

**FAILURE TO LAUNCH:  
THE LACK OF IMPLEMENTATION AND  
ENFORCEMENT OF THE ANIMAL WELFARE ACT**

**Leslie Rudloff<sup>†</sup>**

CONTENTS

INTRODUCTION .....	173
I. BACKGROUND .....	173
II. USDA’S FAILURE TO PROMULGATE CLEAR REGULATIONS .....	178
III. USDA’S FAILURE TO STRICTLY ENFORCE.....	181
IV. IACUCS’ FAILURE TO APPROVE, MONITOR, AND REPORT .....	184
VI. FUNDING AGENCIES’ “JUST-IN-TIME” POLICIES ENCROACH UPON IACUC AUTHORITY .....	189
CONCLUSION.....	190

INTRODUCTION

Failure to launch syndrome “is an increasingly popular way to describe the difficulties some young adults face when transitioning into the next phase of development—a stage which involves greater independence and responsibility.”<sup>1</sup> One might say that the Animal Welfare Act suffers from failure to launch syndrome. The Animal Welfare Act was passed over fifty years ago and yet, it has not matured past its infancy in terms of effectively preventing unnecessary and inhumane animal experiments. This article will explore the failures of Congress, the United States Department of Agriculture (USDA), the Institutional Animal Care and Use Committees (IACUCs), research facilities, and funding agencies to implement and enforce the Animal Welfare Act.

I. BACKGROUND

Pepper, a Dalmatian, was stolen from her yard by an unscrupulous

---

<sup>†</sup> Leslie Rudloff is senior counsel for the Physicians Committee for Responsible Medicine, a nationwide organization of physicians and laypersons that promotes preventive medicine and addresses ethical issues in medical research.

1. Robert Fischer, *Failure to Launch Syndrome: What Does It Mean to Launch Successfully?*, PSYCHOLOGY TODAY (July 20, 2015), <https://www.psychologytoday.com/blog/failure-launch/201501/failure-launch-syndrome>.

animal dealer in 1965.<sup>2</sup> The dealer then sold Pepper to a research facility where she later died during an experimental procedure.<sup>3</sup> Lucky, an English pointer, was described as “a pathetic, emaciated horror” after she was rescued from a similar fate.<sup>4</sup> Lucky’s story was featured in a *Life* magazine article titled *Concentration Camps for Dogs*.<sup>5</sup> The *Life* article highlighted the theft of family pets by immoral dealers.<sup>6</sup> The dealers then forced the dogs to live in deplorable conditions until they were sold to research facilities.<sup>7</sup> After the *Life* article was published, Congress received a large number of angry letters from constituents about the cruel realities of animal experimentation.<sup>8</sup> This public outcry resulted in the passage of the Animal Welfare Act of 1966.<sup>9</sup>

The Animal Welfare Act was originally passed to prohibit the use of stolen animals in research experiments and to insure that the “animals intended for use in research facilities [were] provided humane care and treatment.”<sup>10</sup> The Animal Welfare Act has been amended on several occasions, including in 1970, 1976, 1985, 1990, 2002, 2007, and 2008.<sup>11</sup> The Animal Welfare Act originally defined “animal” as “dogs, cats, monkeys (nonhuman primate mammals), guinea pigs, hamsters, and rabbits.”<sup>12</sup>

In 1970, Congress expanded that definition to include all warm-blooded animals except for farmed animals.<sup>13</sup> A warm-blooded animal is defined as “one that is capable of generating internal heat in its cells so that the internal body temperature of the animal can be warmer than the surrounding environment.”<sup>14</sup> The 1970 amendment also required the “use of anesthetic, analgesic or tranquilizing drugs” during

---

2. See Coles Phinizy, *The Lost Pets that Stray to the Labs*, SPORTS ILLUSTRATED, Nov. 29, 1965, at 36, 36–37 (“Probably in the early hours of the 23rd a dog thief simply stopped his car on the road in front of the Lakavage house, opened the door, invited Pepper to hop in, and then drove away with her.”).

3. *Id.*

4. Stan Wayman, *Concentration Camp for Dogs*, LIFE, Feb. 4, 1966, at 22, 22.

5. *Id.*

6. *Id.*

7. *Id.* at 26–27.

8. David Favre, *Overview of U.S. Animal Welfare Act*, ANIMAL LEGAL & HIST. CTR. (2002), <https://www.animallaw.info/article/overview-us-animal-welfare-act>.

9. *Id.*

10. Act of Aug. 24, 1966, Pub. L. No. 89-544, § 1, 80 Stat. 350, 350 (1966).

11. *Animal Welfare Act*, U.S. DEP’T AGRIC. NAT’L AGRIC. LIBR., <https://www.nal.usda.gov/awic/animal-welfare-act> (last visited Oct. 20, 2016).

12. Act of Aug. 24, 1966 § 2(h).

13. *Animal Welfare Act of 1970*, Pub. L. No. 91-579, § 3, 84 Stat. 1560, 1561 (1970).

14. Favre, *supra* note 8, at 9.

experimentation.<sup>15</sup> The 1976 amendment increased the scope of the Animal Welfare Act to cover animals used in transportation and those forced to fight, like dogs or roosters.<sup>16</sup>

In 1985, Congress passed the Improved Standards for Laboratory Animals Act as a part of the Food Security Act of 1985.<sup>17</sup> The 1985 amendments were meant to define “‘humane care’ by mentioning specifics such as sanitation, housing, and ventilation.”<sup>18</sup> The 1985 amendments included the requirement of consideration of alternatives to the use of animals in experimentation.<sup>19</sup> It required “the principal investigator [to consider] alternatives to any procedure likely to produce pain to or distress in an experimental animal.”<sup>20</sup> It required that the research facility provide “assurances demonstrating that the principal investigator considered alternatives” to procedures likely to produce pain or distress to any experimental animal.<sup>21</sup> It also required that the research facility provide training opportunities on “research or testing methods that minimize or eliminate the use of animals or limit animal pain or distress.”<sup>22</sup> Lastly, the National Agricultural Library was required to provide information “on improved methods of animal experimentation, including methods which could reduce or replace animal use.”<sup>23</sup> The 1985 amendments also directed the Secretary of Agriculture to establish regulations to provide “exercise for dogs and an adequate physical environment to promote the psychological well-being of nonhuman primates.”<sup>24</sup>

The 1985 amendments also established the requirement of Institutional Animal Care and Use Committees (IACUC) at research facilities.<sup>25</sup> The amendment included a description of IACUC’s “roles, composition, and responsibilities to the Animal and Plant Health

---

15. Animal Welfare Act of 1970 sec. 14, § 13.

16. Animal Welfare Act Amendments of 1976, Pub. L. No. 94-279, sec. 17, § 26(g)(5), 90 Stat. 417, 423 (1976).

17. Food Security Act of 1985, Pub. L. No. 99-198, subtitle F, 99 Stat. 1354, 1645 (1976).

18. *Public Law 99-198, Food Security Act of 1985, Subtitle F –Animal Welfare*, U.S. DEP’T AGRIC. NAT’L AGRIC. LIBR., <https://www.nal.usda.gov/awic/public-law-99-198-food-security-act-1985-subtitle-f-animal-welfare> (last visited Oct. 20, 2016) [hereinafter *Food Security Act of 1985*]; see also Food Security Act of 1985 sec. 1752(a), § 13(2)(A).

19. Food Security Act of 1985 sec. 1752(a), § 13(2)(B).

20. 7 U.S.C. § 2143(a)(3)(B) (2012).

21. *Id.* § 2143(a)(7)(B)(i).

22. *Id.* § 2143(d)(2).

23. *Id.* § 2143(e)(3)(A).

24. *Food Security Act of 1985*, *supra* note 17; see also 7 U.S.C. § 2143(a)(2)(B).

25. Food Security Act of 1985 sec. 1752(c), § 13(b)(1).

Inspection Service (APHIS).”<sup>26</sup> Specifically, each research facility is required to have at least one IACUC and that committee can have no less than three members.<sup>27</sup> IACUC members are appointed by the chief executive officer of the research facility.<sup>28</sup> Each IACUC member must be able to “assess animal care, treatment, and practices in experimental research as determined by the needs of the research facility.”<sup>29</sup> IACUCs are supposed to “represent society’s concerns regarding the welfare of animal subjects used at [the research] facility.”<sup>30</sup> The 1985 amendments also prohibit any unnecessary duplication of specific experiments.<sup>31</sup>

In 1985, Senator Robert Dole of Kansas stated, “We need to ensure the public that adequate safeguards are in place to prevent unnecessary abuses to animals and that everything that is reasonably possible is being done to decrease the pain that animals suffer during experimentation and testing.”<sup>32</sup> According to Senator Dole, the 1985 amendments were passed “to minimize pain and distress suffered by animals used for experiments and tests.”<sup>33</sup>

One of the main goals of the Animal Welfare Act was the consideration of alternatives to procedures that were likely to produce pain or distress in animals. This goal appeared in both the text of the Animal Welfare Act and the legislative history of the 1985 amendments that pertain to alternatives.<sup>34</sup> For example, in the bill enacting the 1985 amendments, Congress found that “methods of testing that do not use animals are being and continue to be developed which are faster, less expensive, and more accurate than traditional animal experiments” and that “measures which eliminate or minimize the unnecessary duplication of experiments on animals can result in more productive use of Federal funds.”<sup>35</sup>

In 1990, Congress amended the Animal Welfare Act to establish a

---

26. *Food Security Act of 1985*, *supra* note 17; *see also* *Food Security Act of 1985* sec. 1752(c), § 13(b)(1)–(5).

27. 7 U.S.C. § 2143(b)(1).

28. *Id.*

29. *Id.*

30. *Id.*

31. Animal Welfare Act of 1985, Pub. L. No. 99-198, § 1751(3), 99 Stat. 1645, 1645 (1985).

32. 131 CONG. REC. 14,161 (1985) (statement of Sen. Dole).

33. 131 CONG. REC. 37,610 (1985) (statement of Sen. Dole).

34. Animal Welfare Act of 1985 § 1752(3)(a); *Legislative History of the Animal Welfare Act: 1980s*, U.S. DEP’T AGRIC. NAT’L AGRIC. LIBR., <https://www.nal.usda.gov/awic/public-law-94-279-animal-welfare-act-amendments-1976> (last visited Oct. 20, 2016).

35. Animal Welfare Act of 1985 § 1751(2)–(3).

minimum five day holding period for animals in shelters.<sup>36</sup> This new rule was established so that the animal had a chance to be adopted or recovered by their original owner before being sold into medical research.<sup>37</sup>

In 2002, Congress passed a Farm Bill that amended the Animal Welfare Act to exclude birds, rats, and mice bred for use in research from the definition of “animal.”<sup>38</sup> Due to the 2002 amendment, the definition of “animal” and the Animal Welfare Act now have limited application:

The term “animal” means any live or dead dog, cat, monkey (nonhuman primate mammal), guinea pig, hamster, rabbit, or such other warm-blooded animal, as the Secretary may determine is being used, or 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 improving the quality of food or fiber. With respect to a dog, the term means all dogs including those used for hunting, security, or breeding purposes.<sup>39</sup>

It is estimated that ninety-three to ninety-seven percent of all animals used in research are mice and rats.<sup>40</sup> Thus, the overwhelming majority of animals used in research are not protected under the Animal Welfare Act or corresponding federal regulations.<sup>41</sup> Due to industry influence and subsequent amendments, the Animal Welfare Act is now

---

36. Food, Agriculture, Conservation and Trade Act of 1990, Pub. L. No. 101-624, sec. 2503, § 28, 104 Stat. 3359, 4066 (1990).

37. *Id.*

38. 7 U.S.C. § 2132(g) (2012).

39. *Id.*

40. *USDA Publishes 2014 Animal Research Statistics*, SPEAKING RES. (Jul. 9, 2015), <https://speakingofresearch.com/2015/07/09/usda-publishes-2014-animal-research-statistics/> (“In the UK, where mice, rats, fish and birds are counted in the annual statistics, over 97% of research is on rodents, birds and fish. Across the EU, which measures animal use slightly differently, 93% of research is on species not counted under the Animal Welfare Act. We would expect similar patterns to be true in the US—although there are no statistics to confirm this.”).

41. *See When Are Rats, Mice, Birds and Fish Protected by US Federal Laws?*, SPEAKING RES. (May 23, 2016), <https://speakingofresearch.com/2016/05/23/when-are-rats-mice-birds-and-fish-protected-by-us-federal-laws/>.

widely considered more form than substance.<sup>42</sup> It is estimated that over 100 million birds, rats, and mice are used in research each year but are afforded no protection under the Animal Welfare Act.<sup>43</sup> The animals that do fall within the purview of the Animal Welfare Act are calculated annually by the USDA.<sup>44</sup> According to the 2014 USDA Annual Report, 21,083 cats, 59,358 dogs, 169,528 guinea pigs, 121,930 hamsters, 57,735 nonhuman primates, 45,392 pigs, 150,344 rabbits, 10,315 sheep, and 27,393 farm animals were used in research.<sup>45</sup>

## II. USDA'S FAILURE TO PROMULGATE CLEAR REGULATIONS

Congress instructed the USDA to “promulgate standards to govern the humane handling, care, treatment, and transportation of animals by dealers, research facilities, and exhibitors.”<sup>46</sup> The regulations are supposed to help interpret and enforce the Animal Welfare Act.

The regulations promulgated by the USDA are published annually in the *Code of Federal Regulations*, title nine, chapter one, and may be viewed on the USDA's APHIS website.<sup>47</sup> The regulations promulgated by the USDA track the Animal Welfare Act.<sup>48</sup>

The regulations regarding animals appear in 9 C.F.R. § 2.31(d)(1) and follow the requirements in statutory paragraph 2143(a)(3).<sup>49</sup> In paragraph 2143(a)(3) of the Animal Welfare Act, Congress established minimum requirements for regulations regarding animals in research facilities. Subparagraph (A) requires “that animal pain and distress are minimized” in experimental procedures.<sup>50</sup> Subparagraph (B) requires that a “principal investigator considers alternatives to any procedure likely to produce pain to or distress in an experimental animal.”<sup>51</sup>

---

42. See *USDA Publishes 2014 Animal Research Statistics*, *supra* note 40.

43. *Id.*

44. See *Animal Welfare Act Program Information*, U.S. DEP'T AGRIC. ANIMAL & PLANT HEALTH INSPECTION SERV., [https://www.aphis.usda.gov/aphis/ourfocus/animal\\_welfare/sa\\_awa/ct\\_awa\\_program\\_information](https://www.aphis.usda.gov/aphis/ourfocus/animal_welfare/sa_awa/ct_awa_program_information) (last visited Oct. 20, 2016).

45. ANIMAL & PLANT HEALTH INSPECTION SERV., U.S. DEP'T OF AGRIC., ANNUAL REPORT ANIMAL USAGE BY FISCAL YEAR: 2014 (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).

46. 7 U.S.C. § 2143(a)(1) (2012).

47. See U.S. DEP'T OF AGRIC., ANIMAL WELFARE ACT AND ANIMAL WELFARE REGULATIONS (Nov. 6, 2013), [https://www.aphis.usda.gov/animal\\_welfare/downloads/Animal%20Care%20Blue%20Book%20-%202013%20-%20FINAL.pdf](https://www.aphis.usda.gov/animal_welfare/downloads/Animal%20Care%20Blue%20Book%20-%202013%20-%20FINAL.pdf).

48. *Id.*

49. Compare 9 C.F.R. § 2.31(d)(1) (2016), with 7 U.S.C. § 2143(a)(3).

50. 7 U.S.C. § 2143(a)(3)(A).

51. *Id.* § 2143(a)(3)(B).

Subparagraph (C) and (D) establish requirements for painful and major operative procedures involving animals.<sup>52</sup> Subparagraph (E) imposes requirements on exceptions to the standards.<sup>53</sup>

As in the statute, 9 C.F.R. § 2.31(d)(1)(i) begins by requiring that “[p]rocedures involving animals will avoid or minimize discomfort, distress, and pain to the animals.”<sup>54</sup> Also following the statute, 9 C.F.R. § 2.31(d)(1)(ii) requires that “[t]he principal investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals.”<sup>55</sup> The regulation also requires a “written assurance that the activities do not unnecessarily duplicate previous experiments,” in keeping with the statutory goal to prevent “unintended and unnecessary duplication of research involving animals.”<sup>56</sup> The subsequent provisions of the regulation also mirror paragraph 2143(a)(3) of the statute by establishing detailed medical care and handling requirements for painful and major operative procedures involving animals.<sup>57</sup>

Even though the regulations were promulgated to interpret and enforce the Animal Welfare Act, they fail to allow for practical application. For example, the regulations do not define “alternatives” nor do they elaborate upon what it means to “consider[] alternatives.”<sup>58</sup> To effectively carry out the original intent of the Animal Welfare Act, the USDA needs to amend the regulations to address the aforementioned and other ambiguities. In October 2013, the Physicians Committee for Responsible Medicine (“Physicians Committee”) filed a petition for rulemaking with the USDA/APHIS requesting it amend the regulations to clarify those and other ambiguities.<sup>59</sup> In its petition, the Physicians Committee suggested the USDA codify portions of the “Consideration of Alternatives to Painful/Distressful Procedures”

---

52. *Id.* § 2143(a)(3)(C)–(D).

53. *Id.* § 2143(a)(3)(E).

54. *Compare* 9 C.F.R. § 2.31(d)(1)(i), with 7 U.S.C. § 2143(a)(3)(A).

55. *Compare* 9 C.F.R. § 2.31(d)(1)(ii), with 7 U.S.C. § 2143(a)(3)(B).

56. *Compare* 9 C.F.R. §§ 2.31(d)(1)(ii), 2.32(c)(5)(iii) (2016), with 7 U.S.C. § 2143(e)(2).

57. *Compare* 9 C.F.R. § 2.31(d)(1)(iv)–(v), (vii), (ix)–(xi), with 7 U.S.C. § 2143(a)(3)(C)–(D).

58. *See* 9 C.F.R. § 2.31(d)(1)(ii); *see also* 7 U.S.C. § 2143(a)(3)(B).

59. Petition for Rulemaking from Physicians Comm. for Responsible Med., to Thomas J. Vilsack, Secretary, U.S. Dep’t of Agric. (Oct. 30, 2013) [hereinafter Petition for Rulemaking], <https://www.regulations.gov/document?D=APHIS-2014-0050-0002> (follow “View Document” hyperlink). This was written by the Physicians Committee, a nonprofit organization that promotes effective, ethical scientific research and advocates for alternatives to the use of animals in research, testing, and education. *Id.*

(Policy Number Twelve) published in the *Animal Care Policy Manual* (“*Manual*”), the only agency publication that defines “alternatives.”<sup>60</sup> The *Manual* is an internal USDA reference document intended only to assist inspectors in carrying out their duties under the Animal Welfare Act. Since the *Manual* is neither a statute nor regulation, it has no legal effect.<sup>61</sup>

In its rulemaking petition, the Physicians Committee also asked the USDA to clarify the definition of “painful procedure” by amending 9 C.F.R. § 2.31(d)(1)(ii) to provide guidance on considering alternatives to procedures likely to produce pain or distress to animals.<sup>62</sup> According to current USDA regulations, a “[p]ainful procedure as applied to any animal means any procedure that would reasonably be expected to cause more than slight or momentary pain or distress in a human being to which that procedure was applied, that is, pain in excess of that caused by injections or other minor procedures.”<sup>63</sup> Some researchers believe that the painful procedure provisions do not apply if they use anesthesia or analgesics.<sup>64</sup> The USDA has stated in the *Federal Register* that a procedure in which pain is relieved is still considered to be a painful procedure, thus invoking the provisions for painful procedures.<sup>65</sup>

The Physicians Committee suggested that the USDA amend the definition of “painful procedure” as follows:

Painful procedure as applied to any animal means any procedure that would reasonably be expected to cause more than slight or momentary pain or distress in a human being to which that procedure was applied, that is, pain in excess of that caused by injections or other minor procedures. A procedure in which pain is relieved is still considered to be a painful procedure, and the provisions of the Act that address the conduct of painful procedures apply.<sup>66</sup>

In addition, the Physicians Committee’s petition requested that the USDA acknowledge its own authority to enforce regulations regarding the consideration of alternatives to procedures likely to produce pain or

---

60. ANIMAL & PLANT HEALTH INSPECTION SERV., U.S. DEP’T OF AGRIC., ANIMAL CARE POLICY MANUAL 12.1–12.3 (May 23, 2016), [https://www.aphis.usda.gov/animal\\_welfare/downloads/Animal%20Care%20Policy%20Manual.pdf](https://www.aphis.usda.gov/animal_welfare/downloads/Animal%20Care%20Policy%20Manual.pdf).

61. *Id.*

62. Petition for Rulemaking, *supra* note 59.

63. 9 C.F.R. § 1.1 (2016).

64. Petition for Rulemaking, *supra* note 59.

65. Animal Welfare Definition of Terms, 54 Fed. Reg. 36,112, 36,117 (Aug. 31, 1989) (codified at 9 C.F.R. § 1.1).

66. Petition for Rulemaking, *supra* note 59.



distress to animals.<sup>67</sup> As it stands, IACUCs are solely entrusted with that responsibility.<sup>68</sup> On March 30, 2015, the USDA announced that it was making the Physicians Committee's petition available to the public and soliciting comments regarding the petition.<sup>69</sup> On May 15, 2015, the Physicians Committee submitted a final response to comments on its rulemaking petition, highlighting how the lack of regulatory direction from the USDA leads to research facilities routinely violating the Animal Welfare Act.<sup>70</sup> If the Physicians Committee's rulemaking suggestions are accepted and implemented by the USDA, they will likely prevent unnecessary and inhumane animal experiments.

### III. USDA'S FAILURE TO STRICTLY ENFORCE

In addition to its responsibility to promulgate regulations to implement the Animal Welfare Act, the USDA is also responsible for enforcing them. Congress defined a "research facility" as follows:

[A]ny school (except an elementary or secondary school), institution, organization, or person that uses or intends to use live animals in research, tests, or experiments, and that (1) purchases or transports live animals in commerce, or (2) receives funds under a grant, award, loan, or contract from a department, agency, or instrumentality of the United States for the purpose of carrying out research, tests, or experiments . . . .<sup>71</sup>

The facilities that fall within the aforementioned definition are required to register with the USDA. In doing so, the USDA requires each applicant to (1) "demonstrate that his or her premises and any animals, facilities, vehicles, equipment, or other premises used or intended for use in the business comply with the regulations and standards" and (2) "make his or her animals, premises, facilities, vehicles, equipment, other premises, and records available for inspection . . . to ascertain the applicant's compliance with the standards and regulations."<sup>72</sup>

---

67. *Id.*

68. 9 C.F.R. § 2.31(d) (2016).

69. Petition to Define Alternative Procedures, 80 Fed. Reg. 16,592, 16,593 (Mar. 30, 2015) (to be codified at 9 C.F.R. pt. 1–2).

70. Letter from Mark Kennedy, Dir. of Legal Affairs, Physicians Comm. for Responsible Med., to Jere Dick, Acting Adm'r, Animal & Plant Health Inspection Serv. (May 15, 2015), <http://www.pcrm.org/sites/default/files/pdfs/research/ethics/Comments-re-Petition-for-Rulemaking.pdf>.

71. 7 U.S.C. § 2132(e) (2012).

72. 9 C.F.R. § 2.3(a) (2016).

The Secretary of Agriculture may investigate or inspect research facilities “as he deems necessary.”<sup>73</sup> However, these laws and regulations are only as effective as the USDA’s enforcement of them. In reality, the USDA’s enforcement consists mostly with animals currently involved in experiments and not in questioning animal experiments or the use of alternatives in the first place.<sup>74</sup> The USDA seems to reserve the discretion—regarding consideration of alternatives and animal use in experiments—for IACUCs at research institutions.<sup>75</sup>

Fortunately, there is some oversight of the USDA’s enforcement of the Animal Welfare Act by the Office of Inspector General (OIG). The OIG was administratively established by the Secretary of Agriculture in 1962 following a major criminal fraud scandal affecting several agencies within the USDA. The OIG was later legislatively established by Congress under the Inspector General Act of 1978, as amended.<sup>76</sup> The OIG conducts independent and objective audits to promote the economy, efficiency, and effectiveness of the USDA. The OIG was also established to prevent and detect fraud, waste, and abuse. The OIG also reviews pending legislation and regulations to keep USDA officials and Congress informed.<sup>77</sup>

The OIG publishes an audit report regarding the enforcement of the Animal Welfare Act and related regulations. As a part of the 2005 OIG *Audit Report*, the OIG made numerous recommendations to APHIS regarding its enforcement of the Animal Welfare Act.<sup>78</sup> The OIG noted that

the Eastern Region is not aggressively pursuing enforcement actions against violators of the [Animal Welfare Act]. The Eastern Region significantly reduced its referrals of suspected violators to the Investigative and Enforcement Services (IES) unit—from an average of 209 cases in fiscal years (FYs) 2002-2003 to 82 cases in FY 2004.

---

73. 7 U.S.C. § 2146(a) (2012).

74. See generally ANIMAL CARE POLICY MANUAL, *supra* note 60, at 12.1–12.2. (addressing considerations for alternatives to painful or distressful procedures under Policy Number Twelve, but no official policy in the manual discusses constraints on or regulations of an IACUC’s decision to engage in animal experimentation).

75. *Id.*

76. Intelligence Authorization Act for Fiscal Year 2014, Pub. L. No. 113-126, § 402, 128 Stat. 1390, 1408 (2014).

77. About OIG Audit Division, U.S. DEP’T AGRIC., <https://www.usda.gov/oig/audits.htm> (last visited Oct. 20, 2016).

78. OFFICE OF INSPECTOR GEN., U.S. DEP’T OF AGRIC., REPORT NO. 33002-3-SF, APHIS ANIMAL CARE PROGRAM INSPECTION AND ENFORCEMENT ACTIVITIES 4 (2005) [hereinafter 2005 AUDIT REPORT], <https://www.usda.gov/oig/webdocs/33002-03-SF.pdf>.

When the region did refer cases to IES, management declined to take enforcement action against 126 of 475 violators (27 percent).<sup>79</sup>

If the violators were prosecuted, the fines were “usually minimal and not always effective in preventing subsequent violations.”<sup>80</sup> The OIG further noted that the “inspectors believe the lack of enforcement undermines their credibility and authority to enforce the [Animal Welfare Act].”<sup>81</sup> APHIS offers “an automatic 75-percent discount” on the fines it imposes as an incentive for violators to settle cases.<sup>82</sup> The 2005 OIG *Audit Report* recommended that APHIS not offer discounts to repeat or direct violations because of the serious nature of the offenses.<sup>83</sup> The OIG even offered the following case of as an example of paltry fines: A zoo in Texas was offered a discounted fine of \$5600 even though the original fine was \$22,500 “for violations that led to the death of a rhinoceros and a separate incident that resulted in the death of five gorillas from chlorine gas.”<sup>84</sup>

Despite the dismal 2005 OIG *Audit Report*, Congress did not amend the Animal Welfare Act in accordance with the OIG’s recommendations. Congress could have used the opportunity to strengthen the statutory fines for repeat or direct violations. According to the OIG, seventy-six percent of those who paid stipulated fines “continued to commit violations of the [Animal Welfare Act].”<sup>85</sup> It is obvious from the statistics that the measly fines are not serving as a deterrent to the inhumane treatment of animals.

The USDA filed a complaint against Santa Cruz Biotechnology (SCBT) in 2015.<sup>86</sup> In 2012, a survey published in *The Scientist* ranked SCBT as the second largest supplier of antibodies globally.<sup>87</sup> In addition to SCBT’s worldwide fame for antibody production, the company was infamous for its inhumane treatment of animals.<sup>88</sup> SCBT has been the subject of numerous USDA complaints for Animal Welfare Act

---

79. *Id.*

80. *Id.*

81. *Id.* at 5.

82. *Id.* at 10.

83. 2005 AUDIT REPORT, *supra* note 78, at 12.

84. *Id.* at 10.

85. *Id.* at 11.

86. *See* Complaint at 9, *In re Santa Cruz Biotech., Inc.*, No. 15-0165 (U.S.D.A. Aug. 7, 2015).

87. Christi Bird, *Antibodies User Survey*, SCIENTIST (May 1, 2012), <http://www.the-scientist.com/?articles.view/articleNo/32042/title/Antibodies-User-Survey/>.

88. *See* Complaint, *supra* note 86, at 2.

violations including those in 2002, 2003, 2004, 2012, 2014, and 2015.<sup>89</sup> Prior to 2015, the largest civil penalty paid by SCBT was \$4600.<sup>90</sup> In 2015, the USDA filed a complaint against SCBT for barbaric euthanasia methods, lying to the APHIS officials about the number and location of animals to avoid inspection, and the failure of veterinary staff to properly monitor a large number of goats resulting in unnecessary suffering and death.<sup>91</sup> On May 19, 2016, SCBT signed a settlement agreement with the USDA for its inhumane treatment of animals and agreed to pay a \$3.5 million fine.<sup>92</sup> If the USDA had strictly enforced the Animal Welfare Act violations against SCBT in previous years, it could have prevented the suffering and death of thousands of animals.

#### IV. IACUCs' FAILURE TO APPROVE, MONITOR, AND REPORT

According to the *APHIS Animal Care Policy Manual* "Institutional Official and IACUC Membership" policy, IACUCs are responsible for approving, monitoring, and reporting on experimental procedures on animals.<sup>93</sup> Each IACUC member is supposed to assess animal care, treatments, and practices in experimental research as determined by the needs of the research facility.<sup>94</sup> The IACUC members are also supposed to represent society's concerns regarding the welfare of animals at the facility and prevent any unnecessary duplication of experiments.<sup>95</sup>

In addition to the above responsibilities, the IACUC is also required to do a semi-annual inspection of "all animal areas and animal facilities, including any practices involving pain, the condition of animals, and to minimize pain and distress of the animals."<sup>96</sup> The IACUC must file "inspection certification reports" and make them available to both the USDA and funding agency, and the IACUC must also include reports of "any violation of the standards promulgated, or assurances required, by the Secretary, including any deficient conditions of animal care or treatment, any deviations of research practices from originally approved proposals that adversely affect animal welfare, any notification to the facility regarding such conditions, and any

---

89. *Id.* at 1–2.

90. *Id.* at 2.

91. *See id.* at 2–8.

92. Consent Decision & Order, In re Santa Cruz Biotech., Inc., No. 12-0536, 15-0023, 15-0165 (U.S.D.A. May 19, 2016).

93. ANIMAL CARE POLICY MANUAL, *supra* note 60, at 15.1.

94. *Id.* at 15.2.

95. *Id.*

96. 7 U.S.C. § 2143(b)(3) (2012).

corrections made thereafter.”<sup>97</sup> One could argue that entrusting the IACUC to self-monitor its performance is akin to the fox guarding the hen house.

According to the 2014 *OIG Audit Report*, some IACUCs “did not adequately approve, monitor, or report on experimental procedures on animals.”<sup>98</sup> Between 2009 and 2011, veterinary medical officers (VMOs) “cited 531 of 1,117 research facilities for 1,379 IACUC-related violations regarding their lack of oversight.”<sup>99</sup> Some IACUCs were cited for “inadequate protocol reviews and monitoring.”<sup>100</sup> Others were cited for not properly monitoring the animals, or not “submitting an accurate annual report.”<sup>101</sup> The aforementioned failures of IACUCs lead to the inhumane treatment of animals involved in experimentation and thwart the intent of the Animal Welfare Act. “In FY 2000, APHIS conducted a survey of its VMOs and their supervisors to assess their opinions on the effectiveness of the IACUCs.”<sup>102</sup> The survey concluded that “IACUCs seem to be doing well at functions related to setting up the administrative structure and developing the process, but not as well at monitoring and follow through.”<sup>103</sup> It seems that the OIG made the same remarks about IACUCs in 2005. In the 2005 OIG’s Annual Report, the OIG “reported that IACUCs were not effectively monitoring animal care activities, protocols, or alternative research methods.”<sup>104</sup>

In addition, the failure of the IACUC to effectively suggest or consider alternatives in medical training procedures is particularly troubling. For example, Hennepin County Medical Center (HCMC) in Minneapolis, Minnesota, “uses live sheep and rabbits to teach procedural skills to emergency medicine residents, medical students, and practicing physicians, despite the widespread availability and implementation of educationally superior nonanimal training methods”

---

97. *Id.* § 2143(b)(4).

98. OFFICE OF INSPECTOR GEN., U.S. DEP’T OF AGRIC., REPORT NO. 33601-0001-41, APHIS OVERSIGHT OF RESEARCH FACILITIES 28 (2014) [hereinafter 2014 AUDIT REPORT], <https://www.usda.gov/oig/webdocs/33601-0001-41.pdf>.

99. *Id.*

100. *Id.* at 28–29.

101. *Id.* at 33.

102. *Id.* at 28.

103. 2014 AUDIT REPORT, *supra* note 98, at 28 (quoting ANIMAL AND PLANT HEALTH INSPECTION SERV., U.S. DEP’T OF AGRIC., USDA EMPLOYEE SURVEY ON THE EFFECTIVENESS OF IACUC REGULATIONS IV-1 (2000), [https://www.aphis.usda.gov/animal\\_welfare/downloads/iacuc/iacucaugust.pdf](https://www.aphis.usda.gov/animal_welfare/downloads/iacuc/iacucaugust.pdf)).

104. *Id.*

like Simulab's TraumaMan System.<sup>105</sup> TraumaMan is "a realistic anatomical human body simulator with lifelike skin, subcutaneous fat, and muscle."<sup>106</sup>

HCMC's "three-year protocol for the 'Skills Maintenance in Emergency Medicine' lab is approved to use up to 450 sheep and 450 rabbits. HCMC trainees perform twenty procedures on each sheep and three procedures on every rabbit."<sup>107</sup> Those procedures include:

- Skull trephination (the drilling of a hole into the skull)
- Lateral canthotomy (an incision near the eye to drain previously injected liquid in order to relieve orbital pressure)
- Pericardiocentesis (a needle is inserted below the breastbone to remove fluid from the sac surrounding the heart)
- Intraosseous catheter placement (the insertion of a needle into the bone marrow)
- Cricothyroidotomy (an incision in the throat and the insertion of a breathing tube or needle)
- Endotracheal intubation (a breathing tube is placed in the trachea through the mouth or nose)
- Thoracostomy (an incision between the ribs and the insertion of a tube into the chest cavity to drain air, blood, or other fluids).<sup>108</sup>

HCMC's "animal use is at odds with current standards of practice in emergency medicine training in the United States."<sup>109</sup> Approximately, eighty-eight percent of emergency medicine programs "exclusively use nonanimal methods to teach residents."<sup>110</sup> The "emergency medicine residency at Regions Hospital in nearby St. Paul exclusively uses human-based training methods."<sup>111</sup>

"HCMC meets the statutory definition of a 'research facility' and is therefore required to comply with the Animal Welfare Act. As part of this required compliance, any use of live animals for research, testing,

---

105. E-mail from John J. Pippin et al., Dir. of Acad. Affairs, Physicians Comm. for Responsible Med., to Elizabeth Goldentyer, Reg'l Dir., USDA/APHIS/AC E. Region (Apr. 14, 2016), <http://kstp.com/kstpImages/repository/cs/files/HCMC%20APHIS%20Complaint%202016-04-14.pdf>.

106. *Id.*

107. *Id.*

108. *Id.*

109. *Id.*

110. E-mail from John J. Pippin et al., *supra* note 105.

111. *Id.*

or training, must be approved by the . . . [IACUC].”<sup>112</sup> The “IACUC is responsible for the approval and scheduled use of live sheep and rabbits in the HCMC emergency medicine residency program.”<sup>113</sup>

The principal investigator is required to

consider alternatives to procedures that may cause more than momentary or slight pain or distress to any animal used for research or educational purposes. In addition, the [principal investigator] must provide a written narrative description of the methods and sources used to determine that alternatives were not available. . . . If a database search or other source identifies a bona fide alternative method (one that could be used to accomplish the goals of the animal use proposal), the IACUC may and should ask the [principal investigator] to explain why an alternative that had been found was not used.<sup>114</sup>

It seems impossible for the principal investigator to justify animal use for emergency medicine residency training, given the validation and widespread implementation of purpose-designed nonanimal training methods.

A proper alternatives search would have revealed non-animal methods for the training of all procedures currently taught at HCMC using live sheep and rabbits. All emergency medicine procedural skills, including pericardiocentesis, thoracotomy, chest tube placement, and central line placement, can be taught using human-based medical simulation, task trainers, and cadavers.<sup>115</sup>

The validation and superiority of simulators is routinely noted by experts in the field.<sup>116</sup> “We have entered into an age where artificial

---

112. *Id.*; see also 7 U.S.C. § 2132(e) (2012) (“The term ‘research facility’ means any school (except an elementary or secondary school), institution, organization, or person that uses or intends to use live animals in research, tests, or experiments, and that (1) purchases or transports live animals in commerce, or (2) receives funds under a grant, award, loan, or contract from a department, agency, or instrumentality of the United States for the purpose of carrying out research, tests, or experiments: Provided, That the Secretary may exempt, by regulation, any such school, institution, organization, or person that does not use or intend to use live dogs or cats, except those schools, institutions, organizations, or persons, which use substantial numbers (as determined by the Secretary) of live animals the principal function of which schools, institutions, organizations, or persons, is biomedical research or testing, when in the judgment of the Secretary, any such exemption does not vitiate the purpose of this chapter.”).

113. E-mail from John J. Pippin et al., *supra* note 105.

114. *Id.*; see also 7 U.S.C. § 2143(b) (2012); 9 C.F.R. § 2.31(d)(1)(i)–(ii) (2016); ANIMAL CARE POLICY MANUAL, *supra* note 60, at 12.2.

115. E-mail from John J. Pippin et al., *supra* note 105; see *TraumaMan Never Grows Old*, SIMULAB CORP., <https://www.simulab.com/traumaman/about> (last visited Oct. 20, 2016).

116. See Andrew Hall, *Letters to the Editor*, 179 MIL. MED. vii, vii (July 2014).

simulator models are at least equivalent to, if not superior to, animal models.”<sup>117</sup>

A validated and widely implemented example of these human-based methods includes Simulab’s TraumaMan System, a realistic anatomical human body simulator with lifelike skin, subcutaneous fat, and muscle. The TraumaMan System can be used to replace HCMC’s use of sheep in numerous procedures, including cricothyroidotomy, pericardiocentesis, thoracostomy, peritoneal lavage, intravenous cutdown, and ultrasound examination. In fact, the TraumaMan System is used by nearly all Advanced Trauma Life Support programs to teach many of the same skills for which HCMC is using animals.<sup>118</sup>

In addition to the TraumaMan System, there are numerous other simulators that can also be used in emergency medicine residency training:

Laerdal’s SimMan 3G can be used to teach cricothyroidotomy, endotracheal intubation, retrograde intubation, intraosseous needle insertion, intravenous insertion, chest decompression, and urinary catheterization. In addition, the SimMan 3G can be programmed to simulate a multitude of scenarios requiring defibrillation and the administration of cardiac medications.

Additionally, Simulab’s CentraLineMan System teaches central line placement with lifelike human skin, subcutaneous fat, and muscle. SynDaver’s Lateral Canthotomy Trainer can be used to teach both lateral and medial canthotomy. For skull trephination, the Trauma Craniotomy simulator from Operative Experience, Inc.; SimQuest’s the Burr Hole Training System; and cadaver skulls all offer human-based training methods.<sup>119</sup>

For pediatrics training, CAE Healthcare’s BabySIM is used to teach all three procedures for which HCMC is using live rabbits, including endotracheal intubation, thoracostomy, and intravenous access.<sup>120</sup>

IACUC approval is particularly worrisome since “HCMC already has a state-of-the-art simulation center—the Interdisciplinary Simulation and Education Center—which offers a full range of high-fidelity mannequins and partial task trainers that provide the simulation capabilities to replace the use of animals in the emergency medicine

---

117. *Id.*

118. E-mail from John J. Pippin et al., *supra* note 105.

119. *Id.*

120. *Id.*



residency.”<sup>121</sup>

“The Animal Welfare Act also requires that activities involving animals be designed to ‘assure that discomfort and pain to animals will be limited to that which is unavoidable for the conduct of scientifically valuable research.’”<sup>122</sup> Due to “the widespread availability of validated simulators and the fact that 88 percent of surveyed emergency medicine [residency] programs in the United States do not use animals . . . use of sheep and rabbits is not ‘unavoidable.’”<sup>123</sup> In light of the above, the IACUC is not properly approving or monitoring animal use for HCMC’s program.

#### VI. FUNDING AGENCIES’ “JUST-IN-TIME” POLICIES ENCROACH UPON IACUC AUTHORITY

Federal funding agencies, like the National Institutes of Health (NIH), play an enormous role in medical research being performed in the United States. In fact, “[t]he NIH invests nearly \$32.3 billion annually in medical research.”<sup>124</sup> In 2002, NIH implemented the “Just-in-Time” policy.<sup>125</sup> NIH policy states that “[t]hese procedures allow certain elements of an application to be submitted later in the application process, after review when the application is under consideration for funding.”<sup>126</sup> Given the chronology established through this policy, the IACUC is not given the opportunity to consider alternatives to the use of animals until after NIH has expressed interest in funding the grant. If the IACUC insists on alternatives after NIH has expressed interest in funding, it might threaten the grant. The IACUC is supposed to act as a discretionary body to avoid unnecessary and duplicative animal experiments whenever possible.<sup>127</sup> Policy Number

121. *Id.*

122. *Id.* (quoting 9 C.F.R. § 2.31(e)(4) (2016)).

123. E-mail from John J. Pippin et al., *supra* note 105; *see also Animal Use in Allopathic and Osteopathic (†) Emergency Medicine Residency Programs in the United States: An Ongoing Survey*, PHYSICIANS COMM. FOR RESPONSIBLE MED., <http://www.pcrm.org/research/edtraining/emergency/animal-use-in-emergency-medicine-residency> (last updated Sept. 20, 2016); *Tell Hennepin Medical to End Animal Labs*, PHYSICIANS COMM. FOR RESPONSIBLE MED., <http://www.pcrm.org/research/edtraining/meded/minnesota-deserves-better> (last visited Oct. 20, 2016).

124. *What We Do: Budget*, NAT’L INSTITUTES HEALTH, <https://www.nih.gov/about-nih/what-we-do/budget> (last updated April 4, 2016).

125. Laboratory Animal Welfare, 67 Fed. Reg. 51,289 (Aug. 7, 2002).

126. NAT’L INSTS. OF HEALTH, U.S. DEP’T OF HEALTH & HUM. SERVS., NIH GRANTS POLICY STATEMENT, at I-70 (2015), <http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf>.

127. Throughout the manual, multiple different policies attempt to limit “unnecessary discomfort” in the handling of, or experimentation on, animals. *See* ANIMAL CARE POLICY

Twelve directs that IACUCs should “assess that a reasonable and good faith effort was made to determine the availability of alternatives or alternative methods.”<sup>128</sup> Policy Number Twelve also requests that “the IACUC may and should ask the [principal investigator] to explain why an alternative that had been found was not used.”<sup>129</sup> Policy Number Twelve also states that the IACUC “can withhold approval of the study proposal if [it] is not satisfied with the procedures the [principal investigator] plans to use in his study.”<sup>130</sup> Given that the IACUC is entrusted with the approval of animal usage in research, the IACUC should always be allowed to weigh in *before* any researcher seeks funding. Otherwise, the IACUC’s authority to question the use of animals or suggest an alternative is effectively usurped by the funding agency.

#### CONCLUSION

The failures of Congress, the USDA, the IACUC, research facilities, and funding agencies to implement and enforce the Animal Welfare Act has resulted in the needless use, suffering, and death of animals in experimentation every year. Until Congress, the USDA, the IACUC, research facilities, and funding agencies take responsibility for their respective roles in the implementation and enforcement of the Animal Welfare Act, the original intent will never be fully realized.

---

MANUAL, *supra* note 60, at 5.2, 19.1.

128. *Id.* at 12.2.

129. *Id.*

130. *Id.*