of a pitcher in order to access a floating worm, understanding how many stones were needed, what size stones were most effective, and that sawdust cannot be manipulated like water).
121. Smith & Johnson, *supra* note 119, at 77–78, 80–81 (explaining that blue jays will hide their food, wait, and move it if another bird sees them, and that pigeons understand sameness and differences between images).
122. Bruce Friedrich, Opinion, *Chickens: Smarter than a Four-Year-Old*, *N.Y. DAILY NEWS* (Aug. 16, 2013), <http://www.nydailynews.com/opinion/chickens-smarter-four-year-old-article-1.1428277>.
123. *Id.*; Rosa Rugani et al., *Number-Space Mapping in the Newborn Chick Resembles Humans' Mental Number Line*, 347 *SCIENCE* 534, 534–36 (2015).
124. *See* Kathryn King, *Peeper: A Story of Unending Love*, *POULTRY PRESS*, Winter 2012, at 6, 6–7, <http://www.upc-online.org/pp/winter2012/peeper.html> [<https://perma.unl.edu/R74L-R9QM>] (describing the author's close relationship with a turkey she raised from birth).

Farm animals demonstrate similar intelligence. Livestock, including cows, pigs, sheep, goats, and others—most of which are not used often in traditional laboratory settings but may be subject to food-related experimentation outside the scope of AWA protection<sup>125</sup>—display impressive cognitive abilities. For instance, cows demonstrate excitement when they sense their own understanding and achievement.<sup>126</sup> In one study, cows were separated into two groups, one experimental and the other control.<sup>127</sup> The experimental group had to press a panel to open a gate to access a food reward, while the control group accessed the food after the gate opened automatically.<sup>128</sup> While both groups were excited to reach the food, the experimental group animals demonstrated greater excitement than the control group, suggesting that they “were reacting to their own learning process and thus in a sense to their own achievement.”<sup>129</sup> Another study examined the social bonds of dairy cattle, determining that they have various moods and form deep bonds with other specific cows, sharing social support and becoming stressed when separated.<sup>130</sup> When bonded pairs of cattle were kept together but separated from the rest of the herd, they exhibited substantially weaker stress responses than when they were separated from the herd with different partners.<sup>131</sup> Furthermore, when these pairs were separated from each other for several days, they “showed significant behavioural, physiological and milk production changes.”<sup>132</sup>

Pigs are especially perceptive and clever: they not only learn, but engage with and enjoy playing video games with joysticks;<sup>133</sup> they understand how mirrors work, which is a common test to determine self-

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125. 7 U.S.C. § 2132(g) (2012); see Moss, *supra* note 79.

126. Kristin Hagen & Donald M. Broom, *Emotional Reactions to Learning in Cattle*, 85 APPLIED ANIMAL BEHAV. SCI. 203, 211–12 (2003).

127. *Id.* at 204.

128. *Id.* at 205.

129. *Id.* at 211–12. The researchers noted that their study suggests that cows “may have an emotional perspective on their own agency. However, because of the novelty of the approach and the small number of animals, this study should be seen as a first step towards future investigation of the topic.” *Id.* at 212.

130. Krista Marie McLennan, *Social Bonds in Dairy Cattle: The Effect of Dynamic Group Systems on Welfare and Productivity* (Jan. 2013) (unpublished Ph.D. thesis, University of Northampton) (on file with University of Northampton NECTAR).

131. *Id.* at viii, 60–62, 93.

132. *Id.* at viii, 99–100, 139.

133. *Hog Heaven: Pigs Learn Video Games*, SEATTLE TIMES (Oct. 26, 1997), <http://community.seattletimes.nwsource.com/archive/?date=19971026&slug=2568406> [<https://perma.unl.edu/SYY2-8SXR>]; see PLAYING WITH PIGS, <http://www.playingwithpigs.nl> [<https://perma.unl.edu/2PAK-VWD6>], for a collaborative project of Dutch universities to create a game called “Pig Chase” that humans can play with pigs using a tablet computer.

awareness;<sup>134</sup> they have excellent memories and use that knowledge to adapt to changing circumstances, such as when choosing between sites with different amounts and qualities of food, consistently picking the “more profitable” site even when forced to overcome obstacles to reach it;<sup>135</sup> and if given the opportunity, they can learn to control the temperature in their pens.<sup>136</sup> Pigs also have proven to be beloved household pets<sup>137</sup> and are one of several animal species that endeavor to save the lives of their threatened human and nonhuman companions.<sup>138</sup> Despite—or perhaps due to—these abilities and similarities to humans, pigs often are used in traditional laboratory research in addition to experimentation designed to improve food-production efficiency.<sup>139</sup>

The cognitive capabilities and awareness of these and other mammals and birds not covered by the AWA might be surprising to some, but the sentience of fish may be even more unexpected. It is well-known and accepted that dolphins are highly intelligent and self-aware,<sup>140</sup> but dolphins actually are mammals, not fish.<sup>141</sup> The rather common assumption that fish, such as trout, do not feel pain may

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134. Donald M. Broom, Hilana Sena, & Kiera L. Moynihan, *Pigs Learn What a Mirror Image Represents and Use It to Obtain Information*, 78 ANIMAL BEHAV. 1037, 1040 (2009).
  135. S. Held et al., *Foraging Behaviour in Domestic Pigs (Sus Scrofa): Remembering and Prioritizing Food Sites of Different Value*, 8 ANIMAL COGNITION 114, 120 (2004).
  136. Richard Orr, *Pigs Trained to Control Heat in Their Pens*, MONTREAL GAZETTE, Aug. 27, 1983, at I-7, <https://news.google.com/newspapers?nid=1946&dat=19830827&id=SpEjAAAAIIBAJ&sjid=R6UFAAAAIIBAJ&pg=6043,2564179&hl=en>.
  137. See ESTHER THE WONDER PIG, <http://www.therewonderpig.com> [<https://perma.unl.edu/MS26-RBXS>] (sharing photos and stories of Esther, a full-sized pig originally adopted as a family pet when she was believed to be a smaller breed, who has hundreds of thousands of followers and fans on social media).
  138. See Ingrid Newkirk, *9 Ways Pigs Are Smarter Than Your Honor Student*, HUFFPOST GREEN: BLOG (Apr. 4, 2014, 02:10 PM ET), [http://www.huffingtonpost.com/ingrid-newkirk/9-ways-pigs-are-smarter-t\\_b\\_5154321.html](http://www.huffingtonpost.com/ingrid-newkirk/9-ways-pigs-are-smarter-t_b_5154321.html) [<https://perma.unl.edu/LD9S-P7ZG>] (describing and providing links to stories of a pig who pulled her owner from a bog, a pig who saved a boy from drowning, a pig who alerted a passing car to help a man who had collapsed from a heart attack, a pig who chased away an intruder, a pig who detained a burglary suspect until police arrived, and a pig who led firefighters to a calf trapped in a burning shed).
  139. *Swine in Biomedical Research*, BIOLOGIC RES. LAB., UNIV. OF ILL. AT CHI., <https://www.brl.uic.edu/node/36> [<https://perma.unl.edu/WS26-RSND>]; see *A to Z of Animals*, *supra* note 81.
  140. Jeffrey Kluger, *Inside the Minds of Animals*, TIME (Aug. 5, 2010), <http://content.time.com/time/magazine/article/0,9171,2008867,00.html> (noting that dolphins pass the mirror self-recognition test).
  141. National Ocean Service, *Dolphins are Mammals, Not Fish*, NAT'L OCEANIC AND ATMOSPHERIC ADMIN., <http://oceanservice.noaa.gov/facts/dolphins.html> [<https://perma.unl.edu/C4UC-HJ8C>] (noting that although they spend their lives in the ocean, dolphins breathe air through lungs, give birth to live young that they feed with milk, and have a small amount of hair near their blowholes).

stem from their physiology, notably the size and structure of their brains, which do not include the cerebral cortex often linked to pain perception and emotions in mammals.<sup>142</sup> Knowledge concerning the sentience of fish is limited, but studies suggest that, in spite of these differences, fish are capable both of nociception—the ability to perceive impending harm—as well as feeling the resulting pain itself.<sup>143</sup> Studies have observed that fish also recognize social companions, and their memories allow them to avoid an area for months or even years if they endured a negative experience there.<sup>144</sup> Crustaceans like crayfish and prawn avoid painful stimuli and respond to analgesics in a manner similar to vertebrates.<sup>145</sup> Cephalopods, like the octopus, are common research subjects that also are surprisingly intelligent and capable of feeling pain and other emotions.<sup>146</sup>

All of this establishes that most, if not all, animals used in research possess at least some degree of cognitive skills and therefore can understand and suffer pain,<sup>147</sup> whether they officially are deemed “animals” by the AWA’s definition or not. While this fact supports ethical arguments against animal testing, it does not account for the potential benefits to human society notwithstanding that cost; it does not prove that the ends do not justify the means. Some claim that because these animals are so similar to humans, it only makes sense to use them in laboratory research and to allow researchers the latitude to conduct these experiments without the hindrance of IACUC or other governmental monitoring and intrusion—in other words, to maintain the status quo.<sup>148</sup> But are these animals really that similar to humans, or do they just possess comparable levels of sentience and the ability to experience pain?

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142. Helen Proctor, *Animal Sentience: Where Are We and Where Are We Heading?*, 2 ANIMALS 628, 632 (2012).

143. *Id.* at 633.

144. Bo Algers et al., *General Approach to Fish Welfare and to the Concept of Sentience in Fish*, 954 EUROPEAN FOOD SAFETY AUTHORITY J. 1, 19 (2009).

145. Proctor, *supra* note 142, at 635.

146. *Id.* at 634; Jennifer A. Mather, *Philosophical Background of Attitudes Toward and Treatment of Invertebrates*, 52 INST. FOR LABORATORY ANIMAL RESEARCH J. 205, 210 (2011) (“Octopuses, for example, explore and learn well, play, have personalities, and solve problems”).

147. Robert W. Elwood, *Pain and Suffering in Invertebrates?*, 52 INST. FOR LABORATORY ANIMAL RES. J. 175, 181 (2011) (noting the link between sentience and the ability to feel pain).

148. See Morrell, *supra* note 102 (quoting Dr. Mogil as saying there is no alternative to animal experimentation); Smith, *supra* note 86 (arguing that including rats, mice, and birds in AWA coverage would raise laboratory costs prohibitively).



#### IV. THE EFFECTIVENESS AND NECESSITY OF ANIMAL TESTING

“Choose almost any area of medical research using mice, and you will see a failed paradigm often spanning several decades.”<sup>149</sup> Many in the scientific community argue vigorously in favor of animal testing, pointing to advances benefitting human health and wellbeing that they attribute to animal experimentation.<sup>150</sup> Animal testing gained widespread acceptance and governmental endorsement in the 1930s after some famously unsafe products resulted in great harm and loss of life.<sup>151</sup> A permanent eyelash dye called Lash Lure caused blisters, abscesses, ulcers, and sometimes even blindness and death for the women who used it, and a drug company attempting to market an antibacterial liquid to children added a sweet-tasting compound—ethylene glycol, the main ingredient in antifreeze—which turned out to be poisonous, leading to over one hundred deaths before it was pulled from stores.<sup>152</sup> These tragedies led to enactment of the Federal Food, Drug, and Cosmetic Safety Act of 1938,<sup>153</sup> which required drug companies to prove their products’ safety and obtain approval from the Food and Drug Administration (FDA) before offering them for sale to the public.<sup>154</sup>

There also are vociferous critics of animal experimentation, however. They range from the obvious animal rights activists to medical doctors and scientific organizations around the world who are opposed to vivisection not only due to ethical reasons, but because they do not believe that nonhuman animals are predictive models for how products and treatments will affect humans.<sup>155</sup> The AWA’s most basic as-

149. John J. Pippin, *The Failing Animal Research Paradigm for Human Disease*, INDEP. SCI. NEWS (May 20, 2014), <https://www.independentsciencenews.org/health/the-failing-animal-research-paradigm-for-human-disease/> [<https://perma.unl.edu/4DD4-UMZH>].

150. See *supra* note 27 and accompanying text.

151. NAT’L RESEARCH COUNCIL, SCIENCE, MEDICINE, AND ANIMALS 21–23 (2004).

152. *Id.*

153. Federal Food, Drug, and Cosmetic Act of 1938, Pub. L. No. 75-717, 52 Stat. 1040 (codified as amended at 21 U.S.C. §§ 301–99 (2012)); Tina Sigurdson, *Exposing the Cosmetics Cover-Up: True Horror Stories of Cosmetic Dangers*, ENVTL. WORKING GRP. (Oct. 29, 2013), <http://www.ewg.org/research/exposing-cosmetics-cover-true-horror-stories-of-cosmetic-dangers> [<https://perma.unl.edu/3LNF-JWYX>].

154. NAT’L RESEARCH COUNCIL, *supra* note 151, at 23; see Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–99 (2012).

155. See *About Us*, PHYSICIANS COMM. FOR RESPONSIBLE MED., <http://www.pcrm.org/about/about/about-pcrm> [<https://perma.unl.edu/QT8E-LUK4>]; *About DLRM*, DOCTORS AND LAW. FOR RESPONSIBLE MED., <http://www.dlrm.org/about.htm> [<https://perma.unl.edu/NV6D-3M6J>]; *About Us*, SAFER MEDICINES CAMPAIGN, <http://www.safermedicines.org/page/aboutus> [<https://perma.unl.edu/WT4M-64Q5>]; AM. FOR MED. ADVANCEMENT, <http://www.afma-curedisease.org> [<https://perma.unl.edu/UM23-L5YE>]; DOCTORS AGAINST ANIMAL EXPERIMENTS GER., <http://www.aerzte-gegen-tierversuche.de/agt-en/> [<https://perma.unl.edu/S4GC-BH3K>].

sumption is that animal testing is necessary and will indeed occur, and so it seeks to regulate the practice by setting minimum standards of humane treatment.<sup>156</sup> But even if it were true that experimentation will continue for the foreseeable future, it is useful to explore these opposing arguments, some of which, if accepted, would render much of the AWA moot.

### A. Is Animal Experimentation Effective?

Of course there are clear differences between humans and animals, including primates; otherwise the ethics of involuntary confinement and testing would not be in question. Beyond obvious external distinctions like the presence of a tail, internal inconsistencies also are readily apparent through common knowledge, such as the fact that humans can eat chocolate but it causes illness, and sometimes death, in dogs.<sup>157</sup> Other research animals, like mice, share a large amount of genetic makeup with humans, but studies suggest that these similarities are not sufficient to make animal testing consistently reliable—some say even worthwhile at all—because humans and animals express the same genes differently.<sup>158</sup> While some say that animal experimentation reveals valuable information about certain human maladies, for other conditions it appears to be ineffective.<sup>159</sup>

Take cancer, for example. Numerous studies spanning many years demonstrate that experimentation using mice and rats to determine human responses to cancers and potential treatments provide dubious results at best.<sup>160</sup> As a previous director of the National Cancer Insti-

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156. See Hessler, *supra* note 80, at 595.

157. See *Dog Chocolate Toxicity Meter*, PETMD, <http://www.petmd.com/dog/chocolate-toxicity> [<https://perma.unl.edu/9LBW-T6DF>].

158. Robert A. Coleman, *Of Mouse and Man – What is the Value of the Mouse in Predicting Gene Expression in Humans?*, 8 *DRUG DISCOVERY TODAY* 233, 233 (2003) (noting that the genomes of mice and humans are 95% identical, but different expressions of those genomes leads to misleading experiment results); Ray Greek, *What is Needed in Order to End Vivisection?*, *AM. FOR MED. ADVANCEMENT*, <http://www.afma-curedisease.org/media/10922/whatisneededtoendvivisection.pdf> [<https://perma.unl.edu/LM5E-UDDU>] (advocating an end to vivisection entirely because “animals cannot predict human response”).

159. Coleman, *supra* note 158 (noting that advances have been made using mice to study diseases like Huntington’s chorea and Alzheimer disease, but less so for asthma, cystic fibrosis, and cancer). *But see* Sarah E. Cavanaugh, John J. Pippin, & Neal D. Barnard, *Animal Models of Alzheimer Disease: Historical Pitfalls and a Path Forward*, 31 *ALTEX* 279, 290 (2014) (arguing that animals are unreliable research models that offer poor translation to human Alzheimer disease patients); Ray Greek & Andre Menache, *Systematic Reviews of Animal Models: Methodology Versus Epistemology*, 10 *INT’L. J. MED. SCI.* 206, 216–217 (2013) (“[A]nimal models do not currently qualify as predictive modalities for human response to drugs and disease . . .”).

160. See Coleman, *supra* note 158 (regarding cancer, “mouse models have been less helpful—or even misleading”); J.W. Grisham, *Interspecies Comparison of Liver*

tute famously said, “The history of cancer research has been a history of curing cancer in the mouse. . . . We have cured mice of cancer for decades—and it simply didn’t work in humans.”<sup>161</sup> Many compounds that are safe for human use are carcinogenic or otherwise toxic to animals,<sup>162</sup> and those that show promise for rodents are often ineffective in humans.<sup>163</sup>

These inconsistencies extend well beyond cancer research. For example, studies report inconsistent result translation from mice or rats to humans in experimentation for conditions such as: diabetes; trauma, sepsis, and burns; traumatic brain injury; ALS or Lou Gehrig’s disease; and Alzheimer’s disease.<sup>164</sup> Commonly cited problems occurred with penicillin, which initially proved to be toxic to guinea pigs and hamsters, and aspirin, which caused birth defects in mice and rats.<sup>165</sup> Laboratory animals also are heavily inbred to reduce costs and to help ensure less genetic variability that can affect test results from animal to animal, but this inbreeding can lead to discrepancies with humans that negatively impact those test results in practical use.<sup>166</sup> Furthermore, different species of rodents may

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*Carcinogenesis: Implications for Cancer Risk Assessment*, 18 *CARCINOGENESIS* 59, 59, 71–72 (1997) (noting differences between mice, rats, and humans concerning liver, colon, and other intestinal cancers, as well as hormonal regulation, leading to likely false-positive and false-negative testing risks); Pippin, *supra* note 149 (“Only a small percentage of mouse research into human cancers is even reproducible . . .”).

161. Marlene Cimon et al., *Cancer Drugs Face Long Road From Mice to Men*, *L.A. TIMES* (May 6, 1998), <http://articles.latimes.com/1998/may/06/news/mn-46795> [<https://perma.unl.edu/GX5H-ETRB>] (quoting Dr. Richard Klausner).
162. Hessler, *supra* note 80, at 591; *Frequently Asked Questions*, SAFER MEDICINES CAMPAIGN, [http://www.safermedicines.org/page/faqs\\_faq10](http://www.safermedicines.org/page/faqs_faq10) [<https://perma.unl.edu/3J84-8YMQ>].
163. Marion de Jong & Theodosia Maina, *Of Mice and Humans: Are They the Same? – Implications in Cancer Translational Research*, 51 *J. NUCLEAR MED.* 501, 504 (2010) (stating that animal models are essential in cancer research, “even though results in animals are sometimes not fully applicable to humans because of inherent biologic differences between the species,” and that “[i]t is good to remain critical and cautious about the applicability of animal data to the clinical domain”).
164. Pippin, *supra* note 149.
165. *Animals in Science: The Failure of the Animal Model*, NAT’L ANTI-VIVISECTION SOC’Y (2015), <http://www.navs.org/science/failure-of-the-animal-model> [<https://perma.unl.edu/7FDE-7G28>]. *But see Myth Busting: “Penicillin is Toxic in Guinea Pigs but not to Humans,”* SPEAKING OF RESEARCH (Feb. 28, 2014), <http://speakingofresearch.com/2014/02/28/myth-busting-penicillin-is-toxic-in-guinea-pigs-but-not-to-humans/> [<https://perma.unl.edu/2A9U-9697>] (arguing that the initial failure with penicillin testing led to greater understanding of different animal species and more effective future experimentation).
166. Joanne Zurlo, *No Animals Harmed: Toward a Paradigm Shift in Toxicity Testing*, 42 *HASTINGS CTR. REP. (SPECIAL ISSUE)* S23, S24 (2012). *But see* Directive 2010/63, of the European Parliament and of the Council of 22 September 2010 on the Protection of Animals Used for Scientific Purposes, recital 20, 2010 O.J. (L 276) 33, 35 (EU) [hereinafter “Directive 2010/63”] (providing text of European Union

demonstrate different responses to the same stimuli,<sup>167</sup> and different genders within those species might demonstrate still more varied responses.<sup>168</sup>

Regarding sex, test results also might differ depending upon a factor as seemingly minor as whether a male or female researcher handles the animal.<sup>169</sup> Even if the researcher's sex does not affect an outcome's utility for humans, the sex of the animal might; a treatment that is effective in male mice that in turn benefits human males may prove to be ineffective, or even harmful, for human females.<sup>170</sup> In response, as a condition for funding, the National Institutes of Health will consider whether laboratories that conduct animal testing do so using both genders, although they expect resistance due to potential increased costs and experimental complications.<sup>171</sup>

In contrast to these problems, animal experimentation has offered some valuable information regarding certain human conditions and can contribute to a better understanding of animal health, disease, and welfare.<sup>172</sup> For instance, using rodents to test anticonvulsants led to results that do translate well to humans.<sup>173</sup> Positive results like this are few and far between, however; generally only one of every 250 tested compounds ultimately reaches approval—a conservative

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animal welfare legislation noting that inbreeding of certain species for specific procedures may be beneficial “so that their genetic, biological and behavioural background is well-known” and can lead to “fewer procedures and reduced animal use”).

167. Zurlo, *supra* note 166 (noting that results between rats and mice are predictive at a rate of only 57%); *Frequently Asked Questions*, *supra* note 162 (“Studies show that 46% of chemicals found to be carcinogenic in rats were not carcinogenic in mice.”).
168. Bob Roehr, *Why Sex Matters in Mouse Models*, SCIENTIST (July 1, 2007), <http://www.the-scientist.com/?articles.view/articleNo/25186/title/Why-Sex-Matters-in-Mouse-Models/> [<https://perma.unl.edu/4WCP-H4GT>] (noting that almost all preclinical research is conducted with male animals despite remarkable differences in gene expression and responses between their genders).
169. Robert E. Sorge et al., *Olfactory Exposure to Males, Including Men, Causes Stress and Related Analgesia in Rodents*, 11 NATURE METHODS 629, 629 (2014) (noting that laboratory rodents handled by unfamiliar men, not women, experience stress that affects experimentation results).
170. Roni Caryn Rabin, *Labs Are Told to Start Including a Neglected Variable: Females*, N.Y. TIMES, May 15, 2014, at A1 (“[W]omen have been blindsided by side effects and dosage miscalculations that were not discovered until after the product hit the market.”).
171. *Id.* (noting that it is cheaper and easier to test solely on male subjects since they tend to be bigger and are not subject to reproductive cycle hormonal changes).
172. *Animal Welfare: Laboratory Animals*, AM. VETERINARY MED. ASS'N, <https://www.avma.org/KB/Resources/Reference/AnimalWelfare/Pages/animal-welfare-laboratory-animals.aspx> [<https://perma.unl.edu/DT9S-5GU3>].
173. Elizabeth Landau, *Many Studies Great News for Mice, Not so Much for Humans*, CNN (June 8, 2010, 8:18 AM), <http://www.cnn.com/2010/HEALTH/06/08/mice.rats.studies/> [<https://perma.unl.edu/YPG5-R3SF>].

estimate of the gap that in reality often is much wider—and that development process costs billions of dollars.<sup>174</sup> Many argue that these outcomes do not justify the ethical and financial costs of continuing animal experimentation, at least in its current state.<sup>175</sup> Not only do present testing practices use and destroy millions of animals per year to yield these lackluster approval rates, but also accounts abound of the horrifically painful procedures many of these animals endure.<sup>176</sup> Those opposed to using animals in research propose solutions varying from complete abolition of the practice to stricter adherence to at least two of the Three R's, more significantly reducing the number of animals used in testing and replacing them with alternatives.<sup>177</sup>

## B. Alternatives to Animals Testing

There is no question that experimentation is necessary and that society needs strict parameters in place to ensure the safety of products and treatments used by the medical industry and offered for sale over the counter.<sup>178</sup> The question is how that experimentation should occur, and to what extent live animals should be used if at all.<sup>179</sup>

Three general terms describe the main types of scientific experimentation used today: *in vivo*, *in vitro*, and *in silico*.<sup>180</sup> *In vivo* experimentation uses whole, living animals, including the study of human subjects in certain research endeavors.<sup>181</sup> *In vitro* research involves

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174. *See id.*; PHARMACEUTICAL RESEARCH & MFRS. OF AM., BIOPHARMACEUTICAL RESEARCH & DEVELOPMENT: THE PROCESS BEHIND NEW MEDICINES 1 (2015) (noting that the average cost to get one of “thousands and sometimes millions” of drugs to approval is \$2.6 billion, and the probability of success is less than twelve percent).

175. *See supra* note 155 and accompanying text.

176. *See Ibrahim, supra* note 5, at 206 (describing tests wherein researchers, wishing to explore whether burn victims lose their appetites, constrained pigs and used blowtorches to burn them without administering pain relief or treatment for several days, admitting that these tests occurred prior to the 1985 ISLAA AWA amendments, but noting that the amendments’ deference to the experimentation process would permit the same tests to occur today). The intent of this Article is not to shock the reader’s conscience with graphic accounts of the treatment of laboratory animals, although such commentary could fill many pages. Such information is easily and immediately obtainable by conducting an Internet search using terms as simple as “animal testing.”

177. *See Greek, supra* note 158 (“[T]here is no reason to reduce or refine a technique that is scientifically invalid.”); *Zurlo, supra* note 166 (describing technological advances in toxicity testing that can translate to other scientific areas, and that will drastically reduce, and eventually likely will eliminate, the use of animals in research).

178. Hessler, *supra* note 80, at 589.

179. *Id.*

180. *Differences Between In Vitro, In Vivo, and In Silico Studies*, MARSHALL PROTOCOL KNOWLEDGE BASE AUTOIMMUNITY RESEARCH FOUND., [http://mpkb.org/home/patients/assessing\\_literature/in\\_vitro\\_studies](http://mpkb.org/home/patients/assessing_literature/in_vitro_studies) [<https://perma.unl.edu/56PP-RA2W>].

181. *Id.*

testing in a controlled environment outside of a living organism, such as studying cells in a test tube (“*in vitro*” is a Latin term meaning “in glass”).<sup>182</sup> *In silico* testing is a relatively newer avenue of scientific study, and holds perhaps the most promise for reducing and replacing live animal testing; the phrase was coined about twenty-five years ago and refers to research conducted using technology such as computer modeling.<sup>183</sup>

### 1. *In Vitro* Testing

*In vitro* experimentation, although generally accepted and common in the scientific research community, does suffer some disadvantages.<sup>184</sup> For example, conducting tests on cells outside of whole, living organisms does not always replicate the environment and conditions occurring within those organisms, such as body temperature, cell growth, cell-to-cell interaction, oxygen usage, and other factors, making it difficult to simulate realistic *in vivo* experiments *in vitro*, and possibly leading to results that may not apply in human application.<sup>185</sup>

Despite these detriments, *in vitro* research also offers benefits, such as more detailed control over the experiment process and easy access to the test subject at any time, increasing the chances of predictability and reproducibility. It also offers other benefits: greater time and cost efficiency since animal purchase and care, IACUCs, and similar regulatory schemes are less involved (if at all), and fewer, if any, ethical issues.<sup>186</sup> One recent *in vitro* innovation that usually relies entirely on human cells has caused a stir in scientific journals: organs-on-chips. These transparent microchips, which are about the size of a computer flash drive, contain channels lined with human cells and closely mimic the functions and behaviors of human organs, such as the lung, heart, liver, kidney, or intestines.<sup>187</sup> Researchers plan to use this technology to link multiple organs-on-chips together to replicate a whole human body’s physiology.<sup>188</sup> Because this type of

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182. *Id.*

183. *Id.*

184. *See id.*; Thomas Hartung & George Datson, *Are In Vitro Tests Suitable for Regulatory Use?*, 111 TOXICOLOGICAL SCI. 233, 234 (2009).

185. Hartung & Datson, *supra* note 184; *see In Vitro Studies*, BELGIAN BIOELECTROMAGNETICS GRP., <http://www.bbemg.be/en/main-research/research-methods/info-invitro-studies.html> [<https://perma.unl.edu/ZV69-4C9M>] (examining the positive and negative aspects of different types of experimentation and applying them to studies of the health effects of electric power use).

186. Hartung & Datson, *supra* note 184; *In Vitro Studies*, *supra* note 185.

187. Sangeeta N. Bhatia & Donald E. Ingber, *Microfluidic Organs-on-Chips*, 32 NATURE BIOTECHNOLOGY 760, 762 (2014); *Organs-on-Chips*, WYSS INST., <http://wyss.harvard.edu/viewpage/461/> [<https://perma.unl.edu/Y5PN-BNHZ>].

188. Bhatia & Ingber, *supra* note 187, at 768; *Organs-on-Chips*, *supra* note 187.

study is new, obstacles exist that hinder its widespread functional applicability, such as the need to reduce the amount of engineering expertise required before enabling more efficient mass production, and the need to consider how the chips can work together in a vascular system—that is, how to simulate blood between chips.<sup>189</sup> Overcoming such hindrances may take some time, but progress is rapid, and organs-on-chips hold tremendous potential in laboratory research to reduce ultimate costs, time, and animal use.<sup>190</sup>

Just because an experiment is conducted *in vitro* does not necessarily mean that animals are not part of the process, however.<sup>191</sup> Some research, like that using organs-on-chips, might involve the study of human cell cultures, but nonhuman animals serve as cell and tissue donors in many other experiments, bringing with them complications like those noted above in section III.A.<sup>192</sup> Additionally, due to the possible limitations associated with *in vitro* experimentation, researchers usually combine it with other methods, most frequently *in vivo* practices, to ensure consistency and validation.<sup>193</sup>

## 2. *In Silico Testing*

Many who favor the elimination of any degree of animal testing are excited about the potential of *in silico* technology to take its place in the future, and even those in the scientific community currently engaged in animal experimentation show cautious interest in these developments.<sup>194</sup> As is the case with most novel ideas, though, optimism regarding the practicality of *in silico* research varies, and in fact the view of any type of alternative testing methods may be colored by the preexisting bias of the opinion holder, whether that person is an animal rights activist,<sup>195</sup> whose opinions may be more extreme than those of a person who supports animal welfare,<sup>196</sup> or a scientist

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189. Bhatia & Ingber, *supra* note 187, at 769. *But see* Tobias Hasenberg et al., *Emulating Human Microcapillaries in a Multi-Organ-Chip Platform*, 216 J. BIOTECHNOLOGY 1, 8 (2015) (describing a new discovery that simulates the vascular system between chips).

190. Bhatia & Ingber, *supra* note 187, at 769.

191. Hartung & Datson, *supra* note 184; Zurlo, *supra* note 166.

192. Hartung & Datson, *supra* note 184, at 235.

193. *Id.* at 235; Thomas Hartung, *Food for Thought Look Back in Anger – What Clinical Studies Tell Us About Preclinical Work*, 30 ALTEX 275, 288 (2013).

194. Lauerma, *supra* note 28; Charlie Schmidt, *Testing for Carcinogens: Shift from Animals to Automation Gathers Steam – Slowly*, 101 J. NAT'L CANCER INST. 910, 910–11 (2009).

195. *See Alternatives to Animal Testing*, PETA, <http://www.peta.org/issues/animals-used-for-experimentation/alternatives-animal-testing/> [<https://perma.unl.edu/JP2M-7PLA>] (advocating for an immediate end to all animal experimentation in favor of *in silico* and human-based *in vitro* methods).

196. Patti Strand, *What is Animal Welfare and Why Is It Important?*, NAT'L ANIMAL INT. ALLIANCE (June 10, 2014), <http://www.naiaonline.org/articles/article/what-is->

who fears the cost or challenge of changing longstanding practices.<sup>197</sup> Further, even scientists who currently employ *in silico* techniques often supplement them with animal-based testing for similar reasons that they would mix *in vitro* with *in vivo* procedures, namely to increase reliability and to confirm results of new, unsubstantiated procedures.<sup>198</sup>

Still, advancements in this field are occurring at an impressive rate and not only suggest that they can reduce the overall number of animals used in experimentation, but also cut costs, improve reproducibility of test results, and facilitate easier and more reliable publication of those results.<sup>199</sup> Moreover, many in the research community view the development of *in silico* research—by limiting the dependence on less reliable animal tests and encouraging more individualized human treatment—as simply good science.<sup>200</sup>

*In silico* innovations include the simulation of specific organs and their functions or even an entire organism itself.<sup>201</sup> For one of numerous examples, a chemical compound called the “chemosynthetic liver” allows scientists to force drug interactions in a fabricated model and predict the liver’s reactions in a process that is faster, less expensive, and more accurate than *in vivo* testing—doing so in one sample trial with a degree of specificity which previously would have necessitated testing on roughly 1,000 rats and 100 dogs.<sup>202</sup> In another example,

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animal-welfare-and-why-is-it-important#sthash.b3C1wMoL.dpbs [https://perma.unl.edu/5MXV-WP6F] (explaining that the animal rights movement opposes any use of animals, while animal welfare favors using animals responsibly and humanely). Many in the scientific research community support animal welfare. See, e.g., Walton, *supra* note 103 and accompanying text.

197. See Thomas Hartung & Sebastian Hoffmann, *Food for Thought . . . on In Silico Methods in Toxicology*, 26 ALTEX 155, 157 (2009) (noting that no testing method is perfect on its own yet, but that those who oppose *in silico* testing “fear (consciously or unconsciously) that these authoritative tools will challenge or even destroy their traditional tools, endanger their comfort zone”); see Hartung, *supra* note 193.
198. Hartung & Hoffmann, *supra* note 197, at 155.
199. Schmidt, *supra* note 194; see Hartung & Hoffmann, *supra* note 197, at 158, 163 (noting the considerable speed of *in silico* technology development and explaining that *in silico* research offers more standardized data analysis procedures than *in vivo* and *in vitro* testing, allowing for more relevant results that also are more readily updated and available to the public domain, to the possible detriment of intellectual property protection).
200. John Ericson, *Breakthroughs Might Mean the End of Animal Testing*, NEWSWEEK (March 18, 2014, 1:08 PM); <http://www.newsweek.com/2014/03/28/breakthroughs-might-mean-end-animal-testing-247999.html> [https://perma.unl.edu/FD6V-JZA5]; Lauerman, *supra* note 28.
201. John Gartner, *Virtual Vermin Saves Lab Rats*, WIRED (May 20, 2005, 12:00 PM), <http://www.wired.com/2005/05/virtual-vermin-saves-lab-rats/> [https://perma.unl.edu/UR3R-RMRT].
202. Ericson, *supra* note 200; see *Welcome to Empiriko*, EMPIRIKO, <http://www.empiriko.com/home> [https://perma.unl.edu/YT8E-XRP7] (summarizing the biotechnol-



researchers created a virtual mouse to study Type-1 diabetes, using a physiologically based mathematical model running on a server to test the effects of new drugs on cells, tissues, organs, and bodily processes.<sup>203</sup> The same company developed human models for testing in cardiovascular disease, dermatology, hypertension, and rheumatoid arthritis.<sup>204</sup> As with the other types of testing, *in silico* procedures are not perfect—at least not yet, as the technology still is in its infancy—but they do signal a bright future consisting of more trustworthy results with less cost and animal testing.<sup>205</sup>

The publication and sharing of information about these various advances is vital, as it allows for a remarkable reduction in unnecessarily duplicative experiments, which in turn leads to far fewer animals used overall and significant financial savings for laboratories.<sup>206</sup> This dramatic increase in efficiency may come with a price, however, as some researchers fear the loss of their intellectual property protection if they reveal too much about their work to their peers and the public.<sup>207</sup> Still, many in the field see the increased efficiency and other benefits of sharing knowledge as greater than those concerns,<sup>208</sup> and some countries even require such publication, at least in a generalized format, to protect specific procedure protocols.<sup>209</sup>

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ogy company's chemosynthetic liver testing platform); Emma Davies, *The Art of Alternatives*, CHEMISTRY WORLD (Jan. 16, 2014), <http://www.rsc.org/chemistry/world/2014/01/non-animal-testing> [<https://perma.unl.edu/PFF7-RV4V>] (describing a similar liver-on-a-chip project).

203. L. Shoda et al., *The Type 1 Diabetes PhysioLab® Platform: A Validated Physiologically Based Mathematical Model of Pathogenesis in the Non-obese Diabetic Mouse*, 161 CLINICAL & EXPERIMENTAL IMMUNOLOGY 250 (2010); see Gartner, *supra* note 201.
204. See *PhysioLab Models*, ENTELOS, <http://www.entelos.com/physiolab-models/> [<https://perma.unl.edu/84WH-PLPV>].
205. Ericson, *supra* note 200, Hartung & Hoffmann, *supra* note 197, at 163.
206. Hartung & Hoffmann, *supra* note 197, at 163; K.M. Sullivan et al., *Building on a Solid Foundation: SAR and QSAR as a Fundamental Strategy to Reduce Animal Testing*, 25 SAR & QSAR ENVTL. RES. 357, 359 (2014).
207. Hartung & Hoffmann, *supra* note 197, at 163; Sullivan et al., *supra* note 206, at 363.
208. Sullivan et al., *supra* note 206, at 363; see *Development, Validation, and Promotion of Alternative Approaches by Member States*, EUR. COMM'N, [http://ec.europa.eu/environment/chemicals/lab\\_animals/3r/advance\\_en.htm](http://ec.europa.eu/environment/chemicals/lab_animals/3r/advance_en.htm) [<https://perma.unl.edu/Z48V-P6DG>] (linking to summary reports of the encouragement and use of alternative testing practices voluntarily released to the general public by various countries throughout Europe).
209. See Directive 2010/63, *supra* note 166, art. 47, para. 4, at 49 ("Member States shall, at a national level, ensure the promotion of alternative approaches and the dissemination of information thereon."); *id.* art. 38, at 47, art. 43, at 48 (noting the importance of "safeguarding intellectual property and confidential information" when sharing information).

### 3. *Alternative Testing Advancements in Toxicology*

Much of the progress in alternative testing methods is happening in the toxicology field—which focuses primarily on evaluating the safety of chemicals and possible adverse effects of exposure to potentially toxic substances—although these innovations hold promise for other types of research as well, such as in biomedicine.<sup>210</sup> One relatively new approach to the interpretation of toxicological information uses quantitative structural activity relationship (QSAR) research.<sup>211</sup> QSAR is based on the fact that all chemicals have structural designs that are somewhat like fingerprints, and mapping categories of those chemical structures can inform how chemicals with similar structures will react biologically, including their potential adverse effects.<sup>212</sup> Scientists enter mathematical models of known chemicals into a database, which they use to compare new substances and predict a chemical's risk of causing health issues like allergic reactions, hormonal imbalances, and even cancer all without the use of animals.<sup>213</sup> Using QSAR model comparisons, a researcher can quickly determine if a new chemical presents the risk of unwanted side effects, accelerating their study and possibly discarding it as a poor drug candidate—knowledge previously only gained through animal testing—while saving a great deal of money and time in the process.<sup>214</sup>

Significantly, much of this database information is also published and updated regularly, including guidelines for its use, and is widely available.<sup>215</sup> For instance, the Organisation for Economic Co-operation and Development (OECD)—an intergovernmental association representing over thirty countries in North America, Europe, and Asia—maintains a publicly available database of chemical models and publishes guidelines for QSAR use.<sup>216</sup> One intention of this publication is to enable greater efficiency in scientific research by reducing

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210. Hartung & Hoffmann, *supra* note 197, at 158.

211. Sullivan et al., *supra* note 206, at 357.

212. *Id.* at 358.

213. Kasper Gade, *Can We Avoid Animal Testing Entirely?*, SCIENCE NORDIC (Jan. 14, 2014, 06:18), <http://sciencenordic.com/can-we-avoid-animal-testing-entirely> [<https://perma.unl.edu/5WQ4-Z7ES>]; see Sullivan et al., *supra* note 206, at 360–61.

214. Gade, *supra* note 213.

215. See Sullivan et al., *supra* note 206, at 363 (noting that some industry sectors, like those dealing with pharmaceuticals and pesticides, tend to be reluctant to share their data but that the long-term benefits outweigh any short-term risks).

216. ENV'T DIRECTORATE, ORG. FOR ECON. CO-OPERATION AND DEV., GUIDANCE ON GROUPING OF CHEMICALS 4, 6 (2d ed. 2014) [hereinafter OECD GUIDELINES]. The chemical database, called the OECD Toolbox, is available for download, along with user instructions, at [http://www.oecd.org/chemicalsafety/risk-assessment/theoecdqsartoolbox.htm#Download\\_qsar\\_application\\_toolbox](http://www.oecd.org/chemicalsafety/risk-assessment/theoecdqsartoolbox.htm#Download_qsar_application_toolbox) [<https://perma.unl.edu/PN2X-SUFT>].

the number of tests and resources necessary,<sup>217</sup> and hopefully its encouragement of collaborative efforts will influence the scientific community beyond the toxicology arena.

The United States government took a step in this positive direction in 2013 when the Obama Administration issued a memo directing federal agencies to make the results of federally funded research freely available to the public within a year of publication.<sup>218</sup> Although this is not quite the same as a continuously updated public database and was motivated more by a desire to keep the public informed regarding the use of tax dollars than to reduce the number of animals used in laboratory testing, it indicates a gradual shift in perspective and acknowledgement of the ultimate benefits of sharing information.

Advancements like QSAR and other *in silico* and *in vitro* innovations also should help researchers implement an exciting suggested plan for future testing proposed by a review of toxicity research commissioned by the Environmental Protection Agency (EPA).<sup>219</sup> Under the Toxic Substances Control Act of 1976 (TSCA), the EPA evaluates the toxicity of new or existing chemicals used in commerce and regulates them, but this process is extremely cumbersome and contributes to an information gap in which little is understood about the potential health risks of more than three quarters of the over 80,000 known chemicals now in commerce.<sup>220</sup> Approximately 60,000 chemicals already existed at the enactment of the TSCA, which did not require evaluation of existing substances unless they were proven to be hazardous—a troublesome quandary, since that classification itself requires experimentation.<sup>221</sup> This situation, along with the considerable time and expense involved in testing a single substance, contributes to a huge backlog of thousands of untested chemicals.<sup>222</sup> To address this dilemma, the EPA commissioned a review of toxicity testing by the U.S. National Academy of Sciences (NAS) National Research Council (NRC), which resulted in the 2007 report *Toxicity Testing in the 21st Century: A Vision and a Strategy*.<sup>223</sup>

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217. OECD GUIDELINES, *supra* note 216, at 9.

218. Memorandum from John P. Holdren, Dir., Office of Sci. and Tech. Policy to Heads of Exec. Dep'ts and Agencies (Feb. 22, 2013), [https://www.whitehouse.gov/sites/default/files/microsites/ostp/ostp\\_public\\_access\\_memo\\_2013.pdf](https://www.whitehouse.gov/sites/default/files/microsites/ostp/ostp_public_access_memo_2013.pdf) [<https://perma.unl.edu/7G7R-BCW9>].

219. See Paul A. Locke & D. Bruce Myers, Jr., *Food for Thought . . . A Replacement-First Approach to Toxicity Testing is Necessary to Successfully Reauthorize TSCA*, 28 ALTEX 266, 266–67 (2011).

220. *Id.* at 267.

221. *Id.* at 266.

222. *Id.* at 266–67.

223. *Id.* at 268; COMM. ON TOXICITY TESTING & ASSESSMENT OF ENVTL. AGENTS, NAT'L RESEARCH COUNCIL, *TOXICITY TESTING IN THE 21ST CENTURY: A VISION AND A STRATEGY* xi (2007) [hereinafter NRC Report].

The report considered toxicity testing in light of four stated objectives: “depth of testing, breadth of testing, animal welfare, and conservation of testing resources.”<sup>224</sup> This led the NRC to advocate in its report for an evolution over the twenty years following its publication from whole-animal testing—which it notes is expensive, time-consuming, would not help reduce the backlog of untested substances, and raises ethical issues—to *in vitro* testing and computational approaches based primarily on human biology.<sup>225</sup> An impressive group of federal agencies named Toxicology Testing in the 21st Century, or “Tox21,” is collaborating to implement this plan broadly in the toxicology field.<sup>226</sup> The team consists of the EPA, various arms of the National Institutes of Health, and the Food and Drug Administration, and currently is in the process of prioritizing and testing *in vitro* the toxicity of 10,000 environmental chemicals and approved drugs.<sup>227</sup>

Although the ultimate research goal outlined in the NRC report involves “use of virtually no animals,” the authors concede that such a plan is not without challenges, and acknowledge that some specific, limited animal testing still might be necessary, at least in the immediate future.<sup>228</sup> Still, this shift is a harbinger of changes to come in toxicology experimentation, and due at least in part to the report’s universally appealing objectives, the progress it inspires likely will carry other types of research in its wake.<sup>229</sup> For example, the report’s vision already is consistent with the NRC’s *Guide for the Care and Use of Laboratory Animals*, which several laboratories conducting other forms of experimentation presently follow as a condition to obtain funding.<sup>230</sup>

## V. LABORATORY TESTING IN OTHER COUNTRIES

Changes and innovation in scientific research using animals not only are happening within particular fields of study, but in entire countries as well. Generally, the United States remains somewhat stagnant in many of its testing policies, particularly those pertaining to cosmetics and household products—such as by employing the seventy-year-old Draize test to assess compounds’ likelihood of causing eye irritation<sup>231</sup> or by using animals to test cosmetics at all—but other countries are leading the way to a future of less expensive, more effi-

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224. NRC Report, *supra* note 223, at 43.

225. *Id.* at 44.

226. *Toxicology Testing in the 21st Century (Tox21)*, U.S. ENVT’L PROT. AGENCY, <http://www.epa.gov/chemical-research/toxicology-testing-21st-century-tox21> [https://perma.unl.edu/Q5CW-6AZ8].

227. *Id.*

228. NRC Report, *supra* note 223, at 44, 47.

229. See Hartung & Hoffmann, *supra* note 197, at 158.

230. Locke & Myers, *supra* note 219, at 268; see NRC GUIDE, *supra* note 45, at 4, vii.

231. Wilhelmus, *supra* note 108, at 497.

cient, more ethically sound laboratory testing. At least in the beginning, the reductions are focused mainly on cosmetics, as opposed to medical research, but especially in light of the advances in *in vitro* and *in silico* experimentation outlined above, can medical testing be far behind?

### A. The European Union

The European Union began instituting legislation officially protecting animal welfare in experimentation and other scientific endeavors back in 1986.<sup>232</sup> In 2010, a new Directive repealed that legislation and increased its minimum-protection standards to include animals used in basic research, higher education, and training; to strengthen its advocacy for the Three R's; and to require more regular inspections and transparency through the publication of generalized project data.<sup>233</sup> Further, the Directive's definition of "animal" is far more inclusive than the U.S. AWA's description: "(a) live non-human vertebrate animals, including: (i) independently feeding larval forms; and (ii) foetal forms of mammals as from the last third of their normal development; (b) live cephalopods."<sup>234</sup> Rather than mimicking the AWA by amending the law to exclude certain species, the new EU Directive enlarged the previous law's coverage to ensure that it now applies to almost any laboratory animal.<sup>235</sup>

Like the AWA, this Directive sets forth minimum standards of protection; but in addition to expanding its scope to apply to more species, it increases those basic standards to include: choosing both methods and species for procedures that will result in satisfactory results with the least amount of pain, distress, and individual animals used; humane euthanasia performed by a competent person when necessary;<sup>236</sup> appropriate sharing with other researchers of general data, as well as organs and tissues of animals that are killed to help reduce the use of other animals;<sup>237</sup> the rehoming of suitable animals at the end of a procedure, with appropriate socialization assistance;<sup>238</sup> European Commission-supported regular inspections of procedures and facili-

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232. *Animals Used for Scientific Purposes*, EUR. COMM'N, [http://ec.europa.eu/environment/archives/lab\\_animals/process\\_en.htm](http://ec.europa.eu/environment/archives/lab_animals/process_en.htm) [https://perma.unl.edu/K6N9-XMKW].

233. *Legislation for the Protection of Animals Used for Scientific Purposes*, EUR. COMM'N, [http://ec.europa.eu/environment/chemicals/lab\\_animals/legislation\\_en.htm](http://ec.europa.eu/environment/chemicals/lab_animals/legislation_en.htm) [https://perma.unl.edu/AHX8-FQPT]; see Directive 2010/63, *supra* note 166, arts. 1–6, at 38–40.

234. Directive 2010/63, *supra* note 166, art. 1, para. 3, at 39.

235. See *Legislation for the Protection of Animals Used for Scientific Purposes*, *supra* note 233.

236. Directive 2010/63, *supra* note 166, recital 13, at 34; *id.* art. 6, at 40.

237. *Id.* recital 27, at 35; *id.* arts. 18, 43, at 43, 48.

238. *Id.* recital 26, at 35.

ties, including some without advance warning;<sup>239</sup> and documented, sincere attempts to employ and contribute to the development of alternative research methods.<sup>240</sup> While there is some deference to the needs of science, the Directive does not ask researchers just to “consider” alternatives like the AWA does, but rather it holds that experiments should use them whenever a non-animal procedure exists, recognizing in the legislation that “[a]nimals have an intrinsic value which must be respected.”<sup>241</sup> It does acknowledge that some animal testing continues to be necessary as alternative methods are developed but provides that the use of animals only should be considered when non-animal tests are unavailable, with “the final goal of full replacement of procedures on live animals for scientific and educational purposes as soon as it is scientifically possible to do so.”<sup>242</sup>

The Commission supported actualization of these ideals by, for example, making roughly 238 million Euros available for alternative research between 2007 and 2011, and funding projects like the “Safety Evaluation Ultimately Replacing Animal Testing” research initiative, or “SEURAT-1.”<sup>243</sup> The Commission established the European Centre for the Validation of Alternative Methods, or “ECVAM,” in 1991 to coordinate such research, and called for a central European laboratory for that purpose in the Directive.<sup>244</sup> This laboratory, which is independent from commercial, financial, or specific scientific interests, is now housed in Italy and is called the European Union Reference Laboratory for Alternatives to Animal Testing, or “EURL ECVAM.”<sup>245</sup> EURL ECVAM impartially evaluates scientific tests for chemicals and various products, from medicine to household and agricultural items, to ensure their safety while “progressively” reducing reliance on *in vivo* animal tests.<sup>246</sup>

Regarding the assessment of chemicals, the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulation parallels the Directive by similarly advocating for the use of alternative methods that reduce the number of animals used in toxicity experimentation, permitting *in vivo* animal tests only as a last resort.<sup>247</sup>

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239. *Id.* arts. 34–35, at 46.

240. *Id.* recitals 46–47, at 38; *id.* arts. 46–47, at 48–49.

241. *Id.* recital 12, at 34; *id.* art. 13, para. 1, at 42.

242. *Id.* recitals 10–12, at 34.

243. European Commission Press Release IP/13/210, Full EU Ban on Animal Testing for Cosmetics Enters into Force (Mar. 11, 2013); *Background*, SEURAT-1, <http://www.seurat-1.eu/pages/background.php> [https://perma.unl.edu/4WT3-NVP2].

244. Directive 2010/63, *supra* note 166, recital 47, at 37.

245. *About EURL ECVAM*, EUR. COMM'N JOINT RESEARCH CTR., <https://eurl-ecvam.jrc.ec.europa.eu/about-ecvam> [https://perma.unl.edu/3HFK-EQ9Q].

246. *Id.*

247. *Understanding REACH*, EUR. CHEMICALS AGENCY, <http://echa.europa.eu/web/guest/regulations/reach/understanding-reach> [https://perma.unl.edu/2NMD-GYS6].

REACH mandates that facilities also must share data with each other to avoid duplicative testing and decrease the number of animals used, and they are obligated to submit an inquiry to share data to the European Chemicals Agency before engaging in any research involving vertebrates.<sup>248</sup>

Further, while the latest Directive applies to animal testing for scientific purposes in general, as of 2013 the European Union also prohibits any animal testing of cosmetics—whether of finished products or of their individual ingredients—and, importantly, any marketing of such products.<sup>249</sup> That influences animal testing worldwide and means that other countries cannot sell cosmetics in Europe if they or their ingredients were tested on animals; if a company wishes to conduct animal testing on a new cosmetic item or ingredient, it must absorb the considerable expense of marketing and selling a different version of its product there.<sup>250</sup> Some argue that the ban is too harsh for this reason and claim that alternatives do not yet exist for all ingredients. Despite this, Europe chose to stand firm to set an example for the rest of the world.<sup>251</sup> The ban does contain language that permits the marketing of cosmetics tested on animals before the ban took effect or if their ingredients are tested for the assessment of other products, such as pharmaceuticals.<sup>252</sup> Still, this ultimate ban completes several years of gradually phasing out the widespread practice in cosmetics<sup>253</sup> and reflects the value enshrined in 2007 in the Treaty on the Functioning of the European Union that “animals are sentient beings” deserving “full regard to [their] welfare requirements,” while respecting individual member states’ laws and customs.<sup>254</sup>

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248. *Submit an Inquiry to Share Data for Active Substance*, EUR. CHEMICALS AGENCY, <http://echa.europa.eu/en/support/dossier-submission-tools/r4bp/submit-inquiry-share-data-active-substance> (last visited Nov. 18, 2015).

249. Regulation 1223/2009, of the European Parliament and of the Council of November 30, 2009 on Cosmetic Products, art. 18(1)–(2), 2009 O.J. (L 342) 59, 71–72 (EC).

250. See James Kanter, *E.U. Bans Cosmetics with Animal-Tested Ingredients*, N.Y. TIMES (Mar. 11, 2013), [http://www.nytimes.com/2013/03/11/business/global/eu-to-ban-cosmetics-with-animal-tested-ingredients.html?\\_r=0](http://www.nytimes.com/2013/03/11/business/global/eu-to-ban-cosmetics-with-animal-tested-ingredients.html?_r=0).

251. *Id.*; European Commission Press Release IP/13/210, *supra* note 243 (quoting European Commissioner of Health & Consumer Policy Tonio Borg as stating, “Today’s . . . ban gives an important signal on the value that Europe attaches to animal welfare,” and noting that it corresponds to the beliefs of many European citizens “that the development of cosmetics does not warrant animal testing”).

252. Kanter, *supra* note 250.

253. Regulation 1223/2009, *supra* note 249, art. 18(2), at 72.

254. Consolidated Version of the Treaty on the Functioning of the European Union art. 13, Dec. 13, 2007, 2012 O.J. (C 326) 47.





metics, as well as the marketing of such products.<sup>262</sup> A comparable bill was introduced in Canada in 2015, named the Cruelty-Free Cosmetics Act.<sup>263</sup> Other countries currently entertaining the idea of national animal testing bans for cosmetics include Australia and Japan.<sup>264</sup>

South Korea recently launched legislation that mandates the use of alternative testing methods for cosmetic products, but only if such methods exist and are first approved by the government.<sup>265</sup> Animal testing is permissible if accepted alternative methods are not available, and products tested on animals in other countries to meet those countries' regulations remain marketable in South Korea.<sup>266</sup> While not as advanced as the other laws discussed above, some compare this bill to the initial stages of Europe's phased ban and hope it will lead to a similar, more complete prohibition in coming years.<sup>267</sup>

New Zealand enacted similar legislation in 2015 banning animal testing of cosmetics produced within its borders but allowing such experimentation for other compounds, like pharmaceuticals as well as any imported products.<sup>268</sup> This law focusing on cosmetics followed shortly after another ban of animal testing for synthetic drugs, demonstrating that New Zealand favors reducing animal experimentation in general and is more likely to mimic other countries' stricter examples in the future.<sup>269</sup>

China infamously used to *require* animal testing of all products sold in that market, preventing brands with a cruelty-free business model from participating in the multi-billion-dollar cosmetics trade

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262. *Taiwan Legislator Launches Bill on Cosmetics Animal Testing*, CHEMICAL WATCH (April 30, 2015), <https://chemicalwatch.com/23702/taiwan-legislator-launches-bill-on-cosmetics-animal-testing> [https://perma.unl.edu/5XH8-8EUT].

263. Cruelty-Free Cosmetics Act, S-234, 42nd Parliament (2015) (Can.). *But see Bill S-234 (Historical)*, OPENPARLIAMENT.CA, <https://openparliament.ca/bills/41-2/S-234/> (last visited April 18, 2016) (describing a bill with similar language that was introduced earlier in 2015 and failed).

264. *Creating a Cruelty-Free World: Ending Animal Testing for Cosmetics*, HUMANE SOC'Y INT'L, <http://www.hsi.org/issues/becrueltyfree/facts/infographic/en/> [https://perma.unl.edu/D228-JQFK].

265. *#BeCrueltyFree South Korea Campaign Welcomes Cosmetics Bill Requiring Mandatory Use of Alternatives, but Loopholes Must Be Closed*, HUMANE SOC'Y INT'L (Mar. 11, 2015), [http://www.hsi.org/news/press\\_releases/2015/03/south-korea-cosmetics-animal-testing-bill-031115.html](http://www.hsi.org/news/press_releases/2015/03/south-korea-cosmetics-animal-testing-bill-031115.html) [https://perma.unl.edu/6WKD-A2RW].

266. *Id.*

267. *Cosmetics Animal Testing Bill Introduced in South Korea*, CHEMICAL WATCH (Mar. 12, 2015), <https://chemicalwatch.com/23116/cosmetics-animal-testing-bill-introduced-in-south-korea>.

268. Isaac Davison, *Makeup Tests on Animals Banned*, N.Z. HERALD (Apr. 1, 2015, 2:25 PM), [http://www.nzherald.co.nz/lifestyle/news/article.cfm?c\\_id=6&objectid=11426105](http://www.nzherald.co.nz/lifestyle/news/article.cfm?c_id=6&objectid=11426105) [https://perma.unl.edu/FXJ8-8VWN].

269. *See id.*

there; even that country acquiesced slightly to international pressure to change this practice.<sup>270</sup> As of 2014, companies domestically manufacturing “ordinary” cosmetics for sale within China—such as makeup, fragrances, and skin, hair, and nail care merchandise—now have the option to establish the safety of their products using existing data or validated non-animal tests.<sup>271</sup> While certainly a positive development for animal welfare in general, China still affirmatively requires *in vivo* animal testing of all foreign imported cosmetics, new product ingredients, and domestically produced “special-use” cosmetics, such as hair dyes and hair-growth stimulants, deodorants, sunscreens, and skin-whitening creams.<sup>272</sup> Additionally, although pre-sale testing rules for manufacturers are somewhat more relaxed now, the China Food and Drug Administration still may conduct extensive animal tests of new cosmetics after they reach the market.<sup>273</sup> Nonetheless, welfare advocates are pleased that these changes have the potential to save up to 10,000 laboratory animals from mandatory testing, and they are optimistic that the updates may grow to include both imports and “special-use” cosmetics in coming years.<sup>274</sup>

### C. Cosmetics Testing in the United States

While the AWA seems woefully antediluvian in light of these advances worldwide, the United States slowly is beginning to shift into a more progressive stance with the introduction of the Humane Cosmetics Act in 2015.<sup>275</sup> This Act proposes to outlaw animal testing for cosmetics—both finished products and their ingredients—within one year of its enactment, and would ban the sale and interstate commerce thereof within three years of enactment.<sup>276</sup> In its present introductory state, its language is very similar to the progressive legislation of Europe, Israel, and India, and it enjoys strong bipartisan backing in the legislature as well as support within the cosmetics in-

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270. See Michelle Yeomans, *Can Cosmetic Brands Afford to Opt out of China over Animal Testing?*, COSMETICS DESIGN ASIA (Jan. 21, 2015, 10:46 AM), <http://www.cosmeticsdesign-asia.com/Regulation-Safety/Can-cosmetic-brands-afford-to-opt-out-of-China-over-animal-testing> [https://perma.unl.edu/WV54-Q9ED].

271. Echo Cao, *China Cosmetics Regulation*, CHEMLINKED (Mar. 19, 2014), <https://chemlinked.com/chempedia/china-cosmetics-regulation>; *China Implements Rule Change in First Step Towards Ending Animal Testing of Cosmetics*, HUMANE SOC'Y INT'L (June 30, 2014), [http://www.hsi.org/news/press\\_releases/2014/06/china-implements-rule-change-063014.html](http://www.hsi.org/news/press_releases/2014/06/china-implements-rule-change-063014.html) [https://perma.unl.edu/YNK8-4DR4].

272. *China Implements Rule Change in First Step Towards Ending Animal Testing of Cosmetics*, *supra* note 271.

273. *Id.*; see Cao, *supra* note 271.

274. *China Implements Rule Change in First Step Towards Ending Animal Testing of Cosmetics*, *supra* note 271.

275. See Humane Cosmetics Act, H.R. 2858, 114th Cong. (2015).

276. *Id.*

dustry.<sup>277</sup> Those opposed to unnecessary animal testing hope the Humane Cosmetics Act will continue to gather support, pass into law, and possibly help influence a change in the language of the Animal Welfare Act.<sup>278</sup>

The Humane Cosmetics Act would strengthen current regulations propagated by the FDA, the organization that oversees the safety and accurate labeling of many different products, such as food not regulated by the USDA, medical devices, drugs, biological products, and cosmetics, operating under the authority of the Federal Food, Drug, and Cosmetic Act.<sup>279</sup> The FDA does not require animal testing for any products, either medical or cosmetic, but rather leaves the products' safety guarantees up to the companies that manufacture them.<sup>280</sup> Animal testing is the default method that has been in place for decades, however, particularly for medical products, and most of these companies understandably do not wish to jeopardize approval of their expensive new products by employing novel safety assessments.<sup>281</sup> The FDA also notes that validated non-animal alternatives that effectively can test the safety of every drug and medical device do not exist yet, making animal testing necessary at times.<sup>282</sup> It is, however, one of about fifteen U.S. regulatory agencies that participate in the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), the mission of which parallels the ECVAM.<sup>283</sup> The FDA also claims to advocate for reduction in and replacement of the use of animals, requiring new product sponsors to

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277. Monica Engebretson, *Humane Cosmetics Act Introduced with Bipartisan and Industry Support*, HUFFINGTON POST (June 23, 2015, 4:16 PM), [http://www.huffingtonpost.com/monica-engebretson/humane-cosmetics-act-intr\\_b\\_7648492.html](http://www.huffingtonpost.com/monica-engebretson/humane-cosmetics-act-intr_b_7648492.html) [<https://perma.unl.edu/8BT4-MABC>].

278. See *AWI Applauds Humane Cosmetics Act Introduction*, ANIMAL WELFARE INST. (June 23, 2015), <https://awionline.org/content/awi-applauds-humane-cosmetics-act-introduction> [<https://perma.unl.edu/7TGN-A4Z3>]; Stephen Wells, *Legally Brief: The U.S. Must Ban Cosmetic Testing on Animals*, ANIMAL LEGAL DEF. FUND (June 5, 2014), <http://aldf.org/blog/legally-brief-the-u-s-must-ban-cosmetic-testing-on-animals/> [<https://perma.unl.edu/KUU7-UJQ3>].

279. *What Does FDA Do?*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194877.htm> [<https://perma.unl.edu/2KGV-JAJX>]; see 21 U.S.C. §§ 1-2252 (2012).

280. See *Frequently Asked Questions About Animal Experimentation Issues*, PHYSICIANS COMM. FOR RESPONSIBLE MED., <http://www.pcrm.org/research/animaltestalt/animaltesting/faqs-animal-experimentation-issues#3> [<https://perma.unl.edu/M9A6-LPZ8>]; *Why Are Animals Used for Testing Medical Products?*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/aboutfda/transparency/basics/ucm194932.htm> [<https://perma.unl.edu/G7KK-HDDY>].

281. *Frequently Asked Questions About Animal Experimentation Issues*, *supra* note 280.

282. *Why Are Animals Used for Testing Medical Products?*, *supra* note 280.

283. *About ICCVAM*, U.S. DEP'T HEALTH & HUMAN SERVS. NAT'L TOXICOLOGY PROGRAM, <http://ntp.niehs.nih.gov/pubhealth/evalatm/iccvam/index.html> [<https://perma.unl.edu/CXV2-PS99>]; *Animal Testing & Cosmetics*, U.S. FOOD & DRUG AD-

adhere to the Good Laboratory Practice for Nonclinical Laboratory Studies regulations.<sup>284</sup>

These regulations are not exactly focused on animal welfare, however, even though they begin by declaring that “[t]here shall be standard operating procedures for the housing, feeding, handling, and care of animals.”<sup>285</sup> The subsequent provisions do note, for instance, that different species “ordinarily” should not be housed together, that the animals “may” be treated for disease, and that they should be identified, given clean cages and bedding, and be fed and watered; but most include the caveat that any procedures or treatments should not interfere with the study for which the animals are being used.<sup>286</sup> Even the provisions requiring feed and water note that these necessities should be “analyzed periodically,” not for their appropriateness for the animal using them, but for “contaminants known to be capable of interfering with the study and reasonably expected to be present in such feed or water.”<sup>287</sup> Suffice to say that the Humane Cosmetics Act is necessary to bring the United States at least a little closer to the speed at which so many other nations already are traveling.

## VI. “SPENT” ANIMALS

Another specific provision of the European Union Directive discussed above deserves special mention, as it can result in a proverbial “win-win” situation: It does not cost laboratories much if they partner with other organizations—in fact, it might even save them money, space, time, and staff morale—and it provides happy endings for the animals used in their research.<sup>288</sup> This portion of the Directive permits member states to place suitable animals in adoptive homes once laboratories are finished with them.<sup>289</sup> Such animals often are re-

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MIN., <http://www.fda.gov/cosmetics/scienceresearch/producttesting/ucm072268.htm> [<https://perma.unl.edu/HXG6-XE3V>].

284. *Why Are Animals Used for Testing Medical Products?*, *supra* note 280; see 21 C.F.R. § 58.90 (2015). *But see The FDA’s Drug Review Process: Ensuring Drugs Are Safe and Effective*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/drugs/resourcesforyou/consumers/ucm143534.htm> [<https://perma.unl.edu/A723-SS6Z>] (stating that new drug sponsors “must show the FDA results of preclinical testing in laboratory animals and what they propose to do for human testing”).

285. 21 C.F.R. § 58.90.

286. *Id.* § 58.90(c)–(h).

287. *Id.* § 58.90(g).

288. See Directive 2010/63, *supra* note 166, art. 19, at 43; Larry Carbone et al., *Adoption Options for Laboratory Animals*, LAB ANIMAL, Oct 2003, at 37–40.

289. Directive 2010/63, *supra* note 166, art. 19, at 43 (including the conditions that the animals must be healthy enough to rehome and pose no danger to the public and environment, and that “appropriate measures,” such as socialization work, have been undertaken to ensure the animals’ wellbeing).

ferred to as “spent,” because they no longer serve a purpose for their current owners.<sup>290</sup>

Typically, laboratories in countries like the United States euthanize spent animals even if not harvesting the animals’ organs or tissues for future experiments, incurring the costs of the procedure and disposal of the remains.<sup>291</sup> There are nonfiscal costs as well; research scientists are not automatons, and while they may learn adaptive ways of thinking in order to conduct their experiments, it also is not difficult for them to grow attached to their lab subjects, especially after working with them for an extended period of time.<sup>292</sup> Applied euthanasia techniques include procedures like: gassing, barbiturate injection, exsanguination (excessive blood loss), blunt force head trauma, electrocution, and decapitation, among others.<sup>293</sup> Such measures can take a substantial emotional toll on the humans employing them, especially if it is a common occurrence.<sup>294</sup> To complicate matters, the research technician tasked with killing an animal may not conduct a procedure perfectly the first time or the method just may not work very well in general, leaving the animal conscious and very distressed until death—to say nothing of the emotional toll on the person handling the animal.<sup>295</sup> It is difficult enough when the animal already is suffering and euthanasia truly is the most humane option, but it is worse yet when the animal generally is healthy and could make a good candidate for rehoming as a pet.<sup>296</sup>

Despite these burdens, a survey found that most IACUCs did not even permit the adoption of spent lab animals; in fact, only 20% of those questioned did.<sup>297</sup> This reticence to institute adoption programs was understandable to a degree, since most research facilities had to orchestrate adoptions themselves, either coordinating the transac-

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290. See Jennifer Fearing & Gaverick Matheny, *The Role of Economics in Achieving Welfare Gains for Animals*, in *THE STATE OF THE ANIMALS IV: 2007* 159, 169 (2007).

291. See Carbone et al., *supra* note 288, at 37, 41; AM. VETERINARY MED. ASS’N, *AVMA GUIDELINES FOR THE EUTHANASIA OF ANIMALS: 2013 EDITION* 16 (2013).

292. Carbone et al., *supra* note 288, at 38; *Adoption Can be an Option for Animals After Their Use in Research*, 59 *ANIMAL WELFARE INST. Q.*, Spring 2010, at 14, 17.

293. AM. VETERINARY MED. ASS’N, *supra* note 291, 14–16, 18–42.

294. *Adoption Can be an Option for Animals After Their Use in Research*, *supra* note 292, at 17.

295. See Daniel Cressey, *Best Way to Kill Lab Animals Sought*, 500 *NATURE* 130, 130–31 (2013).

296. See Carbone et al., *supra* note 288, at 38 (noting that lab animals whose health statuses make them suitable for adoption are not different from other animals available in shelters); *Adoption Can be an Option for Animals After Their Use in Research*, *supra* note 292 (noting that some researchers are willing to put themselves at risk personally and professionally to rehome their subjects).

297. Gary Borkowski et al., *Institutional Animal Care and Use Committees: A Survey Covering 10 Years of Experience*, *CONTEMP. TOPICS IN LABORATORY ANIMAL SCI.*, Sept. 1997, at 42, 44.

tions directly with adopters—necessitating potential-adopter screening, training, follow-ups, and possibly managing the return of an animal after an unsuccessful match—or at least working extensively with local shelters to acquaint them with the special needs of animals used in experimentation generally, plus providing details regarding each individual animal’s possible issues.<sup>298</sup> Further, laboratories tend to be secretive concerning the practices that take place within their walls, and many therefore balk at the idea of sharing information with members of the public, both for intellectual property protection and public relations reasons.<sup>299</sup>

The AWA does not mention private adoption of spent laboratory animals, and the PHS Policy also is silent on the matter.<sup>300</sup> The Office of Laboratory Animal Welfare (OLAW), which oversees application of the PHS Policy to grantees, supports the general idea, but it is careful to note that grant money may not be used to implement adoption programs and that the PHS will not accept any legal or financial obligations relating to them.<sup>301</sup> OLAW encourages grantees that wish to engage in adoption procedures to ensure that they adhere to state and local regulations and to work with local shelters in doing so—essentially permitting the practice but leaving all financial, legal, and other responsibilities to the research facilities themselves.<sup>302</sup> Still, those institutions that endeavor to see their adoptable laboratory subjects find loving homes in their retirements see significant benefits that they argue outweigh the costs, including improved employee morale.<sup>303</sup> These benefits also can lead to positive public relations for an industry often plagued by the opposite.<sup>304</sup>

Thankfully for those institutions unwilling to assume the economic and other obligations of in-house adoption programs, today specialized rescue organizations focused on laboratory animals exist that are

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298. Carbone et al., *supra* note 288, at 38–41 (noting that statistics support that these animals are just as “adoptable” as other animals in shelters, but they may need assistance learning how to walk on a leash, how to use a litter box, or how to deal with other common household activities that are not present in laboratories, sometimes including walking on foreign surfaces like carpet, or even just understanding how to accept affection from humans).

299. *Adoption Can be an Option for Animals After Their Use in Research*, *supra* note 292, at 14–15.

300. *Frequently Asked Questions: PHS Policy on Humane Care and Use of Laboratory Animals*, OFFICE OF EXTRAMURAL RESEARCH, NAT’L INST. OF HEALTH, <http://grants.nih.gov/grants/olaw/faqs.htm#675> [<https://perma.unl.edu/4629-6TFK>].

301. *Id.*

302. *Id.*

303. Carbone et al., *supra* note 288, at 41; *Adoption Can be an Option for Animals After Their Use in Research*, *supra* note 292, at 17.

304. See Carbone et al., *supra* note 288, at 40 (stating that local shelters and veterinarians who think and speak highly of a research program can have a positive influence on the public and politicians).

more than happy to step in and help, removing qualified animals, preparing them for adoption, and assuming financial and legal responsibility for them.<sup>305</sup> Some research facilities still prefer to coordinate their own direct adoption programs,<sup>306</sup> maintaining control over the parties involved and the information that may reach the public. Working with rescue groups that focus specifically on research animals and their unique needs can help ease the process, relieving many, if not all, of the burdens discussed above.<sup>307</sup> Further, these groups do not limit their assistance to more traditional domestic pets like cats and dogs; they remove, socialize, monitor, and arrange rehoming for those species, plus mice, rats, rabbits, horses, pigs, sheep, cows, goats, birds, primates, and others—even fish.<sup>308</sup> This expands the usefulness of these groups significantly for research facilities, since although cats and dogs are used by the thousands, those species still represent only a small percentage of the total number of animals currently found in laboratories.<sup>309</sup>

Additionally, while federal law is silent on the research animal adoption issue, groups like the Beagle Freedom Project have lobbied for bills in state legislatures that parallel the intent of the European Directive concerning the rehoming of laboratory animals.<sup>310</sup> Thus far, these “right to release” bills have received bipartisan support and

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305. See, e.g., ANIMAL RESCUE CORPS, <http://animalrescuecorps.org> [<https://perma.unl.edu/ST7K-RKZQ>]; BEAGLE FREEDOM PROJECT, <http://www.beaglefreedomproject.org> [<https://perma.unl.edu/4PNE-8RMY>]; CHIMP HAVEN, <http://www.chimpaven.org> [<https://perma.unl.edu/6HX8-3TR4>]; KINDNESS RANCH, <http://kindnessranch.org> [<https://perma.unl.edu/ALY9-3CAU>]; NEW LIFE ANIMAL SANCTUARY, <http://newlifeanimalsanctuary.org> [<https://perma.unl.edu/SQ8D-YJ52>]. These are only a few of the organizations in the United States that concentrate on rehoming research animals; there are many others both here and in other countries.
306. See *IACUC Resources: Animal Adoption Forms and Policies*, AM. ASS'N FOR LABORATORY ANIMAL SCI., [https://www.aalas.org/iacuc/iacuc\\_resources/animal-adoption-forms#.VmGmqYQ2JUR](https://www.aalas.org/iacuc/iacuc_resources/animal-adoption-forms#.VmGmqYQ2JUR) [<https://perma.unl.edu/34NV-84W3>] (linking to the adoption policies of several universities with animal experimentation programs).
307. See *Adoption Can be an Option for Animals after Their Use in Research*, *supra* note 292, at 14–15 (“[A]nonymity and discretion are the cornerstones of an association of this nature [between laboratories and rescue groups].”).
308. See *ARC FAQ*, ANIMAL RESCUE CORPS, <http://animalrescuecorps.org/about-us/frequently-asked-questions/> [<https://perma.unl.edu/3RCZ-LFL7>] (“Animal Rescue Corps rescues any species of animals.”); *Meet the Animals*, KINDNESS RANCH, <http://kindnessranch.org/meet-the-animals> [<https://perma.cc/H8FH-TVE4>] (sharing details about their dogs, cats, horses, sheep, pigs, and cows); *Rescues*, BEAGLE FREEDOM PROJECT, <http://www.beaglefreedomproject.org/rescues> [<https://perma.unl.edu/3G4C-S7FC>] (describing their rescued dogs, cats, rabbits, pigs, and fish).
309. See *Laboratory Animals Species in Research*, *supra* note 82.
310. See *Support the Beagle Freedom Bill!*, BEAGLE FREEDOM PROJECT, [http://www.beaglefreedomproject.org/right\\_to\\_release](http://www.beaglefreedomproject.org/right_to_release) [<https://perma.unl.edu/PJ2T-NVKQ>].

have been adopted into law in Minnesota, Connecticut, Nevada, and California, with other states on the horizon.<sup>311</sup>

The statutes vary slightly from state to state, but each law requires research facilities to “offer” otherwise healthy dogs and cats to animal rescue organizations before resorting to euthanasia, provided that killing the animal is not required for purposes of the study for which the animal was used.<sup>312</sup> These laws do not require successful adoption or even confirmed acceptance from the rescue groups; they just allow the groups that opportunity.<sup>313</sup> They also may include provisions removing liability from the research facilities for any potential problems that arise during the adoption process or at least expressly permitting them to enter into protective agreements with the rescue organizations.<sup>314</sup> Thus far, most laws focus on research programs within higher education institutions and only cover dogs and cats. However, once a laboratory establishes a relationship with a rescue group and experiences the benefits other research facilities with adoption programs describe, it is quite possible that the group may be able to rehome other species from that laboratory as well and other facilities may hear of the benefits and institute their own programs voluntarily.<sup>315</sup>

## VII. RECOMMENDATIONS

The Animal Welfare Act arose from good intentions fifty years ago, but despite several similarly good-intentioned amendments over the years—and perhaps due to some others—it has fallen short of the promise of its name, at least with respect to the animal testing provi-

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311. *Id.*; *Dogs and Cats No Longer Used for Research May Have a Chance for a Loving Home*, NAT'L ANTI-VIVISECTION SOC'Y, <http://www.navs.org/dogs-and-cats-no-longer-used-for-research-may-have-a-chance-for-a-loving-home-2/> [<https://perma.unl.edu/NU4P-2L2E>]; Kevin Chase, *The Beagle Freedom LAW!*, BEAGLE FREEDOM PROJECT (May 20, 2014), [http://www.beaglefreedomproject.org/the\\_beagle\\_freedom\\_law](http://www.beaglefreedomproject.org/the_beagle_freedom_law) [<https://perma.unl.edu/NJ4B-8DJ7>].

312. 2014 Minn. Laws 150 (requiring higher education research facilities receiving public money, and facilities collaborating with them, to offer dogs and cats from their programs to rescue organizations before euthanizing them); CONN. GEN. STAT. § 10a-150e (Supp. 2016) (requiring higher education research facilities to offer cats and dogs from their programs to rescue organizations prior to euthanizing them); 2015 Nev. Stat. 1731–32 (requiring research and product testing facilities to offer for adoption appropriate dogs and cats about to be euthanized “for any purpose other than scientific, medical or education research” and limiting civil liability for “any act or omission relating to such an adoption”); 2015 Cal. Stat. 4651 (requiring higher education facilities to offer healthy, non-newborn cats and dogs from their programs to rescue organizations prior to euthanizing them).

313. *See* sources cited *supra* note 312.

314. *Id.*

315. *Id.*; *see* Carbone et al., *supra* note 288, at 37, 41 (describing the benefits of laboratory animal adoption programs for the participating research facilities).



sions upon which this Article focuses.<sup>316</sup> In addition to not keeping up with progressive changes in international laws,<sup>317</sup> its protections lag behind domestic public opinion, which polls show grows more concerned about research animal welfare each year.<sup>318</sup> Partly resulting from this mounting concern and pressure, all chimpanzees—both wild and captive—recently received endangered species status, thus ending their use in all forms of scientific research.<sup>319</sup> Could this be just the beginning of changes to come that affect the welfare of other primates and laboratory species as well?

Some scholars believe that a foundational flaw of the AWA is its assumption that animal testing is necessary in the first place, but despite the tremendous breakthroughs occurring in alternative research methods, most believe that a complete end to animal testing is unlikely, at least in the immediate future.<sup>320</sup> Because reduction is a more probable scenario than elimination, following are some suggestions that could help bring the AWA more in line with heightened public interest and concern, shifting international standards, scientific advances, and ethical principles.

#### A. Expand the Definition of “Animal”

First, the AWA’s definition of “animal” needs to expand to more closely reflect the AWA’s original, pre-2002 intentions, as well as international definitions like that of the European Union’s Directive.<sup>321</sup> As

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316. *See supra* section II.A.

317. *See supra* sections V.A.–B.

318. CARY FUNK ET AL., PEW RESEARCH CTR., PUBLIC AND SCIENTISTS’ VIEWS ON SCIENCE AND SOCIETY 6–7, 41 (2015) (noting that 50% of the general American public opposes the use of animals in scientific research while 89% of scientists favor animal testing); Rebecca Riffkin, *In U.S., More Say Animals Should Have Same Rights as People*, GALLUP (May 18, 2015), <http://www.gallup.com/poll/183275/say-animals-rights-people.aspx> (calculating that 67% of Americans are “somewhat” or “very” concerned about the welfare of animals used in research, and the percentage of those who believe nonhuman animals should have the same rights as humans grew from 25% in 2008 to 32% in 2015, increasing across all demographics).

319. Sara Reardon, *US Government Gives Research Chimps Endangered-Species Protection*, NATURE (June 12, 2015), <http://www.nature.com/news/us-government-gives-research-chimps-endangered-species-protection-1.17755> [<https://perma.unl.edu/8TT2-9W4U>] (noting the exception that limited research designed to “benefit the species in the wild” is permissible).

320. Hessler, *supra* note 80, at 595 (positing that the AWA cannot be successfully amended because it is predicated on the incorrect proposition that it is necessary today to use animals in testing); Ericson, *supra* note 200 (“The most progressive scientists will tell you animals are still indispensable in numerous areas of science . . . .”); Gartner *supra* note 201 (quoting the Director of the Center for Bioethics at the University of Pennsylvania as stating that animal testing still is necessary).

321. *See supra* section V.A.

described *supra* in section IV.A., that particular definition includes all “live non-human vertebrate animals,” specifically incorporating fetuses and cephalopods.<sup>322</sup> Science itself supports this broader definition, and studies show that living animals—including mice, rats, birds, livestock, and even fish—are capable of suffering pain and distress.<sup>323</sup> It is troubling that federal law would draw a line providing protection for some species, yet denying it for others—namely, those that comprise the vast majority of animals found in laboratories.<sup>324</sup>

Further, a less discriminatory definition would be more consistent with policies like that of the PHS, thereby automatically placing research facilities adhering to federal standards in a more convenient and favorable position to apply for and benefit from grant funding from the National Institutes of Health.<sup>325</sup> That policy, to which some U.S. research facilities already adhere, defines “animal” as “[a]ny live, vertebrate animal used or intended for use in research, research training, experimentation, or biological testing or for related purposes.”<sup>326</sup>

A negative aspect of this update for research facilities, however, is that a definition including commonly used species like mice and rats may cause some IACUCs to have to establish more comprehensive record-keeping and monitoring systems if they did not already maintain such records for those species, thus increasing costs.<sup>327</sup> The countering positive is that more stringent oversight should result in greater welfare for these sentient species, as well as more transparency when reporting general animal-use information to an increasingly concerned public—some of the reasons that IACUCs were to be established in the first place.<sup>328</sup>

These benefits hinge on whether IACUCs adequately fulfill their assigned duties, which as the latest audit revealed many do not,<sup>329</sup> but hopefully increased monitoring requirements would encourage facilities with less effective IACUCs to devote a reasonable amount of additional resources and staff to them. Of course, the alternative is that added responsibilities could overwhelm some IACUCs that do not receive more resources or that already do not meet present standards, leading them to maintain performance below minimum expectations;

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322. Directive 2010/63, *supra* note 166, art. 1, para. 3, at 39.

323. *See supra* section III.C.

324. *See Laboratory Animals Species in Research, supra* note 82.

325. *See* PHS POLICY, *supra* note 45, at 8; *see supra* section III.B; *supra* text accompanying notes 48–51.

326. PHS POLICY, *supra* note 45, at 8.

327. *See supra* note 100 and accompanying text (noting that the OIG Audit did not consider animals excluded from the AWA definition).

328. Masonis, *supra* note 25, at 159; *see* sources cited *supra* notes 39–40 and accompanying text.

329. *See supra* note 61 and accompanying text.

but these are the same risks associated with IACUCs both at their inception and today.<sup>330</sup>

### **B. Increase the Diversity and Power of IACUCs**

To reinforce the abilities of IACUCs to fulfill the goals originally envisioned for them, their power and internal diversity minimums should increase. The AWA requires a minimum of only three IACUC members, one of whom is not otherwise affiliated with the research facility.<sup>331</sup> This arrangement makes it very easy for the unaffiliated person's opinions and concerns—although they must be recorded—to be ignored.<sup>332</sup> The PHS Policy, on the other hand, requires a minimum of five IACUC members, including one who is unaffiliated with the facility and another without primary scientific concerns (such as a lawyer or ethicist).<sup>333</sup> Especially if the AWA's definition of "animal" broadens—as it should—its IACUC member minimums also should expand to accommodate the increased reporting and monitoring obligations that will follow for institutions that do not already account for omitted species. This expansion should mimic the PHS Policy's requirements that at least one member be otherwise unaffiliated with the research institution, and at least one other be from a primarily nonscientific field, so as to represent general public opinion. Ideally the AWA's Regulations also would require a third member from any field, scientific or otherwise, from outside the immediate facility, or at least documented consideration thereof. This would further reduce the risk of bias, as well as the ineffectiveness displayed in the OIG Audit, which noted problems with deficient IACUC monitoring, as well as substandard facility and program reviews, that have persisted over the years.<sup>334</sup> That Audit and its predecessor demonstrate that the current system does not work and is ripe for reevaluation. An IACUC's minimum number should continue to be odd to allow for a majority opinion, but the makeup should be such that a vote within the committee is a true, balanced consideration of the process at issue, and not just a rubber stamp in favor of the institution (which the current Regulations minimums permit even if unintentionally).

Additionally, an organization such as APHIS Animal Care or OLAW should convene a group of veterinarians from various areas and specialties, some with experience in research laboratories, to create a more descriptive, universally applicable guide defining and categorizing degrees of pain and distress for different species, determining humane endpoints based on these categories, and delineating other

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330. *See id.*

331. 9 C.F.R. § 2.31(b)(2)–(3) (2015).

332. *See supra* notes 45–47 and accompanying text.

333. PHS POLICY, *supra* note 45, at 11.

334. OIG AUDIT, *supra* note 57, at 28.

considerations IACUCs currently must determine on their own, often resulting in stark differences from institution to institution.<sup>335</sup> Such guidelines cannot provide bright-line determinations for every situation since pain may be specific to the individual animal and procedural environment,<sup>336</sup> but they at least can provide more uniform, concrete examples than are currently available in one location. This guide can draw upon—and importantly, help unify—others published by various entities, such as the NRC, USDA, individual facilities, and international organizations.<sup>337</sup> The AWA Regulations then should reference this guide and recommend that all IACUCs follow it to increase consistency and greater animal welfare.

Finally, the Regulations should remove the repeated deference to practices that violate standards but are “justified for scientific reasons.”<sup>338</sup> That language is over-encompassing and carries the potential for considerable misuse by laboratories that do not wish to be burdened by the IACUC oversight otherwise mandated by federal law. Some degree of pain and discomfort is inherent in many animal experiments. But if IACUCs are balanced with members from within and outside the institution and the subsequent institutional review processes do their jobs, such dangerously broad allowances enshrined in the law are unnecessary. The European Union Directive, which does not contain such language, demonstrates this.<sup>339</sup>

### C. Strengthen Commitment to the Three R’s

It is commendable that ISLAA formally recognized the Three R’s and the value of reducing the number of live animals used in testing, refining experiments to cause less pain and distress, and replacing live animals whenever possible; but the AWA’s commitment to these

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335. Fish, *supra* note 48.

336. COMM. ON RECOGNITION & ALLEVIATION OF PAIN IN LAB. ANIMALS, NAT’L RESEARCH COUNCIL, RECOGNITION AND ALLEVIATION OF PAIN IN LABORATORY ANIMALS 48 (2009).

337. *See id.*; *A Reference Source for the Recognition & Alleviation of Pain & Distress in Animals*, NAT’L AGRIC. LIBR., U.S. DEP’T OF AGRIC. (Oct. 2000), <http://pubs.nal.usda.gov/sites/pubs.nal.usda.gov/files/awic200003.pdf> [<https://perma.unl.edu/MT9K-7CB3>] (including a reference list of multiple other articles and guides on the matter, including some from other countries like Australia).

338. Animals and Animal Products, 9 C.F.R. § 2.31(d)(1), (d)(1)(iv)(A), (d)(1)(x)(A), (d)(1)(xi) (2015).

339. Directive 2010/63, *supra* note 166. Recital 10 acknowledges that the use of live animals is necessary for certain tests, but it also notes the ultimate goal of full replacement of live animals as soon as scientifically possible. *Id.* recital 10, at 34. Article 4, paragraph 2 also provides, “Member States shall ensure that the number of animals used in projects is reduced to a minimum without compromising the objectives of the project,” but this still is far less all-encompassing than the U.S. deferential language. *Id.* art. 4, at 39–40.

ideals should strengthen.<sup>340</sup> For example, its Regulations should affirmatively require—or at least officially recommend—use of validated alternative testing methods whenever available, much like the European Union’s Directive.<sup>341</sup> Further, in addition to removing the broadly deferential language that allows violations “justified for scientific reasons,” the Regulations should explain more about what it means to “consider[.]” alternatives to *in vivo* testing,<sup>342</sup> and should require more comprehensive exploration and evaluation of available non-animal methods as well as specific documentation of these investigations, including the reasoning if a facility chooses not to use an available method. The ICCVAM should maintain a current database containing information regarding these methods, coordinating with the ECVAM to provide a comprehensive, up-to-date library of available alternatives while maintaining individual institutions’ intellectual property rights.<sup>343</sup>

Moreover, if the Humane Cosmetics Act is in fact enacted,<sup>344</sup> the AWA, its Regulations, or both should reference and coordinate with it to impose the use of non-animal alternatives for the testing of cosmetics. These changes would bring the United States much closer to the progressive status of many other countries.<sup>345</sup> This also would enhance the profit-earning potential of domestic companies, because an American company following such standards would not need to readjust to different regulations in order to market its products internationally.<sup>346</sup>

#### **D. Include a Provision Encouraging Adoption for Spent Animals**

Another way in which the AWA should mirror international law is by including a provision encouraging research facilities intending to destroy their otherwise-adoptable animal subjects to first just offer those animals to a rescue organization for rehoming.<sup>347</sup> Such a provision should not impose additional duties on the facilities, and contracts with the rescue groups would absolve them of any potential future liabilities.<sup>348</sup> Further, if the definition of “animal” is broadened and IACUC monitoring and reporting minimum requirements are increased, as they should be, a research facility should not have to spend

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340. Ibrahim, *supra* note 5, at 201; *see supra* section II.C.

341. Directive 2010/63, *supra* note 166, recitals 10–12, at 34.

342. *See* 7 U.S.C. §§ 2143(a)(3)(B), (a)(3)(C)(i), (a)(3)(C)(iv), (a)(3)(D)–(E).

343. *See About EURL ECVAM, supra* note 245; *About ICCVAM, supra* note 283.

344. Humane Cosmetics Act, H.R. 2858, 114th Cong. (2015).

345. *See supra* section V.B.

346. *Id.*

347. *See* Directive 2010/63, *supra* note 166, art. 19, at 43.

348. *See supra* note 305 and accompanying text.

time and resources providing rescue groups additional information about individual animals unless it desires to do so.

Several states already enacted laws to this effect, and more likely will follow.<sup>349</sup> The AWA should codify a general provision stating this minimum requirement, allowing individual states to expand upon it if preferred. Not only would this action help unify state practices, bring this country more up to speed with others, and permit adoptable research animals to end their lives in loving homes, but it also would benefit research facilities by eliminating costs associated with euthanasia (such as drugs, instruments, employee training, and body disposal) by increasing staff morale and possibly by enhancing the facilities' reputations within the public.<sup>350</sup>

These are only a few suggestions among many that would help bring the AWA more in line with its original objectives and the promise of its title. For instance, some scholars have argued convincingly in favor of a provision in the AWA that would allow private citizens a right of action to sue persons or entities violating AWA standards, much like citizen-suit rights provided by environmental protection statutes.<sup>351</sup> Such a right is likely to become even more relevant and demanded with the prevalence of social media and easy publicity of graphic undercover exposés of abusive practices.<sup>352</sup> In response to this phenomenon, some states enacted legislation commonly termed "ag-gag," which criminalizes ongoing documentation and publication of animal abuse in places like factory farms and research laboratories;<sup>353</sup> but a federal court in Idaho recently classified that state's ag-gag law as unconstitutional, calling the fates of others into question.<sup>354</sup>

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349. *Dogs and Cats No Longer Used for Research May Have a Chance for a Loving Home*, *supra* note 311.

350. *See* Carbone et al., *supra* note 288, at 40–41.

351. *See, e.g.*, De Anna Hill, *Combating Animal Cruelty with Environmental Law Tactics*, 4 J. ANIMAL L. 19, 19, 22 (2008); Shigehiko Ito, *Beyond Standing: A Search for a New Solution in Animal Welfare*, 46 SANTA CLARA L. REV. 377, 379 (2006); Karen L. McDonald, *Creating a Private Right of Action Against Abusive Animal Research*, 134 U. PA. L. REV. 399, 400 (1986).

352. *See, e.g.*, *Professional Laboratory and Research Services Undercover Investigation*, PETA, <http://www.peta.org/features/professional-laboratory-research-services/> [<https://perma.unl.edu/S36L-BXQ2>] (describing an undercover laboratory investigation that led to public outcry concerning the treatment of the animals there, and its ultimate closing).

353. Dayton Martindale, *Ag-Gag Laws: The Less You Know The Better*, IN THESE TIMES (June 19, 2015, 10:31 AM), <http://inthesetimes.com/rural-america/entry/18071/ag-gag-laws-what-you-dont-know-might-hurt-you> [<https://perma.unl.edu/97CG-YV6J>].

354. *Animal Legal Def. Fund v. Otter*, No. 1:14-CV-00104-BLW, 2015 WL 4623943 (D. Idaho Aug. 3, 2015).

## VIII. CONCLUSION

We now are equipped with more information than ever before regarding things like the sentience of the animals used in laboratory testing and our abilities to conduct tests with non-animal technologies, and many other countries' laws reflect these advances. Public opinion and concern also is changing as this knowledge base—and access to it—continues to grow. The Animal Welfare Act was born in 1966 to provide fundamental, minimum protections for the animals under its purview. At fifty, it is suffering a mid-life crisis, and needs to change to fulfill its intended purpose and live up to the potential and promise of its name.