

IF ANIMAL RIGHTS ACTIVISTS COULD WRITE FEDERAL RESEARCH POLICY

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I. INTRODUCTION

The use of animal subjects in research experiments has caused heated debate between animal rights activists and scientists. With the growth of the animal rights movement, pro-animal agendas were given a stronger voice that was heard not only by researchers, but also by the government that funds and approves the research. In response to social pressure to curb animal experimentation, two major sources of federal policy were developed: the Animal Welfare Act of 1970¹ and the funding policy of the U.S. Public Health Service (PHS).²

The efficacy of these programs is suspect. Do they fulfill their intended purpose, or are they simply rhetoric that allows research facilities to maintain their former problematic practices? Animal rights activists have continually criticized that the current policies do little to protect laboratory animals. They feel that the regulations give too much control to researchers. Further, they believe that the regulations protect animals only as property and thus do not recognize the inherent rights embodied within animals. At a national animal rights rally, John Kullberg of the American Society for the Prevention of Cruelty to Animals summarized these feelings toward changing current law: "we're committed to an evolving ethic that recognizes that all sentient creatures, human and non human, have rights that need to be protected."³

This comment proposes a new federal animal research statute that would reform or terminate many current practices. Part II provides examples of animal research that the proposed new statute is designed to prevent. Next, Part III describes the current federal policy covering the use of

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¹ 7 U.S.C. §§ 2131-2159 (1994).

² OFFICE FOR PROTECTION FROM RESEARCH RISKS, NATIONAL INSTITUTES OF HEALTH, PUBLIC HEALTH SERVICE POLICY ON HUMANE CARE AND USE OF LABORATORY ANIMALS § II, at 1 (rev. ed. 1986) [hereinafter PHS POLICY].

³ *Animal Rights Activists Hold First National Rally*, 1990 Drug Research Reports, The Blue Sheet, June 13, 1990, at 8.

animals in research. It summarizes the current rules in the Animal Welfare Act and PHS Policy concerning research animals. The philosophy behind these rules is explored and possible drawbacks of the policy are highlighted. Part II presents the general justifications for using animals in research and how current federal research policy using animals upholds these values.

Part IV gives an overview of the animal rights position concerning animal research. Part IV focuses on the works of Peter Singer and Tom Regan and puts forth arguments that aim to reduce and possibly eliminate animal research. This directly contrasts the previous section that describes how critics and current policy favor using animals in experimentation.

Finally, Part V takes the basic ethical principles discussed in Part IV and combines them with the current legal framework discussed in Part III to propose a federal policy that promotes useful research while caring for and respecting animals. Part V gives a thorough explanation of how a carefully drafted federal policy that incorporates the substantive ideals of animal rights can respect the rights of animals while still allowing valuable research to continue.

II. EXAMPLES OF ANIMAL EXPERIMENTATION

There are many examples of animal research that show a blatant disregard for both animal welfare and rights. One poignant example is the Draize eye irritancy test. The purpose of the test is to assess how potentially harmful a product could be to the human eye.⁴ The test consists of spraying the animal subject's eye with the selected substance and noting the level of irritancy on a pass-fail basis. This test, usually used purely to test cosmetic products, has been criticized as to its questionable application to humans, the reproduction of unreliable results from different labs, and its general lack of refinement.⁵ The actual result is that hundreds of animal subjects (usually rabbits) are blinded by the chemicals with no apparent benefit for animals or humans.⁶ One author has gone so far as to say that the Draize Test is "probably one of the most futile and utterly pointless tests ever devised and it is nothing but a tribute to human cruelty and wickedness."⁷

Another gruesome example of animal cruelty in scientific research involves the Head Injury Clinical Laboratory at the University of Pennsylvania.⁸ The directors of this federally funded research facility, Dr. Thomas Langfitt and Dr. Thomas Gennarelli, conducted experiments that consisted of fitting the heads of living baboons with bone helmets and

⁴ ANDREW N. ROWAN, *OF MICE, MODELS, & MEN: A CRITICAL EVALUATION OF ANIMAL RESEARCH* 219 (1984).

⁵ *Id.*

⁶ *Id.*

⁷ VERNON COLEMAN, *WHY ANIMAL EXPERIMENTS MUST STOP* 82 (1994).

⁸ GARY L. FRANCIONE, *ANIMALS, PROPERTY, AND THE LAW* 179-83 (1995).

accelerating their heads forward at a force as much as two thousand times the force of gravity.⁹ The researchers taped these experiments.¹⁰

These videos, later obtained by animal rights groups, showed a host of extremely disturbing scientific practices that totally defy the notion of animal welfare.¹¹ For example, although the doctors insisted that the animals were anesthetized, the videos clearly revealed the baboons were "conscious and struggling against their restraints" before the experiments began.¹² Another horrible display depicted two scientists performing an operation on the exposed brain of a conscious baboon.¹³ The video shows the conscious animal writhing in pain as the researchers cut into its skull and brain.¹⁴ In addition to these atrocities, the videos showed the researchers mocking and cruelly teasing the animals throughout the experiment.¹⁵

A final example shows both the abuse of laboratory animals and the utter uselessness of the experiments designed to induce "learned helplessness,"¹⁶ a model to gain insight into human depression. The basic setup of this experiment is to put a lab animal (dogs were first used) into a box divided into two compartments by a barrier. The grid floor of the box could be electrified and the height of the wall was as high as the dog's back. Given this setup, Peter Singer, a pioneer in the Animal Rights movement, gives an account of how researchers conducted the experiment.

Hundreds of intense electric shocks were delivered to the dogs' feet At first the dog could escape the shock if they learned to jump the barrier In an attempt to discourage one dog from jumping, the experimenters forced the dog to jump one hundred times onto a grid floor in the other compartment that also delivered a shock to the dog's feet. They then blocked the passage between the compartments with a piece of plate glass and tested the dog again. The dog "jumped forward and smashed his head against the glass." The dogs began showing symptoms such as "defecation, urination, yelping and shrieking, trembling, attacking the apparatus, and so on["]; but after ten or twelve days of trials dogs who were prevented from escaping shock ceased to resist. The experimenters reported themselves "impressed" by this¹⁷

After over 30 years of performing such painful experiments on animals, researchers (many of whom performed the experiments in the first place) have concluded that the results of such experimentation are of no use. One experimenter remarks:

[i]t can be argued that there is not enough agreement about the characteristics, neurobiology, induction, and prevention/cure of depression to make such comparison [between the human and animal models] meaningful It would thus

⁹ *Id.* at 179.

¹⁰ *Id.*

¹¹ *Id.*

¹² *Id.* at 180.

¹³ *Id.*

¹⁴ *Id.*

¹⁵ *Id.* at 181.

¹⁶ PETER SINGER, *ANIMAL LIBERATION* 45-47 (2d ed. 1990).

¹⁷ *Id.* at 45.

appear unlikely that learned helplessness is a model of depression in any general sense.¹⁸

Imagine how many animals suffered through years of this experiment to come to the result that the entire experiment was futile.

These are just a few examples of the atrocities that animal subjects must face in scientific research given our current federal protection concerning research animals. Although all animal subjects are not faced with similar horrendous circumstances, millions face situations that obviously put their welfare as a last priority and ignore their inherent rights.¹⁹ It is disturbing that our current laws allow such practices to continue. How do the laws fail to protect animal rights? Can a suitable compromise be reached between science and animal rights?

This paper reviews the current federal research policy and how it conforms and conflicts with the beliefs of animal rights activists. Further, this paper proposes a revised federal policy that incorporates the animal rights beliefs into the framework of existing federal policy. The proposed policy will satisfy the need for both greater ethical considerations of laboratory animal interests and the continued use of animal-related research to promote human interests. With the proposed statute, we can avoid the atrocious pain inflicted on animals present in the examples above.

III. CURRENT FEDERAL RESEARCH POLICY

A. *The Animal Welfare Act*

1. *Relevant Provisions*

The Animal Welfare Act (the Act)²⁰ is the cornerstone for regulation of animal research in the United States. In addition to covering the care and use of animals in research facilities,²¹ the Act also covers animal care during "transportation in commerce."²² The Act grew out of the public outrage from a shocking exposé in Life magazine covering the abuse of dogs by animal dealers.²³ Many of these animals were stolen from homes and sold to animal research facilities. Fueled by public opinion, opponents to the bill were defeated and the Act became law on August 24, 1966.²⁴

The Act has several important provisions relevant to animal research. The stated purpose of the Act is "to insure that animals intended for use in research facilities . . . are provided humane care and treatment."²⁵ Congress then defines a research facility as:

¹⁸ *Id.* at 47.

¹⁹ *Id.* at 173-74.

²⁰ 7 U.S.C. §§ 2131-2159 (1994).

²¹ *Id.* § 2143.

²² *Id.* § 2131.

²³ F. BARBARA ORLANS, IN THE NAME OF SCIENCE: ISSUES IN RESPONSIBLE ANIMAL EXPERIMENTATION 50 (1993).

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

²⁵ 7 U.S.C. § 2131.

any school (except elementary or secondary school), institution, organization, or person that uses or intends to use live animals in research, tests, or experiments, and that (1) purchases or transports live animals in commerce, or (2) receives funds under a grant, award, loan, or contract from a department, agency, or instrumentality of the United States for the purpose of carrying out research, tests or experiments . . .²⁶

The Act describes animals as “any live or dead dog, cat, monkey (non-human primate mammal), guinea pig, hamster, rabbit, or other such warm-blooded animal, as the secretary may determine is being used, or is intended for use, for research, testing, [or] experimentation.”²⁷

The Act goes on to set the regulations for animal research facilities, including minimum standards of care for animals covered by the statute. With regard to research animals, the Act requires that researchers minimize animal pain and take alternatives into account when such pain is likely to occur.²⁸ The Act also requires that a doctor of veterinary medicine is consulted in such procedures.²⁹ The Act directs research facilities to register with U.S. Department of Agriculture (USDA),³⁰ to allow federal inspections, and to make annual reports on how they are fulfilling provisions of the Act.³¹

The Act further requires that the research facility establish a committee to oversee a facility’s animal care and “represent society’s concerns regarding the welfare of animal subjects used at such a facility.”³² This committee must have at least three members and include at least one veterinarian and one member from the local community.³³ The committee is to inspect the research facility at least semi-annually to ensure that the facility is in compliance with the provisions of the Act.³⁴

2. Problems with the Act

As much as the Act proposes to give protection to research animals, this protection is rendered ineffective by a large number of loopholes. A major example of one of these loopholes is the caveat that:

[n]othing in this act . . . shall be construed as authorizing the Secretary to promulgate rules, regulations, or orders with regard to the design, outlines, or guidelines . . . [or] performance of actual research or experimentation by a

²⁶ *Id.* § 2132(e).

²⁷ *Id.* § 2132(g).

²⁸ *Id.* § 2143(a).

²⁹ *Id.*

³⁰ *Id.* § 2136.

³¹ *Id.* § 2143(a)(7)(A).

³² *Id.* § 2143(b)(1).

³³ *Id.* § 2143(b)(1)(B)(i)-(iii). The community representative on the committee should provide the general community perspective on the care of animals and cannot be either affiliated with the research facility or an immediate family member of a research facility employee. *Id.*

³⁴ *Id.* § 2143(b)(3).

research facility . . . ; and [nothing] shall authorize the Secretary, during inspection, to interrupt the conduct of actual research and experimentation.³⁵

This clause in the Act prevents it from instituting any significant change in the actual conduct of the research. Rather, the researcher is given full control of how to design the experiment, how to conduct it, and, consequently, how to use animals that are in it.

The Act also allows researchers to escape the requirement of using anesthesia by requiring it only when it is "scientifically necessary."³⁶ As before, this puts all discretion as to continuing the experiment in the hands of the researcher and allows the scientist to subject the animal to any degree of pain for any amount of time, as long as the researcher believes it necessary. Similarly, the requirement that "no animal [be] used in more than one major operative experiment from which it is allowed to recover,"³⁷ is curtailed by scientific necessity,³⁸ effectively negating its power. All that the researcher need do to circumvent the regulation is to show that the change will detrimentally affect the scientific results of his experiment. Because any change in research design will detrimentally affect the experiment,³⁹ the excuse of "scientific necessity" takes much of the potency out of the Act.

Given the flimsy protection offered by the Act, the omission of a large group of animals from even this protection shows that the Act further fails in fulfilling its Congressional purpose. The Act's definition of "animal" explicitly omits horses and poultry from its protection.⁴⁰ Further, the Act fails to include cold-blooded animals, aquatic animals, birds, rats, and mice.⁴¹ Although there is no precise statistic as to the number of animals used in research,⁴² one estimate (taking various sources into account) has tallied this number at over 71 million.⁴³ In this estimate, the Act excludes 3 million frogs; 5 million birds; 15 million rats; and 45 million mice.⁴⁴ This results in at least 68 million animals being excluded from the Act's coverage thereby excluding over 95% of the research animals from protection.

³⁵ *Id.* § 2143(a)(6)(A)(i)-(iii) (giving the minimal exceptions of requiring annual reports and the consultation of a veterinarian).

³⁶ *Id.* § 2143(a)(3)(C)(v).

³⁷ *Id.* § 2143(a)(3)(D).

³⁸ *Id.* § 2143(a)(3)(D)(i).

³⁹ It will detrimentally affect the experiment in the minimum sense that the researcher must obtain the results in a different way than he had originally planned.

⁴⁰ *Id.* § 2132(g).

⁴¹ *Id.* Section 2132(g) lists as animals "any live or dead dog, cat, monkey (nonhuman primate mammal), guinea pig, hamster, rabbit, or such other warm-blooded animal [and] all dogs including those used for hunting, security, or breeding purposes." *Id.*

⁴² Rebecca Dresser, *Animal Experimentation*, in *BIO-LAW* § 11, at 253 (James F. Childress ed., 1986).

⁴³ *Id.* at 254.

⁴⁴ ROWAN, *supra* note 4, at 71 (animals included within protection include 1 million hamsters; 1 million guinea pigs; 750,000 rabbits; 250,000 dogs; 100,000 cats; 25,000 primates; and 200,000 ungulates totaling approximately 3.32 million animals under protection or a little over 4.5 percent of the total animals used in research).

Even in the final instance where a research facility has, "in spite of all the licensing, registrations, consultations and promulgations,"⁴⁵ violated the law and has allowed animals in its care to suffer, the Act cannot take the animal out of the facility and dispose of it humanely. Removal is permitted only when the animal is "no longer required by such research facility to carry out the research, test, or experiment for which such animal has been utilized."⁴⁶ Thus, the researcher once again has full authority to disregard the Act's provisions and continue harming his animal subjects with impunity as long as it furthers his research.

Finally, officials' failure to enforce the Act⁴⁷ makes the protections it claims to offer just a vague ideal. With the budget for enforcement of the Act lagging behind the ever-increasing number of research institutions, the number of possible inspections constantly decreases.⁴⁸ When the bill first passed in 1966, the USDA appropriated barely \$300,000 for enforcement of the Act.⁴⁹ By 1989, this number had grown to \$6.19 million, despite constant attempts to reduce the number.⁵⁰ Although this seems to be a significant increase, it is not when compared to the growth of research facilities during the same relative time period. In 1975 there were 985 research facilities.⁵¹ This grew to 1,296 facilities in 1989,⁵² and 1,474 in 1991.⁵³ In 1989, there were only 63 USDA officers to inspect the covered research facilities.⁵⁴ Because the agency is so severely understaffed, it cannot thoroughly inspect facilities.⁵⁵ Many facilities were not inspected at all. In California and New York, where a large number of research facilities are located, about half of the facilities were overlooked.⁵⁶ Additionally, laboratory inspections were not completed to an acceptable standard because "inspectors were too few in number, were inadequately trained or not trained at all, and . . . there was no consistent quality-control of inspections."⁵⁷ Thus, inspections under the Act are not as useful as they could be in protecting animals to the extent intended under the Act.

The congressional purpose that animals should be treated in a humane and caring fashion has not been fulfilled by the Act.⁵⁸ Since the

⁴⁵ DALLIS PRATT, *PAINFUL EXPERIMENTS ON ANIMALS* 129 (1976).

⁴⁶ 7 U.S.C. § 2146 (a) (1995).

⁴⁷ See Dresser, *supra* note 42, at 162 (stating that fines are rarely assessed); FRANCIONE, *supra* note 8, at 208-16 (arguing that the Animal Welfare Act is a "symbolic" statute and discussing U.S. Department of Agriculture's reluctance to enforce it).

⁴⁸ ORLANS, *supra* note 23, at 58.

⁴⁹ *Id.*

⁵⁰ *Id.*

⁵¹ *Id.*

⁵² *Id.*

⁵³ *Id.* at 67.

⁵⁴ *Id.* at 58.

⁵⁵ Dresser, *supra* note 42, at 262.

⁵⁶ AMY BLOUNT ANCHOR, *ANIMAL RIGHTS: A BEGINNER'S GUIDE* 99 (1996) (citing Physicians Committee for Responsible Medicine, *Inspections: Infrequent at Best*, PCRM UPDATE, Sep/Oct. 1987, at 2).

⁵⁷ *Id.*

⁵⁸ Karen L. McDonald, *Creating a Private Cause of Action Against Abusive Animal Research*, 134 U. PA. L. REV. 399, 403 (1986).

"AWA [the Act] places few real restrictions on animal researchers and is premised on the assumption that animals must be killed and harmed in the name of scientific progress, the AWA does not qualify as a true 'animal rights' statute."⁵⁹ How well does the PHS Policy on Humane Care and Use of Laboratory Animals fulfill its goals of protecting animals? The next section deals with this question.

B. PHS Policy on Humane Care and Use of Laboratory Animals

1. Relevant Provisions

Another significant federal policy affecting the use of animals in research settings is the Public Health Service's (PHS) Policy on Humane Care and Use of Laboratory Animals.⁶⁰ Enacted in 1986, the PHS Policy applies to all research facilities that receive any financial support from a PHS institution.⁶¹ The PHS Policy became binding federal law when the Health Research Extension Act of 1985⁶² mandated regulation of animals in research.⁶³ It requires significantly more compliance with policies covering both husbandry and experimentation of animal subjects than the Animal Welfare Act (the Act).

Like the Animal Welfare Act, the PHS Policy's main goal is to "ensure the appropriate care and use of all animals used in research, research training, and biological testing activities . . . conducted or supported by the PHS."⁶⁴ The specific principles it utilizes are provided in an appendix entitled *U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training*.⁶⁵ These principles provide a good foundation for any proposed animal research regulations and include the following:

- II. Procedures involving animals should be designed and performed with due consideration for their relevance to human or animal health, the advancement of knowledge, or the good of society.
- III. The animals selected for the procedure should be . . . the minimum number required to obtain valid results. Methods such as mathematical models, computer simulations, and *in vitro* biological systems should be considered.
- IV. Proper use of animals, including the avoidance or minimization of . . . pain when consistent with sound scientific practices, is imperative. Unless the con-

⁵⁹ David R. Schmahmann & Lori J. Polacheck, *The Case Against Rights For Animals*, 22 B.C. ENVTL. AFF. L. REV. 747, 767 (1995).

⁶⁰ PHS POLICY, *supra* note 2.

⁶¹ The PHS Policy applies to such institutions as: The National Institute of Health, the Center for Disease Control, the Food & Drug Administration, the Health Resources & Services Administration, and the Alcohol, Drug Abuse and Mental Health Administration. U.S. Dept. of Health and Human Services. NIH GUIDE SUPPLEMENT FOR GRANTS AND CONTRACTS, LABORATORY ANIMAL WELFARE, 2 (1985); Dresser, *supra* note 42, at 263.

⁶² Pub. L. No. 99-158, § 495 (1985).

⁶³ *Id.*

⁶⁴ PHS POLICY, *supra* note 2, § I, at 1.

⁶⁵ *Id.* at 27-28 [hereinafter PHS POLICY Animal Care Principles].

trary is established, investigators should consider that procedures that cause pain . . . in human beings may cause pain . . . in other animals.

V. Procedures with animals that may cause more than momentary . . . pain . . . should be performed with the appropriate . . . anesthesia. Surgical or other painful procedures should not be performed on unanesthetized animals paralyzed by chemical agents.

VI. Animals that would otherwise suffer severe . . . pain . . . that cannot be relieved should be painlessly killed at the end of the procedure or, if appropriate, during the procedure.

. . . .

VIII. Investigators . . . shall be appropriately qualified . . . for conducting procedures on living animals. Adequate arrangements shall be made for their in-service training, including the proper and humane care and use of laboratory animals.

IX. Where exceptions are required in relation to the provisions of these Principles, the decisions shall not rest with the investigators directly concerned but should be made, with due regard to Principle II, by an appropriate review group⁶⁶

These principles are reflected throughout the provisions of the PHS Policy. The Policy covers "[a]ny live, vertebrate animal used or intended for use in research, research training, experimentation, or biological testing or for related purposes,"⁶⁷ as opposed to the limited list of animals covered by the Act.⁶⁸ In this instance, the Policy surpasses the Act, because its protections are extended to a greater variety of animals used in research.

The Policy requires that institutions intending to use animals in their research submit a detailed assurance showing the institution's compliance with the Policy before any research can begin.⁶⁹ This report must include (among other things) the qualifications and responsibilities of the veterinarian who will be involved, a synopsis of training in humane animal use, instruction in reducing the number of animal intended for use, and minimizing animal distress for those involved with the research.⁷⁰

The Policy next lists the requirements for Institutional Animal Care and Use Committees (IACUCs) that review research facilities for adherence to the Policy. IACUCs must have at least five members and must include one veterinarian, one practicing scientist in animal research, one nonscientist, and one person not affiliated with the research facility.⁷¹ One member can fulfill more than one of these roles, as long as there are at least five members.⁷² The committees are to review research facilities

⁶⁶ *Id.*

⁶⁷ *Id.* § III(A), at 1.

⁶⁸ *See supra* note 41 and accompanying text.

⁶⁹ PHS POLICY, *supra* note 2, § IV(A), at 3.

⁷⁰ *Id.* § IV(A)(1)(g), at 4.

⁷¹ *Id.* § IV(A)(3), at 5.

⁷² *Id.*

every six months, taking note of any deficiencies in a facility's care and use of animals.⁷³

In their review of facilities, IACUCs must determine whether the facilities conform to the assurance and numerous additional requirements, including using procedures that will avoid discomfort to animals.⁷⁴ For those procedures that cause more than momentary pain, appropriate anesthesia will be used unless written justification is given by the scientist.⁷⁵ For animals that receive severe or chronic pain, they will be "painlessly sacrificed" at the end or during the procedure.⁷⁶ Other requirements overseen by the IACUC include that the "living conditions of animals will be appropriate for their species and contribute to their health and comfort."⁷⁷ Finally, the IACUC is to make sure the facility has enlisted a qualified veterinarian for medical care of the animals.⁷⁸ If the committee finds that the research facility is not conforming to the PHS Policy, it is empowered to suspend the research.⁷⁹

In PHS grant applications, scientists must describe the number of animals and the species intended for use, as well as the rationale behind these decisions.⁸⁰ Further, the facility must fully detail the proposed use of these animals and how they will insure that the "discomfort and injury to animals will be limited to that which is unavoidable in the conduct of scientifically valuable research."⁸¹ The Policy also requires facilities to keep records for at least three years for federal inspection.⁸²

2. *Problems with the Policy*

Although the PHS Policy is drafted to secure more protection for animal research subjects, it also includes language that keeps the scientist in control at the expense of animal suffering. One example of this is in the criteria used by the IACUC to approve research. The Policy requires the researcher to minimize pain only if the resulting procedure is "consistent with sound research design."⁸³ Further, by written scientific justification, the researcher can circumvent the requirement to use anesthesia to alleviate distress in more painful procedures.⁸⁴ Thus, animals can be in distress and the Policy would be powerless to help them.

Another criticism of the Policy is that it applies solely to federally funded projects and is not a legal mandate with which all research facili-

⁷³ *Id.* § IV(B)(1)-(3), at 6.

⁷⁴ *Id.* § IV(C)(1), at 7.

⁷⁵ *Id.*

⁷⁶ *Id.*

⁷⁷ *Id.*

⁷⁸ *Id.*

⁷⁹ *Id.* § IV(C)(6), at 8.

⁸⁰ *Id.* § IV(D)(1), at 9.

⁸¹ *Id.*

⁸² *Id.* § IV(E)(2), at 11.

⁸³ *Id.* § IV(C)(1), at 7.

⁸⁴ *Id.*

ties must comply.⁸⁵ Finally, the lack of enforcement of the PHS Policy adds to its ineffectiveness.⁸⁶ The PHS rarely enforces compliance with the policy and its self-enforcement policies are not likely to have much of an effect on research institutions.⁸⁷ In fact, one author states from practical experience that the National Institutes of Health (NIH), an organization governed by the PHS Policy, rarely followed its own guidelines.⁸⁸ He states "though the [NIH] did promulgate, since 1962, excellent guidelines for laboratory animal care, which every researcher and institution receiving federal funding through NIH theoretically had to adhere to, this was never enforced and thus, given human nature, was cavalierly ignored."⁸⁹

However, in general, the PHS Policy is an improvement over the Animal Welfare Act (the Act). It covers more research animals and provides more meaningful coverage. Although the PHS Policy is explicitly only applicable to PHS-funded projects, "the nature of the assurance mechanism encourages institutions to apply uniform standards to all its facilities and program components."⁹⁰ On the other hand, the PHS Policy and the Act do not do enough to protect animals "in the real world." "Laziness, ignorance, habit, ideological disregard for animal suffering and of the morality of animal use all combine[] to assure that animals [do] not receive the best treatment possible in research."⁹¹ Can this policy be improved to better include the views of animal rights activists and still promote meaningful scientific research?

3. *Justifications for Current Federal Policy and Animal Research* †

Despite short bursts of pro-animal sentiment, the federal regulatory control over animal research shows a strong societal preference to keep animal research relatively unencumbered.⁹² What are the justifications that lie behind these preferences? This section addresses the arguments that animal research supporters use to oppose regulations that benefit animals and that explain the current status of the policy.

Animals are used in research to learn about living things and how illnesses affect living systems.⁹³ This information helps to find cures that help both animals and humans in the future. Because society finds it unethical to test new drugs on humans, animals are used to determine the

⁸⁵ Thomas A. Decapo, Comment, *Challenging Objectionable Animal Treatment With the Share Holder Proxy Rule*, 1988 U. ILL. L. REV. 119, 129 (1988).

⁸⁶ Dresser, *supra* note 42, at 265.

⁸⁷ Rebecca Dresser, *Research on Animals: Values, Politics, and Regulatory Reform*, 58 S. CAL. L. REV. 1147, 1167 (1985).

⁸⁸ BERNARD E. ROLLIN, *ANIMAL RIGHTS & HUMAN MORALITY* 185 (rev. ed. 1992).

⁸⁹ *Id.*

⁹⁰ Dresser, *supra* note 42, at 264.

⁹¹ ROLLIN, *supra* note 88, at 185.

⁹² Dresser, *supra* note 42, at 266.

⁹³ For a more in-depth discussion of the rationale for animal research, see COMMITTEE ON THE USE OF ANIMALS IN RESEARCH, SCIENCE, MEDICINE, AND ANIMALS, 4 (1991) (hereinafter COMMITTEE ON ANIMAL USE).

harmful or beneficial effects of these drugs and judge their usefulness for humans.⁹⁴

One reason scientists support animal research as a study method is the amount of control scientists can exert over such experiments.⁹⁵ Scientists can precisely monitor environmental and nutritional aspects of the experiment at a level that would simply not be possible for human subjects.⁹⁶ In addition to the experiment control aspect, many test animals have biological systems similar to humans; thus the results culled from animal research can be very useful in human applications.⁹⁷ As this last point implies, “[m]ost researchers generally hold that non-animal experiments are adjuncts rather than alternatives to animal experiments.”⁹⁸ Although useful, alternatives like computer models and tissue cultures cannot duplicate the detailed actions and reactions of a complex organism. It is only the animal subjects that will give the useful information the researcher desires.

Finally, there is a utilitarian argument for animal research. Many scientists feel that it “makes no sense to sacrifice future human health and well-being by not using animals in research today.”⁹⁹ Further, “it would be immoral and selfish not to use animals in research.”¹⁰⁰ This position is based on the many benefits that have come from animal research. Researchers look with disdain at any regulations that impede their scientific creativity and increase the cost of using animals in research.¹⁰¹ Both the constraints on creativity and the higher cost of research will affect humans in the long run as cures for diseases slow or do not arise.

Given these reasons for animal research, it is not hard to see why the regulations have mainly been fashioned to accommodate the researchers. While researchers may complain about animal research regulation affecting their scientific progress, they fail to see that in the vast majority of

⁹⁴ This avoids the question of whether it is unethical to conduct research on animals.

⁹⁵ COMMITTEE ON ANIMAL USE, *supra* note 94, at 4.

⁹⁶ *Id.* The questions to ask here are why these conditions are unacceptable for human beings and why don't those reasons also apply to animal subjects?

⁹⁷ It is important to note that besides the animal rights justifications described later in this comment, another important reason to limit animal research is that such research is inherently unreliable. This can be seen by trying to extrapolate the results of an animal experiment to a human. Such results are usually totally irrelevant because humans are physiologically and mentally different from animals. Don Barnes, *Vivisection: A Window to the Dark Ages of Science*, THE ANIMALS' AGENDA, July/Aug. 1996, at 20, 21. “The truth is that vivisection is based on a faulty premise; despite some similarities between mammals, the vast differences negate the hoped-for extrapolative properties.” *Id.* For further information regarding this argument against animal research, see generally COLEMAN, *supra* note 7. Not surprisingly, non-animal research methods have been scientifically demonstrated to equal or exceed traditional animal-based experiments used to predict human acute toxicity. See *Making a Difference*, THE ANIMALS' AGENDA, Jan./Feb. 1997, at 6, 7.

⁹⁸ COMMITTEE ON ANIMAL USE, *supra* note 93, at 15.

⁹⁹ *Id.* at 27.

¹⁰⁰ *Id.*

¹⁰¹ *But see* ORLANS, *supra* note 23, at 21 (“many researchers have sought to minimize and reduce unnecessary use of animals”).

cases "the research scientists still holds the key to the laboratory door"¹⁰² and thus retains an immense amount of control in the face of animal suffering. What are the reasons that animal rights activists give to combat these justifications for using animals in research? These reasons are reviewed in the next section.

IV. ANIMAL RIGHTS JUSTIFICATIONS AGAINST ANIMAL RESEARCH

A. *Defining the Animal Rights Position*

Before giving the animal rights view of animal research as stated by Tom Regan, some time must be devoted to what exactly is meant by the term "animal rights." The media portrays animal rights activists as everything from law abiding citizens favoring legal avenues to voice their concerns to radicals who will do and destroy anything to protect animals from research. Because the latter activities are greatly publicized, most animal activists are "portrayed as anti-science and anti intellectual terrorists."¹⁰³ To continue this analysis with such a broad definition of animal rights will not help to formulate an ideal federal policy.

Barbara Orlans summarizes the attitudes towards animals in research by placing the attitudes on a spectrum of increasingly pro-animal sentiment.¹⁰⁴ Her interpretation presents views from the "animal exploitation" to the "animal rights" ends of the spectrum.¹⁰⁵ The following discussion of animal research positions is a brief summary and explanation of Orlans' spectrum.

On the far left of the spectrum comes the "animal exploitation" view. Here, people who hold this view fanatically feel that animals exist solely for human use. Consequently they strongly believe that there should be absolutely no regulations concerning animal use in research. If laws are made, animal exploiters feel justified in breaking them to maintain their dominion over animals. Many feel that researchers tend to hold the animal exploitation view.¹⁰⁶

Moving to the right on the continuum comes the "animal use" attitude. Here, believers feel that they can self-regulate animal use in research themselves. They do not need federal regulation coming in and telling them what to do. Animal users do not want further regulations to be passed and are willing to fight for their beliefs legally.¹⁰⁷

Further right on the spectrum is the "animal welfare" position. Here, people who follow this mentality feel that they have some responsibility to protect the well-being of animals. Thus, they feel legal limits should be imposed on animal research. They also welcome further regulations restricting animal use in research.¹⁰⁸

¹⁰² H.R. REP. NO. 91-1651 (1970), reprinted in 1970 U.S.C.C.A.N. 5103, 5104.

¹⁰³ ORLANS, *supra* note 23, at 21.

¹⁰⁴ *Id.* at 22, fig. 2.1.

¹⁰⁵ *Id.*

¹⁰⁶ *Id.*

¹⁰⁷ *Id.*

¹⁰⁸ *Id.*

The more pro-animal attitude towards animal research, "animal rights," is the one focused on in this paper. The "animal rights" supporters feel that animals are instilled with certain intrinsic rights similar to human beings. They would agree to animal research if the intrinsic rights of animal subjects could be preserved and respected. They also believe that killing animals should only be performed to eliminate its suffering. The majority of animal rights activists favor demonstrations, legal challenges, and civil disobedience to ensure protection of animals' rights.¹⁰⁹

Finally the most extreme view to the right of Orlans' continuum is the "animal liberation" attitude. Many critics of animal regulations confuse this group with the animal rights activist group and use the animal liberation group's activities to bolster their arguments for animal research and against animal rights. Individuals of this group believe that animals should not be used by humans in any way. Many advocate the downfall of capitalism and property rights to completely protect animals. Just like the animal exploitation group, followers here will undertake breaking laws, in this case if it furthers their goals of saving animals. Such activities usually include raiding laboratories to free animals.¹¹⁰

The primary focus of this paper utilizes the animal rights position as defined above with current federal policy to come to a compromise between the two extremes of the "attitude" continuum. The current federal regulations described in Section III above seem to fall somewhere between the animal use and welfare attitudes. This Comment attempts to construct a new federal statute that will push federal policy on animal experimentation to the right on the continuum to encompass the animal rights view.

Before stating and explaining such a statutory provision, it is important to go behind the words of the animal rights view and see what justifications support it. Further, by addressing and diffusing the common criticisms usually brought against this view, the animal rights viewpoint for a federal policy will be even stronger.

B. *The Premises of Animal Rights*¹¹¹

1. *Moral Status of Animals*

A primary foundation for the animal rights view is that animals "have feelings, desires, and preferences and that their moral status should be based on their capacity to suffer or experience pleasure."¹¹² Peter Singer

¹⁰⁹ *Id.*

¹¹⁰ *Id.*

¹¹¹ This section presents only a cursory overview of the most important arguments underlying the animal rights movement. For sources including compilations of animal rights materials, see generally ANCHOR, *supra* note 56 (providing an excellent and updateable resource list in addition to a thorough overview of all aspects of animal rights and activism); BETTINA MANZO, *THE ANIMAL RIGHTS MOVEMENT IN THE UNITED STATES, 1975-1990* (1994); CHARLES R. MAGEL, *KEYGUIDE TO INFORMATION SOURCES IN ANIMAL RIGHTS* (1989).

¹¹² *Id.* at 25 (summarizing Peter Singer's view).

believes that "there are no good reasons, scientific or philosophical, for denying that animals feel pain."¹¹³ All sentient creatures (humans and non-humans)¹¹⁴ that feel pain have an equal interest in avoiding this pain and that these equal interests should be treated equally. Singer is not saying animals and humans are morally equal or feel the same amount of pain from the same stimulus. However, he believes unjustified pain should not be inflicted on either humans or animals because both have an equal interest in avoiding equivalent amounts of pain. Peter Singer explains this with an example:

If I give a horse a hard slap across its rump with my open hand, the horse may start but it presumably feels little pain. Its skin is thick enough to protect it against a mere slap. If I slap a baby in the same way, however, the baby will cry and presumably feel pain, for its skin is more sensitive. So it is worse to slap a baby than a horse, if both slaps are administered with equal force. But there must be some kind of blow—I don't know exactly what it would be, but perhaps a blow with a heavy stick—that would cause the horse as much pain as we cause a baby by slapping it with our hand. That is what I mean by "the same amount of pain," and if we consider it wrong to inflict that much pain on a baby for no good reason then we must . . . consider it equally wrong to inflict the same amount of pain on a horse for no good reason.¹¹⁵

Inflicting pain in either humans or animals is unjustified any time the benefits of causing the pain are exceeded by the harm. Jeremy Bentham, an eighteenth-century philosopher on whom Singer based much of his work, sums Singer's premise stating "[t]he question is not, Can they *reason*? nor, Can they *talk*? but, Can they *suffer*?"¹¹⁶

A common retort to such a theory states that pain may be inflicted on animals for no justifiable reason and not on humans simply because humans are humans and animals are animals. Singer addresses this view commonly known as "speciesism" by comparing it to other forms of discrimination like racism and sexism.¹¹⁷ Because these forms of discrimination "fail to accord equal consideration to equally significant interests[,] . . . [they] are morally wrong."¹¹⁸ Similarly, to ignore the interests of spe-

¹¹³ SINGER, *supra* note 16, at 15. Singer bases his premise that animals feel pain on three main criteria. The first is that animals react to pain stimuli like humans. Both animals and humans display external signs of which the inference of pain may be deduced. These are generally writhing, calling out and attempts to avoid the source of the stimuli. Another reason on which to base that animals feel pain is that animals and humans have similar nervous systems. Finally, Darwinian theory supports the fact that animals feel pain for it is only through the avoidance of pain that creatures can survive. *Id.* at 10-15.

¹¹⁴ Sentient creatures are "organisms that are responsive to or conscious of sense impressions." CLIFFORD J. SHERRY, *ANIMAL RIGHTS: A REFERENCE HANDBOOK* 4 (1994).

¹¹⁵ SINGER *supra* note 16, at 15.

¹¹⁶ JEREMY BENTHAM, *AN INTRODUCTION TO THE PRINCIPLES OF MORALS AND LEGISLATION* 175-76, at n.1 (J.H. Burns ed., Clarendon Press 1996) (1780).

¹¹⁷ Speciesism is the view that humans are better than other species solely because of their species. *Id.* Singer defines the word as "a prejudice or attitude of bias in favor of the interests of members of one's own species and against those of other species. Singer, *supra*, note 16, at 15.

¹¹⁸ ORLANS, *supra* note 23, at 25.

cies solely because of their species is just as morally wrong as racism and sexism.¹¹⁹ Thus, the speciesism argument cannot be used to effectively justify that animals are not entitled to the same interests and rights as humans. This argument is just as ineffective as racism being used to prove that black Americans are not entitled to the rights afforded to white Americans. Both arguments have no justification and as such are "morally irrelevant."¹²⁰

To experiment on animals and cause suffering is morally wrong if such efforts are not for a significant purpose. Thus, finding new cosmetics would not seem to be a sufficiently important justification for exposing millions of animals to extreme levels of research-inflicted pain. The Draize test, described in Section II above, is a good example of such an experiment. What about the justification for research towards finding a cure for cancer? With the analysis so far, animals could be used here without restriction, because such research is for a good reason. The animal rights view carries this analysis further with its stance on inherent rights of animals.

2. *Inherent Animal Rights*

Tom Regan has put forth the theory that animals have basic and inherent rights. These rights are based on the premise that animals have inherent worth that is totally separate from human involvement. For example, even if humans did not exist, animals would have some value that is independent from humans just as a cow's milk would have value to a calf regardless of human involvement.¹²¹ This value may be aesthetic or for the pure value of its existence.¹²² That is, because it exists it has a certain amount of value. This value may also come from the symbolic value of life and how precious it is regardless of species. Whatever the nature of the value, because it exists it must be respected and not destroyed for the use of others without restriction.

If animals do have some rights as argued in the discussion above, then there is a limit to what can be done to animals.¹²³ Additionally, these limits are not placed on the animal by statutes or case law but are fundamental to the animals' existence. Therefore, animals should have rights that must be respected and would require significant changes in how humans could use animals in research.

From this foundation, Regan continues his argument by describing animals as "subjects-of-a-life."¹²⁴ He defines subjects-of-a life as having:

beliefs and desires; perception, memory and a sense of the future, including their own future, an emotional life together with feeling of pleasure and pain, preference and welfare interests; the ability to initiate action in pursuit of their

¹¹⁹ *Id.*; SINGER, *supra* note 16, at 7.

¹²⁰ ORLANS, *supra* note 23, at 25.

¹²¹ PETER WENZ, ENVIRONMENTAL JUSTICE 137 (1988).

¹²² *Id.*

¹²³ *Id.*

¹²⁴ TOM REGAN, THE CASE FOR ANIMAL RIGHTS 243 (1983).

desires and goals; a psychophysical identity over time; and an individual welfare.¹²⁵

Following this reasoning, animals have inherent worth, and as such, the right to be free from being seriously harmed or sacrificed for the good of others in all situations including biomedical research.

The definition of subject-of-a-life can be hard to picture. The terms within the definition cannot be readily seen by some as applying to animals. To aid in this understanding Peter Wenz, an associate professor of philosophy and legal studies, applies this definition to his pet to show how his dog is a subject-of-a-life.

Consider my dog, Chamois. *She clearly has perception and memory.* If she sees me in jogging clothes, she will go into her house. She remembers that if I take her to the park when I have just put on my jogging clothes, she will have to run. *She has desires and goals.* For example, on hot days she likes to escape the heat by sitting in a dirt hole. *She is able to initiate action in pursuit of her desires and goals.* On a hot day she begins digging a hole so that she can later sit in it. On some other days she digs a hole underneath our fence so that she can escape from our yard and eat the neighbor's garbage. *She obviously can feel pleasure and pain;* pleasure, for example, when she plunges into the pond in the park; pain when, having an ear infection, she scratches at her ear and whines. So she has an experiential life that can fare well or ill *for her*, independently of how her life affects anyone else. She has a *welfare of her own* and, therefore, is a subject-of-a-life.¹²⁶

Just about anyone can try this same exercise with the behavior of his or her own pets, and a similar result will follow. These perceptions are not scientifically gathered in a laboratory but come from simple perception of animal behavior resulting from a close relationship with the animal. However, personal perceptions are not the sole foundation for showing that animals are subjects-of-a-life.¹²⁷ Rather, animal behavior studies indicate conclusively that all normal nonhuman animals over one year of age (including birds) display similar behavior as Chamois and therefore should be treated as subjects-of-a-life.¹²⁸

One response to this reasoning is the speciesist argument that only humans possess these inherent rights. Speciesist proponents defend this view by saying that only humans have "immortal souls."¹²⁹ Thus, only humans are entitled to having rights and therefore are the only subjects-of-a-life. Regan counters that this justification is itself highly controversial and vague. To depend on such a theory to justify a position is to "dig one's hole deeper, not to climb out."¹³⁰ Also as described above, speciesism is a very weak argument in its own right. Thus, the immortal soul justification

¹²⁵ *Id.*

¹²⁶ WENZ, *supra* note 121, at 140 (emphasis added).

¹²⁷ Personal perceptions of animal behavior can be the most compelling justification for animals being subjects of a life.

¹²⁸ WENZ, *supra* note 121, at 140.

¹²⁹ TOM REGAN, *The Case for Animal Rights*, in ANIMAL RIGHTS AND HUMAN OBLIGATIONS 105, 112 (Tom Regan & Peter Singer eds., 2d ed. 1989).

¹³⁰ *Id.*

for only humans having rights is a vague theory based on a morally irrelevant justification. The efficacy of such an attack on the animal rights view is thus extremely low.

Another approach used to diffuse Regan's argument is to counter-argue that while animals may have some value, it is much less than the value of a human life, and therefore it is acceptable to use animals in experimentation.¹³¹ This argument is based on the theory that humans have more value than animals because humans have greater intellect and reasoning ability than animals.¹³² While this is true between most humans and most animals, it is not completely true. The mentally retarded and young children are all mentally deficient compared to the majority of humans and are often unable to give informed consent. This does not mean that society may consider such groups of lesser value and thus subject them to unrestricted experimentation. Rather, these groups have inherent value as subjects-of-a-life and deserve the right to be treated fairly. The law has enforced this moral view in its staunch protection of these vulnerable groups.¹³³

Many non-human mammals have been shown to possess intellectual reasoning and ability at least equal to children.¹³⁴ Similarly, mammals, like children and the mentally retarded, are unable to give informed voluntary consent to participate in research. Since this is the case, mammals must be afforded the same rights given to children if rights are based on intellect and reasoning ability. The moral argument should be augmented by the law to give animals this level of respect and protection under a statutory umbrella. As has been shown with current federal law, this is far from being true in the present day. How could federal policy be constructed so that the inherent rights of animals would be respected, while still allowing valuable research to proceed? The next section deals with this question.

V. THE REVISED FEDERAL POLICY

By changing current federal policy to incorporate animal rights, our society can come closer to respecting animals not only because of what they do for us, but as valuable entities in themselves. The first step in constructing a federal policy incorporating such a theory is to decide how animal rights will be represented in a statutory framework. With humans, the law focuses on the informed consent of the subject to assure that the person fully understands what will be happening. With animals, obtaining informed consent is not yet possible. However, since animals possess rights and qualities similar to those of children, an animal rights statute should be modeled after regulations controlling how children will be used in research. For children, the level of risk compared to the benefit is the primary concern, not the level of informed consent.

¹³¹ *Id.*

¹³² *Id.*

¹³³ *Id.*

¹³⁴ ORLANS, *supra* note 23, at 26.

The most authoritative policy covering adults and children is Title 45, Part 46 of the Code of Federal Regulations (C.F.R).¹³⁵ By modeling a new animal research federal policy on such a framework, with changes that incorporate true animal rights beliefs, animals will finally be given the protection the current policies profess to give. The new policy outlined below begins with language from the current policies and adds significant improvements using an animal rights philosophy. It incorporates the C.F.R. and portions of the PHS Policy to result in a true "animal rights" regulation.

A. *The Animal Rights Act (Selected Provisions)*

§ 100 To what creatures shall these Policies Apply?

- (a) This act shall apply to all research involving any animals.
- (b) Exceptions:
 - (i) Where the research is strictly observing the animal subjects in their natural environment and involves no interference of the researcher on the animal.
 - (ii) Where the research is strictly concerned with collecting and studying already existing data.¹³⁶

§ 101 Definitions.

- (a) "Animals" are to include any warm or cold-blooded vertebrate creature, and any other sentient animal. For the purposes of this act, "animal" does not include tissue cultures or other single celled organisms.
- (b) "Minimal Risk" means that the risk of harm anticipated in the proposed research is not greater, considering possibility and magnitude, than those encountered in daily life.¹³⁷
- (c) "Serious health concern" includes any treatment of an animal or human related disease or ailment that affects animals or humans in a extremely grave fashion. The term can also mean gaining knowledge concerning such grave health conditions. This term is not to include any cosmetic or other non-health use or product.

§ 102 Assurances.

- (a) Each research institution shall give a written assurance to the Animal Rights Committee (ARC) that it will follow and comply with all of the requirements set forth.¹³⁸ This shall include at a minimum:
 - (1) A statement outlining the principles the institution will follow when conducting the proposed research. This statement shall specifically outline:
 - (i) how the institution views the rights of its animal subjects;
 - (ii) the degree to which these rights extend;

¹³⁵ 45 C.F.R. § 46.101-409 (1997).

¹³⁶ *Id.* § 46.101 (b)(5).

¹³⁷ *Id.* § 46.102 (g).

¹³⁸ *Id.* § 46.103 (a).

- (iii) justifications for the institution's view of animal rights; and
- (iv) how it will preserve the rights of its animal subjects during the research.

(2) A statement outlining the proposed goals and benefits of the research and how these goals compare to the proposed risks to animal subjects. If the risks exceed the proposed benefits and/or the probability of success is unreasonably low compared to the risks to animal subjects, the institution shall sufficiently justify this imbalance to allow the animal research to proceed.

§ 103 ARC Membership.

(a) Each ARC shall have only five members with varying backgrounds to conduct the complete and adequate review of research activities commonly conducted by the institution. The ARC shall be sufficiently qualified through the experience and expertise of its members to promote respect for its advice and counsel in safeguarding the rights and welfare of animal subjects.

(b) Each ARC will consist of:

(1) "[O]ne Doctor of Veterinary Medicine, with training or experience in laboratory animal science and medicine";¹³⁹

(2) One practicing scientist with experience in animal research that will be commonly used in the institution;¹⁴⁰

(3) One member representing an animal rights society that deals with the particular or similar species of animals that are proposed to be used at the institution, and this member having the responsibility to keep the rights of the animal subject(s) foremost in his or her mind;

(4) "[O]ne member whose primary concerns are in a nonscientific area (for example an ethicist, lawyer, member of the clergy)";¹⁴¹ and

(5) One member of the general public.

(c) All members of the ARC will not be affiliated with the institution in any way other than as a member of the ARC, and will not be a member of the immediate family of a person who is affiliated with the institution.¹⁴²

(d) The research institution shall have the responsibility of recruiting the members of the ARC under the rules of this Act. Members of the ARC shall come from the immediate surrounding community if possible. If one or more members of the ARC are not obtainable from the immediate community, the research institution is permitted to extend its search a reasonable distance to obtain such committee members.

(e) The research institution shall compensate members of the ARC the amount of reasonable travel and housing expenses only. Any further remuneration is strictly forbidden. All matters of remuneration are to be kept confidential.

¹³⁹ PHS Policy, *supra* note 2, § IV(A)(3)(b)(1), at 5.

¹⁴⁰ *Id.* § IV(A)(3)(b)(2), at 5.

¹⁴¹ *Id.* § IV(A)(3)(b)(3), at 5.

¹⁴² *Cf. id.* § IV(A)(3)(b)(4), at 5 (expanding the requirement from one individual not affiliated or related to members of the institution to an entirely unaffiliated Animal Rights Committee (ARC)).

§ 104 ARC review of research.

- (a) An ARC shall review and have the authority to approve, require modifications in (to secure approval), disapprove, and discontinue all research activities covered by these regulations.¹⁴³
- (b) An ARC shall review at least once every six months the institution's program for humane care and use of animals.¹⁴⁴
- (c) An ARC shall inspect at least once every six months without warning all of the institution's animal facilities (including satellite facilities).¹⁴⁵
- (d) If the ARC discovers that the research institution has failed to abide by the standards maintained by this Act, or that the research institution has violated the rights of animal subjects involved in the research, the ARC shall immediately suspend all research activities and remove all animal subjects to proper care facilities until such time as the violation has been resolved.
- (e) If the ARC discovers the research institution has violated any provision of this Act twice, the ARC is fully authorized to discontinue the research and remove all animal subjects to proper care facilities.

§105 Criteria for ARC approval of research.

- (a) In order to approve research covered by these regulations, the ARC must determine that all of the following requirements are satisfied:
 - (1) Risks to animal subjects are minimized by using procedures that, while consistent with sound research design, do not unnecessarily expose animal subjects to unreasonable risks.¹⁴⁶
 - (2) Risks to animal subjects are reasonable in relation to anticipated benefits and the importance of the knowledge that may reasonably be expected to result.¹⁴⁷
 - (3) The animals selected for the procedure should be . . . the minimum number required to obtain valid results. Methods such as mathematical models, computer simulations, and *in vitro* biological systems must be fully utilized and documented before animal subjects are requested.¹⁴⁸
 - (4) Proper use and respect of animals, including the avoidance or minimization of pain is of utmost importance. Unless the contrary is established, actions that cause pain in humans will do the same for animals.¹⁴⁹
 - (5) Action that may cause more than momentary pain for the animal subject and expose the animal subject to greater than minimal risk must be fully justified and authorized before they are conducted. In analyzing such procedures consider the following:

¹⁴³ Cf. 45 C.F.R. § 46.109(a) (1997) (adding the power to discontinue research to the arsenal of the ARC).

¹⁴⁴ PHS Policy *supra* note 2, § IV(B)(1), at 6.

¹⁴⁵ Cf. *id.* § IV(B)(2) (adding the element of surprise to ARC review of institutions).

¹⁴⁶ 45 C.F.R. § 46.111(a)(1) (1997).

¹⁴⁷ *Id.* § 46.111(a)(2).

¹⁴⁸ PHS Policy Animal Care Principles, *supra* note 65, § III, at 27.

¹⁴⁹ *Id.* § IV, at 27.

(i) "The risk represents only a minor increase over minimal risk";¹⁵⁰ and

(ii) The increase in risk is fully justified against the importance of the results and the probability that the goal to be reached will materialize. In such procedures, the importance of the knowledge to be obtained must concern serious health matters of either the animal subjects or of similar human health concerns. Under no circumstances may procedures that cause more than minimum pain be utilized to conduct any product testing not specifically focused on a serious health concern.

(iii) If approved, such procedures may only be performed with the appropriate anesthesia. Surgical or other painful procedures that are a great increase over minimal risk should never be performed on animals.

(6) Animals will not intentionally be made to suffer severe pain for any purpose. Animals that do suffer severe pain that cannot be relieved should be painlessly killed whenever such pain ensues.¹⁵¹

(i) If an animal subject does suffer such severe pain, the institution will review their research design with the ARC to prevent such a result from occurring again. If such a result should happen a second time, the ARC shall investigate the matter as dictated by this Act.

(ii) Again, a procedure that would cause severe pain in humans should be considered to do the same to the animal subject.

(7) Investigators will be appropriately qualified for conducting procedures on animals. They shall be required to successfully complete and document the following training:

(i) thorough in-service training, including the proper and humane care and use of laboratory animals.¹⁵²

(ii) minimum philosophical training in animal rights and its justifications.

(8) Medical care for animals will be available and provided as necessary by a qualified veterinarian.

(b) There will be no exceptions in relation to the provisions of these Principles.

§ 106 Review by institution.

Research covered by these regulations that has been approved by an [ARC] may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an [ARC].¹⁵³

.....

§ 108 ARC Records.

¹⁵⁰ 45 C.F.R. § 46.406 (a) (1997).

¹⁵¹ PHS POLICY Animal Care Principles, *supra* note 65, § VI, at 27.

¹⁵² *Id.* § VIII, at 28.

¹⁵³ 45 C.F.R. § 46.112 (1997).

(a) An institution, or where appropriate an ARC, shall prepare and maintain adequate documentation of ARC activities, including the following:

(1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, progress reports submitted by investigators, and reports or injuries to animal subjects.¹⁵⁴

(2) Minutes of ARC meetings shall have sufficient detail to show:

(i) which members attended the meetings;

(ii) what each member contributed to each meeting;

(iii) actions taken by the ARC;

(iv) the vote from the members that resulted in such actions including which members approved, denied or abstained on each action;

(v) the justification for approving or disapproving research including how this decision affects the rights of the animal subjects; and

(vi) a written summary of debated issues and how they were resolved.¹⁵⁵

§ 109 Applications and proposals lacking definite plans for involvement of animal subjects.

Applications in this category need not be reviewed by an ARC before approval is given; however, no animal subjects may be involved in any project until the project has been reviewed and approved by the ARC, as provided by this regulation.¹⁵⁶

§ 110 Research undertaken without the intention of involving animal subjects.

In the event any research is undertaken without the intention of involving animal subjects, but it is later proposed to use animal subjects in the research, the research shall first be reviewed and approved by an ARC, as provided by these regulations, a certification submitted to the department, and final approval given to the proposed change by the Department.¹⁵⁷

B. Analysis of the Animal Rights Act

Although the policy proposed above incorporates the language of the current federal policy concerning research animals, it goes much further in representing the rights inherent in animal subjects and in rectifying some of the glaring mistakes in current policy. The following analysis of the proposed Animal Rights Act (ARA) highlights corrections made to the old policy and indicates how the rights of animals can truly be protected. This new policy will help to balance the needs of animals and science.

The first section deals with the general scope of the ARA. The provision makes clear that the ARA will cover all aspects of research including animals. The definition of "animal," defined in section 101(a), is a huge

¹⁵⁴ *Id.* § 46.115(1).

¹⁵⁵ *Id.* § 46.115(2).

¹⁵⁶ *Id.* § 46.118.

¹⁵⁷ *Id.* § 46.119.

change from the current Animal Welfare Act.¹⁵⁸ The ARA defines "animal" as all species of vertebrate animals and leaves room for other animals that are sentient or experience pain. From this definitional foundation, the ARA goes on to protect more animals and their rights than current federal policy.

Another important definition included in section 101(c) is "serious health concern." This term will be used by the ARC to determine which research experiments to allow and what degree of risk will be permissible in these experiments. The new definition will try to include only health-related matters of a degree significant enough to justify greater than minimal risk. The definition also specifically excludes cosmetic or other similar product testing.

Section 102 addresses written assurances from institutions promising to follow the guidelines of the ARA. Besides following the current policy for research involving children, the animal research context requires some additional information from researchers. Specifically, section 102(a)(1) of the ARA requires that the institution's written assurance includes a full explanation of how the institution views animal rights and directs the researcher to justify its philosophical stance. Then the researcher must describe how the experiment will not violate the institution's level of animal rights. This requirement will force the researcher to incorporate animal rights into the design of the experiment and to consider how the experiment will effect the rights of the animal subjects.

Additionally, section 102(a)(2) requires the researcher to balance the risks for animal subjects against the likely results of the experiment and the importance of these results. Where the level of risk is greater than the benefits, the institution must justify this imbalance. By making the institution think about the likely risks and benefits of his proposed research, the researcher is more likely to intelligently construct his experiment making sure the rights of the animal subjects are preserved.

The guidelines to the ARC, outlined in section 103 are of particular importance to the effectiveness of the ARA. The provision differs from other federal policy because section 103(a) limits the number of members to five well-defined people with specific backgrounds. The most important change here is that section 103(b)(3) requires that one ARC member must be from an animal rights group concerned with the types of animals being used in the research. This provision is meant to insure that there is at least one voice on the panel who is a proponent of animal rights. The ARA balances this pro-animal interest with a scientist experienced in the type of animal research being proposed. The rest of the ARC is comprised of specialists in non-science areas and one member of the general public to bring other points of view, as well as common sense, to the ARC's decision.

The ARA goes on in section 103(c) with another departure from current policy: none of the ARC members is to have any association with the

¹⁵⁸ See Rowan, *supra* note 44 and accompanying text (describing the animals currently covered by the Animal Welfare Act).

research institution. This is to intended to reduce bias and self interest of ARC members. Similarly, ARC members may not be associated with members of the researcher's family. The main goal is to for the ARC to weigh the rights of the animal subjects against the benefits of research in the most objective setting possible. Additionally, as stated by section 103(d), all members of the ARC are to come from the surrounding area (as much as is reasonably feasible) to establish a community standard for the treatment of animal subjects in research.

To further enhance the ARC members' objectivity, the ARA section 103(e) limits payment of their services to reasonable travel and housing expenses while the members are on the committee. Any further compensation is strictly forbidden. The main goal with these limitations is to mitigate possible bias caused by the research institution "bribing" members of the committee for favorable judgments through increased salaries. Further, all matters regarding payment of members of the ARC are to be kept secret to maintain objectivity within members of the committee.

The main change to federal policy embodied in section 104 is to include the element of surprise into ARC review of research facilities. Section 104(c) calls for the ARC to visit the research facilities of institutions unannounced so that the ARC can see a true measure of compliance with the ARA by the research institution. The current federal policy does not specifically provide for "surprise" inspections.¹⁵⁹ By specifically prohibiting such notice, the ARC will be able to observe how the institution actually treats animal subjects. This provision also should encourage institutions to keep their day-to-day standards within the minimum the ARA requires because a violation would stop the research. This eventually will lead to better treatment of animal subjects throughout their stay at the research facility because the threat of a surprise visits keeps the researcher's hands "clean."

Section 104 also proposes a progressive punishment program. This punishment scheme involves giving the researcher a large incentive to comply with the ARA and thus properly respect the rights of his animal subjects. If the research institution fails one time to abide by the provisions of the ARA, the ARC is authorized by section 104(d) to suspend research and make sure the animal subjects are properly cared for until the researcher comes into compliance. If the institution violates the ARA a second time, the ARC is further enabled by section 104(e) to permanently discontinue the research experiment at its discretion. Such provisions are directly opposite to current federal policy that gives the researcher, the most biased of the participants in this struggle of rights, the ultimate power in deciding which provisions to follow.

Section 105 of the ARA gives the essential guidelines that the ARC must consider in approving research and thus defines the main purposes of the ARA. Drastic improvements are made to respect animal rights while allowing valuable experimentation to continue. Section 105(a)(3) makes sure that all alternatives to animal research are fully used and documented

¹⁵⁹ PHS POLICY, *supra* note 2, § IV(B)(2), at 6.

and if animals are still needed, such use is fully justified. This provision has two main purposes relating to respecting animal rights. The first is that requiring researchers to explore all alternatives to animal subjects may encourage the researcher to choose an alternative that meets his scientific objectives. Thus, the need for animal subjects can be reduced, if not eliminated, keeping animals out of the laboratory and thereby out of the range of experimental risk.

The second reason to require an analysis of alternatives is to weed out frivolous experiments. To engage in the amount of pre-testing required by the ARA will require a substantial sum of money before any of the actual research commences. By tacking this additional expense onto all proposed research, institutions will drop projects that are not economically viable and further reduce the chances that animals will be subjected to superficial research.

Section 105 also categorizes research by the level of risk for the animal subjects. For experiments that subject the animal to minimal risks, section 105(a)(2) requires the benefits and the probability of those benefits at least meet the level of the risk. For risks greater than minimal the ARA becomes much more restrictive. Section 105(a)(5)(i) states that the increase in risk (beyond minimal risk) can only be a minor increase that the committee must consider. Further, section 105(a)(5)(ii) requires the level and probability of benefit from the research must not only be greater but must also pertain to a "serious health concern." Any procedure that will cause the animal subject to experience a greater increase over minimal risk is strictly prohibited. If an animal subject does suffer extreme pain, section 105(a)(6)(i) makes sure that this event will be immediately looked into to prevent a similar occurrence from happening again.

Section 105(7) requires the researcher to undergo significant training. This training not only includes the normal care and use of animals required by current law, but also a minimum level of philosophy concerning animal rights and its justifications. This serves two purposes. First, the researcher must learn why animals have rights and must be able to justify this position. With this knowledge, the researcher will be able to properly design and conduct his experiment fully taking into account the rights of animals. The second reason for requiring such training is to make it more time consuming for researchers to conduct animal experiments. Taking the time to learn about animal rights will be a powerful incentive to some researchers to avoid using animals in favor of the many alternatives available or to discontinue the research altogether. This again lessens the chances that animals will be used in a research setting, thereby preserving their rights.

Section 106 makes the point that the ARA is the minimum protection for animal subjects. Thus, institutions may increase the level of protection but may not go below what the ARA requires. This again insures a minimum level of security for the rights of animals.

Section 108 of the ARA allows more detail in review of ARC meetings. ARC members are required to do more than simply vote on issues covering animal research: they are also required to attend meetings, participate

in discussions, and justify their decisions in regards to how they will affect the rights of the animal subjects. This will ensure that all members of the committee are heard and that one person is not guiding the other members. It will also assure that the members of the ARC will fully debate and ponder their decision. This section will not allow the ARC members to arbitrarily decide on the rights of animals because it requires a full justification of the decision.

Finally, research that inadvertently or unexpectedly requires animal subjects may not escape the authority of the provisions of the ARA through sections 109 and 110. The ARA takes effect as soon as the researcher needs to use animal subjects and the researcher must comply and follow all of the provisions of the ARA even though he did not anticipate using animals when the research began. Again, unexpected circumstances will not detrimentally affect the importance of the animal subject's rights.

VI. CONCLUSION

This Comment proposes a new federal statute that protects the rights of animals and still allows valuable research to continue benefiting both humans and animals. Current federal policy was analyzed to see where such policy succeeds in protecting animals and where such policy fails to do so. By next reviewing the justifications of the opposite camp, those of animal rights, and how these justification stand up to the reasons given by the current policy, a definite need for change can be seen. Next, by taking the current federal policy and combing it with the animal rights perspective and correcting the flaws that clash with animal rights, a new federal policy has been proposed and explained that makes the compromise occur.

Thus, the Animal Rights Act succeeds in fulfilling the goals of current federal policy while continuing to allow valuable research to continue. This does not mean that if such a policy ever was enacted, researchers would embrace the change. In all probability, such a change in policy would be met with much resistance because research involving animals would become much harder to conduct.

All types of research activities would have to make drastic changes. Passage of the proposed new statute would require those wishing to perform "frivolous" research to use their ingenuity to find new ways to test and market their products without violating the rights of animals. If some of the current research practices are carefully reviewed before research begins, "a little more thought . . . [may result in] . . . a lot less animal suffering."¹⁶⁰ For more significant health matters, the ARA still allows research to continue while requiring that the researcher respect the rights of animals. No doubt, the demarcation line between worthwhile studies and worthless studies may become extremely hazy. However, the ARA provides for this, because the ARC will debate and churn through these is-

¹⁶⁰ ROWAN, *supra* note 4, at 173.

sues. In the end, extreme cases would be dealt with according to philosopher Bernard Rollin's standard: "[i]nvasive research aimed at developing a new weapon, a new nail polish, or at discovering knowledge of no clear benefit to humans and/or animals . . . would clearly not be permitted."¹⁶¹ Regardless of the worth of the proposed project, the flexibility and the creativity of our economic system will cause new solutions to come to the surface that will both comply with the Animal Rights Act and still provide a wide variety of products.

Even if such a statute were approved, researchers' concept of animals would also have to change to respect that animals have rights that are as valid as those of children. It is not that scientists are generally cruel people in their dealings with animals; rather, their education has taught them to use animals merely as tools to further their goals.¹⁶² The Animal Rights Act helps in this regard by educating researchers on animal rights. However, there will still be a level of inertia that both researchers and society must overcome in regards to respecting the rights of animals. As society shifts into incorporating the ideology that the Animal Rights Act embraces, this inertia will gradually diminish.

Although such a policy as the Animal Rights Act would significantly change how society conducts research, one must remember that such a change is necessary to force society to incorporate the rights of animals into our decisions concerning them. A true level of justice might then be reached. Science will not only be for science's sake, but also for the sake and consideration of those involved in the research regardless of their species. Animals (just like humans) "have a life, and a value, of their own. A morality that fails to incorporate this truth is empty. A legal system that excludes it is blind."¹⁶³

¹⁶¹ ROLLIN, *supra* note 88, at 195.

¹⁶² SINGER, *supra* note 16, at 46-48.

¹⁶³ TOM REGAN, *ALL THAT DWELL THEREIN* 163 (1982).