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Lay Persons and Community Values in Reviewing Animal Experimentation

Jeff Leslie

Is it morally acceptable to use animals in scientific experiments that will not benefit those animals, but instead solely benefit people? Most people would say yes; but at the same time most would view the use of animals as a regrettable necessity, to be pursued only when the benefits to people outweigh the harm to the animals, and only after everything possible is done to minimize that harm. Identifying benefits and harms may require specialized scientific and technological understanding, to be sure, but evaluating the tradeoff between them requires not technical expertise, but rather the capacity to make difficult moral judgments. We do not usually think of moral judgments as the unique terrain of any particular set of professionals or experts. Anyone capable of ethical reasoning has an equal claim to expertise, and a pluralistic society can be expected to exhibit a wide range of moral beliefs.

Because of the need to make controversial moral judgments in justifying animal research, there should be some mechanism for bringing community values to bear on deciding which animal experiments should move forward, especially for publicly funded research. Yet, the review committees that currently exist for evaluation of proposed animal experiments do a poor job of making sure that the moral judgments inherent in the process reflect the range of values held in the wider community. Closer examination of the role of community values—and the involvement of laypersons as a vehicle for infusing community values into the review process—suggests a need to reform the institutions that currently exist for the review of animal experimentation.

In many countries, decisions about animal experimentation occur at three levels. First, the researcher who proposes an ex-

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† Associate Clinical Professor of Law and Director, Chicago Project on Animal Treatment Principles, University of Chicago Law School. Many thanks are due to the McCormick Companions' Fund for its support of the Chicago Project on Animal Treatment Principles, out of which this paper arises. Excellent research assistance was provided by Susie Cowen, Shon Lo, Brad Grossman, and Ari Shapiro.
periment also performs a cost-benefit analysis and explores strategies to minimize the impact on animals; second, governmental funding agencies analyze that proposal; and third, a committee, either centralized or decentralized, typically composed of fellow scientists, veterinary specialists, trained ethicists, and lay people, reviews the proposed protocol, suggests changes, and ultimately approves or vetoes the experiment.\(^1\) In the United States, the committee review function occurs within each research institution, which is required by federal law to have its own Institutional Animal Care and Use Committee ("IACUC"). The day-to-day review of experimental protocols is made by the IACUC.\(^2\) In the U.K., there is a central, national committee (the Animal Procedures Committee) that reviews experiments raising novel or controversial issues,\(^3\) such as those involving primates caught in the wild, and there are also committees within each research institution (called Ethical Review Processes) that review experiments conducted at that institution.\(^4\)

One interesting feature of these committees is that they often include nonscientists and other lay people. In some countries, the law requires institutions to include lay people in these committees,\(^5\) although some institutions do so even when the law does not so require.\(^6\) Two reasons are usually put forward for in-

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\(^5\) See, for example, 7 USC § 2143(b)(1)(B) (West 2000) (requiring in the United States that committees include at least one member unaffiliated with the facility in order "to provide representation for general community interests"); National Health and Medical Research Council, *The Australian Code of Practice for the Care and Use of Animals for Scientific Purposes*, § 2.2.2 (7th ed 2004), available at <http://www.nhmrc.gov.au/publications/files/ea16.pdf> (last visited Apr 22, 2006) (requiring animal ethics committees in Australia to include at least one person who is independent of the institution and inexperienced in animal research beyond their undergraduate education); Anna Cowperthwaite, *Animal Ethics Committees and Experimentation on Animals: A Need For Reform*, 2 Animal Rights Legal Advocacy Network 5, 6 (Mar 2003), available at <http://www.arlan.org.nz/newsletters/newsletter_march03.pdf> (last visited Apr 22, 2006) (noting that animal ethics committees in New Zealand are required to consist of at least four members, three of which are to be laypersons unaffiliated with the institution).

\(^6\) See F. Barbara Orlans, *Ethical Decision Making About Animal Experiments*, 7
including lay people. First, they bring a fresh eye to animal experimentation and can raise questions and issues that regular players in the industry might overlook or take as a given. Second, they bring some measure of accountability to the other committee members: they can ensure that the deliberative process is working well, even if they do not fully understand and cannot fully evaluate the scientific and technical issues that are the subject of deliberation.

In the United States, the legislation that requires lay participation on IACUCs explicitly articulates a goal of infusing wider community values into the decisionmaking process: "to provide representation for general community interests in the proper care and treatment of animals." This is a goal worth pursuing, for the appropriateness of animal experimentation depends on ethical values which, in a pluralistic society, are often best accessed through democratic processes. Unfortunately, both the composition and the mandate of IACUCs under current law make them poor vehicles for incorporating community values. In large part, this is because the IACUC is modeled on the Institutional Review Board ("IRB") structure, which has long been used to guide experimental research involving human subjects. IRBs have served as important safeguards against abuse of human subjects, but they are not designed to be self-contained mechanisms for accessing community values about the experiments under review. When thinking about lay participation in decisions on animal experimentation, we should look to other democratic institutions—particularly juries—for our models.

Part I below provides an overview of current regulation of animal experimentation in the United States. Part II discusses the appropriateness of incorporating community values into the

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8 Smith and Jennings, A Resource Book for Lay Members § 3.1(iii) (cited in note 7).
9 7 USC § 2143(b)(1)(B)(iii).
11 See notes 105-107 and accompanying text.
review of animal experimentation and considers proposals for reforming the IACUC structure to include a broader range of viewpoints. Part III examines the lessons that the American jury system may hold for incorporating community values.

I. CURRENT REGULATION OF ANIMAL EXPERIMENTATION IN THE UNITED STATES

The federal Animal Welfare Act12 ("AWA") and the policies promulgated by the Public Health Service ("PHS")13—the major governmental funder for scientific research—are the primary sources of regulation for animal experimentation in the United States.

A. The Animal Welfare Act

The AWA dates back to 1966, when Congress enacted the Laboratory Animal Welfare Act14 to address the theft of family pets (cats and dogs) and their subsequent sale to research facilities for use in experiments. The legislation empowered the Secretary of Agriculture to license and regulate animal dealers in various ways, and prohibited research facilities from buying dogs or cats from any source other than a licensed dealer.15 It also required that dealers and certain research facilities follow standards promulgated by the secretary to ensure the humane handling, care, treatment, and transportation of animals.16

The Laboratory Animal Welfare Act was amended in 1970 and rechristened the "Animal Welfare Act."17 The 1970 amendments expanded the range of animals covered to include "any live or dead dog, cat, monkey (nonhuman primate mammal), guinea pig, hamster, rabbit, or such other warm-blooded animal, as the

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12 7 USC § 2131 (West 2000).
13 The Public Health Service includes the following: the Agency for Healthcare Research and Quality, Centers for Disease Control and Prevention, the Food and Drug Administration, the Health Resources and Services Administration, the Indian Health Service, the National Institutes of Health, and the Substance Abuse and Mental Health Services Administration. Office of Laboratory Animal Welfare ("OLAW"). Public Health Service Policy on Humane Care and Use of Laboratory Animals III H, (NIH Aug 2002), available at <http://grants.nih.gov/grants/olaw/references/phspol.htm> (last visited Apr 22, 2006).
15 Id.
16 Id.
Secretary may determine is being used, or is intended for use, for research, testing, experimentation, or exhibition purposes, or as a pet."\(^{18}\) The amendments also extended existing regulations to additional categories of research facilities.\(^{19}\) Amendments in 1976 added transporters and carriers of animals to the list of regulated entities.\(^{20}\)

Amendments made to the AWA in 1985 added the requirement that each research facility maintain at least one IACUC.\(^{21}\)

The structure of the IACUC is laid out in the statute:

Each Committee shall be appointed by the chief executive officer of each such research facility and shall be composed of not fewer than three members. Such members shall possess sufficient ability to assess animal care, treatment, and practices in experimental research as determined by the needs of the research facility and shall represent society's concerns regarding the welfare of animal subjects used at such facility. Of the members of the Committee—

(A) at least one member shall be a doctor of veterinary medicine;

(B) at least one member—

(i) shall not be affiliated in any way with such facility other than as a member of the Committee;

(ii) shall not be a member of the immediate family of a person who is affiliated with such facility; and

(iii) is intended to provide representation for general community interests in the proper care and treatment of animals; and

(C) in those cases where the Committee consists of more than three members, not more than three members shall be from the same administrative unit of such facility.\(^{22}\)

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\(^{18}\) 7 USC §§ 2132 (West 2000).

\(^{19}\) Id.


\(^{22}\) 7 USC § 2143(b)(1).
The IACUC must inspect all animal study areas and animal facilities, must review practices involving pain to animals, and must review the condition of animals. In particular, the IACUC is supposed to ensure compliance with provisions of the AWA aimed at minimizing pain and distress to animals. These provisions require, among other things, adequate veterinary care with the appropriate use of anesthetic, analgesic, tranquilizing drugs, euthanasia, and pre-surgical and post-surgical care. Furthermore, principal investigators must consider “alternatives to any procedure likely to produce pain or distress in an experimental animal.” The IACUC is required to file with the U.S. Department of Agriculture a certification report of each inspection at the research facility, describing any violation of the AWA standards, any deficient conditions in animal care or treatment, any deviations from originally-approved proposals that adversely affect animal welfare, any notification to the facility regarding such conditions, and any corrections made thereafter. The USDA conducts annual inspections.

B. The Health Research Extension Act of 1985 and Policy Guidance from the Public Health Service

The second statutory foundation for IACUCs is the Health Research Extension Act of 1985 (“HREA”). Under the HREA, the National Institutes of Health (“NIH”) is authorized to establish guidelines for the proper care of animals to be used in biomedical and behavioral research. Like the AWA, the HREA requires each research facility to establish an IACUC. Each IACUC is appointed by the chief executive officer and is composed of at least three members. The committee must include at least one individual who has no association with the research facility and at least one veterinarian.

23 Id at § 2143(b)(3).
24 Id.
25 Id at § 2143(a)(3)(A), (C).
26 7 USC § 2143(a)(3)(B).
27 Id at § 2143(b)(4)(A).
28 Id at § 2143(a)(7)(A).
30 42 USC § 289d(a) (2000).
31 42 USC § 289d(b)(1).
32 42 USC § 289d(b)(2).
33 Id.
Pursuant to the HREA, the Public Health Service published the *Public Health Service Policy on Humane Care and Use of Laboratory Animals* ("PHS Policy"),\(^3\) which provides further guidance on IACUC composition. According to the PHS Policy, IACUCs are required to have at least five members, including one veterinarian—with training or experience in laboratory animal science and medicine—who has program authority and responsibility for activities involving animals at the institution; one practicing scientist experienced in research involving animals; one member whose primary concerns are in a nonscientific area (for example, an ethicist, lawyer, or member of the clergy); and one individual who is not affiliated with the institution in any way other than as a member of the IACUC, and is not a member of the immediate family of a person who is affiliated with the institution.\(^3\) An individual who meets the requirements of more than one of these categories may fulfill more than one position.\(^3\)

The PHS Policy requires that IACUC review of animal experiments must comply with all AWA requirements and also with another governing document, the *Guide for the Care and Use of Laboratory Animals*, which contains detailed standards for animal treatment and care.\(^3\) According to the Guide, the IACUC must include "[a]t least one public member to represent general community interests in the proper care and use of animals. Public members should not be laboratory animal users, be affiliated with the institution, or be members of the immediate family of a person who is affiliated with the institution."\(^3\)

Finally, the PHS Policy incorporates the *U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training* ("U.S. Principles").\(^3\) The U.S. Principles were developed in 1985 by the Interagency Research Animal Committee, and they apply to federal agencies that either develop requirements for or sponsor procedures involving the use of vertebrate animals.\(^3\) The U.S. Principles do

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\(^{3}\) OLAW, *Public Health Service Policy* (cited in note 13).
\(^{35}\) Id at IV.A.3.b.
\(^{36}\) Id at IV.A.3.c.
\(^{37}\) Id at IV.C.1.
\(^{40}\) OLAW, *Public Health Service Policy* at Preface (cited in note 13).
not speak directly to the composition of IACUCs, but provide
guidance on the substantive principles that should direct animal
experimentation, and state that “whenever [federal] agencies
actually perform or sponsor such procedures, the responsible In-
stitutional Official shall ensure that these principles are adhered
to.”

C. IACUCs in Practice

1. The Three Rs and ethical merit review.

The substantive standards for animal treatment and care
under the federal regulatory regime require, in short, that ani-
mals be treated under the rubric of the “Three Rs.” That is, IA-
CUCs are to review experiments with the goal of replacing ani-
mals with humane alternatives; reducing animal use; and refini-
ing husbandry and procedures to reduce suffering and improve
welfare.

IACUC review begins with submission by the researcher of a
protocol form that describes the proposed experiment. The
IACUC may approve, disapprove, or request modification of the
protocol. In so doing, it may have access to outside consultants
or experts if needed. IACUCs vary in their procedures and the
scope of their review, making generalizations difficult. Although
some critics have labeled IACUCs as rubber stamps, supporters
argue that this label is increasingly less accurate as IACUCs
have gained experience and matured since their inception in
1985. Even so, the effectiveness of IACUCs in promoting the
Three Rs has been uneven. According to one commentator:

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41 NRC, Guide for the Care and Use of Laboratory Animals at Appendix D (cited in
note 38).
42 F. Barbara Orlans, The Three Rs in Research and Education: A Long Road Ahead
in the United States, 24 Alternatives to Lab Animals 151 (Mar-Apr 1996). For a discus-
sion of the history of the Three Rs and a critique of their limitations as a regulatory
framework, see Darian M. Ibrahim, Reduce, Refine, Replace: The Failure of the Three R's
43 Orlans, 24 Alternatives to Lab Animals at 154 (cited in note 42).
44 Id.
45 See, for example, Lawrence Finsen, Institutional Animal Care and Use Commit-
(arguing that the difficulty faced by nonexperts in assessing the scientific merit of pro-
posed research involving animal subjects and the fact that IACUCs need not ever allow
even moderate opposition to animal research to constitute a majority of the IACUC hin-
ders advocacy on behalf of animals).
46 Orlans, 24 Alternatives to Lab Animals at 153 (cited in note 42).
A primary activity of most IACUCs is refinement. Researchers are frequently urged to modify a protocol to improve the type and dose of analgesics and anaesthetics used and the method of euthanasia. The most thorough committees also consider other methodological refinements, such as not using immobilisation chairs for primates. . . . Occasional attention is given to reduction in the numbers of animals used. Replacement with non-animal methods in research is rarely, if ever, addressed. . . . Some committees require investigators to produce evidence that databases have been searched to find out whether project design refinements are available.47

Scientists continue to develop computer simulations and other technologies to serve as alternatives to using animals, as well as new data analysis techniques that would decrease the numbers of animals used, but progress on this front has been slow.48

Despite an uneven record in implementing the Three Rs, there is clear consensus that Three R review is the purview of the IACUC. Far more controversial is the role, if any, that IACUCs should play in conducting cost-benefit analysis or considering the ethical merit of experiments involving animals. If qualified researchers present a well-designed experiment, for which no further refinements can be made under the Three Rs, could the IACUC nevertheless disapprove the experiment because the harm to animals outweighs the expected benefit for humans? For convenience, I refer to this kind of decision as ethical merit review.49

The AWA appears to prevent IACUCs from conducting ethical merit review. It states that the USDA is not empowered "to promulgate rules, regulations, or orders with regard to the design, outlines, or guidelines of actual research or experimentation by a research facility as determined by such research facility."50 With respect to the AWA, at least, this statutory language

47 Id at 153-54.
48 Consider Alan M. Goldberg and Thomas Hartung, Protecting More than Animals, 294 Sci Am 84 (Jan 2006).
49 The term is from Mimi Brody, Animal Research: A Call for Legislative Reform Requiring Ethical Merit Review, 13 Harv Envir L Rev 423 (1989).
has been read to deny IACUCs the authority to consider the purpose of an experiment or engage in ethical merit review.  

The limitation placed on IACUCs in this regard stands in contrast to the regimes in other parts of the world, where the law requires local committees to weigh the benefits of research against the costs to animals. In the United Kingdom, the Animals (Scientific Procedures) Act requires cost-benefit analysis by the Secretary of State in approving licenses for experimentation. The Home Office, which has responsibility for implementing the Act, interprets this provision to require cost-benefit analysis by Local Ethical Processes, which are the British analogues to IACUCs. In the Netherlands, amendments enacted in 1997 to the Experiments on Animals Act give local committees similar authority to perform ethical merit review. Comparable reviews are conducted by local committees in Sweden and Australia as well. Ethical merit review is now common enough to have sparked a growing literature on how such review should be conducted and to have prompted calls for international harmonization of processes in different countries.

In the United States, some support for IACUC ethical merit review may be found in the U.S. Principles. Principle II states that "[p]rocedures involving animals should be designed and performed with due consideration of their relevance to human or

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56 National Health and Medical Research Council, The Australian Code of Practice at § 2.1-2.2.1 (cited in note 5).
58 See, for example, Michael Balls, et al, The Three Rs: The Way Forward—The Report and Recommendations of ECVAM Workshop 11, 23 Alternatives to Lab Animals 838, 859 (1995) ("Discussions should be encouraged at the national and international level with a view to setting targets and time limits for the achievement of specific goals in the reduction, refinement, and replacement of the use of vertebrate animals in experiments and other scientific procedures.").
59 See notes 39-41 and accompanying text.
animal health, the advancement of knowledge, or the good of society." This language, while admittedly sweeping and vague, nevertheless suggests that some cost-benefit analysis is appropriate. This sentiment, though, may be drowned out by other aspects of PHS Policy that are deferential to researchers and a research culture that is supportive of animal experimentation.

Though the legal basis for ethical merit review is tenuous at best, some IACUCs view it as part of their mission. For instance, Michael D. Mann and Ernest D. Prentice describe an IACUC process at the University of Nebraska Medical Center that seeks information on the "potential value of the study with respect to human or animal health." They categorically state their belief "that there are some research projects that should not be done despite the importance of the hypotheses being tested or the potential value of the results." They further note that institutional review boards for experimentation involving human subjects engage in just such an evaluation, and conclude that "[i]t is not clear to what extent IACUCs conduct similar cost-benefit analyses. In reviewing the discussions of the committees, one often sees evidence of such analyses, but it is seldom done overtly." Other commentators have similarly concluded that IACUCs cannot avoid considering ethical merit as part of their review process.

2. The experience of nonscientific, lay members on IACUCs.

Nonscientist members have been an important part of IACUCs since the 1985 AWA amendments, and in fact were present prior to that date at a few, more progressive institutions. Many commentators see their involvement as essential to the

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60 NRC, Guide for the Care and Use of Laboratory Animals at Appendix D (cited in note 38).
61 Brody, 13 Harv Envir L Rev at 431-32 (cited in note 49). But see Rebecca Dresser, Measuring Merit in Animal Research, 10 Theor Med 21, 28 (1989) (citing Principle II and concluding that, "most commentators believe that IACUCs cannot avoid at least a certain level of merit assessment").
63 Id.
64 Id. See also 45 CFR § 46.111(a)(2) (2005).
65 Mann and Prentice, 33 Lab Animal at 29 (cited in note 62).
67 Orlans, 7 Ethics & Behav at 168 (cited in note 6).
sound functioning of the committee. Lay members are prized for their ability to raise questions and issues that are not commonly part of the discourse of the research community, causing that community to consider their work from a broader perspective than they otherwise might.\footnote{Smith and Jennings, \textit{A Resource Book for Lay Members} at § 3.1 (cited in note 7); \textit{Report of the Animal Procedures Committee for 2003} at 38 (cited in note 7); Animal Procedures Committee, \textit{Review of Cost-Benefit Assessment} at 69 (cited in note 1).} Lay members help keep researchers in touch with the concerns and interests of the broader community outside the research institution.\footnote{F. Barbara Orlans, \textit{In the Name of Science: Issues in Responsible Animal Experimentation} 115 (Oxford 1993).}

Despite more than twenty years of experience, however, we still do not know very much about lay participation on IACUCs. The fullest account of lay participation in the United States comes from a study conducted in 1991, in which F. Barbara Orlans reported the results of her survey and interviews with lay members and committee chairs in an admittedly unscientific sampling of IACUCs.\footnote{Id at 103-17.} Orlans reports that although some lay members report feelings of satisfaction with their committee role and a sense that their presence has made a difference,\footnote{Id at 109-10. See also, for example, Joan Dieter Peck, \textit{Reflections of a Public Member}, in F. Barbara Orlans, R.C. Simmonds, and W.J. Dodds, eds, \textit{Effective Animal Care and Use Committees}, 37 Lab Animal Sci 85, 85-87 (Special Issue Jan 1987); Jane Hutchinson, \textit{Thoughts on Educating Community Members of Animal Care and Use Committees}, in Helene N. Gutman, et al, eds, \textit{Science and Animals: Addressing Contemporary Issues} 129, 129-32 (Scientists Center for Animal Welfare 1989).} others report disaffection and feelings of marginalization.\footnote{Orlans, \textit{In the Name of Science} at 103-13 (cited in note 69).} Dominated by scientists and constantly confronted with technical issues and jargon, IACUCs are not particularly amenable to equal participation by nonscientists, especially those who do not fully share the prevailing view in the research community that animal experimentation is generally justified. According to Orlans:

Community members who represent the animal advocacy community may or may not be satisfied [with their role as a community member in an IACUC]. Those persons from moderate animal welfare organizations may be quite content with their role; others -- largely those from the animal rights movement -- are highly critical. . . . Disapprovals and modifications of protocols that the animal
rights movement want [sic] are unlikely to be effected by this route.\textsuperscript{73}

The situation appears to be similar in other countries. Animal welfare representatives have withdrawn or have threatened to withdraw from animal ethics committees in Australia because of their dissatisfaction with the committees,\textsuperscript{74} and a 1998 survey found that half of the animal welfare representatives had experienced “animosity or aggression from researchers on the [committee] during decision making” and almost that number also indicated that “pressure [has been] brought to bear on them to go with the status quo.”\textsuperscript{75} In New Zealand, lay committee members have reported feeling intimidated by other members because they are statistically outnumbered and lack scientific knowledge.\textsuperscript{76}

In the United Kingdom, the Royal Society for the Prevention of Cruelty to Animals (“RSPCA”) seeks to counteract such feelings of powerlessness and intimidation. The RSPCA has been active in promoting and facilitating lay participation on local ethical review committees. It has organized conferences and annual forums for lay participants to compare experiences.\textsuperscript{77} The work product from these conferences and the RSPCA training materials give some sense of the cultural divide between scientific researchers and their lay colleagues. For instance, one RSPCA manual encourages lay members to feel confident, not to feel apologetic about their lack of expertise, to ask any questions

\textsuperscript{73} Id at 116.

\textsuperscript{74} Animal Liberation Inc. (South Australia), \textit{Laboratory Animals and the Law—Do Ethics Committees Work?}, available at <http://www.animalliberation.org.au/law.php> (last visited May 11, 2006) (reporting that Animal Liberation (SA) had members on four committees in South Australia, and three have resigned); \textit{Animals Australia, Fact Sheet: Animal Experimentation}, available at <http://www.animalsaustralia.org.au/default2.asp?idL1=1273&idL2=1295> (last visited May 11, 2006) (threatening to withdraw Animals Australia representatives from committees unless reforms are implemented).


\textsuperscript{76} Cowperthwaite, \textit{Animal Ethics Committees} at 6 (cited in note 5).

they feel are important, and to look for support from other lay members, as well as other committee members.\(^7\)

Although it is less frequently invoked as one of their virtues, lay members can also provide some small measure of public representation to the deliberations of their committees.\(^7\) In the animal experimentation context, and in particular experimentation using public funds, ethical merit review should be informed by the values of the populace as expressed through democratic processes. Congress has recognized the importance of public representation in the AWA’s requirement that IACUCs include a member “to provide representation for general community interests in the proper care and treatment of animals.”\(^8\) The PHS Policy similarly requires that committees have “at least one public member to represent general community interests in the proper care and use of animals.”\(^8\) The idea that committees must include public or community representation is difficult to reconcile with the current structure of IACUCs and their analogues in other countries. IACUCs are required only to have one community member, and anecdotal evidence suggests that it is the rare institution that voluntarily exceeds this number.\(^8\) Given the range of moral beliefs about the appropriate use of animals to advance human interests, the idea that one person can represent the interests of the “community” is a fantasy. Adequate representation of community interests requires a longer, ongoing dialogue and participation of many more voices than a single lay member on a committee.

The next part of this analysis explores public representation and the motivation behind it, examining some proposed reforms to increase representation of a broader range of viewpoints.

II. COMMUNITY VALUES AND EVALUATION OF ANIMAL EXPERIMENTS

Deciding whether an animal experiment ought to be pursued has moral and social dimensions. The examples of horrific experiments that have survived IACUC review serve well to illustrate this point. To study whether human burn victims lose their

\(^7\) Smith and Jennings, *A Resource Book for Lay Members* at § 3.2 (cited in note 7).
\(^7\) Id at § 3.1.
\(^8\) 7 USC § 2143(b)(1)(B)(iii).
\(^8\) NRC, *Guide for the Care and Use of Laboratory Animals* at 9 (cited in note 38).
\(^8\) See Finsen, 13 J Med & Phil at 154-56 (cited in note 45) (noting that the committees require only token community representation and that the system is still committed to the use of animals in research as much as possible).
appetites, pigs are tied down and blowtorched, without pain relief, and then left untreated for several days while effects on appetite are observed.\textsuperscript{83} The Three Rs failed to prevent this experiment from proceeding because the Three Rs have nothing to say about the premises on which the experiment is based—that learning about effects of burns on appetite is important enough to justify putting the pigs through such an experience.\textsuperscript{84} The Three Rs are at their core only tools for choosing means, not ends. They ask: “Given a proposed experiment, what reduction, refinements and replacements might be available to minimize the impact on animals?” They do not ask whether the experiment is worth pursuing in the first place.

Determining whether an experiment is worthwhile calls for an ethical judgment, albeit one that must be informed by scientific knowledge of various kinds. Specialized knowledge is required to evaluate the project design (in other words, whether the experiment is designed to yield reliable, verifiable data), the qualifications of the investigators, the contribution that data from the experiment could be expected to make, and the intensity, duration, and subjective experience\textsuperscript{85} of the harm suffered by the animals involved. But even if we could know for certain the expected payoff from an experiment, and the subjective harms suffered by the animals in the experiment, we would not have answered whether that payoff is worth the harm inflicted on animals to obtain it. Scientists are well situated to weed out poorly designed experiments and unqualified researchers, but they do not have greater expertise than the rest of us in comparing payoffs for humans with harms to animals, a comparison that requires moral reasoning and judgment.

How then can one best assign decisionmaking responsibility for the moral judgments inherent in animal experimentation review? The legislative requirement that “general community interests” be represented suggests this principle as a starting point: Where moral questions intersect with public policy, democratic processes should generally be used to resolve those questions. This will not be true in all circumstances, for where moral questions involve matters of fundamental individual

\textsuperscript{83} Ibrahim, 2006 U Chi Legal F at 210 (cited in note 42).
\textsuperscript{84} Id.
\textsuperscript{85} Understanding the subjective harm to the animal is an evolving field of inquiry. It is only recently, for instance, that researchers have concluded that fish feel pain. Alex Kirby, \textit{Fish do feel pain, scientists say}, BBC News (Apr 30, 2003), available at <http://news.bbc.co.uk/1/hi/sci/tech/2983045.stm> (last visited Apr 22, 2006).
rights, decisionmaking may properly be taken away from democratic institutions in order to protect those rights against infringement by majoritarian institutions. For those who think that animals have fundamental rights that deserve countermajoritarian protection, appealing to democratic processes to resolve moral questions about the use of animals is unconvincing. However, the debate about what rights animals have or should have shows no signs of winding down, and as of the current moment, society has not adopted the rights-based view. We continue to experiment on animals, and a broad consensus exists that some experimentation (perhaps a great deal) is and will continue to be desirable and ethically justified.

If we accept as a starting point that societal values should be brought to bear on the tradeoff between human and animal interests in experimentation, the need for community representation on IACUCs becomes all the more evident. For the reasons already given, IACUCs and their foreign counterparts are not up to the task, given the small numbers and frequent marginalization of lay members charged with representing community interests. To broaden the range of societal perspectives represented on committees, some proposals for IACUC reform have suggested that committees should include representatives drawn from animal advocacy organizations. After all, Australia and New Zealand require local committees to include animal advocates, and Germany, Denmark, and Switzerland require committees at the regional and national level to include them as well. Sweden has committees half of whose membership are animal advocates. Usually the animal advocates are not animal rightists.

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See notes 69-82 and accompanying text.

See, for example, Lisa Hara Levin and Martin L. Stephens, Appointing Animal Protectionists to Institutional Animal Care and Use Committees, 5 Animal Welfare Information Center Newsletter (Winter 1994/1995), available at <http://www.nal.usda.gov/awic/newsletters/v5n4/5n4steph.htm> (last visited Apr 24, 2006) (recommending that facilities appoint not one, but two animal protectionists to their IACUCs); Orlans, 7 Ethics & Behav at 167-69 (cited in note 6) (noting that “representatives of animal protection societies were more likely to raise ethical questions than other [IACUC] members”).

Levin and Stephens, 5 Animal Welfare Information Center Newsletter (cited in note 87) (“Australian policy calls for at least one person who is an animal welfarist to serve on that country’s equivalent of the IACUC.”).

Monamy, Animal Experimentation: A Guide to the Issues at 68 (cited in note 1) (noting that each institutional committee in New Zealand must contain at least one member from a recognized animal welfare group).

Levin and Stephens, 5 Animal Welfare Information Center Newsletter (cited in note 87).

opposed to the entire enterprise of animal experimentation, but instead animal welfarists who think some experimentation is warranted if properly regulated.

Adding animal advocates to IACUCs is a good idea, but does not go far enough. Such a move would increase the diversity of perspectives, but would still not provide for adequate representation of community values. Increasing the range of interest groups represented on the IACUC is not the same thing as giving full expression to community values relating to animal research. Full expression of community values may result in outcomes that differ from the pro-experimentation research community position, the anti-experimentation animal advocacy position, and the moderate position produced by the interaction of the two extremes.

Requiring inclusion of animal advocates in IACUCs would instead serve a different function; it would counter the potential for “group polarization” within committees. Group polarization refers to the tendency of like-minded deliberative groups to arrive at conclusions that represent more extreme versions of the beliefs the group members held going into the deliberation. IACUCs are composed mostly of research scientists, including scientists who are themselves directly involved in animal experimentation. Nonscientist members are outsiders to the institution, few in number, and unfamiliar with the technical issues under discussion. Participants in group decisionmaking tend to give the least weight to the views of low-status members, and lay members of IACUCs will often fit the bill. Further, like-minded deliberators tend to have limited “argument pools” within the group, which pushes deliberation toward a limited number of endpoints supported by those pools. People also generally desire to be perceived favorably by other group members, and to live up to their own self-conception, and accordingly move their judgments in order to preserve their image to others and to

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92 Cass R. Sunstein, Deliberative Trouble? Why Groups Go to Extremes, 110 Yale L J 71, 74 (2000) ("[G]roup polarization means that members of a deliberating group predictably move toward a more extreme point in the direction indicated by the members’ predeliberation tendencies.").

93 Id at 74-75.


95 See id at 272-76; text accompanying notes 71-82.

96 See sources collected at Sunstein, 110 Yale L J at 89-90 (cited in note 92).
themselves. It is not surprising, then, that IACUCs tend to gravitate towards pro-experimentation positions, given the relative lack of diversity in perspective among IACUC members.

Group polarization can be countered by introducing new, persuasive arguments, and by ensuring that "group[s] consist[] of individuals drawn equally from two extremes." Inclusion of animal advocates within IACUCs would serve both functions. Animal advocates are likely to be both better informed than the average citizen about alternatives to animal experimentation, and better equipped to suggest new ways of thinking about permissible limits to experimentation. If a critical mass of animal advocates participated on an IACUC, the balance of perspectives should lead to adoption of more moderate positions on experimentation.

Still, tempering the research community's yin with animal welfarists' yang leaves out a whole range of perspectives in the middle, not to mention the animal rightists' abolitionism. It is worth considering whether there are better ways to infuse societal values into animal experimentation than further entrenchment of interest group politics, however evenhanded, in committee composition.

Institutional review boards ("IRBs"), which review experiments on human subjects, have grappled with the problem of how to take into account societal values in designing research protocols. When IRBs confront emergency research or research involving vulnerable populations, they are required to consult and engage in dialogue with the communities from which research subjects will be drawn. This may be done through town hall meetings, local radio or television talk shows, invitations to community members to participate in IRB meetings, or the creation of community advisory boards. The strategy has not been to tinker with IRB membership or structure, but to engage

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97 Id at 88-89.
98 Id at 92-93.
in an exchange of information about the study and the community attitudes with respect to research. Similar community consultation might be beneficial for IACUCs. At the very least, it is evident that we need to look to other institutions beyond the IACUC for new models of how to access community values in ethical merit view.

III. LESSONS FROM THE JURY SYSTEM

Some democratic institutions that could do a fine job of expressing community values in animal experimentation can be swiftly dispensed with on practical grounds. Voting on whether a particular animal experiment's payoffs for humans outweigh its costs to animals would be the purest way to express community values. Referenda could be held, or deliberative bodies could be elected. But for a variety of reasons—the difficulty in informing voters on the issues, motivating people to vote, the costs of administration, the enormous number of experiments involved—voting regimes are hopelessly unrealistic in this context.

A more promising alternative is to consider the jury system as a democratic institution that may hold lessons for those seeking to reform or augment the IACUC structure. In particular, I want to examine whether our experience with juries lends any support or insight to the suggestion that panels of local citizens be convened to conduct ethical merit review of animal experiments. Bernard Rollin has written, for instance, in critiquing IACUCs, that

[a] better alternative, perhaps, would be to allow local committees with greater representation from the citizenry at large to pass on the value of a piece of animal research. Society pays for animal research; researchers ought to be able to successfully defend to a set of citizens their need to spend public money to hurt animals. Such an approach works for our justice system; perhaps researchers need to convince something comparable to a jury of their need to hurt animals for the sake of research.102

There are several features of juries that are interesting in this regard. Juries can serve as vehicles for infusing community

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values into a process—the resolution of civil and criminal justice matters—with many manifestations that are too numerous and complicated to be decided by the populace at large. Juries are often asked to cope with issues of scientific or other technical complexity. And their functions and deliberations are mediated by interactions with professional, repeat players with specialized expertise—the judge, and to a lesser extent, the lawyers for the parties—that help the jury to perform their tasks more efficiently and appropriately. Each of these features has lessons for animal experimentation review.

Juries are drawn, theoretically at least, from the citizenry as a whole, which works to ensure that a wide range of beliefs and value systems are brought to bear on the issues that juries decide. Although any particular jury's deliberations express only the values and beliefs of the people on that jury, the presence of juries in every jurisdiction and the proliferation of juries over time means that, when the justice system is viewed as a whole, citizen participation can serve to infuse community values into that system. The same points would hold for a jury-like system for animal experimentation review. Any local panel convened to review an experiment would only be as representative of societal values as the composition and size of the panel permits. But given that there are sixteen hundred IACUCs across the country, overseeing experiments involving millions of animals each year, there would be a need for many panels across many jurisdictions.

103 This discussion admittedly takes a somewhat idealized view of the jury. The contemporary jury system may not adequately represent the citizenry, for a host of factors: the ease with which professionals avoid jury duty, the use of preemptory challenges, and the overall decline in cases that are brought to a jury. See generally Albert W. Alschuler, Our Faltering Jury, in Jeffrey Abramson, ed, Postmortem: The O.J. Simpson Case: Justice Confronts Race, Domestic Violence, Lawyers, Money, and the Media 135 (BasicBooks 1996) (setting out examples of jury shortcomings and recommending changes to reform the jury trial). All of these are serious problems, but they are in large measure functions of the particular, often racially charged, history of juries in the U.S., and it is not at all clear that they would carry over into a jury-like system created to review animal experimentation.

104 For a general discussion of this point, see Heather K. Gerken, Second-Order Diversity, 118 Harv L Rev 1099, 1108-09, 1137-38 (2005).


106 The official USDA animal use statistics show that 1,101,958 animals were used in research during 2004, the most recent year for which statistics are available. USDA, Animal Care Report Fiscal Year 2004, available at <http://www.aphis.usda.gov/ac/awreports/awreport 2004.pdf> (last visited Apr 25, 2006). The actual number is much higher. The USDA report reflects only those species covered under the Animal Welfare
Over time, viewing animal experimentation as a whole, the use of community panels would serve to infuse community values into that system. Repeated panel decisions rejecting a certain type of experiment would send a message to the research community about societal perspectives. Local variation in outcomes would be inevitable, but perhaps (and this may be different from the civil and criminal jury context) not objectionable. If community values are to infuse review of animal experimentation, local variation in those values should make a difference. Also, the variety in outcomes among panels convened in different localities might reduce the risk of an unjustified chilling effect on particular modes of research. Isolated instances of rejected research could be explained away, but research that attracts widespread rejection among juries in different localities would probably deserve to be halted.

Expression of societal values in jury verdicts—particularly in its starkest form, jury nullification—has a complicated and often ugly history. Depending on one's perspective and the historical context, jury nullification can be seen as a crucial safeguard against government tyranny and manifestly unjust laws, or as a means by which local, invidious prejudices can trump the rule of law. This is just to say that community values can be either good or evil, and the jury system can give voice to either or both. In the context of animal experimentation, though, there is serious, good faith disagreement about the appropriateness of using animals to advance scientific knowledge. Unless and until a consensus emerges on the moral status of animals, a jury system that gives voice, potentially, to the full range of moral beliefs on this issue has legitimacy under democratic principles.

Act—primates, dogs, cats, rabbits, gerbils, and certain other animals. Rats, mice, and birds are excluded from the AWA, and it is estimated that these three species comprise 90 percent of all animals used in laboratory research. F. Barbara Orlans, The Injustice of Excluding Laboratory Rats, Mice, and Birds from the Animal Welfare Act, 10 Kennedy Institute of Ethics Journal 229, 229 (2000), available at http://muse.jhu.edu/journals/kennedy_institute_of_ethics_journal/v010/10.3orlans.pdf (last visited Apr 25, 2006).

107 Compare Albert W. Alschuler and Andrew G. Deiss, A Brief History of the Criminal Jury in the United States, 61 U Chi L Rev 867, 871-74 (1994) (describing the historical circumstances when, despite his evident guilt, grand juries refused to indict and a trial jury refused to convict John Peter Zenger of seditious libel for criticizing English authority), with Alschuler, Our Faltering Jury at 139 (cited in note 103) (“Southern juries in the 1960s repeatedly failed to convict defendants accused on strong evidence of killing civil-rights activists.”).

108 Gerken, 118 Harv L Rev at 1108-09 (cited in note 104) (“While no single jury is likely to be ‘representative’ in any sense because of its size, the jury system, in the aggregate, should give us a rich picture of communal norms.”).
Local lay panels would help achieve the goal of bringing community values to bear, but could such panels handle the scientific and technical issues involved in evaluating research protocols? Juries are often asked to cope with issues of scientific and technical complexity. For example, juries famously have been confronted with the problem of deciding causation in asbestos litigation, medical products liability cases, and toxic tort cases. One could conclude that this is no argument in favor of the jury system, as aberrant verdicts in some of these cases demonstrate the inability of those juries to distinguish "junk" from real science. But even critics of juries concede that most of the time, juries are able to process scientific evidence appropriately.

The trial judge's role is often crucial in enabling juries to understand and evaluate scientific evidence. Through their oversight of jury selection, trial judges can play a role in "ensuring that knowledgeable people are not allowed to exclude themselves from juries and are not excluded by the lawyers." Judges can make use of court-appointed experts to provide testimony on the scientific issues or "to work with the litigants' experts to simplify issues, establish procedures for analyzing data, [and] to dispose of [unscientific or junk science approaches]." The wide latitude given to judges' rulings on admissibility of scientific evidence also provides an important, if controversial, filter on the scientific information that reaches the jury.

Jury-like panels for review of animal experimentation would similarly benefit from gatekeeping mechanisms to help the panels understand the scientific and technical issues. This in turn suggests a continuing role for the IACUC in facilitating ethical

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110 Id at 281. See also Richard O. Lempert, *The Jury and Scientific Evidence*, 9 Kan J L & Pub Pol 22, 27 (1999) (noting that some research indicates jurors will follow the lead of their more knowledgeable members and that a decisionmaking body consisting of different opinions may help the group as a whole assess difficult scientific evidence).
112 Id at 25.
113 *Daubert v Merrell Dow Pharmaceuticals, Inc*, 509 US 579, 593-94 (1993) (explaining that the following factors are relevant in assessing the reliability of scientific evidence: whether or not it has been tested, "whether [it] has been subjected to peer review and publication, . . . the known or potential rate of error, [and its] 'general acceptance' [within the] relevant scientific community"); *General Electric Co v Joiner*, 522 US 136, 146 (1997) (holding that a trial court's decision to admit or exclude expert testimony under *Daubert* is subject to abuse of discretion standard on appellate review). See also Bert W. Rein, *The Role of the Jury in the Evaluation of Scientific Evidence*, 9 Kan J L & Pub Pol 28, 29 (1999) (arguing that FRE 702 has become a vehicle for vesting trial judges, rather than juries, with a practical power to resolve scientific issues, particularly issues of causality in toxic tort cases).
merit review while staying within its core competency of working through scientific and technical issues under the Three Rs.

The IACUC can play a role, similar to that of the trial judge in the jury context, in helping the lay panel access the specialized expertise that factors into ethical merit review. If consensus can be reached within the IACUC on the expected benefits of the experiment, for example, those benefits could be presented to the lay panel, thereby avoiding the need for the panel to wade through the technical issue itself. If consensus cannot be reached, the IACUC could be assigned responsibility for preparing plain-language summaries of the differing views regarding expected benefits.\(^{114}\) The same is true for the costs side of the balance. IACUCs' access to expertise in animal behavior or physiology would help the panel understand and evaluate the subjective experience of the animals participating in the experiment.

Another gatekeeping mechanism is to limit jury-like review to experiments that are close calls. A panel review of every proposed animal experiment would be unnecessary, for with many experiments the ethical merit decision will be uncontroversial. There could be a triggering mechanism within the IACUC—say, the agreement of at least two members of the IACUC—before a protocol would be referred for panel review. All referred protocols could first be required to undergo Three R review and modification, if necessary, before the lay panel would consider them. Here is an area where the lay participant on the IACUC could play a really valuable role in ethical merit review—not in attempting to represent "community" values all by herself, but in flagging those experiments that raise ethical merit issues and deserve further community consideration.

Even with effective gatekeepers, practical difficulties would beset any proposal to institute jury-like review of animal experimentation. Where would jurors come from, and what would motivate them to serve? State-coerced participation would be enormously expensive. Although the practical difficulties are

\(^{114}\) The best practices for local review committees already include a requirement that technical issues be summarized in plain language accessible to lay members. Report of the Animal Procedures Committee for 2003 at 38 (cited in note 7); Animal Procedures Committee, Review of Cost-Benefit Assessment in the Use of Animals in Research at 65 (cited in note 1). For years, the RSPCA has advocated for more user-friendly summaries for lay persons, see Lay Members' Newsletter: Report on the RSPCA Lay Members' Forum at 2 (cited in note 77), and the Home Office in 2005 approved a template for summaries to facilitate this. Parliamentary Under-Secretary of State for the Home Department (Caroline Flint), Written Ministerial Statements (Feb 23, 2005), available at <http://www.publications.parliament.uk/pa/cm200405/cmhansrd/cm050223/wmstext/50223m01.htm> (last visited Apr 25, 2006).
very real, any number of experimental or half-measures are possible that could have some value. Voluntary lay panels could be convened by a research institution, and paid a nominal fee akin to what they might receive from participating in a focus group. If local panels are too burdensome, regional panels with a more selective caseload of controversial cases could be assembled instead.

The more fundamental point is that it is misguided to focus on IACUCs as the sole regulatory institution for animal experimentation. IACUCs cannot adequately reflect community values—no single, standing committee could—and if community values are to play their proper role, we will need to look outside the committee structure to design new participatory institutions.

CONCLUSION

If one accepts the centrist position that animal experimentation can be morally acceptable when appropriately regulated, then that regulation should include a process for making sure that societal values inform decisions about which experiments on animals are permitted. Current IACUC structures fail in this regard, and it is unlikely that tinkering with committee composition could ever result in a committee that was representative of the wide range of moral beliefs that bear on animal experimentation. We must look outside the IACUC structure for other models where democratic institutions facilitate community participation and expression.

The jury system is one such institution. Several of its features hold lessons in designing new structures for reviewing animal experimentation: the drawing of members from the citizenry as a whole, the repeated iterations of jury decision-making over time and across localities, and the mediation of lay decision-making by repeat players who possess specialized knowledge and technical expertise. Ultimately, for economic or political reasons, it may prove infeasible to use community panels to conduct ethical merit review of every animal experiment. Some versions of panel review, however, may in fact be viable, such as regional panels to review only those experiments identified as controversial. And regardless of the form it takes, new structures such as this are certainly necessary if we are to strike a balance between human and animal interests that is reflective of a fuller range of societal values.