

9-1-1988

## The Improved Standards for Laboratory Animals Act and the Proposed Regulations: A Glimmer of Home In the Battle Against Abusive Animal Research

Robert J. Masonis

Follow this and additional works at: <http://lawdigitalcommons.bc.edu/ealr>

 Part of the [Animal Law Commons](#)

---

### Recommended Citation

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. Env'tl. Aff. L. Rev. 149 (1988), <http://lawdigitalcommons.bc.edu/ealr/vol16/iss1/7>

This Comments is brought to you for free and open access by the Law Journals at Digital Commons @ Boston College Law School. It has been accepted for inclusion in Boston College Environmental Affairs Law Review by an authorized administrator of Digital Commons @ Boston College Law School. For more information, please contact [nick.szydowski@bc.edu](mailto:nick.szydowski@bc.edu).

# THE IMPROVED STANDARDS FOR LABORATORY ANIMALS ACT AND THE PROPOSED REGULATIONS: A GLIMMER OF HOPE IN THE BATTLE AGAINST ABUSIVE ANIMAL RESEARCH

*Robert J. Masonis\**

In the opinion of the [Animal Liberation Front], however, [the researcher] is another egghead engaged in redundant, costly, worthless research: another sadist torturing animals in the name of science . . . . “[The researcher has] been doing the same experiment for fifteen years,” the [ALF] members will be told at their briefing. “[The researcher has] been feeding infected mice brains by stomach tubes into the cats, and then he kills them or lets them die of vomiting, diarrhea, convulsions, and then he either uses their tissue for injection into other animals or disposes of them . . . .” This is not exactly true. In fact, it is false. . . . To the [ALF], it doesn’t matter. Human animals have no right to exploit non-human animals for *any* purpose whatsoever. . . . To the ALF, the world is an animal Auschwitz: the death toll is in the billions.<sup>1</sup>

## I. INTRODUCTION

Few topics in contemporary society evoke more emotion than does the use of animals in biomedical research. The passage quoted above illustrates the fervency with which extremist animal rights groups, such as ALF, embrace their cause. Not all animal welfare organizations are as militant or extreme in their beliefs as ALF. Many organizations seek only the prohibition of animal research where alternatives exist and the minimization of animal suffering when animal experimentation must be conducted. A substantial number

---

\* Articles Editor, 1988-89, BOSTON COLLEGE ENVIRONMENTAL AFFAIRS LAW REVIEW.

<sup>1</sup> Mahurin & Sager, *Inhuman Bondage (Animal Liberation Front)*, ROLLING STONE, March 24, 1988, at 89 [hereinafter *Inhuman Bondage*] (quoting an anonymous ALF member).

of researchers, however, believe that extensive animal experimentation regulation will cripple medical advancement. These researchers are convinced that animal experimentation is the key to remedying the many ailments that plague mankind.<sup>2</sup> Consequently, animal rights proponents often disagree with researchers over how much government regulation is necessary to preserve essential research while also ensuring that laboratory animals are treated humanely.

The Animal Welfare Act (AWA or Act)<sup>3</sup> is the primary federal statute regulating the care and treatment of animals intended for use in biomedical research and experimentation. The scarcity of federal case law<sup>4</sup> addressing the use of laboratory animals in medical research under AWA's provisions does not reflect accurately the intensity of the controversy surrounding both the Act's substance and the United States Department of Agriculture's (USDA) enforcement of AWA's provisions.<sup>5</sup> Both topics have received much attention from commentators over the past decade.<sup>6</sup>

---

<sup>2</sup> "Every single major medical break-through in this century has involved animal experimentation . . . Measles, mumps, chicken-pox vaccines. Open-heart surgery. Virtually every single item that you can think of has been possible because we've been able to use animals." *Id.* at 176 (quoting Dr. Ronald Fayer, Director of the Animal Parasitology Institute).

<sup>3</sup> 7 U.S.C. §§ 2131-2157 (1982 & Supp. IV 1986). The Animal Welfare Act is the short title of the statute that was enacted in 1966, Pub. L. No. 89-544, 80 Stat. 350 (1966), and was amended in 1970, Pub. L. No. 91-579, 84 Stat. 1560 (1970), 1976, Pub. L. No. 94-279, 90 Stat. 417 (1976), and 1985, Pub. L. No. 99-198, 99 Stat. 1645 (1985). 7 U.S.C. § 2131 (1982). See *infra* notes 19-39 and 58-86 and accompanying text for a more detailed description of AWA and its evolution.

<sup>4</sup> *International Primate Protection League v. Institute for Behavioral Research*, 799 F.2d 934 (4th Cir. 1986), *cert. denied*, 107 S.Ct. 1624, *reh'g denied*, 107 S.Ct. 2492 (1987), is one of a few cases where a private party sought judicial review for violations of AWA provisions protecting laboratory animals. Yet, it is the only case where the merits of such a claim have been addressed fully. See *supra* note 142.

<sup>5</sup> Seven U.S.C. § 2143(a) (1982 & Supp. IV 1986) authorizes the Secretary of Agriculture to promulgate regulations pursuant to AWA, which are codified at 9 C.F.R. § 1.1-167.10 (1987). Chapter 7 U.S.C. § 2146(a) (1982 & Supp. IV 1986) authorizes the Secretary of Agriculture to conduct periodic inspections to ensure AWA compliance.

<sup>6</sup> See, e.g., Dresser, *Research on Animals: Values, Politics, and Regulatory Reform*, 58 S. CAL. L. REV. 1147 (1985) (article suggests review processes should be created to enhance the statutory protection afforded to laboratory animals during experimentation); Dukes, *The Improved Standards For Laboratory Animals Act: Will It Ensure That The Policy Of The Animal Welfare Act Becomes A Reality?*, 31 ST. LOUIS U.L.J. 519 (1987) (article criticizes USDA's AWA enforcement effort and advocates passage of a statute authorizing citizen suits to compel USDA to enforce AWA); Rickleen, *The Animal Welfare Act: Still a Cruelty to Animals*, 7 ENVTL. AFF. 129 (1978) (USDA's enforcement effort has failed to provide animals the protections afforded them under AWA); Thomas, *Antinomy: The Use, Rights, and Regulation of Laboratory Animals*, 13 PEPPERDINE L. REV. 723, 752-53 (1986) [hereinafter *Antinomy*] (article argues that AWA should be replaced with new, comprehensive federal legislation affording laboratory animals adequate protection); Note, *They Asked For Protection And They Got Policy: International Primates Mutilated Monkeys*, 21 AKRON L. REV. 97

The passage of the Improved Standards for Laboratory Animals Act (ISLAA) in 1985 and the new regulations proposed by USDA pursuant to ISLAA (Proposed Rules),<sup>7</sup> have fueled the battle between the medical research community seeking scientific autonomy<sup>8</sup> and animal welfare organizations seeking increased protection for laboratory animals used in experimentation. Since the passage of ISLAA, the statutory tide that once favored the research community at the expense of laboratory animal welfare<sup>9</sup> has begun to ebb; laboratory animals are afforded greater protection, while the freedom of research facilities to regulate themselves has been curtailed.<sup>10</sup> Despite the progress made under ISLAA toward striking a more egalitarian balance between the conflicting interests vying for legislative attention,<sup>11</sup> animal welfare organizations maintain a guarded optimism<sup>12</sup> about the prospects for finalizing the USDA-proposed

---

(1987) [hereinafter *Mutilated Monkeys*] (note criticizes the Fourth Circuit's decision in *IPPL*); Comment, *Out From Under The Microscope: A Case For Laboratory Animal Rights*, 2 DET. C.L. REV. 511 (1987) [hereinafter *Out From Under The Microscope*] (comment argues that the post-ISLAA AWA does not protect laboratory animals adequately from abusive research and proposes new, more stringent protective legislation); Comment, *Creating a Private Cause of Action Against Abusive Animal Research*, 134 U. PA. L. REV. 399, 404 (1986) [hereinafter *Creating a Private Cause of Action*] (comment argues that the failure of AWA to provide adequate protection for laboratory animals is attributable to the level of discretion afforded scientists under the Act and inadequate enforcement of AWA provisions); Note, *Use of Animals in Medical Research: The Need for Governmental Regulation*, 24 WAYNE L. REV. 1733 (1978) [hereinafter Note, *Use of Animals*] (note argues that more pervasive regulation is needed to strike the proper balance between the needs of the research community and the care afforded laboratory animals).

<sup>7</sup> 52 Fed. Reg. 10,292, 10,298 (1986) (to be codified at 9 C.F.R. Pts. 1 & 2) (proposed March 31, 1987).

<sup>8</sup> Not all researchers are opposed to regulating the experimentation process. For example, during the congressional hearings on the proposed ISLAA legislation, H.R. 5725, a number of renowned members of the biomedical community expressed their support for the bill. Supporters included: Franklin M. Loew, Dean, School of Veterinary Medicine, Tufts University; Peter D. Wood, D.Sc., Ph.D., Professor of Medicine (Research), Stanford University Medical School Associate Director, Stanford Center for Research in Disease Prevention; and Herbert Rackow, M.D., Diplomate, American Board of Anesthesiology; Professor Emeritus, College of Physicians and Surgeons, Columbia University. *Improved Standards for Laboratory Animals Act; and Enforcement of the Animal Welfare Act by the Animal and Plant Health Inspection Service: Hearings on H.R. 5725 Before the Subcomm. on Department Operations, Research, and Foreign Agriculture, 98th Cong., 2d Sess. (1984)* [hereinafter *ISLAA Hearings*].

<sup>9</sup> Note, *Use of Animals*, *supra* note 6, at 1746; see also *Antinomy*, *supra* note 6, at 742-44 (the pre-1985 AWA does not include freedom from pain nor does it prevent inefficient and unnecessary experimentation).

<sup>10</sup> See H.R. CONF. REP. NO. 447, 99th Cong., 1st Sess., reprinted in 1985 U.S. CODE CONG. & ADMIN. NEWS 2518, 2519.

<sup>11</sup> See *infra* note 213.

<sup>12</sup> Telephone interview with Christine Stevens, Secretary of the Society for Animal Protective Legislation, Washington D.C. (Sept. 30, 1987).

regulations to accompany ISLAA. Substantial pressure applied by researchers on USDA to develop less restrictive regulations has prompted this caution.<sup>13</sup>

This Comment analyzes the progress made by ISLAA toward expanding the protection afforded laboratory animals under AWA. In order to comprehend exactly what ISLAA has accomplished, it is first essential to understand what has transpired over the twenty-two years since AWA was passed in 1966.<sup>14</sup> First, this Comment discusses AWA and its early amendments<sup>15</sup> in light of their legislative histories. Second, this Comment focuses on ISLAA and the accompanying Proposed Rules, in particular the enforcement provisions. The reactions of both the research community (dissatisfaction) and the animal welfare community (enthusiasm) to the legislation and proposed regulations are also discussed. Finally, this Comment evaluates ISLAA's potential effectiveness in balancing the need to continue valuable biomedical research and the humane desire to avoid inflicting unnecessary pain on laboratory animals.

## II. THE ANIMAL WELFARE ACT: FORMATION AND EVOLUTION THROUGH THE 1976 AMENDMENTS

AWA has undergone radical changes since its enactment. Originally established to prevent the theft of household pets,<sup>16</sup> the Act now provides the necessary framework for regulating how laboratories treat research animals, even extending to the research pro-

---

<sup>13</sup> *Id.*; see generally Comments of the National Association for Biomedical Research on Proposed Rules Regarding Definition of Terms and Animal Welfare Regulations (June 31, 1987) (comments to proposed rules at 52 Fed. Reg. 10,292, 10,298 (March 31, 1987)) [hereinafter *NABR Comments*]; Comments of the National Association for Biomedical Research on the Information Collection Provisions of the Proposed Rules Regarding Animal Welfare Regulations (June 31, 1987) (comments to proposed rules at 52 Fed. Reg. 10,298 (March 31, 1987)) [hereinafter *NABR ICP Comments*]; see *infra* notes 104-25 and accompanying text for a more detailed discussion of these comments.

In addition to the research community's opposition, it is evident that the President's Office of Management and Budget (OMB), which must approve the Proposed Rules before they can be finalized, is also dissatisfied with the Proposed Rules in their present form. A recent letter sent by OMB on August 12, 1988, to all federal agencies that use animals, indicates that OMB believes that compliance with the Proposed Rules would be too costly. In the letter, OMB requests feedback from the agencies and specifically asks the agencies to consider whether the Proposed Rules should be repropounded in their *entirety*. Letter from the Society for Animal Protective Legislation (August 24, 1988).

<sup>14</sup> Act of August 24, 1966, Pub. L. No. 89-544, 1966 U.S. CODE CONG. & ADMIN. NEWS (80 Stat.) 400 (codified as amended at 7 U.S.C. §§ 2131-2157 (1982 & Supp. IV 1986)).

<sup>15</sup> "Early amendments" refers to the 1970, Pub. L. No. 91-579, 84 Stat. 1560 (1970) and 1976, Pub. L. No. 94-279, 90 Stat. 417 (1976) amendments to AWA.

<sup>16</sup> See *infra* notes 19-24 and accompanying text.

tocols themselves.<sup>17</sup> This development, however, has not proceeded evenly throughout the twenty-two year history of the Act. AWA regulation of research and experimentation involving animals was not established until the passage of ISLAA. Congress instituted this regulation to insure that animals do not suffer needlessly in the guise of scientific progress.<sup>18</sup> To grasp just how dramatic ISLAA's impact is on the Act's vitality, a brief overview of AWA's evolution is helpful.

Prompted by the need to curb the illicit trade of stolen household pets for use in research facilities,<sup>19</sup> Congress passed the Laboratory Animal Welfare Act (LAWA) in 1966.<sup>20</sup> LAWA was designed to: 1) protect dog and cat owners from the theft of their pets for use in research facilities; 2) prevent the sale or use of stolen dogs and cats in research facilities; and 3) insure that certain animals receive humane care and treatment in research facilities.<sup>21</sup> To achieve those objectives, LAWA required that the Secretary of Agriculture issue licenses to animal dealers only if the dealers complied with LAWA provisions.<sup>22</sup> LAWA also made it unlawful for research facilities to purchase dogs or cats from unlicensed dealers.<sup>23</sup> In addition, LAWA authorized the Secretary to promulgate standards governing the humane handling, care, treatment, and transportation of animals by dealers and research facilities.<sup>24</sup>

Congress limited the Secretary's authority, however, by preventing the Secretary from interfering with the actual research and experimentation<sup>25</sup> conducted within research facilities.<sup>26</sup> Conse-

---

<sup>17</sup> See *infra* notes 58-86 and accompanying text. "Protocol" is defined as "an investigator's plan for the use of animals in a study of a biomedical problem." 52 Fed. Reg. 10,297 (1987).

<sup>18</sup> See *infra* note 61 and accompanying text.

<sup>19</sup> See S. REP. NO. 1281, 89th Cong., 2d Sess., *reprinted in* 1966 U.S. CODE CONG. & ADMIN. NEWS 2635, 2636.

<sup>20</sup> Act of August 24, 1966, Pub. L. No. 89-544 § 1, 80 Stat. 350 (1966). The Act of August 24, 1966, is commonly referred to as the "Laboratory Animal Welfare Act" and will be cited as such throughout this Comment.

<sup>21</sup> *Id.* § 1, 80 Stat. 350.

<sup>22</sup> *Id.* § 3, 80 Stat. 351.

<sup>23</sup> *Id.* § 7, 80 Stat. 351.

<sup>24</sup> *Id.* § 13, 80 Stat. 352.

<sup>25</sup> *Id.* §§ 13, 18, 80 Stat. 352; *see also* S. REP. NO. 1281, 89th Cong., 2d Sess., *reprinted in* 1966 U.S. CODE CONG. & ADMIN. NEWS 2635, 2637 ("[i]t is not the intention of the committee to interfere in any way with research or experimentation").

<sup>26</sup> The statute defines "research facility" as "any school (except an elementary or secondary school), institution, or 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 [federal] funds . . . for the purpose of carrying out research, tests, or experiments. . . ." 7 U.S.C. § 2132(e)(1982).

quently, although LAWA took steps to insure that animals received humane care and treatment prior to experimentation, it was not designed to alleviate the most basic abuses animals experience during experimentation: needless suffering, unnecessarily repetitive experiments, and careless or insensitive treatment by researchers.<sup>27</sup>

The Animal Welfare Act of 1970 (1970 AWA)<sup>28</sup> extended to more species the protection afforded animals under LAWA, while expanding simultaneously the classes of people subject to LAWA's statutory provisions.<sup>29</sup> The 1970 AWA also recognized the need to supply animals covered by the statute with basic necessities by requiring the Secretary of Agriculture to promulgate standards for the provision of "basic creature comforts."<sup>30</sup> In addition, the 1970 AWA increased the Secretary's enforcement powers by increasing penalties against people convicted of interfering with government inspectors, and expanding the discovery procedures for obtaining information.<sup>31</sup> Despite these greater protections, Congress reemphasized the need to keep the actual research and experimentation process free from government interference.<sup>32</sup>

---

<sup>27</sup> See Note, *Use of Animals*, *supra* note 6, at 1740-41.

<sup>28</sup> Animal Welfare Act of 1970, Pub. L. No. 91-579, 84 Stat. 1560 (codified as amended at 7 U.S.C. §§ 2131-2157 (1982 & Supp. IV 1986)).

<sup>29</sup> See H.R. REP. No. 1651, 91st Cong., 2d Sess., *reprinted in* 1970 U.S. CODE CONG. & ADMIN. NEWS 5103, 5104 (the 1970 AWA extended protection to all warm-blooded animals designated by the Secretary with certain exceptions and brought animal exhibitors and wholesale pet dealers into the rubric of regulated classes).

<sup>30</sup> *Id.* at 5104 (basic creature comforts include proper handling, adequate housing, nutrition, sanitation, ventilation, shelter, and veterinary care).

<sup>31</sup> *Id.* at 5105.

<sup>32</sup> *Id.* at 5104. "The bill in no manner authorizes the disruption or interference with scientific research or experimentation. Under this bill the research scientist still holds the key to the laboratory door." *Id.*

Congressional reluctance to expand animal protection measures to the experimentation process reflects a fear that laboratory regulations will disrupt and stymie biomedical research that benefits both humans and animals. Consider the statement of Rep. Montgomery in support of the 1970 AWA: "The important point to be made is that we are not tying the hands of researchers who are working with animals daily to unlock the secrets of dread diseases." 116 CONG. REC. 40,156 (1970). If research utilizing laboratory animals is the only means of obtaining specific types of medical advancements, then the urgency to maintain such essential research is acutely felt.

Tremendous technological improvements have occurred, however, over the past few decades. Consequently, alternatives to animal experimentation exist today that were not available twenty years ago. For example, consider the following statement. "Many of the presently available alternative techniques are more reliable and more time and cost effective than the traditional methods. Animal tests for carcinogens can take three and a half years and a half million dollars to complete. Use of comprehensive non-animal alternatives would provide identical protection and take only three months at a cost of only \$25,000." *ISLAA Hearings*, *supra* note 8, at 144 (statement of John E. McArdle, Director, Laboratory Animal Welfare,

In enacting the Animal Welfare Act Amendments of 1976 (1976 Amendments),<sup>33</sup> Congress targeted animal treatment during transportation and the use of animals in animal fights.<sup>34</sup> The 1976 Amendments extended AWA to cover intermediate handlers and carriers who were not covered under prior AWA provisions.<sup>35</sup> The 1976 Amendments also established a criminal penalty for persons involved with animal fighting.<sup>36</sup> In addition, the 1976 Amendments established uniform civil penalties for any AWA violation.<sup>37</sup>

Even though the 1976 Amendments declared for the first time a congressional intention to provide humane care and treatment for research animals,<sup>38</sup> Congress did not express a willingness to open up the research and experimentation process to government regulation. In fact, Congress reiterated that decisions regarding animal experimentation were exclusively the province of research facilities.<sup>39</sup>

After the 1976 Amendments, AWA was not amended again until ISLAA was enacted in 1985. The early AWA legislation was beneficial because it established federal regulations governing the pre-experimentation care of research animals. Prior to 1985, AWA's most glaring substantive deficiency was its failure to shield animals from abuse suffered in the experimentation process.<sup>40</sup> Research protocols were insulated from external review. Any regulation of animal treatment within the laboratory was the sole prerogative of the research facility.<sup>41</sup>

---

the Humane Society of the United States). Thus, requiring researchers to consider alternatives to animal experimentation has multiple benefits. First, it prevents the unnecessary infliction of pain on research animals. Second, it hastens biomedical progress by forcing researchers to consider alternative methods that may be more efficient, accurate, and cost effective than animal experimentation.

<sup>33</sup> Animal Welfare Act Amendments of 1976, Pub. L. No. 94-279, 90 Stat. 417 (codified as amended at 7 U.S.C. §§ 2131-2157 (1982 & Supp. IV 1986)).

<sup>34</sup> See H.R. REP. NO. 801, 94th Cong., 2d Sess., reprinted in 1976 U.S. CODE CONG. & ADMIN. NEWS 758, 759.

<sup>35</sup> 7 U.S.C. § 2132(i),(j) (1976).

<sup>36</sup> *Id.* § 2156(e).

<sup>37</sup> *Id.* § 2149(b).

<sup>38</sup> *Id.* § 2131. "[R]egulation of animals and activities as provided in this Act is necessary . . . to insure that animals intended for use in research facilities or for exhibition purposes or for use as pets are provided humane care and treatment." *Id.*

<sup>39</sup> *Id.* § 2143(a). "Nothing in this chapter shall be construed as authorizing the Secretary to promulgate rules, regulations, or orders with regard to design, outlines, guidelines, or performance of actual research or experimentation by a research facility as determined by such research facility." *Id.*

<sup>40</sup> See Dresser, *supra* note 6, at 1162.

<sup>41</sup> The Secretary of Agriculture was only authorized to promulgate standards requiring the



From an animal welfare perspective, congressional reluctance toward granting USDA the power to regulate research protocols was not the only deficiency limiting the legislation's effectiveness. Enforcement of AWA has been suspect since its inception.<sup>42</sup> The Animal and Plant Health Inspection Service (APHIS) is the USDA agency that administers AWA. From 1968 through 1980, there were only three criminal prosecutions against AWA violators and only 122 completed administrative prosecutions.<sup>43</sup> An earlier study of prosecutions conducted during the first decade of AWA's existence revealed that even when violators were prosecuted, there were substantial time lags between discovery of the violations and their resolution.<sup>44</sup>

A 1985 General Accounting Office (GAO) report analyzed USDA's Animal Welfare Program.<sup>45</sup> The report revealed some of the major difficulties APHIS encountered when implementing AWA. These difficulties included the following: 1) APHIS inspectors spent a minimal amount of time conducting AWA inspections because of the numerous programs APHIS administers;<sup>46</sup> 2) APHIS personnel indicated that four inspections per site per year was the optimal inspection level,<sup>47</sup> however, research facilities in the six states studied

---

appropriate use of anesthetic, analgesic, or tranquilizing drugs, when the use of such drugs is proper in the opinion of the attending veterinarian at research facilities. 7 U.S.C. § 2143(a) (1976).

<sup>42</sup> See *infra* note 44 and accompanying text.

<sup>43</sup> Animal and Plant Health Inspection Service, United States Dep't. of Agriculture, Prosecutions for Animal Welfare Violations 1968-1980 *passim* (December 1980). Twenty-eight administrative prosecutions were started by October 1, 1980 but had not been completed at the time of the study. *Id.* at 19.

<sup>44</sup> See Rickleen, *supra* note 6, at 137-40 for a more detailed description of enforcement inadequacies from 1966-1976. It should be noted, however, that in the two years prior to ISLAA, the number of completed prosecutions increased dramatically over previous years. In 1980 and 1981 there were 20 and 23 cases closed by prosecution, respectively. In contrast, there were 50 and 45 cases closed by prosecution in 1983 and 1984. Cf. Animal Plant and Health Inspection Service, United States Dep't. of Agriculture, Animal Welfare Enforcement Report, Fiscal Years 1980, 1981, 1983, and 1984.

<sup>45</sup> The Dep't. of Agriculture's Animal Welfare Program, Document No. RCED-85-8 (May 16, 1985) [hereinafter *GAO Report*] (audit by the U.S. General Accounting Office). The report studied the APHIS Animal Welfare Program which implements the USDA regulations, 9 C.F.R. §§ 1.1-12.10 (1987), under AWA. The GAO report focused on six APHIS area offices in California, Iowa, Kansas, Missouri, New York, and Texas. *GAO Report* at ii.

<sup>46</sup> During fiscal year 1983, the year of the study, 13.4% of inspector time was devoted to AWA inspections. The amount of time allocated to AWA inspections, however, varied from state to state. For example, California inspectors spent 5.7% of their time while Kansas inspectors spent 25.9% of their time conducting AWA inspections. *Id.* at 7; see also *infra* note 51 and accompanying text.

<sup>47</sup> *GAO Report*, *supra* note 45, at 21.

were inspected an average of .82 times in 1983;<sup>48</sup> and 3) the training of APHIS inspectors was considered inadequate by approximately half of the APHIS regional and area office officials interviewed, and some inspectors also found their training to be inadequate while others expressed reservations about their training.<sup>49</sup>

USDA emphasized to the GAO that the primary reason for inadequate training and infrequent inspections was insufficient funding of the Animal Welfare Program.<sup>50</sup> APHIS administers nineteen animal health programs including the Animal Welfare Program which was allotted only 2.8 percent of USDA's 1983 funds.<sup>51</sup> USDA requested program funding cuts in 1983, 1984, and 1985, and proposed that the program be eliminated in 1986.<sup>52</sup> USDA supported these cuts claiming that: 1) the states, industry, humane societies, and individuals should be the principal enforcers of the animal welfare regulations; and 2) USDA fiscal constraints necessitated resource concentration on areas that protect agriculture from pests and diseases.<sup>53</sup> GAO concluded that if Congress decided to continue to fund AWA enforcement, it should consider allowing USDA to recover more of the cost from the regulated parties.<sup>54</sup>

The difficulties APHIS experienced in administering the Animal Welfare Program were not surprising. The Office of the Secretary of Agriculture expressed its reluctance concerning USDA's enforcement responsibilities during the original enactment of LAWA, and during the subsequent amendments in both 1970 and 1976.<sup>55</sup> The

---

<sup>48</sup> *Id.* at 20. The average of .82 inspections per research facility in 1983 is misleading. Statistics for the two states with substantially more research facilities than the other four, New York and California, revealed that 50% of New York research facilities and 52.4% of California research facilities were not inspected in 1983. *Id.* at 45-46.

<sup>49</sup> *Id.* at 16-17. In fiscal year 1983, an average of .56 staff days were allocated to formal inspector training at the six area offices. *Id.* at 8.

<sup>50</sup> *Id.* at 33.

<sup>51</sup> *Id.*

<sup>52</sup> *Id.* at 3.

<sup>53</sup> *Id.* In its fiscal year 1981 plans, however, APHIS projected a request for increased funding for 1982-87 hoping to increase inspection frequency to six times per year at all licensees and registrants except for carriers and dealers where 36 inspections per year was the goal. APHIS stated that this was the desired inspection level for an effective enforcement program. *Id.* at 21. USDA's apparently contradictory stances regarding the Animal Welfare Program's funding were basically the result of "Reaganomics." According to one APHIS veterinarian, USDA's request for funding cuts in 1983 was a manifestation of the Reagan Administration's general policy to shift the burden of administering various programs from the federal government to the states. Telephone interview with Dr. William Smith, Veterinarian in Charge of the APHIS New England Area Office, Waltham, MA (March 7, 1988).

<sup>54</sup> *GAO Report, supra* note 45, at 33.

<sup>55</sup> See Letter from Secretary of the United States Department of Agriculture (USDA), as

GAO report indicates that USDA's enforcement difficulties were an inevitable consequence of an overburdened governmental agency, tackling responsibilities it was ill-equipped to handle. The APHIS enforcement effort prior to ISLAA was understaffed, underfunded, and without adequate knowledge to carry out productive inspections.<sup>56</sup> Others, however, believe that USDA's unwillingness to enforce AWA was a prominent factor in the agency's shortcomings.<sup>57</sup>

Against this background of limited regulatory authority and minimal enforcement, ISLAA arose.<sup>58</sup> ISLAA expanded USDA's regulatory authority and provided a new enforcement scheme to aid APHIS in administering the Act.

### III. THE IMPROVED STANDARDS FOR LABORATORY ANIMALS ACT

On December 23, 1985, Congress took a major step toward rectifying AWA's inadequacies by enacting ISLAA. ISLAA's passage marked the fruition of a two-year legislative effort to provide laboratory animals increased protection from abusive research.<sup>59</sup> ISLAA attempts to balance the needs of the biomedical research community and the public concern for the humane treatment of laboratory animals.<sup>60</sup> ISLAA, for the first time in AWA's twenty-two year history, seeks to limit the amount of pain and distress animals suffer during the actual experimentation process.<sup>61</sup>

---

*contained in S. REP. NO. 1281, supra note 19, at 2642-43 ("Accordingly, there is a question as to whether it would be desirable that a law such as that in question be administered by a Federal agency more directly concerned and having greater expertise with respect to the subject than this Department."); Letter from the Office of the Secretary of USDA, as contained in H.R. REP. NO. 1651, supra note 29, at 5105-06 ("This Department agrees with the objective of the bill . . . However, we believe that the Department of Health, Education, and Welfare is the appropriate agency to administer such an activity."); Letter from the Office of the Secretary of USDA, as contained in H.R. REP. NO. 801, supra note 34, at 766-67. ("There are available alternative measures which can achieve many of the objectives of the bill. These alternatives should be fully explored and tested before any additional legislative action is taken.")*

<sup>56</sup> Dresser, *supra* note 6, at 1162-63.

<sup>57</sup> Dukes, *supra* note 6, at 525-27; Rickleen, *supra* note 6, at 141 (USDA's poor enforcement record manifests the agency's attitudes and priorities regarding AWA).

<sup>58</sup> Food Security Act of 1985, Pub. L. No. 99-198, §§ 1751-59, 99 Stat. 1645 (1985) (codified in relevant part at 7 U.S.C. §§ 2131-2157 (Supp. IV 1986)).

<sup>59</sup> Senator Dole and Congressman Brown initially introduced two bills in their respective houses. S. 657, 98th Cong., 1st Sess., 129 CONG. REC. 2013 (1983) and H.R. 5725, 98th Cong. 2d Sess., 130 CONG. REC. 2453 (1984). These bills eventually resulted in ISLAA to AWA which became law in the Food Security Act of 1985. See Reagan, *Federal Regulation of Testing with Laboratory Animals: Future Decisions*, 3 PACE ENVTL. L. REV. 165, 169-70 n.25 (1986) for a more detailed analysis of ISLAA legislative history.

<sup>60</sup> 7 U.S.C. § 2131 (Supp. IV 1986).

<sup>61</sup> *Id.* § 2143(a)(3)(A).

To ensure minimal animal pain during experimentation procedures,<sup>62</sup> Congress directed the Secretary to promulgate requirements for: 1) the use of anesthetics, analgesics, tranquilizing drugs, and euthanasia when appropriate;<sup>63</sup> 2) the consideration by the principal investigator of alternative research practices if an animal will suffer pain or distress;<sup>64</sup> 3) the consultation with a veterinarian in planning research protocols that could cause pain to animals;<sup>65</sup> and 4) the use of animals in only one major operation, from which they are allowed to recover, unless it is a scientific necessity, or the Secretary deems that special circumstances require that further research be conducted.<sup>66</sup>

ISLAA directs the Secretary to require each facility to submit reports, at least annually, to verify facility compliance with the ISLAA provisions set forth above.<sup>67</sup> These reports must contain: 1) information of pain-producing procedures and assurances that the principle investigator considered alternatives;<sup>68</sup> 2) assurances of compliance with the provisions of ISLAA section 2143;<sup>69</sup> and 3) explanations for deviations from the prescribed standards.<sup>70</sup>

ISLAA also created an internal review mechanism known as an Institutional Animal Care and Use Committee (IACUC or Committee) which is responsible for representing society's concerns for the welfare of laboratory animals.<sup>71</sup> Each facility covered by AWA must have at least one IACUC.<sup>72</sup> The Committee must consist of at least three members appointed by the chief executive officer of each research facility.<sup>73</sup> Of these Committee members, at least one must be a veterinarian,<sup>74</sup> and at least one cannot be connected with the research facility and should provide representation of the general community's interest in animal welfare.<sup>75</sup>

IACUCs must conduct at least semi-annual inspections of research facilities<sup>76</sup> and submit a certification report for each inspection

---

<sup>62</sup> *Id.* § 2143(a)(3).

<sup>63</sup> *Id.* § 2143(a)(3)(A).

<sup>64</sup> *Id.* § 2143(a)(3)(B).

<sup>65</sup> *Id.* § 2143(a)(3)(C).

<sup>66</sup> *Id.* § 2143(a)(3)(D).

<sup>67</sup> *Id.* § 2143(a)(7)(A).

<sup>68</sup> *Id.* § 2143(a)(7)(B)(i).

<sup>69</sup> *Id.* § 2143(a)(7)(B)(ii).

<sup>70</sup> *Id.* § 2143(a)(7)(B)(iii).

<sup>71</sup> *Id.* § 2143(b)(1) ("committee" is defined in § 2143(n)).

<sup>72</sup> *Id.*

<sup>73</sup> *Id.*

<sup>74</sup> *Id.* § 2143(b)(1)(A).

<sup>75</sup> *Id.* § 2143(b)(1)(B).

<sup>76</sup> *Id.* § 2143(b)(3).

made.<sup>77</sup> The reports must include: 1) the signatures of a majority of the IACUC members;<sup>78</sup> 2) any violations of standards and deviations from approved protocols that adversely affected animal welfare;<sup>79</sup> and 3) minority views of the Committee members.<sup>80</sup> If any violations of ISLAA's provisions are found during an inspection, the IACUC will notify the facility to allow for corrective action.<sup>81</sup> If the research facility fails to take corrective action, the Committee will notify APHIS and the federal agency funding the research.<sup>82</sup> For federal research facilities, a federal committee will be appointed to carry out the same functions as the IACUCs. The federal committee must report any deficiencies to the head of the agency conducting the research who is then responsible for corrective measures.<sup>83</sup>

To augment the animal protection measures, ISLAA provides training for facility personnel on how to provide better animal care.<sup>84</sup> ISLAA also established an information service at the National Agricultural Library to aid in such employee training.<sup>85</sup> Furthermore, ISLAA increases the civil penalties for AWA violations by research facilities.<sup>86</sup>

In accordance with ISLAA mandates, the Secretary of Agriculture proposed revised regulations, the Proposed Rules, to incorporate

---

<sup>77</sup> *Id.* § 2143(b)(4)(A).

<sup>78</sup> *Id.* § 2143(b)(4)(A)(i).

<sup>79</sup> *Id.* § 2143(b)(4)(A)(ii).

<sup>80</sup> *Id.* § 2143(b)(4)(A)(iii). Requiring IACUCs to set forth minority views in inspection reports is an extremely important provision. It provides a check against unlimited Committee discretion regarding the content of inspection reports. APHIS personnel, pursuant to ISLAA section 2143(b)(5), are afforded the opportunity to review the inspection reports. Minority views preserved in the reports enable APHIS personnel to review Committee assessments from a variety of perspectives. If legitimate concerns expressed by a minority of Committee members are ignored by the majority, the inspection reports will notify APHIS of such concerns.

If Committee non-compliance with AWA and the Proposed Rules is established, the question remains about how to address the problem. Neither AWA nor the Proposed Rules define a remedial procedure to correct Committee irresponsiveness. Congress should close this loophole by authorizing the Secretary to replace, or compel research facilities to replace, Committee members who persistently approve facility actions that, in USDA's view, violate AWA. The necessity for such a removal mechanism becomes even more apparent when one considers the potential problems with IACUC composition discussed *infra* notes 208-11 and the accompanying text.

<sup>81</sup> *Id.* § 2143(b)(4)(C).

<sup>82</sup> *Id.*

<sup>83</sup> *Id.* § 2143(c).

<sup>84</sup> *Id.* § 2143(d).

<sup>85</sup> *Id.* § 2143(e).

<sup>86</sup> *Id.* § 2149(b). Civil penalties were increased to a maximum of \$2,500 for an AWA violation and \$1,500 for failure to obey a cease and desist order. Each day an AWA violation or failure to obey a cease and desist order continues is considered a separate violation. *Id.*

the ISLAA requirements.<sup>87</sup> APHIS clearly states in the Proposed Rules that both ISLAA and weak past and present enforcement efforts demand stronger requirements and more specific responsibilities for each IACUC to ensure that animals receive humane care and treatment in research facilities.<sup>88</sup> The Proposed Rules thus require Committee review of all pain-inflicting protocols and the condition of the animals exposed to such treatment.<sup>89</sup> ISLAA has two exceptions to research areas subject to Committee inspection: where animals are studied in their natural environments and where the study areas are not readily accessible.<sup>90</sup> The Proposed Rules, however, would require that requests for exceptions be made specifying why the inspection should not be conducted.<sup>91</sup>

An important addition to the current regulations would require Committee approval of pain-inflicting research protocols used on warm-blooded animals prior to the actual experimentation.<sup>92</sup> In addition, the Committee cannot approve pain-inflicting research protocols where the pain is not dissipated, unless the Committee, after evaluating the researcher's justification, deems that such procedures are scientifically necessary.<sup>93</sup> Before any protocol approval, the IACUC must require assurance from the principal investigator that: 1) alternatives were considered; 2) the experiment is necessary; 3) pain-relieving drugs will be administered properly according to the attending veterinarian; 4) appropriate post- and pre-surgical care will be administered; and 5) aseptic surgery will be properly conducted.<sup>94</sup>

The Secretary also proposed a new section<sup>95</sup> to the Animal Welfare Regulations to provide for better veterinary care at research facilities.<sup>96</sup> The inability of attending veterinarians to inspect research areas properly under the current regulations prompted this addition.<sup>97</sup> The new section would require the IACUC's attending veter-

---

<sup>87</sup> 52 Fed. Reg. 10,292 (1987) (to be codified at 9 C.F.R. Pts. 1 & 2) (proposed March 31, 1987).

<sup>88</sup> *Id.* at 10,301.

<sup>89</sup> *Id.*

<sup>90</sup> 7 U.S.C. § 2143(b)(3)(B) (Supp. IV 1986).

<sup>91</sup> 52 Fed. Reg. 10,301 (1987), *supra* note 87.

<sup>92</sup> *Id.* at 10,302.

<sup>93</sup> *Id.*

<sup>94</sup> *Id.*

<sup>95</sup> *Id.* at 10,303. The new section (§ 2.40) is entitled "Attending Veterinarian and Adequate Veterinary Care" and replaces duplicative sections in 9 C.F.R. Part 3.

<sup>96</sup> 52 Fed. Reg. 10,303, *supra* note 87.

<sup>97</sup> *Id.* (APHIS was informed by attending veterinarians that they were denied access to

inarian to provide consultation and guidance in planning protocols and in conducting experiments to ensure that animal welfare is safeguarded.<sup>98</sup>

Finally, it is important to realize that AWA, since its enactment in 1966, had stated that “[n]othing in this chapter shall be construed as authorizing the Secretary to promulgate rules, regulations or orders with regard to design, outlines, guidelines, or performance of actual research or experimentation by a research facility as determined by such research facility.”<sup>99</sup> That statement was modified in ISLAA which now directs the Secretary to regulate the experimentation process<sup>100</sup> within certain limits specified in the statute.<sup>101</sup> Consequently, the Proposed Rules contain a new proviso stating: “exceptions . . . to the standards [promulgated pursuant to the ISLAA mandates in section 2143] may be made for research facilities only when such exceptions are specified in the research protocol; are explained in detail; and are approved by the Committee.”<sup>102</sup> USDA believes that this new proviso reflects congressional determinations regarding the desired level of research regulation.<sup>103</sup>

ISLAA and the Proposed Rules indicate that both Congress and USDA realized AWA needed a substantial revision if animal experimentation under AWA is to be conducted humanely. Prior to ISLAA, researchers were free to disregard the pain they inflicted on laboratory animals during experimentation. Under ISLAA and the Proposed Rules, such insensitivity will not go unchecked. Response to the Proposed Rules, however, has not been entirely supportive. The research community has voiced concern that the Proposed Rules, if implemented, would significantly impede valuable biomedical research.

#### IV. RESPONSE TO THE PROPOSED RULES

##### A. *The Research Community's Response*

The National Association for Biomedical Research (NABR) submitted comments to USDA regarding the Proposed Rules on June

---

research sites and were pressured to accept the veterinary care being provided even if it was inadequate).

<sup>98</sup> *Id.* at 10,304.

<sup>99</sup> 7 U.S.C. § 2143(a) (1982).

<sup>100</sup> 7 U.S.C. § 2143(a)(3) (Supp. IV 1986). See *supra* notes 63–66 and accompanying text for a more detailed discussion of the Secretary's regulatory authority.

<sup>101</sup> 7 U.S.C. § 2143(a)(6) (Supp. IV 1986).

<sup>102</sup> *Id.* at 10,305.

<sup>103</sup> *Id.*

30, 1987.<sup>104</sup> The NABR Comments reveal the research community's immediate concern and disappointment with the Proposed Rules. NABR disagrees with the Proposed Rules on several major points. First, NABR believes that the Proposed Rules are not an accurate reflection of congressional intent, and go beyond the statutory authority of ISLAA.<sup>105</sup> Specifically, NABR is concerned with: 1) the review and approval of research protocols; 2) the categories of research use animals; 3) USDA's delegation of enforcement responsibility to the IACUCs and the attending veterinarians; and 4) the procedures whereby facility employees report alleged deficiencies to APHIS.<sup>106</sup> NABR alleges that the Secretary, in proposing the new regulations, exceeded his authority and created new law instead of carrying out the congressional intent embodied in ISLAA.<sup>107</sup>

Second, NABR contends that USDA failed to demonstrate how the agency record supports the Proposed Rules.<sup>108</sup> According to NABR, USDA assertions substantiating many of its "expansive intrusions" are unsupported by fact, lack citation to the appropriate statutory sections justifying their creation, and lack adequate references to ISLAA's legislative history.<sup>109</sup> In addition, NABR claims that many of the proposals, founded on a factual basis, fail to reveal how they would remedy the problems at hand.<sup>110</sup>

Third, NABR argues that the Proposed Rules do not permit the "flexibility and innovation" essential to ensure laboratory animal welfare and instead impermissibly interfere with research.<sup>111</sup> NABR asserts that, in promulgating the Proposed Rules, the Secretary failed to limit interference with research and experimentation to the extent required by ISLAA.<sup>112</sup> Supporting this contention, NABR

---

<sup>104</sup> See *NABR Comments*, *supra* note 13. NABR defines itself as "a non-profit organization of more than 300 institutions—universities, medical and veterinary schools, teaching hospitals, academic and professional societies, voluntary health organizations, pharmaceutical, laboratory, animal breeder and other related research-related companies—all intimately involved in essential biomedical research, safety testing and education which, of necessity, require the use of laboratory animals." *Id.* at 1.

<sup>105</sup> *Id.* at 18–22.

<sup>106</sup> *Id.* at 20–21.

<sup>107</sup> *Id.* at 22.

<sup>108</sup> *Id.* In support of its assertion, NABR cites *Bowen v. American Hosp. Ass'n*, 476 U.S. 610, 621 (1986) which states that there must be a "rational connection" between the facts justifying agency action and the action taken.

<sup>109</sup> *Id.* at 23.

<sup>110</sup> *Id.* at 23–24. APHIS addressed this allegation in part, however, when it sent evidentiary documentation supporting the Proposed Rules to NABR on June 18, 1987, pursuant to NABR's Freedom of Information Act request. *Id.* at 24.

<sup>111</sup> *Id.*

<sup>112</sup> *Id.* at 27–28.



states that prior versions of the legislation, granting the Secretary much broader regulatory power, were amended to contain the compromise language of section 2143(a)(6) of ISLAA.<sup>113</sup> Section 2143(a)(6) precludes the Secretary from regulating research beyond specific areas designated in ISLAA.<sup>114</sup> Consequently, NABR claims that the Proposed Rules' sweeping regulations are inconsistent with ISLAA's legislative history and concise language.<sup>115</sup>

Fourth, NABR insists that the Proposed Rules are inconsistent with the Public Health Service (PHS) requirements.<sup>116</sup> According to NABR, these inconsistencies include: 1) what constitutes review and approval of research protocols; 2) the scope and basis of IACUC inspections; 3) the IACUC's and attending veterinarian's responsibilities to the research facility; and 4) the definition of "painful procedure."<sup>117</sup> In accordance with congressional intent,<sup>118</sup> NABR requests that the Secretary of Agriculture coordinate with the Secretary of Health and Human Services to ensure that the codified rules maintain consistency with PHS regulations.<sup>119</sup> Such consistency is appropriate because over half of the research facilities subject to AWA's provisions must also comply with PHS policy.<sup>120</sup>

Fifth, cited "as perhaps the most disturbing aspect" of the Proposed Rules, is the extent of the enforcement authority given to the

<sup>113</sup> *Id.* at 26-27.

<sup>114</sup> 7 U.S.C. § 2143(a)(6) (Supp. IV 1986).

<sup>115</sup> *NABR Comments*, *supra* note 13, at 24-28 (specific NABR objections are set forth in § III(c) of the *NABR Comments*).

<sup>116</sup> *See id.* at 28. The Public Health Service (PHS) also funds research which utilizes laboratory animals. PHS has its own requirements regarding the humane treatment of laboratory animals which must be met by those facilities receiving PHS funding. *See generally* The National Institutes of Health, Department of Health and Human Services, Guide for the Care and Use of Laboratory Animals, Publication No. 85-23 (1985); Public Health Service Policy on Humane Care and Use of Laboratory Animals (Sept. 1986) (setting forth PHS policy and requirements).

<sup>117</sup> *NABR Comments*, *supra* note 13, at 29. The National Institutes of Health (NIH) utilizes IACUCs to police NIH guidelines. The Health Research Extension Act of 1985, Pub. L. No. 99-158, 99 Stat. 820 (codified at 42 U.S.C. § 201 (1982 & Supp. III 1985)), expanded the role of IACUCs in implementing PHS policy. *See* 42 U.S.C. § 289d(b) (Supp. III 1985), for the IACUC statutory requirements.

IACUC composition and responsibility under the Health Research Extension Act and ISLAA are basically consistent. Compare NIH requirements in the Public Health Service Policy on Humane Care and Use of Laboratory Animals at 5-9 (Sept. 1986), with USDA IACUC requirements, 52 Fed. Reg. 10,312-15 (1987) (proposed March 31, 1987).

<sup>118</sup> H.R. CONF. REP. NO. 447, 99th Cong., 1st Sess., 598 (1985), *reprinted in* 1985 U.S. CODE CONG. & ADMIN. NEWS 2524 ("it is hoped that the agencies continue an open communication to avoid conflicting regulations wherever possible").

<sup>119</sup> *See NABR Comments*, *supra* note 13, at 30.

<sup>120</sup> *Id.*

IACUCs and the attending veterinarians.<sup>121</sup> NABR questions the validity of allocating to private individuals the direct responsibility of carrying out USDA enforcement efforts under AWA.<sup>122</sup> NABR contends that the proper role of IACUCs is not to function as agents of the federal government but as agents of the research facilities which, in most instances, possess an employer/employee relationship with the Committee members.<sup>123</sup>

Beyond these primary points of contention with the enforcement provisions of the Proposed Rules, NABR claims that the record-keeping requirements are too costly and unnecessarily burdensome on the research community.<sup>124</sup> Furthermore, NABR asserts that the overall cost of compliance with the regulations would: 1) delay research progress; 2) erode the competitive position of American research in the world market; 3) shift the scientific and trade strength from the United States to foreign countries; and 4) result in the divergence of funds previously allocated to research endeavors to the absorption of costs associated with administering the Proposed Rules.<sup>125</sup>

NABR, in short, believes that the Proposed Rules, if implemented, would have a detrimental impact on biomedical research. NABR claims that USDA surpassed congressional intent by estab-

---

<sup>121</sup> *Id.* at 30-33. NABR contended that under the Proposed Rules, Committee involvement interjects APHIS into the research facility's decision-making process, *id.* at 31, and attending veterinarians serve as deputized 24-hour inspectors. *Id.* at 33.

Conversely, some researchers say that, at least in a university setting, internal review committees are necessary to assure the humane treatment of laboratory animals. Dr. Herbert Rackow pointed out that a study entitled "Whistleblowing in Biomedical Research" (1981), revealed the need for internal review.

"It points out that scientists in a university setting are under pressure to produce results and justify more money for more research. Promotion, tenure, salary, laboratory space and help, travel, and other professional prerequisites depend upon research productivity. There is a strong conflict of interest that may affect even the best persons. The university system of governance grants almost complete autonomy to departments and individual scientists . . . . If these considerations concerning research on human subjects are valid, then the need for protection is even greater when the subjects are animals."

*ISLAA Hearings*, *supra* note 8, at 98-99 (statement of Herbert Rackow, M.D., Diplomate, American Board of Anesthesiology; Professor Emeritus, College of Physicians and Surgeons, Columbia University; Representing Scientists Group for Reform of Animal Experimentation).

<sup>122</sup> *Id.* at 31.

<sup>123</sup> *Id.* at 35.

<sup>124</sup> See *NABR ICP Comments*, *supra* note 13, *passim*.

<sup>125</sup> See NABR study entitled *Economic Impact of Animal Welfare Regulation on Biomedical Innovation, Research and Development*, 9 (June, 1987). The Association estimates that the cost to the research community of implementing the Proposed Rules would reach \$144 million. *Id.*

lishing regulatory measures not explicitly warranted by ISLAA.<sup>126</sup> NABR's primary concern, however, involves the IACUC's and the attending veterinarian's enforcement authority pursuant to the Proposed Rules.<sup>127</sup> NABR perceives such authority as an unreasonable usurpation of researcher autonomy.<sup>128</sup>

### *B. The Animal Welfare Community's Response*

In stark contrast to NABR's position, organizations advocating increased protection for laboratory animals applauded the USDA's Proposed Rules which, in their view, take a large step toward providing an effective safeguard for laboratory animal welfare.<sup>129</sup> Though the Comments submitted by the Animal Legal Defense Fund (ALDF) support the USDA's strong stance in the Proposed Rules, ALDF believes that ISLAA grants the agency even greater freedom to require stricter compliance standards.<sup>130</sup>

For example, ALDF recommended additions to the Proposed Rules in several areas. ALDF suggested that the Proposed Rules include rats, mice, and birds in the definition of "animal," thereby affording them AWA protection.<sup>131</sup> ALDF believed that the annual reports which research facilities submit to USDA should be more exacting to ensure facility compliance.<sup>132</sup> ALDF also advocated the

---

<sup>126</sup> See *supra* notes 112-15 and accompanying text.

<sup>127</sup> See *supra* notes 121-22 and accompanying text.

<sup>128</sup> *NABR Comments, supra* note 13, at 31. Requiring IACUC approval of pain-inflicting protocols "effectively interjects APHIS into the decision-making process of the facility itself, since APHIS can dictate the procedures which require enhanced scrutiny." *Id.*

<sup>129</sup> See Animal Legal Defense Fund Comments on the U.S. Department of Agriculture's Proposed Rules to Implement the 1985 Amendments to the Animal Welfare Act, at 27 (June 26, 1987) [hereinafter *ALDF Comments*] ("ALDF commends the USDA for its foresight in promulgating rules which aggressively seek to further the intent of Congress in its passage of the [ISLAA]"); see also Letter from Christine Stevens of the Society for Animal Protective Legislation to USDA (May 22, 1987) ("The serious and thorough work accomplished in the writing of the proposed regulations, . . . deserves high commendation."); Letter from Dennis J. White of the American Humane Society to USDA (June 15, 1987) (the Proposed Rules reflect deep thought and hard work . . . those who drafted the proposal should be complimented).

<sup>130</sup> Letter from Joyce Tischler, Executive Director of ALDF, to Dr. Crawford of APHIS (June 26, 1987) (contained in *ALDF Comments, supra* note 129).

<sup>131</sup> *Id.* at 2. "The term 'animal' means any live or dead dog, cat, monkey (non-human primate mammal), guinea pig, hamster, rabbit, or such other warm-blooded animal, as the Secretary may determine is being used, or is intended for use, for research, testing, experimentation . . ." 7 U.S.C. § 2132(g) (1982).

<sup>132</sup> *ALDF Comments, supra* note 129, at 8-10. ALDF asserted that the current form used for annual reports allows researchers to summarize their actions without providing explanations. ALDF studied a number of research projects in fiscal year 1984 and discovered that a number of experiments that would be considered "painful" under section 2.35 of the Proposed

following changes in IACUC composition and duties: 1) all research protocols should be subject to Committee review;<sup>133</sup> 2) the number of non-affiliated members should remain proportionate to the total size of the IACUC;<sup>134</sup> 3) no person who has engaged in research using animal subjects should serve as a non-affiliated Committee member;<sup>135</sup> 4) a non-affiliated member should be appointed through a formal mechanism;<sup>136</sup> and 5) the IACUC should have the power to suspend activity not in accordance with the Act.<sup>137</sup>

In addition, the Society for Animal Protective Legislation and the Michigan Humane Society submitted replies to USDA regarding NABR's Comments.<sup>138</sup> The apparent purpose of the replies was to reinforce the organizations' support for the Proposed Rules and to thwart NABR's efforts to persuade USDA to promulgate less intrusive regulations.

#### V. PRIVATE CAUSES OF ACTION: AN INVIABLE ALTERNATIVE TO ADMINISTRATIVE ENFORCEMENT

The necessity for thorough regulations giving USDA the ability to police AWA's provisions effectively should not be underestimated.

Rules, were not reported as such in the annual reports of those facilities conducting the research. *Id.* at 9 (citing ALDF Submission on Pain and Anesthesia With Reference To The Improved Standards For Laboratory Animals Act of 1985, at 11-29 (1986) [hereinafter *Submission on Pain*]). Therefore, ALDF claimed that without a more detailed annual report, USDA will be unable to rectify the apparent discrepancies between USDA and research facilities regarding what constitutes a painful procedure. *ALDF Comments, supra* note 129, at 9.

ALDF also argued that researchers' explanations in the annual reports for withholding pain relieving drugs, in the few instances where such withholding was acknowledged, were "conclusory and inadequate." *Id.* (citing *Submission on Pain*, at 30-41).

In order to alleviate these problems, ALDF suggested that the annual reports of research facilities contain adequate information to allow USDA to make its own determinations regarding: 1) whether a procedure is "painful" under section 2.35 of the Proposed Rules; 2) whether pain-relieving drugs were properly administered during painful procedures; 3) whether the withholding of pain-relieving drugs was justified; and 4) whether the principal investigator actually considered alternatives to painful procedures. *Id.* at 8-9.

<sup>133</sup> *Id.* at 11.

<sup>134</sup> *Id.* at 15.

<sup>135</sup> *Id.* at 16.

<sup>136</sup> *Id.* ALDF proposes that the non-affiliated member be selected by a "formal review of the applications of qualified individuals, consultation with recognized leaders of the animal welfare community . . . and a noticed hearing which is open to the public." *Id.* (citing § 2.35(a)(5)(ii) of the Proposed Rules).

<sup>137</sup> *Id.* at 17.

<sup>138</sup> Letter from Christine Stevens, Secretary of the Society for Animal Protective Legislation to Dr. Crawford of USDA (August 27, 1987); Letter from Eileen Liska of the Michigan Humane Society to James C. Miller at the Office of Management and Budget (August 24, 1987) (concerning *NABR Comments* on the Proposed Rules).

The animal welfare community's enthusiasm for the Proposed Rules, expressed in their Comments, is readily understandable given that no viable alternatives currently exist for enforcing AWA outside of the regulatory framework established in ISLAA.<sup>139</sup> The obstacles blocking private parties from obtaining judicial review of alleged AWA violations are substantial. A Fourth Circuit case, *International Primate Protection League v. Institute for Behavioral Research*<sup>140</sup> (*IPPL*), illustrates two major difficulties associated with private party lawsuits to enforce AWA: 1) establishing standing to sue; and 2) establishing that an implied cause of action exists to enforce the Act.<sup>141</sup>

*IPPL* is the only<sup>142</sup> federal case to date that addresses these issues with respect to AWA.<sup>143</sup> The case involved the plaintiff organizations'<sup>144</sup> attempt to enjoin the defendant institute (IBR) from regaining possession of primates that were confiscated after the head of the institute was convicted in Maryland state court of criminally violating the state's anti-cruelty statutes.<sup>145</sup> The court based its con-

<sup>139</sup> See *infra* note 185 and accompanying text.

<sup>140</sup> 799 F.2d 934 (4th Cir. 1986), *cert. denied*, 107 S.Ct. 1624, *reh'g denied*, 107 S.Ct. 2492 (1987).

<sup>141</sup> See generally Comment, *Private Rights of Action Under Amtrack and Ash: Some Implications for Implication*, 123 U. PA. L. REV. 1392 (1975). The standing and implied private cause of action determinations are related but not the same. Standing focuses on whether the *party* bringing the suit is the proper one. In contrast, determining whether an implied cause of action exists depends on whether the *action* is authorized by the statute allegedly violated. *Id.* at 1409.

<sup>142</sup> Civil Action No. 81-2691, *Humane Society of the United States v. Block*, and Civil Action No. 81-2977, *Fund for Animals v. Malone*, were two other actions commenced because of the IBR incident. However, the District Court for the District of Columbia dismissed these cases. The plaintiffs in *Humane Society* sought to compel the Secretary of Agriculture to enforce AWA provisions against IBR. The plaintiffs in *Fund for Animals* sought a general declaration of the responsibilities of USDA and NIH to control the treatment of research animals and also requested an injunction preventing the return of the primates to IBR. The district court dismissed these actions because, in the court's view, the enforcement authority of NIH and USDA officials under NIH regulations and AWA is "wholly discretionary." *IPPL*, 799 F.2d at 937.

<sup>143</sup> The reason for the lack of litigation stemming from attempted private enforcement of AWA provisions appears to be twofold. First, AWA standards are designed to be enforced administratively. Second, the "injury in fact" necessary for standing is difficult to establish without actual contact with abused laboratory animals. Research facility confines effectively insulate laboratory animals from contact with potential plaintiffs.

<sup>144</sup> In addition to *IPPL*, two corporations, the Animal Law Enforcement Association (ALEA) and People for Ethical Treatment of Animals (PETA), along with several individuals, brought the suit. *IPPL*, 799 F.2d at 936.

<sup>145</sup> In 1981, Dr. Taub, the chief of the Biology Center of IBR, was convicted of violating Article 27, § 59 of the Maryland Code. The conviction was eventually reversed on appeal because the court found that the Maryland statute did not apply to an institution conducting

viction on the inadequate care the facility provided the primates being used for research.<sup>146</sup> The civil complaint in the federal case alleged that the IBR had violated both Maryland law and AWA.<sup>147</sup> The civil action was commenced to prevent IBR from regaining possession of the primates and to designate the organizations as guardians of the monkeys.<sup>148</sup> The Fourth Circuit Court of Appeals, however, affirmed the decision of the district court dismissing the suit for lack of standing and for failure to establish an implied cause of action that could entitle the organizations to injunctive relief.<sup>149</sup> The following two sub-sections explore why the *IPPL* plaintiffs were unable to establish standing and, in addition, why AWA does not provide for an implied private cause of action.

### A. *Standing to Sue*

Standing involves the determination of whether "a party has a sufficient stake in an otherwise justiciable controversy to obtain resolution of that controversy."<sup>150</sup> The standing doctrine finds its origin in article III of the United States Constitution which limits the courts to hearing only "cases and controversies."<sup>151</sup> The Supreme Court has fashioned a two-part test for standing: 1) the plaintiff must have suffered an injury in fact; and 2) the injury must be within the zone of interests protected by the allegedly violated statute.<sup>152</sup>

The *IPPL* appellate court found that neither the financial nor non-financial injuries the organizations allegedly suffered satisfied the injury in fact requirement.<sup>153</sup> First, the mere fact that the organi-

---

research under a federal program. See *Taub v. State*, 296 Md. 439, 440, 463 A.2d 819, 820 (1983).

<sup>146</sup> The primates were used in experimentation where researchers were studying the monkeys' ability to learn to use a limb after nerves had been severed. *IPPL*, 799 F.2d at 936.

<sup>147</sup> *Id.*

<sup>148</sup> *Id.* at 937.

<sup>149</sup> *Id.* at 938-39.

<sup>150</sup> *Sierra Club v. Morton*, 405 U.S. 727, 731 (1972).

<sup>151</sup> U.S. CONST. art. III, § 2; see also, *Baker v. Carr*, 369 U.S. 186, 204 (1962) (the question of standing focuses on whether the party bringing the action has alleged such a personal stake in the outcome of the controversy to assure concrete adverseness which sharpens the presentation of issues); Brilmayer, *The Jurisprudence of Article III: Perspectives on the "Case or Controversy" Requirement*, 93 HARV. L. REV. 297, 300 (1979) (the case and controversy requirement has been understood as establishing that federal courts can only resolve abstract legal issues when they are the "necessary byproduct" of the resolution of individual disputes).

<sup>152</sup> *Association of Data Processing Service Organizations v. Camp*, 397 U.S. 150, 152-53 (1970); *Barlow v. Collins*, 397 U.S. 159, 164 (1970).

<sup>153</sup> *International Primate Protection League v. Institute for Behavioral Research*, 799 F.2d 934, 938 (4th Cir. 1986), *cert. denied*, 107 S.Ct. 1624, *reh'g denied*, 107 S.Ct. 2492 (1987). The

zations were taxpayers whose money was used to fund the institute<sup>154</sup> did not afford them standing to enforce the AWA provisions.<sup>155</sup> Second, funds volunteered by the organizations to maintain the monkeys once they had been confiscated also did not amount to a “personal stake in the outcome” sufficient to grant the organizations standing.<sup>156</sup>

The court also rejected the organizations’ arguments that their non-financial injuries constituted injury in fact. First, the court concluded that the organizations’ special interest in the humane care and treatment of laboratory animals was precisely the type of injury not recognized as an injury in fact.<sup>157</sup> Second, the *IPPL* court also rejected the organizations’ contention that their direct and personal interaction with the abused primates constituted an injury in fact.<sup>158</sup> The court stressed that the organizations only came into contact with the monkeys through the litigation proceedings.<sup>159</sup>

This limited view of the organizations’ personal contact with the primates is inaccurate. A member of one plaintiff organization, PETA, became acquainted with the primates as a volunteer at IBR.<sup>160</sup> Thus, the organizations’ personal relationship with the primates originated *prior* to the litigation.<sup>161</sup> This volunteer’s contact with the primates instigated the litigation.<sup>162</sup>

---

*IPPL* court cited *Gladstone Realtors v. Village of Bellwood*, 441 U.S. 91 (1979), for the proposition that the plaintiffs have to allege that they suffered or were threatened with personal injury as a result of the defendant’s putatively illegal conduct in order to have standing. *Gladstone*, 441 U.S. at 99.

<sup>154</sup> The National Institutes of Health (NIH), a federal agency, funded the IBR research. *IPPL*, 799 F.2d at 937.

<sup>155</sup> *Id.* (citing *United States v. Richardson*, 418 U.S. 166, 174–75 (1974), for the proposition that the payment of taxes does not purchase the authority to enforce regulations).

<sup>156</sup> *Id.* at 938 (quoting *Baker v. Carr*, 369 U.S. at 204); *but cf. Mutilated Monkeys*, *supra* note 6, at 104–05 (funds to maintain the monkeys were volunteered before the suit and therefore the *IPPL* court concluded erroneously that the economic harm the organizations suffered was only a response to the contested conduct and not part of that conduct).

<sup>157</sup> *Id.* (citing *Sierra Club v. Morton*, 405 U.S. 727, 735 n.8 (1972)). The *Sierra Club* Court stated “a mere interest in a problem,’ no matter how longstanding the interest and no matter how qualified the organization is in evaluating the problem, is not sufficient by itself” to establish standing. *Sierra Club*, 405 U.S. at 739.

<sup>158</sup> *IPPL*, 799 F.2d at 938.

<sup>159</sup> *Id.* The court analogized the plaintiffs’ situation to that of the plaintiff organization in *Animal Lovers Volunteer Association v. Weinberger*, 765 F.2d 937 (9th Cir. 1985), where the court found that the plaintiff association suffered no injury in fact because its members lacked personal contact with goats being shot on a federal enclave and therefore did not have standing to sue.

<sup>160</sup> The volunteer, Alex Pacheco, founded PETA and served on the board of directors. *IPPL*, 799 F. Supp. at 936.

<sup>161</sup> *Mutilated Monkeys*, *supra* note 6, at 1106.

<sup>162</sup> *IPPL*, 799 F.2d at 936.

Consequently, the district and appellate court decisions in *IPPL* appear to be inconsistent with prior decisions. The organizations cited several cases to support this contention. First, in *Sierra Club v. Morton*,<sup>163</sup> the plaintiffs' failure to allege a direct, personal harm of the type asserted in *IPPL* was fatal to their claim.<sup>164</sup> The language of the *Sierra Club* Court suggests that if a personal harm had been alleged, the plaintiff organization would have established standing to sue.<sup>165</sup>

The organizations also cited *Animal Welfare Institute v. Kreps*,<sup>166</sup> where an organization had standing to sue even though only two or three of its members were personally aggrieved.<sup>167</sup> The *Kreps* decision is consistent with the Supreme Court's decision in *United States v. Students Challenging Regulatory Agency Procedures (SCRAP)*.<sup>168</sup> In *SCRAP*, the Court emphasized that the injury in fact requirement is satisfied when a plaintiff alleges "specific and perceptible harm," regardless of degree.<sup>169</sup> Accordingly, even though the majority of the organizations in *IPPL* did not come in contact

<sup>163</sup> 405 U.S. 727 (1972).

<sup>164</sup> *Id.* at 734-35.

<sup>165</sup> "We do not question that this type of harm [aesthetic and environmental] may amount to an 'injury in fact' sufficient to lay the basis for standing under § 10 of the APA . . . . But the 'injury in fact' test requires . . . that the party seeking review be himself among the injured." *Id.*

<sup>166</sup> 561 F.2d 1002 (D.C. Cir. 1977).

<sup>167</sup> *Id.* at 1007. The *Kreps* court stated: "It is well settled that an organization may have standing to sue as the representative of its members or any one of them. Appellants have satisfied this requirement by alleging injury to the recreational, aesthetic, scientific, and educational interests of their members." *Id.* The organizations, in their brief, also stated:

"Appellees make much of the fact that appellants' affidavits describe only two members who have traveled to South Africa to view the seals in the past, and one who plans to do so in the future. *But it is well settled that standing does not depend on the size or quantum of harm to the party.* The Supreme Court has stated, 'The association must allege that its members, or any one of them, are suffering immediate or threatened injury as a result of the challenged action.'"

Reply Brief for Appellants at 24, *International Primate Protection League v. Institute for Behavioral Research*, 799 F.2d 934 (4th Cir. 1986), *cert. denied*, 107 S.Ct. 1624, *reh'g denied*, 107 S.Ct. 2492 (1987) (No. 86-1508) [hereinafter *Reply Brief*] (quoting *Kreps*, 561 F.2d at 1008, quoting *Warth v. Seldin*, 422 U.S. 490, 511 (1975)).

Though the *IPPL* organizations did not cite this case in their brief, *American Horse Protection Ass'n. v. Frizzel*, 403 F. Supp. 1206 (D. Nev. 1975) also supports their contention. Only one member of the plaintiff organization viewed the horses that were to be rounded-up; however, the court found the fact that one member was personally aggrieved sufficient to confer standing on the plaintiff organization. *Id.* at 1214.

<sup>168</sup> 412 U.S. 669 (1973).

<sup>169</sup> *Id.* at 689. Whether a person is "adversely affected" or "aggrieved" distinguishes a person with a direct stake in the litigation—even though small—from a person with a mere interest in the problem. *Id.* at 689 n.14.



with the monkeys until after the litigation was commenced, at least a member of one organization had contact prior to the litigation; therefore, that organization should have had standing. Despite determining that the organizations lacked standing to sue in this instance, the *IPPL* court proceeded to address whether the organizations had a right to seek judicial relief.<sup>170</sup>

### B. Implied Cause of Action

The statutory authorization of a private cause of action does not have to be explicit; rather, it can be implied from the statute.<sup>171</sup> The primary inquiry regarding whether an implied cause of action exists focuses on whether the language and history of the statute allegedly violated evinces a congressional intent to create such relief.<sup>172</sup>

The *IPPL* court found that the appellants were not entitled to judicial relief because there was no implied cause of action under AWA.<sup>173</sup> The court pointed out that AWA's language<sup>174</sup> and legislative history<sup>175</sup> reveal a congressional intent to provide for exclusive administrative enforcement,<sup>176</sup> in order to prevent unnecessary and damaging interference with medical research.<sup>177</sup> The "comprehen-

<sup>170</sup> *IPPL*, 799 F.2d at 938-39.

<sup>171</sup> See, e.g., *Cort v. Ash*, 422 U.S. 66 (1974). There, the Supreme Court employed a four-part test to determine whether a statute creates an implied private cause of action: 1) the plaintiff must be a member of the class for whose benefit the statute was enacted; 2) the legislature must have intended such a remedy to exist; 3) a private cause of action must be consistent with the underlying purposes of the legislative scheme; and 4) the subject matter must not be traditionally relegated to state law. *Id.* at 78.

<sup>172</sup> See *Touche Ross & Co. v. Redington*, 442 U.S. 560 (1979). If there is no congressional intent to create a private right of action, the *Cort* inquiry need not be pursued any further. *Id.* at 575-76.

<sup>173</sup> *IPPL*, 799 F.2d at 938-40.

<sup>174</sup> *Id.* at 938-39 (quoting 7 U.S.C. § 2143(a)). The court noted that AWA "directs the Secretary of Agriculture to 'promulgate standards to govern the humane handling, care, treatment, and transportation of animals,' but cautions that 'nothing in this chapter shall be construed as authorizing the Secretary to promulgate rules, regulations, or orders with regard to design, outlines, guidelines, or performance of actual research or experimentation . . .'" *Id.* at 939. ISLAA, however, changed this provision and now allows "the Secretary to promulgate rules, regulations, or orders with regard to the performance of actual research or experimentation by a research facility as determined by such research facility; and shall authorize the Secretary, during inspection, to interrupt the conduct of actual research or experimentation." 7 U.S.C. § 2143(a)(3)(A) (Supp. IV 1986).

<sup>175</sup> See H.R. CONF. REP. NO. 99-447, 99th Cong., 1st Sess., reprinted in 1985 U.S. CODE CONG. & ADMIN. NEWS 1676, 2518.

<sup>176</sup> *IPPL*, 799 F.2d at 940 (citing *Northwest Airlines, Inc. v. Transport Workers*, 451 U.S. 77, 93-94 (1981)); but cf. *Mutilated Monkeys*, *supra* note 6, at 107-08 (arguing that AWA provisions can be interpreted to provide a private cause of action).

<sup>177</sup> The court stated that allowing a private cause of action under AWA might result in

sive" regulatory scheme utilizing administrative enforcement to ensure compliance was, in the court's view, the only enforcement mechanism that Congress envisioned when it enacted AWA.<sup>178</sup> Accordingly, the court rejected the organizations' arguments to imply a private cause of action under AWA.

The *IPPL* case was decided under pre-ISLAA AWA.<sup>179</sup> Even though congressional intent regarding the purpose of the Act<sup>180</sup> and the amount of allowable interference with research and experimentation<sup>181</sup> were altered by ISLAA, the *IPPL* court would probably reach the same decision today—that the Act does not create impliedly a private cause of action.<sup>182</sup> ISLAA provides the framework for a more pervasive and precisely defined regulatory scheme. Under ISLAA, the IACUC is the primary enforcement mechanism backed by the authority of USDA.<sup>183</sup> ISLAA's legislative history reveals that Congress intended the Secretary of Agriculture to continue to be the exclusive enforcer of the Act.<sup>184</sup>

*IPPL* indicates that a private cause of action is not a viable enforcement alternative. Even if the *IPPL* organizations had standing to sue, they would have been denied injunctive relief because no private cause of action is available under AWA. Furthermore, the fact that the plaintiffs in the *IPPL* case arguably had standing to sue is an uncommon occurrence. Most research facilities do not have members of animal welfare organizations working within their con-

---

judges and juries with limited knowledge of medical research failing to provide consistent decisions on which researchers could rely. In addition, subjecting research facilities to extensive pre-trial discovery of their practices, beyond the administrative inspections of such practices already designated in AWA, would seriously burden medical research. *IPPL*, 799 F.2d at 940.

<sup>178</sup> *Id.* (citing Middlesex County Sewerage Authority v. National Sea Clammers Ass'n, 453 U.S. 1, 15 (1981)). In the absence of strong indicia of contrary congressional intent, the court concluded that the remedies provided by Congress were precisely those it considered appropriate. *Id.*

<sup>179</sup> This case was decided in September, 1986, three months before ISLAA became effective. See 7 U.S.C. § 2131 (Supp. IV 1986) listing December 23, 1986 as the effective date.

<sup>180</sup> See *supra* note 140 and accompanying text.

<sup>181</sup> See *supra* note 174.

<sup>182</sup> *IPPL*, 799 F.2d at 939 n.4 and accompanying text (the use of IACUCs to supplement USDA enforcement mandated by ISLAA does not alter the fact that AWA provides for exclusive administrative enforcement).

<sup>183</sup> See 7 U.S.C. § 2143 (Supp. IV 1986).

<sup>184</sup> See H.R. CONF. REP. NO. 447, 99th Cong., 1st Sess., 592-98 reprinted in 1985 U.S. CODE CONG. & ADMIN. NEWS 1103, 2524 ("The Conferees expect the Secretary of Agriculture to have full responsibility for enforcement of the Animal Welfare Act."); cf. Humane Society of Rochester and Monroe County, Inc. v. Lyng, 633 F. Supp. 480 (W.D.N.Y. 1986) (New York law authorizes the Humane Society to prosecute animal cruelty law violations).

fines. Consequently, laboratory animals rarely come into contact with individuals sympathetic to their conditions. Thus, injury in fact would be difficult if not impossible to prove. Without the requisite contact necessary to render one personally aggrieved or adversely affected, standing is not attainable. Realizing that private enforcement of AWA's provisions is not a viable concept<sup>185</sup> leads one back to legislation<sup>186</sup> as the most practical and expedient means for obtaining increased protection of laboratory animals under AWA.

## VI. THE PROPOSED RULES: A PROMISING STEP TOWARD EFFECTIVE REGULATION

ISLAA, coupled with the Proposed Rules, possesses the potential to transform the once "toothless" AWA into an effective regulatory device. Despite the outcry from the medical research community claiming that USDA should propose new, less burdensome regulations to comply with ISLAA's language and congressional intent, the fact remains that the primary purpose of ISLAA was to "improve the authority of the Secretary of Agriculture to insure the proper care and treatment of animals used in research."<sup>187</sup> Recognizing the need to preserve responsible and necessary research, Congress specifically set forth those "general areas" in which the Secretary could promulgate regulations limiting the conduct of research and experimentation.<sup>188</sup>

---

<sup>185</sup> See *IPPL*:

To imply a cause of action in these plaintiffs might entail serious consequences. It might open the use of animals in biomedical research to the vicissitudes of courtroom litigation. . . . It might unleash a spate of private lawsuits that would impede advances made by medical science in the alleviation of human suffering. To risk consequences of this magnitude in the absence of clear direction from the Congress would be ill-advised.

799 F.2d at 935.

<sup>186</sup> Currently there are a number of pending bills in Congress designed to protect laboratory animals. For example, H.R. 1708 sponsored by Rep. Torricelli (D-NJ), proposes the enactment of a "Research Accountability and Information Dissemination Act" that would establish a national center where full-text literature searches would be conducted before research utilizing live animals would receive funding. A second bill, H.R. 1770 sponsored by Rep. Rose (D-NC) proposes that AWA be amended to allow private individuals to sue USDA to compel enforcement of the Act. See *CHL's Legislative Update*, ACTIONLINE, (published by Friends of Animals) Feb./Mar. 1988, at 29-30; see also Dukes, *supra* note 6, at 538-39 (describing the benefits of legislation authorizing citizen suits to compel USDA enforcement of AWA).

<sup>187</sup> H. R. CONF. REP. No. 447, 99th Cong., 1st Sess., 592, 594 reprinted in 1985 U.S. CODE CONG. & ADMIN. NEWS 2518, 2520.

<sup>188</sup> *Id.*

*A. Breadth of the Regulatory Scheme*

The Proposed Rules appear to be consistent with ISLAA's mandate. ISLAA section 2143(a)(6),<sup>189</sup> upon which NABR relied to support its conclusion that the Proposed Rules are too expansive and exceed congressional intent,<sup>190</sup> only precludes the Secretary from interfering with research outside of the "general areas" identified in ISLAA as open to regulation.<sup>191</sup> NABR, however, concluded that these "general areas" are in fact "very limited exceptions" and were intended to maintain researcher autonomy.<sup>192</sup>

In reality, the Secretary's authority to promulgate regulations within these "very limited exceptions" is quite broad. For example, ISLAA directs the Secretary to promulgate regulations pertaining to experimental procedures to ensure that: 1) "animal pain and distress are minimized;"<sup>193</sup> 2) alternatives to "any procedure likely to produce pain" are considered;<sup>194</sup> and 3) certain measures are taken "in any practice which could cause pain to animals."<sup>195</sup> ISLAA also requires research facilities to provide "assurances satisfactory to the Secretary that such facility is adhering to the standards described in this section."<sup>196</sup> Such sweeping language is indicative of a congressional willingness to allow the Secretary to exercise his or her discretion in determining, for instance, which protocols must meet certain standards and what information the facilities must present in their annual reports to substantiate their compliance with the Act. Thus, ISLAA's comprehensiveness belies NABR's objections that the Proposed Rules exceed congressional intent.

The research community's objections are hardly surprising. The Proposed Rules' imposition of substantive restrictions on the research process strikes at the very heart of the controversy between the research community seeking scientific autonomy and the animal welfare organizations seeking research regulation.<sup>197</sup> Research community opposition to ISLAA, which for the first time authorized the Secretary to impose substantive restrictions on the experimentation

---

<sup>189</sup> 7 U.S.C. § 2143(a)(6) (Supp. IV 1986).

<sup>190</sup> See *supra* notes 113-15 and accompanying text.

<sup>191</sup> 7 U.S.C. §§ 2143(a)(3) and (7) (Supp. IV 1986), define those areas in which the Secretary is required to promulgate regulations governing the experimentation process.

<sup>192</sup> See *NABR Comments*, *supra* note 13, at 125.

<sup>193</sup> 7 U.S.C. § 2143(a)(3)(A) (Supp. IV 1986).

<sup>194</sup> *Id.* § 2143(a)(3)(B).

<sup>195</sup> *Id.* § 2143(a)(3)(C).

<sup>196</sup> *Id.* § 2143(a)(7).

<sup>197</sup> See *Dresser*, *supra* note 6, at 1194.

process, was inevitable.<sup>198</sup> Given that prior to ISLAA experimentation was virtually unregulated<sup>199</sup> and existing AWA regulations were inadequately enforced,<sup>200</sup> the substantial step taken by USDA in drafting the Proposed Rules was necessary to establish parity between the competing interests.

### *B. The IACUC's Internal Review Process*

USDA's Proposed Rules evince a more accepting agency attitude toward its AWA enforcement responsibility.<sup>201</sup> The formation of IACUCs to provide internal review lifts a tremendous burden from APHIS personnel assigned the formidable task of enforcing AWA's provisions. The IACUCs alleviate many of the problems faced previously by APHIS<sup>202</sup> by allowing for qualified personnel to review actively individual facility compliance on a regular basis. APHIS is effectively removed from its former position as the "front-line" enforcer of AWA. Instead, APHIS becomes the support base for the Committees, providing the necessary authority to persuade research facilities to cooperate with the IACUCs.

Despite NABR's claim that Committees are granted too much authority to carry out regulatory enforcement,<sup>203</sup> the IACUCs appear to be a commendable attempt to achieve a delicate balance between increasing animal protection and preserving essential biomedical research. IACUCs should be given an opportunity to operate under the terms of the Proposed Rules before any major revisions of Committee composition and duties are implemented. Unfounded fears on either side should not be allowed to dictate changes in regulations that have not yet been tested in their current form.

The creation of IACUCs mandated by ISLAA allows at least one objective observer at each research facility to review and voice an opinion on the various pain-inflicting protocols being utilized.<sup>204</sup> From an animal welfare perspective, however, there are some potential problems with the current Committee formation procedures and composition that should be addressed if the need arises. The ALDF

---

<sup>198</sup> *Id.* at 1195.

<sup>199</sup> *See supra* note 39 and accompanying text.

<sup>200</sup> *See supra* notes 45-54 and accompanying text.

<sup>201</sup> *See supra* note 88 and accompanying text.

<sup>202</sup> *See supra* notes 45-54 and accompanying text.

<sup>203</sup> *See supra* note 123 and accompanying text.

<sup>204</sup> *See supra* note 75 and accompanying text.

Comments on the Proposed Rules identify some of these trouble spots.<sup>205</sup>

First, ALDF suggested that the outside or non-affiliated Committee members be selected via a formal review of qualified applicants<sup>206</sup> instead of being appointed by the chief executive officer (CEO) of each research facility as ISLAA now requires.<sup>207</sup> ALDF's suggestion would insure the objectivity of the non-affiliated member. The possibility exists that objectivity would be jeopardized if the outside member was chosen by a CEO to place simply a rubber stamp of approval on research protocols without adequate consideration of the pain being inflicted on animal subjects, the necessity of the research, and the availability of alternatives.

Second, ALDF was concerned that research facilities will appoint other researchers, not affiliated with their own facility, as non-affiliated Committee members.<sup>208</sup> In the absence of a formal selection process, research facilities should not be permitted to appoint outside members who may be naturally biased toward the researchers' views. This practice, if utilized, violates ISLAA's requirement that the non-affiliated member "provide[s] representation for *general community interests* in the proper care and treatment of animals."<sup>209</sup>

Third, ALDF proposed that the number of outside members on each IACUC be proportionate to the total number of Committee members.<sup>210</sup> AWA places no ceiling on the number of Committee members a CEO can appoint.<sup>211</sup> The possibility exists that a large majority of Committee members could apply pressure on an outside member to reach assessments of protocols consistent with their own, thereby stifling objective analysis. Maintaining a one-to-three ratio of outside members to the total number of Committee members would help to preserve the minority opinion.

Another troubling aspect of the IACUCs is that ISLAA and the Proposed Rules do not designate a specific removal mechanism for Committee members. There is a danger that if a research facility views a Committee member as being hostile to its interests, the

---

<sup>205</sup> See *supra* notes 132-37 and accompanying text.

<sup>206</sup> See *supra* note 136 (ALDF did not specify who should do the reviewing or what the exact criteria should be for choosing the outside member).

<sup>207</sup> 7 U.S.C. § 2143(b)(1) (Supp. IV 1986).

<sup>208</sup> See *ALDF Comments, supra* note 129, at 16.

<sup>209</sup> *Id.* (emphasis added). It came to ALDF's attention that some research facilities have selected outside members who are researchers from other facilities. *Id.* at 16.

<sup>210</sup> *Id.* at 15.

<sup>211</sup> 7 U.S.C. § 2143(b)(1) (Supp. IV 1986); *ALDF Comments, supra* note 129, at 15 (some larger research facilities have 10-15 Committee members).

facility could dismiss that member, even though the Committee member's complaints may be well-founded. Research facilities should not be able to avoid legitimate opposition by dismissing members who offer constructive criticism and replacing them with less antagonistic candidates. If dismissals become too frequent, USDA should establish a review board that would listen to the grievances of both the facility and the Committee member before determining whether dismissal is appropriate.

Whether any of these corrective measures will be necessary depends on the willingness of research facilities to accept the Committees' regulatory responsibilities under AWA. Cooperation is the essential ingredient if the Act is to serve the interests of both the animal welfare and research communities. If researchers perceive the IACUCs as opponents rather than allies and attempt to circumvent the regulatory system established by ISLAA, not only will stricter controls be in order, but researchers will also jeopardize vital research and experimentation by inviting retaliation from militant anti-vivisectionist organizations such as the Animal Liberation Front.<sup>212</sup>

## VII. CONCLUSION

ISLAA embodies the first major effort to strike a statutory balance between biomedical research and the humane treatment of laboratory animals. Twenty-two years after LAWA was first enacted, animal welfare organizations finally have reason to be optimistic that the needless infliction of pain on animals behind laboratory doors will not be insulated from scrutiny. Congress, along with the rest of society, has become increasingly aware of the suffering experienced by animal subjects and has taken a significant step toward eliminating unnecessary animal experimentation.<sup>213</sup>

---

<sup>212</sup> See *Antinomy*, *supra* note 6, at 750-51 n.184 for a brief synopsis of some Animal Liberation Front operations; see also *Inhuman Bondage*, *supra* note 1, for a description of ALF covert activities from the perspective of ALF members.

<sup>213</sup> Compare the main purpose of ISLAA discussed in the text *supra* at notes 60-61, with the commentary of Senator Monroney during the enactment of LAWA in 1966:

Let me make it crystal clear that this bill in no way will impair the rights of researchers and the managers of research facilities to subject animals to medical or surgical procedures required for research and experimentation. . . . The researcher is left completely free to use an animal in his research project in whatever way, no matter how painful, and for as long as he deems necessary, including removing any organs or vital parts, or even experimentation that he knows will result in the death of the animal.

112 CONG. REC. S13,893 (June 22, 1966) (statement of Sen. Monroney).

By design, the early AWA legislation was impotent to prevent abusive animal research. ISLAA and the Proposed Rules remedy this substantive deficiency by establishing the regulation of research procedures.

The inability of animal rights organizations to obtain standing to sue, coupled with clear congressional intent to preclude private enforcement of the Act, emphasize the need for a comprehensive regulatory scheme to insure compliance with AWA's provisions. The regulatory scheme outlined in ISLAA and detailed in the Proposed Rules, utilizing the Committees as the primary enforcement mechanism, possesses the potential to revitalize the Act. After experiencing years of enforcement difficulties, APHIS is well aware of what the regulations must entail in order to enforce properly AWA in its present form. Accordingly, it is hoped that in drafting its final regulations USDA will address any legitimate concerns regarding the Proposed Rules, without compromising those provisions which will make effective enforcement of AWA a reality.