

C

Animals in Science

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Section 1

Policy Discussion — The Nature of Science

The use of animals in experiments or research has long been a focus of controversy. (See Descartes's & Voltaire's discussion in Topic 1 – "Introduction.") The issue of how the activity might be regulated from the national level arose in Great Britain first. The National Anti-Vivisection Society was formed in Britain in 1875 and the first law concerning the use of animals in science passed in 1876. The first comprehensive anti-cruelty law adopted in New York in 1867 specifically exempted scientific research. At the national level in the United States, the first detailed national discussion occurred in 1896-1900, culminating in a U.S. Senate Hearing on Vivisection. (February 21, 1900 Hearing on SB 34 - For the Further Prevention of Cruelty to Animals in the District of Columbia. Published by Government Printing Office 1900.) But no law was adopted at that time.

A quick list of some of the questions that form a matrix of difficult issues and policies about the use of animals in research includes:

1. Should science be exempt from the general animal protection laws known as the anti-cruelty laws?
2. When there is a chance of gaining knowledge that will lead to increasing the future quality of life for humans and animals should experimentation be allowed? What level of odds/chance would be acceptable? Who should calculate the odds – the experimenter, the institution, the government, the public, or animal advocates?
3. What actions constitute science? Who is appropriate to engage in science?
4. Do we know what constitutes pain and suffering in various species?
5. Since animals, unlike humans, usually cannot volunteer to partake in experiments, when is it appropriate to subject animals to activities which produce pain, suffering or death?
6. If some use of animals is appropriate, then how do you draw the line between acceptable and unacceptable?
7. Are different species or sources of animals more acceptable than others? (Animals specifically bred for research use versus stray pets from local government pounds.)
8. Are there duties toward the animals used in research that deal with conditions of housing and care before experiments? What level of pain may be inflicted? What are the duties toward the animal after the experiment?

Context and Terms

As discussed in Topic 7 – "Anti-Cruelty Laws," state law recognizes the general proposition that animals should be free from the unnecessary and inappropriate infliction of pain and suffering – this is the primary animal "interest" recognized by our legal system. Another interest that some, but not all, state laws recognize is access to appropriate veterinarian care when an animal is sick or injured. (More about an "interest" analysis can be found in the Topic 14 – "Animal Rights.") But no law supports the position that animals will have a idyllic and pain-free life. The needs of humans can and will trump or supercede the acknowledged interests of animals. The pursuit of science has long been one of the areas where the interests of animals have been set aside for the needs

of human science. This is stated as a fact not as a value judgment on the usefulness of such use.

In the first true anti-cruelty law in the United States (adopted in 1867 in New York) only one exception to its provisions existed. The exception that received special consideration was not the agricultural use of animals, as might be expected, but rather the perceived needs of science.

Section 10. PROVISIO.

Nothing in this act contained shall be construed to prohibit or interfere with any properly conducted scientific experiments or investigations, which experiments shall be performed only under the authority of the faculty of some regularly incorporated medical college or university of the state of New York.

As no law in the US prohibits the use of animals in scientific experimentation, then the nature of the present policy debate is clear: when will the interests of the public outweigh the interests of animals to be free from pain and suffering? The answer to this question is not fixed but evolving. Each passing decade in the US gives more weight to the interests of the animals, without changing the public's core interest in the advancement of science. This evolution at the federal level can be seen in the increasingly detailed focus of the federal Animal Welfare Act on the actions of science. The lessons of the past twenty or thirty years have shown that considerable reduction of animal pain and suffering can occur without impacting the ability of science to proceed.

Animals in Research (from USDA Animal Welfare Reports):

Total animals reported used in research (excluding rats, mice and birds):

- 1985 - 2,153,787 at 1,105 reporting facilities
- 1999 - 1,217,998 at 1,232 reporting facilities
- 2001 - 705,602 at 1,216 reporting facilities

[Remember that rats and mice represent approximately 90 percent of the animals used in research. They are not included in the above numbers because facilities are not required to report on them. See Topic 12, section 3, for full table.]

As might be noted by the numbers, there has been a meaningful reduction in the number of reported animals used in research. A number of factors help explain this reduction:

Individual scientists are increasingly unable to make these decisions hidden behind closed laboratory doors. Most institutions have Animal Care Committees in place that require anyone undertaking scientific research where animals are involved to first justify their proposal by full presentation to the Committee.

There has been increasing awareness that the housing of animals before and after experiments raises as many – if not more – issues than the experiments themselves, and the legislature is much more willing to adopt strictures in this area.

Additionally, the cost of keeping animals has become significant enough that economic factors can contribute to reductions in the number of animals used. This increased cost even prompts some researchers to seek alternatives to the use of live animals.

The USDA itself has become a focus point for the finding of alternatives to the use of animals in research. For considerable information on the topic see the USDA website on alternatives, http://awic.nal.usda.gov/nal_display/index.php?tax_level=1&info_center=3&tax_subject=183.

The Nature of Science

If science is such a special case, do we know what is encompassed within the term “science”? When does an activity constitute a scientific investigation?

First, most science does not deal with the infliction of pain on nonhuman animals. Questions about the origin of the universe, or the nature of black holes obviously does not involve animals. Most science which focuses upon the natural world also does not involve the infliction of pain by humans. For example, the field research conducted by Jane Goodall—the observation of wild families of chimpanzees—has provided a wealth of information about their social nature. (See, *The Chimpanzee of Gombe: Patterns of Behavior*, 1986, Belnap Press.) Likewise, the observation of confined chimpanzees by Roger and Debbie Fouts has given great insight about the mental ability of chimpanzees who can communicate with American Sign Language. Again, this science was done without the infliction of pain, albeit with the confinement of chimps (See, Roger Fouts, *Next of Kin* (1997), Living Planet Books). But when a researcher in Maryland sought to study the nature of serious neurological injury, such as a stroke, the nerves of primates were intentionally cut in order to seek this information. (See, **IPPL v. Institute for Behavioral Research, Inc.**, 799 F.2d 934 (4th Cir. 1986), reprinted in Topic 11—“Standing.”)

News Bits

Nearly 70 percent of medical schools have abandoned the use of live animals as teaching tools for students, opting for alternatives such as computer simulators and videos, experts say.

Primary purpose of live animals at medical schools:

- *Pharmacology*. Instructors use live anesthetized dogs to demonstrate the effects of various drugs on organ systems.
- *Physiology*. Students cut open anesthetized dogs to view organ systems of a live mammal.
- *Surgery*. Students practice cutting and sewing before moving to surgical rotations.

The animals are killed at the end of all procedures.

By Tim Friend USA TODAY 11/20/02

Another aspect of science is *who* is doing it, and, *where* they are doing it. Consider the act of intentionally placing a hot iron on the skin of a dog. This might be done by ten year old boys in a backyard or PhD candidates in a lab at Big State University. Both may have as a primary goal obtaining information about the universe around them. However, the PhD students are in a position to record, analyze and publish information about their experiment, while the boys are not. Even though the process of science can occur anywhere, the law has accepted the presumption that useful science occurs only on premises—private and public laboratories—built to support the process. Thus, the boys’ activity will be considered a criminal event; the PhD students’ a socially protected activity.

The nature of science—its pursuit of universal truths—is a book topic in and of itself, and a few larger thoughts about this topic are included in Appendix C of this topic. For purposes of this book, however, it is accepted as a premise that significant social and personal benefit is derived from the advance of science. What is still in dispute is the degree to which, if at all, it is now necessary to inflict pain and suffering on ani-

mals in order to support the orderly advance of scientific information.

Some individuals and organizations believe that animals should not be used in research at all.

We believe that although animal experiments are sometimes intellectually seductive, they are poorly suited to addressing the urgent health problems of our era, such as heart disease, cancer, stroke, AIDS and birth defects. Even worse, animal experiments can mislead researchers or even contribute to illness or deaths by failing to predict the toxic effects of drugs. Fortunately other, more reliable methods that represent a far better investment of research funds can be employed.

Neal Barnard and Stephen R. Kaufman, “*Animal Research Is Wasteful and Misleading*,” *Scientific American* (Feb. 1997) at 80. Also see National Anti-Vivisection Society, www.navs.org.uk.

A Focusing Question

If a society can demand the sacrifice of human life for its benefit—such as by the institution of a military draft—may it not then also demand the sacrifice of nonhuman life for society’s benefit?

Others vigorously defend the use of animals:

Experiments using animals have played a crucial role in the development of modern medical treatments, and they will continue to be necessary as researchers seek to alleviate existing ailments and respond to the emergency of new disease.

Jack H. Botting and Adrian R. Morrison, “*Animal Research Is Vital to Medicine*,” *Scientific American* (Feb. 1997) at 83. This volume of *Scientific American* also has an informative article on the history of animals used in research.

Finally, some accept that animals must be used in research, but they would allow it only under strict criteria and only when absolutely necessary. See, David Favre, *Laboratory Animal Act: A Legislative Proposal*, 3 **Pace Environmental L. Rev.** 123 (1986).

Case Study C-1

Now consider a simple, modest example of the use of mice for research:

Science News, March 24, 2001 p. 182 - *Veggies prevent cancer through key protein*:

It was reported that researchers from John Hopkins University have confirmed through animal experiments that a certain compound found in broccoli, cauliflower and other veggies boost defenses against DNA damage and cancer.

Twenty mice with the protein and twenty mice without the protein were exposed to four weeks of high doses of a carcinogen found in cigarettes. After the mice were killed and examined, it was found that those mice with a particular protein present (Nrf2) had fewer stomach cancers and that the growths were smaller. Further research will focus upon the role of this molecule in fighting cancer.

Was this science? Did this new information justify the death of the forty mice? Assume the death was painless and prior living conditions for the mice acceptable. Then assume living conditions were terrible and death was by whacking their heads on the lab table? What if information from this study helps convince people to eat more veggies and reduces the number of agricultural animals killed? How can you weigh the life and death of the mice with the information gained?

Questions & Notes

1. How important to the advancement of Western society is the scientific process? Consider its impact on the military, food security, human health, our capitalist system and our legal system.
2. Is there such a thing as good science and bad science?
3. In the above mouse experiment, what if the scientists had found no difference in outcome with the two sets of mice? Would it then be bad science – the death of animals without any new useful information? One of the great difficulties in the regulation of science is that you cannot sort or control experiments by outcome, since by its very nature the outcome will not be known until after the experiment. Additionally, it is often impossible to judge the usefulness of a specific experiment at the time of the experiment. It may be years later that the information from one experiment is added to other information and produces new insight of some event or activity. Therefore, any attempt to limit the use of animals by allowing only good and useful science is difficult if not impossible.
4. Why twenty mice in a group? Could they have done it with only 10 in a group? Who decides? Why mice? Why not rabbits or fruit flies? Would this experiment have been covered under the Animal Welfare Act?
5. Could the government pass a law which said that no animal may be used in any experiment that results in the premature death or causes pain more than that which is inflicted by an injection? Should it? (As you formulate your answer, do a police power analysis.)
6. Katrina Sharman, *Opening The Laboratory Door*, 2 **Jour. of Animal Law** 67

(2006). Discussion of slavery and removal of property status.

Problem C 1

What about cloning—animal research with a twist of DNA? Normally the humane concern is about the pain of experimentation and the death at the end. Yet cloning does not involve any pain at the creation stage and results, hopefully, in new life, not death.

What are the motivations for humans to clone animals? To clone *humans*? What are the concerns?

Jonathan Hill of Cornell University, who clones cattle, has noted that about one-third of the cloned embryos that are implanted do not survive even the first month of a cow's normal 9-month gestation period. He also noted that surviving to birth is not a guarantee of survival. Some 25% to 50% of the cloned cattle are oxygen-deprived at birth. Some of these are saved, but some die. Many of the clones who survive past this point go on to lead normal lives, like Dolly, the first sheep to receive international attention. See, John Travis, *Dolly was Lucky*, Science News, Oct. 20, 2001, p.250–251.

What is a Research Facility?

CASE BY CASE

In re: Lee Roach and Roach Laboratories, Inc.

51 Ag. Dec. 252 (1992) (summary by Katherine Zoph)

The complaint filed by the Administrator of APHIS alleged that Roach operated as a dealer without being licensed, operated a research facility without being registered, and refused to allow APHIS to inspect the records and facilities of Roach Laboratories.

ORDER: To cease and desist all activities requiring a license or registration until he secures appropriate licenses and registrations. A civil penalty of \$5,000.00 was imposed.

Defendant produce antiserum from the blood of animals, including rabbits, goats, and sheep. Antiserum is sold in interstate commerce, partially for diagnostic testing and research purposes. The production of the antiserum involves injection into a live animal, followed by the extraction of blood from the same animal. 198 rabbits obtained from Shelton's Bunny Barn, which is an AWA licensed dealer. Lee Roach and Roach Laboratories have never been licensed or registered under the AWA.

Defendant argues that Roach Laboratories is not a "research facility" as defined by the AWA. The AWA definition looks to the testing of live animals. Roach Laboratories is not included because it makes a product from animals used by others to tests animals, rather than participating in the testing of live animals.

The Administrative Law Judge (ADJ) determined that defendant's reading of the statute was too narrow, and that the AWA applies to all those individuals that USE animals in research, tests, or experiments. The use of the animals to produce antiserum for medical diagnostic testing of humans satisfies the AWA definition. Roach Labora-

tories is thus a “research facility” within the meaning of the AWA. Therefore, Roach Laboratories is required to be registered as a research facility.

The defendant argues that Lab is not a dealer, and thus does not require a dealer’s license. Defendant asserts a distinction between testing blood from an individual animal and testing blood pooled from a group of animals. Additionally, defendant argues a 2nd distinction – that it produces antiserum, rather than serum.

The Court notes that the distinction between individual animals and pools of animals does not exempt defendant from the requirements of the statute. Additionally, the Court notes that antiserum is merely serum that has reacted with an antibody, but because the production of antiserum in a laboratory requires the introduction of an antigen by injection, the production involves a more invasive procedure than does the mere extraction of the serum. Therefore, the Court holds that there is no reason that the AWA should apply to the sellers of serum, but not the sellers of antiserum, as antiserum is merely a special form of serum.

Defendant argues that he did not obtain rabbits from a dealer in commerce. This is not true, as defendant stipulated that he purchased 198 rabbits from Shelton’s Bunny Barn, which is a licensed dealer under the AWA.

7 U.S.C. §2131 states that Congress finds that animals and activities which are regulated under the AWA are either in interstate or foreign commerce or substantially affect such commerce. Therefore, defendant’s argument cannot stand.

The Secretary of Agriculture is charged with the duty of developing regulations under the AWA. *Havialnd v. Butz* shows the principle that courts are bound to follow the construction of a statute by those charged with that responsibility, UNLESS there are compelling indications that the construction is wrong. That did not occur in this case.

ALJ CONCLUDES that Roach falls within the definition of a “dealer.”

APHIS also alleged that Roach did not allow the inspection of facilities and records. The only evidence offered to support this charge was a notation on an inspection report which read “An attempted inspection of this facility was refused.”

Testimony revealed that the inspector never made a direct request to search the facilities, and therefore, the ALJ determined that there was insufficient evidence to support the allegation of refusal to allow inspections.

Questions & Notes

1. So, what constitutes research? What does the Law say?

7 U.S.C. § 2132 (e) The term “research facility” means any school (except an elementary or secondary school), institution, organization, or person that uses or intends to use live animals in research, tests, or experiments, and that (1) purchases or transports live animals in commerce, or (2) receives funds under a grant, award, loan, or contract from a department, agency, or instrumentality of the United States for the purpose of carrying out research, tests, or experiments:

The regulations do not expand upon this. What if a zoo begins a program of observing a colony of green monkeys to determine what they eat on a daily basis?

2. Distinguish between an experiment and the testing of a commercial product.
3. If an institution is a research or testing facility, and using animals under the AWA, what are they required to do? Is there a difference between the institution and individual researchers? Who is responsible under the law? Only the facility is registered, individual researchers have no federal license or permit. What are the consequences for failure to comply with the requirements of the AWA? Section 19 of the law sets out the civil and criminal enforcement options. There is nothing suggesting and individual researcher will be held civilly liable and research facilities are not even listed as being subject to criminal law actions. See, www.animallaw.info/statutes/stusawa.htm#2149.

Case Study C-2

Over the past decade the southern parts of the United States have been invaded by fire ants, which are difficult to control and have the capacity to inflict painful bites on any mammal who might be in the wrong place at the wrong time. The State of Texas posted a law to support research into this problem. In 1998, a professor at Texas Tech obtained a \$120,000 grant from the State to do a research project. He proposed to capture pregnant deer and put half of them in pens with fire ants and see what happened, e.g. whether the newly born fawns would be injured or killed by the fire ants. (The full proposal was approved by the Animal Care Committee of the University.)

Is this science? What are the possible outcomes of the exercise and what use might be made of this information?

Would this otherwise be a violation of the state anti-cruelty law? Is this a good use of public money?

Are there alternatives for obtaining the same information?

What if you knew that the collection of the 25 deer would result in the death of seven within five days of capture from heat and stress, and that, in addition to four of the fawns being stillborn, another two died of unrelated causes?

What if the initial report of the researcher was that the fire ants apparently had no effect of the surviving fawns? Would you continue the research for a second year?

What do you think would be the institution's response to a citizen group law suit to stop the experiment? After considerable coverage in the press, the courts ultimately rule that the plaintiffs action was barred for lack of "standing" by the plaintiffs, and that sovereign immunity was a bar to the action. See, **Barns v. Texas Tech University**, Order entered Jun 17, 1999 (Cause No. 99-04564 - Travis County, Texas).

Section 2

Legal Framework and the Scope of AWA

There are two very different laws that assert control over the use of animals in research. The first and most visible is the federal Animal Welfare Act. The second is the law that controls the National Institutes of Health. Tying these different laws together at the individual institutional levels are the Institutional Animal Care Committees,

with responsibilities under both laws.

A. Evolving Congressional Attitude

Congressional condemnation of pet thieves and animal dealers who abuse dogs and cats was readily forthcoming. However, stories and evidence of animal cruelty within scientific research centers posed a difficult conflict for Congress. Clearly, advances in science and technology can be a critical positive force in shaping our society. Scientists, and medical researchers in particular, are given a near god-like status. Until the deliberations of Congress in 1966, society-at-large was either ignorant of the extent and types of use of animals in research, or presumed it was a necessary evil, suffered for the good of progress. The facts, however, revealed a much more complex problem in which thousands of animals suffering stress, pain, and/or death without having added anything meaningful to the body of scientific knowledge. Nevertheless, after significant lobbying by a number of national scientific organizations, in 1966, Congress did not feel it appropriate to interfere with the use of animals in research, teaching or tests by research facilities. The general attitude of Congress was expressed by Representative Pepper on the floor of the House:

I just wanted to say that the purpose of those bills which many of us are sponsoring, and which we hope will yet come to consideration in this House, is not to retard research, not in any sense of the word, nor to deny to laboratories and to research institutions the full use of the animals that they feel should be employed, but to establish some standards of scrutiny and inspection so that unnecessary brutal, barbaric, callous cruelty might not be perpetrated upon those animals that are already condemned to this service of mankind as instruments of research..

This philosophy was given the effect of law under Section 18 of the 1966 Act which stated:

Nothing in this Act shall be construed as authorizing the Secretary to promulgate rules, regulations, or orders for the handling, care, treatment, or inspection of animals during actual research or experimentation by a research facility as determined by such research facility.

Having clearly established that Congress and the federal government were not going to interfere with the actions and decisions of the researcher or tester, the obvious question remained as to what would be regulated? Again, the focus was limited to that of housing and caring for the animals. In 1966, this concern was limited to the care, handling, housing and transport conditions of dogs, cats, monkeys, guinea pigs, hamsters and rabbits prior to their ultimate use by research facilities. The 1966 Act represented the smallest of possible openings toward regulating the many complex issues regarding the use of animals in science. In 1970 this opening was expanded, but Congress still showed great reluctance in going forward. This area was out of the spotlight during discussions over the 1976 amendments when the focus was on animal fighting and the transportation of animals. The amendments of 1985, however, again focused upon the use of animals in experimentation moving Congress deeper into the controversy.

By the time of the 1970 amendments, it was believed that scientific research would not be harmed and, indeed, ought to be improved by requiring that the animals be looked after by veterinarians, that cages be of sufficient size, that they be cleaned, and generally that an animal's well-being be considered. Good science requires healthy animals so that no outside, unknown or uncontrollable factors influence the outcome

of the experiment. Nevertheless, examples of bad science and of inhumane conditions continued to come to light.

The 1985 amendments retained this basic language but broke it into two sections and added specific exceptions. Thus, Sec. 13(a)(6)(A) states:

(6)(A) Nothing in this Act –

(i) except as provided in paragraphs (7) of this subsection, shall be construed as authorizing the Secretary 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;

(ii) except as provided subparagraphs (A) and (C) (ii) through (v) of paragraph (3) and paragraph (7) of this subsection, shall be construed as authorizing the Secretary to promulgate rules, regulations, or orders with regard to the performance of actual research or experimentation by a research facility as determined by such research facility; and

The legal effect of this provision is to make it clear that the Secretary does not have any general regulatory authority to regulate animals and experimentation. The only authority available to justify regulations is that given in Sec. 13(a)(7), Sec. 13(a)(3)(A) and Sec. 13 (a)(3)(C)(ii). Housing before experimentation, care afterwards and, as will be discussed below, the issues of pain relief are all within the focus of Congress.

B. The AWA Provisions

Section 13 of the AWA contains the humane care provisions. The first subsection applies generally to dealers, exhibitors and research facilities. Subsection (a)(2)(A) contains the usual list of care categories: housing, feeding watering ventilation and shelter, etc. Subsection (a)(2)(B) contains some unique language about the scope of the required agency regulations, and will be discussed below:

(B) for exercise of dogs, as determined by an attending veterinarian in accordance with general standards promulgated by the Secretary, and for a physical environment adequate to promote the psychological well-being of primates.

The implementation of this in the regulations was the subject of a law suit that took many years to proceed through the courts and had to first overcome the problems of standing (see, **Animal Legal Defense Fund v. Glickman**, 154 F.3d 426, 332 U.S.App.D.C. 104 (1998) in Topic 11 – “Standing”) and is fully discussed in the case set out in the subsequent section on regulations.

The next subsection, (a)(3) is specifically focused on animals in research. Some of the individual phrases from this section are considered below (the structure of the law is requiring the USDA to adopt regulation):

News Bits

The Friday, January 17, (2003) *New York Times*, World Briefing section (p. A8):

The European Parliament passed a law this week that will ban the use of most animal tests to develop cosmetic products in the European Union by 2009. The vote marked the end of years of fierce debate over how strict to make rules on cosmetics testing. The ban will cover animal tests in Europe, and the law also calls for a ban on imports of cosmetics that have been tested on animals. As a concession to the cosmetics industry, though, the import ban will be delayed until 2013 for products for which no alternative to animal tests has yet been found.

(A) for animal care, treatment and practices in experimental procedures to ensure that animal pain and distress are minimized including...

Note the key phrase “in experimental procedures.” This language from the 1985 amendments represents the first time that Congress directly stated its intent to govern by regulation certain actions that might occur during a scientific experiment. Congress has chosen to concern itself with how experiments are carried out while leaving the decision of what issues should be researched to the scientific community.

However, the law does not require the elimination of pain and distress, but rather that they be “minimized.” This is often an illusive term, for that which is judged as minimum by some people may be unacceptably high to others. The best minimum in this setting would be zero: no pain or distress. But, there may be other circumstances where that is not possible. The problem is that Congress did not give us, or the Secretary, a standard by which to decide what level of effort is demanded before the “minimized” requirement of the law is met. What if it would require \$100 worth of equipment to eliminate one cause of distress in a lab, but another cause would require \$100,000 worth of lab reconstruction? What if the hiring of trained support staff to reduce the stress animals suffer during handling cost \$30,000 per year? There is a large amount of gray area in this part of the AWA. While the AWA does not state that cost is a factor to be balanced against levels of pain, at some level it inevitably becomes part of the regulatory equation. The Secretary must seek minimization, but it is unlikely that it will always be zero.

Case Study C-3

In the case study above concerning deer fawns and fire ants, the experimental procedure explicitly says that the use of pain relief would not be appropriate:

Effects of fire ant stings and bites on fawns *must* be excluded from analgesic/anesthetic treatment until it is clear that RIFA stings have reduced likelihood of survival. This is the treatment effect we are trying to measure during the experiment. Fawns that appear unable to rise and do not attempt to nurse when the doe is available to nurse them will immediately be weighed and examined by the Graduate Assistant, Technician III, or the attending veterinarian. If it is determined that the animal would be unlikely to survive in the wild that fawn will be removed from the study and euthanized. Euthanasia will be by intra-venous injection of 100mg/lb of sodium phenobarbital or by gunshot to the head.

In other words, the fawns must remain in pain until it is clear they will die from the ant attacks. This is an example where pain is an inherent part of the experiment. Good science? Does the AWA allow this outcome? If you were on the Animal Care Committee what would you say?

The next and final phrase of this paragraph is but a subpart of veterinary care, but it represents a primary focus of concern for all the groups and individuals that have been lobbying on behalf of animals.

with the appropriate use of anesthetic, analgesic tranquilizing drugs or euthanasia;

“appropriate use of” This term has two different potential contexts. First, it might refer to the decision of whether or not to use drugs at all. Alternatively, it could be referring to which drug to use once a decision is made to use drugs. It is best understood in this

paragraph to refer to the broader, critical issue of deciding when a drug should be used. The narrower, but still important issue of which drug to use would arise under the language of Sec. 13(a)(3)(C)(ii) (see discussion, *infra*). The broader interpretation is also supported by the other language of this particular paragraph. Remember that this entire paragraph has a clearly stated goal, the minimization of pain and distress. Other than not performing the experiment at all, the most critical decision will be whether or not to use drugs in order to reduce pain and distress.

“anesthetic, analgesic, or tranquilizing drugs” These are the broad categories of drugs which Congress mandates that researchers use. There is significant overlap between the three categories. A drug falls into these categories if it produces one of two effects. First, if it blocks the transmittal of pain signals by the neurons either locally where the pain originates or within the brain itself, this effect is caused by either an anesthetic or an analgesic. A general anesthetic accomplishes this by rendering the animal unconscious. A local anesthetic blocks the pain signals from only a part of the body (like the shot the dentist gives prior to filling a cavity). Secondly, the drug may make the animal less concerned about the incoming pain perception. These drugs are tranquilizers. With the use of lower levels of morphine, for example, a pain signal may reach the conscious brain but the animal is not distressed by the signal, e.g., it does not react to the pain, tranquilizers are also used to reduce negative conditions related to environmental conditions broader than just pain. These drugs can be used to reduce the distress an animal may have because of the conditions of confinement or the stress of the research itself. See Appendix A for more details about these terms.

The remainder of this subsection has language that is not prohibitory but process-focused. There are issues that an investigator should take into account before proceeding with the experiment. These issues become points of review for the Institutional Animal Care Committees before allowing an experiment to proceed.

C. The AWA Regulations For Dog Exercise and Primate Well-Being

All of the legal provisions of the AWA had to be implemented through the adoption of regulations by the administration before they became binding on the research institution. With the extensive 1985 Amendments it took many years before final regulations were adopted in 1991. The full set of regulations, as found in the 9 Code of Federal Regulations, (available at www.animallaw.info/administrative/adusawaregtofc.htm) is upwards of 100 pages of fine print.

Dog Space and Exercise

For the issue of dog exercise, which is only a clause in the AWA itself, the regulations say, in part:

Space for dogs:

Sec. 3.6(c) Additional requirements for dogs—(1) Space. (i) Each dog housed in a primary enclosure (including weaned puppies) must be provided a minimum amount of floor space, calculated as follows: Find the mathematical square of the sum of the length of the dog in inches (measured from the tip of its nose to the base of its tail) plus 6 inches; then divide the product by 144. The calculation is: (length of dog in inches + 6) × (length of dog in inches + 6) = required floor space in square inches. Required floor space in inches/144 = required floor space in square feet.

Sec. 3.8 Exercise for dogs.

Dealers, exhibitors, and research facilities must develop, document, and follow an appropriate plan to provide dogs with the opportunity for exercise. In addition, the plan must be approved by the attending veterinarian. The plan must include written standard procedures to be followed in providing the opportunity for exercise. The plan must be made available to APHIS upon request, and, in the case of research facilities, to officials of any pertinent funding Federal agency. The plan, at a minimum, must comply with each of the following:

(a) Dogs housed individually. Dogs over 12 weeks of age, except bitches with litters, housed, held, or maintained by any dealer, exhibitor, or research facility, including Federal research facilities, must be provided the opportunity for exercise regularly if they are kept individually in cages, pens, or runs that provide less than two times the required floor space for that dog, as indicated by Sec. 3.6(c)(1) of this subpart.

(b) Dogs housed in groups. Dogs over 12 weeks of age housed, held, or maintained in groups by any dealer, exhibitor, or research facility, including Federal research facilities, do not require additional opportunity for exercise regularly if they are maintained in cages, pens, or runs that provide in total at least 100 percent of the required space for each dog if maintained separately. Such animals may be maintained in compatible groups, unless: [omitted]

(3) The opportunity for exercise may be provided in a number of ways, such as:

(i) Group housing in cages, pens or runs that provide at least 100 percent of the required space for each dog if maintained separately under the minimum floor space requirements of Sec. 3.6(c)(1) of this subpart;

(ii) Maintaining individually housed dogs in cages, pens, or runs that provide at least twice the minimum floor space required by Sec. 3.6(c)(1) of this subpart;

(iii) Providing access to a run or open area at the frequency and duration prescribed by the attending veterinarian; or

(iv) Other similar activities.

Questions & Notes

1. If you have a client that has six golden retrievers, how might the regulations be satisfied? Do you see any problems with the languages of the regulation? What do you think was the intention of Congress? Do you think that the regulations carry out the intent of Congress?

Housing for Primates

As it has become clear that Congress would not stop the use of animals in research, then the focus of concern became the quality of life for those used in research. As the law from 1985 requires “a physical environment adequate to promote the psychological well-being of primates,” strong leverage ought to exist to impose conditions on facilities that would be beneficial to primates. Note that the phrase “economically feasible” or “within ten years” or other limited phrases are not in the law. Therefore the focus of the regulations should be on the animals. The reality is also that considerable economic cost would be incurred by any institution moving away from the traditional

individual animal cage/cell. The regulations first establish a minimum cage size:

(i) The minimum space that must be provided to each nonhuman primate, whether housed individually or with other nonhuman primates, will be determined by the typical weight of animals of its species, except for brachiating species and great apes\3\ and will be calculated by using the following table:
\4\

\3\ The different species of nonhuman primates are divided into six weight groups for determining minimum space requirements, except that all brachiating species of any weight are grouped together since they require additional space to engage in species-typical behavior. The grouping provided is based upon the typical weight for various species and not on changes associated with obesity, aging, or pregnancy. These conditions will not be considered in determining a nonhuman primate's weight group unless the animal is obviously unable to make normal postural adjustments and movements within the primary enclosure. Different species of prosimians vary in weight and should be grouped with their appropriate weight group. They have not been included in the weight table since different species typically fall into different weight groups. Infants and juveniles of certain species are substantially lower in weight than adults of those species and require the minimum space requirements of lighter weight species, unless the animal is obviously unable to make normal postural adjustments and movements within the primary enclosure.

\4\ Examples of the kinds of nonhuman primates typically included in each age group are:

Group 1 marmosets, tamarins, and infants (less than 6 months of age) of various species.

Group 2 capuchins, squirrel monkeys and similar size species, and juveniles (6 months to 3 years of age) of various species.

Group 3 macaques and African species.

Group 4 male macaques and large African species.

Group 5 baboons and nonbrachiating species larger than 33.0 lbs. (15 kg.).

Group 6 great apes over 55.0 lbs. (25 kg.), except as provided in paragraph (b)(2)(ii) of this section, and brachiating species.

Group	Weight		Floor area/animal			Height
	lbs.	(kg.)	ft.\2\	(m \2\)	in.	(cm.)
1	under 2.2	(under 1)	1.6	(0.15)	20	(50.8)
2	2.2-6.6	(1-3)	3.0	(0.28)	30	(76.2)
3	6.6-22.0	(3-10)	4.3	(0.40)	30	(76.2)
4	22.0-33.0	(10-15)	6.0	(0.56)	32	(81.28)
5	33.0-55.0	(15-25)	8.0	(0.74)	36	(91.44)
6	over 55.0	(over 25)	25.1	(2.33)	84	(213.36)



This is the cage size which satisfies the regulations for great apes. Consider how this cage can support the goal of the next set of materials.

Sec. 3.81 Environment enhancement to promote psychological well-being.

Dealers, exhibitors, and research facilities must develop, document, and follow an appropriate plan for environment enhancement adequate to promote the psychological well-being of nonhuman primates. The plan must be in accordance with the currently accepted professional standards as cited in appropriate professional journals or reference guides, and as directed by the attending veterinarian. This plan must be made available to APHIS upon request, and, in the case of research facilities, to officials of any pertinent funding agency. The plan, at a minimum, must address each of the following: [omitted]

Questions & Notes

1. These standards apply to both research facilities and exhibitors. Do you think any credible zoo would display chimpanzees in a 5' x 5' x 5' cage? Or a marmoset in a cage 20 inches high? Why is it acceptable for research facilities to adhere to such standards when exhibitors would not do so regardless of the law?
2. What do you think would happen if the public could walk through the housing facilities at research laboratories?
3. A news report in March of 2007 noted that wild rhesus monkeys in Nepal have been and are to be captured for vaccine research. Of course the provisions of the AWA do not extend to animals outside the U.S. and Nepal has no protective legislation equal to the AWA.

The following is offered to show why some individuals are concerned about the conditions of primates in research facilities.

An Insider's View:

Viktor Reihardt, *The Impossible Housing and Handling Conditions of Monkeys in Research Laboratories*

IPPL News (International Primate Protection League), Vol 28 No. 2 at p. 5 (Aug 2001)

I used to associate cruelty against monkeys with pictures of individual animals subjected to experimental procedures that obviously inflicted extreme pain.

Personally I see no ethical justification for any research which inflicts pain, distress, or suffering on animals, and primates in particular

However, this type of research is a given reality and, as long as it continues, I feel a strong obligation to at least promote refinement techniques that lessen the suffering of animals whose lives are involuntarily sacrificed for a questionable research enterprise. When I do nothing I betray not only the animals but I also betray my humane nature.

When I saw a primate research facility from the inside for the first time, I quickly realized that the cruelty against monkeys is much more pervasive than I had concluded from the horrible pictures. The suffering is not restricted to the inhumane experimental procedure itself but extends to every single hour of the animal's life in the laboratory.

More than 700 macaques – the prevailing primates in the research laboratory – were locked behind bars, fearfully waiting to be forcefully removed and immobilized during life-threatening procedures.

The situation was reminiscent of a high security prison for convicted criminals, though none of the animals was guilty of any crime other than being a helpless victim.

Each monkey was kept alone, in a cage that was so small that he/she could not take a few steps in one direction, let alone jump or run in monkey fashion. There was no companion to huddle, groom or play with.

It should be remembered that macaques are primates – just like us – who have an intensive need for social contact and social interaction. Solitary living conditions are similarly unbearable for them as they would be for us.

Most cages were completely barren, offering not even a perch that would have allowed the animals to make use of the arboreal dimension. In the wild, macaques spend most of the day in elevated sites – away from ground predators – and seek the refuge of trees at night.

When kept in cages without a high perch, the animals have no way of retreating to a “safe” place during alarming events, such as when a staff member approaches them. Being cornered in this manner must, indeed, be a very distressing experience for a helpless monkey who associates people with painful and distressing handling procedures.

In order to accommodate as many monkeys in one room as possible, cages were arranged in double-tiers with one row stacked on top of the other. This condemned half of the animals to confinement in a permanently shady, cave-like environment. Needless to say, this was not a living quarter that was suitable for diurnal animals.

The conditions I witnessed were so depressing that most monkeys had developed stereotypic behaviors such as pacing, rocking, bouncing, somersaulting, swaying from side to side, biting parts of their own bodies, pulling their ears, tossing their heads back and forth, or smearing feces on the cage walls.

When I expressed my concern about these alarming signs of distress, I was told that they are “abnormal” behaviors that the animals develop when kept in cages for a long

time. My conclusion was different: the appalling caging environment was abnormal – not the behavior of the monkeys.

It was hard for me to believe that the situation I had seen was typical. I therefore decided to contact animal care personnel of other laboratories and survey the scientific literature to find out how macaques are housed and handled in other research facilities.

What I heard and what I read confirmed what I had seen myself, leading me now to the following conclusion. In the U.S. there are currently approximately 15,000 macaques imprisoned in double tier stacked solitary cages waiting in fear to be subjected to distressing procedures.

The conditions under which these animals are forced to live are so inadequate that researchers themselves have repeatedly admitted in scientific publications that about 10 out of 100 caged monkeys are so desperate that they mutilate themselves.

The recent scandal at the Oregon Regional Primate Research Center – one of the most prestigious facilities in this country – gives the public a rare opportunity to get a sobering look behind the doors and see for themselves that the manner in which most primates are currently being housed and handled is not only inhumane but at the same time counterproductive to good research.

Wouldn't it be naive to expect scientifically valid research data from an intelligent, social animal who is forced to live alone in a barren cage with nothing to do but engage in self-injurious behavior out of utter frustration?

Providing monkeys in research institutions with primate-adequate housing and humane handling conditions would be a guarantee that scientific data are not unnecessarily skewed by uncontrolled extraneous variables.

There is no doubt that primatological investigators could do their research with fewer animals – and hence avoid a lot of unnecessary suffering and squandering of tax dollars – if they would make sure that the animals are not behavioral cripples as a result of under-stimulation, and that they do not suffer distress during handling procedures.

The ethical and scientific concerns arising from the prevailing housing and handling practices of monkeys have been acknowledged by the United States Department of Agriculture in 1991 stipulating in the **Regulations and Standards of the Animal Welfare Act** that:

*The housing arrangement of monkeys **must** [emphasis added by author] address the social needs of the animals, the cage environment **must** [emphasis added by author] be enriched by providing means of expressing monkey-typical behaviors, lighting **must** [emphasis added by author] be uniformly diffused and provide sufficient illumination for the well-being of the monkeys, handling should be done as carefully as possible in a manner that does not cause stress or unnecessary discomfort.*

These legal requirements are consistent with guidelines promulgated by the International Primatological Society in 1989/1993 and recommendations set forth by the National Research Council in 1998.

Many reports have been published in scientific journals outlining well-tested options for addressing the social needs of monkeys in the research laboratory, for enriching their environment in a species-adequate manner, for assuring uniform lighting condi-

tions, and for training the animals to cooperate, rather than resist, during common handling procedures such as capture, injection, topical drug application, and blood collection.

This information has also been compiled in bibliographies and a comprehensive database which can be accessed on the Internet at no cost.

How is it possible that investigators keep research monkeys under living conditions and handle them in ways that are in gross violation of federal rules and professional standards?

Here are my thoughts.

Lack of interest

A prestigious researcher conceded in an American scientific journal:

Most investigators think only briefly about the care and handling of their animals and clearly have not made it an important consideration in their work.

It is true, for many researchers the monkey is merely an identification number attached to a computer-processed data entry, and they consider it a waste of their time to visit the animals and check for themselves if they are properly housed and handled.

Arrogance

To quote from the same article:

Finally, I think that all investigators consider themselves upstanding citizens of excellent ethical and moral character. Their feeling may be that since they are moral and ethical in every sense of the word, they are quite capable of monitoring their own animals without outside interference.

Without question, most investigators regard compliance with the minimum housing standards set forth by the federal Animal Welfare Act as a nuisance.

Inertia of tradition

Many scientists resist any changes in the traditional husbandry practices of research monkeys, probably because of fear that historical data will be invalidated by different, albeit better, housing and handling conditions.

Lack of ethical concern

It is not uncommon for investigators to treat monkeys with few, or even without, ethical reservations. A world-famous scientist made this quite clear when he explained that experimentation with human patients is hampered by "sound ethical constraints," but that, "No such problems exist for the monkey researcher."

The present situation in primate research laboratories strongly suggests that professional judgment is no guarantee that the inhumane housing and handling conditions of laboratory monkeys will ever improve.

Progress will be possible only if USDA makes more serious efforts to enforce the federal law as Congress intended.

Until then, the well-being of research monkeys will continue to depend on the mercy

of scientists who traditionally view them as research objects and treat them accordingly.

USDA Regulations and Standards give the public the impression that monkeys in research laboratories are housed and handled in ways that reflect minimum ethical concern for their well-being. The prevailing housing and handling conditions of monkeys give testimony that these federal rules are not enforced properly. If you care for the well-being of animals, and of caged primates in particular, you may want to contact:

Deputy Administrator, USDA, APHIS, AC, 4700 River Road, Unit 97, Riverdale, MD, 20737 USA

Please request that APHIS enforce more effectively the Animal Welfare Act's **Specifications for the Humane Handling, Care and Treatment of Nonhuman Primates**. Rules have no meaning unless provision is made that they are actually followed! Emphasize that stronger regulations are needed to ensure the well-being of captive primates.

Meet the Author

Viktor Reinhardt has worked for ten years as an ethologist and clinical veterinarian at a primate research facility where he took care of the animal's health and introduced more humane housing and handling conditions for them.

After the laboratory hired a new director, Dr. Reinhardt's work was no longer appreciated and his contract terminated in 1994.

He joined the Animal Welfare Institute, Washington DC, in the same year where he continues "from outside" to promote better living conditions for nonhuman primates in research institutions.

The Animal Welfare Institute has recently published **Environmental Enrichment for Caged Rhesus Macaques – A Photographic Documentation and Literature Review**.

CASE BY CASE

The legality of the primate regulation is considered in the next case.

Animal Legal Defense Fund v. Glickman (2000)

204 F.3d 229, 340 U.S.App.D.C. 191 (2000)

[This case is the follow up to **ALDF v. Glickman**, 154 F.3d 426, 332 U.S.App.D.C. 104 (1998) which found that one plaintiff had sufficient standing to reach the merits of the claim, that the regulations adopted by the agency were an inadequate expression Congressionally mandated language of the AWA. See case in Topic 11 – "Standing."]

In 1985 Congress passed the Improved Standards for Laboratory Animals Act, Pub. L. No. 99-198, 99 Stat. 1645, amending the Animal Welfare Act of 1966. See 7 U.S.C. § 2131 et seq. The 1985 amendments directed the Secretary of Agriculture to promulgate "standards to govern the humane handling, care, treatment, and transportation of animals by dealers, research facilities, and exhibitors." Id. § 2143(a)(1). The Act specified that among these must be "minimum requirements ... for a physical environment adequate to promote the psychological well-being of primates." Id. § 2143(a)(1)-(2).

There are over 240 species of non-human primates, ranging from marmosets of South America that are a foot tall and weigh less than half a pound to gorillas of western

Africa standing six feet tall and weighing up to 500 pounds. It proved no simple task to design regulations to promote the psychological well-being of such varied species as they are kept and handled for exhibition and research. Notice of intent to issue regulations was first published in the Federal Register in 1986, 51 Fed.Reg. 7950 (1986), but the Secretary did not publish proposed regulations until 1989. 54 Fed.Reg. 10897 (1989). After receiving a flood of comments (10,686 timely ones, to be precise), the Secretary reconsidered the regulations and published new proposed regulations in 1990. 55 Fed.Reg. 33448 (1990). After receiving another 11,392 comments, he adopted final regulations in 1991. 56 Fed.Reg. 6426 (1991); 9 C.F.R. § 3.81.

The final regulations consist of two separate modes of regulation, typically known as engineering standards and performance standards. The former dictate the required means to achieve a result; the latter state the desired outcomes, leaving to the facility the choice of means. See 56 Fed.Reg. at 6427 (discussing engineering and performance standards generally). The Secretary identifies five guidelines that he considers engineering standards, which in substance require as follows: (1) restraints are generally prohibited subject to certain exceptions as determined by the attending veterinarian or the research proposal, 9 C.F.R. § 3.81(d); (2) primary enclosures must be “enriched” so that primates may exhibit their typical behavior, such as swinging or foraging, *id.* § 3.81(b); (3) certain types of primates must be given special attention, including infants, young juveniles, individually housed primates, and great apes over 110 pounds, again in accord with “the instructions of the attending veterinarian,” *id.* § 3.81(c); (4) facilities must “address the social needs of nonhuman primates ... in accordance with currently accepted professional standards ... and as directed by the attending veterinarian,” but they may individually house primates under conditions further specified in the regulations, *id.* § 3.81(a); and (5) minimum cage sizes are set according to the typical weight of different species, *id.* § 3.80(b)(2)(i).

To implement these guidelines and to promote the psychological well-being of the primates, facilities must develop performance plans: Dealers, exhibitors, and research facilities must develop, document, and follow an appropriate plan for environment enhancement adequate to promote the psychological well-being of nonhuman primates. The plan must be in accordance with the currently accepted professional standards as cited in appropriate professional journals or reference guides, and as directed by the attending veterinarian. This plan must be made available to APHIS [Animal and Plant Health Inspection Service] upon request, and, in the case of research facilities, to officials of any pertinent funding agency. *Id.* § 3.81.

Jurnove primarily maintains that nothing about these regulations establishes “minimum requirements ... for a physical environment adequate to promote the psychological well-being of primates,” and that the Secretary’s use of performance plans and his apparent deference to on-site veterinarians amount to an impermissible delegation of his legal responsibility.

The district court agreed. *Animal Legal Defense Fund v. Glickman* (“ALDF”), 943 F.Supp. 44 (D.D.C.1996). It held that the regulation “fails to set standards,” by which the district court meant engineering standards, and that “the regulation completely delegates the establishment of such standards to the regulated entities” because “[a]t best, the regulation refers these entities to the direction of their attending veterinarians—who are not under the control of the agency.” *Id.* at 59. The district court also concluded that the Secretary had a duty to require social housing of primates given a finding by the Secretary that “[i]n general, housing in groups promotes psychological well-being more assuredly than does individual housing.” *Id.* at 60 (quoting 56 Fed.

Reg. at 6473). As the court read the regulation “the agency delineates only when social grouping might not be provided,” and therefore “the regulation does not contain any minimum requirement on a point recognized by the agency itself as critical to the psychological well-being of primates.” *Id.*

* * *

Jurnove argues that the plain language of the statute—the Secretary shall establish “minimum requirements ... for a physical environment adequate to promote the psychological well-being of primates” —requires that the Secretary spell out exactly how primates may and may not be housed and handled (i.e., engineering standards), or at least spell out the “minimum requirements” in this manner. The Secretary’s emphatic first response is: we did.

Jurnove consistently reads the regulations, as did the district court, as if the only “requirement” of the facilities is the production of a performance plan and that, basically, anything goes—provided the facilities honor what he views as the empty formality of finding some sort of support from “currently accepted professional standards as cited in appropriate professional journals or reference guides” and from “the attending veterinarian.” 9 CFR § 3.81. This reading yields an obvious parade of horrors. Facilities will find unscrupulous veterinarians to rubber-stamp outrageous practices, and fringe periodicals will be the coin of the animal realm. This, argues Jurnove, is not the setting of “standards” or “minimum requirements” that the statute plainly commands.

We need not decide when performance standards alone could satisfy a congressional mandate for minimum requirements, or whether the sort of agency deference depicted by Jurnove could ever do so. The regulations here include specific engineering standards. The most obvious example is the regulation of cage sizes, *id.* § 3.80, which even Jurnove grants is an engineering standard. Jurnove attempts to discount the “primary enclosure” requirements because they appear in a different section of the regulations, and the Animal Welfare Act had previously mandated standards for “housing.” But the Secretary stated that the cage requirements were set as part of the standards for promoting psychological well-being, 56 Fed.Reg. at 6468, and it is perfectly permissible to implement congressional commands through complementary regulations, some of which serve multiple goals. See *Public Citizen, Inc. v. FAA*, 988 F.2d 186, 192-93 (D.C.Cir.1993).

The Secretary’s requirement bases cage size on the weight of the primate, with special provisions for great apes, whereas the previous regulations merely required “sufficient space to allow each nonhuman primate to make normal postural adjustments with adequate freedom of movement.” 56 Fed.Reg. at 6469. By hiking the requirements, the Secretary addressed an issue that Congress considered one of the central elements of a primate’s psychological well-being. The statutory language speaks of minimum requirements for the “physical environment” of the primate, 7 U.S.C. § 2143(a)(2)(B), and the Conference Committee noted that “[t]he intent of standards with regard to promoting the psychological well-being of primates is to provide adequate space equipped with devices for exercise consistent with the primate’s natural instincts and habits.” H.R. Conf. Rep. No. 99-447, at 594 (1985) (emphasis added).

Similarly, the regulations on environmental enrichment, special consideration of certain primates (infants, juveniles, etc.), and restraint devices all plainly provide engineering standards. 9 C.F.R. § 3.81(b)-(d). The facilities “must” provide environmental enrichment and special consideration for certain primates, *id.* § 3.81(b), (c), and they “must not” maintain primates in restraint devices “unless required for health reasons

as determined by the attending veterinarian or by a research proposal approved by the Committee at research facilities," *id.* § 3.81(d). The regulation on restraints then makes clear that even where a veterinarian approves of restraints, there are still limits:

Maintenance under such restraint must be for the shortest period possible. In instances where long-term (more than 12 hours) restraint is required, the nonhuman primate must be provided the opportunity daily for unrestrained activity for at least one continuous hour during the period of restraint, unless continuous restraint is required by the research proposal approved by the Committee at research facilities.

Id. Although research facilities may be allowed to restrain primates continuously, this limited exception is not offered to non-research handlers and is in keeping with the statute's bar on the Secretary from interfering with research. See 7 U.S.C. § 2143(a)(6)(A)(i)-(iii).

These "requirements" may be minimal but they are clearly mandatory. *Jurnove* argued, and the district court agreed, that this case begins and ends with the fact that the Secretary provided no engineering standards. *ALDF*, 943 F.Supp. at 59. But in fact he did.

Having found that the Secretary "ha[s] not yet issued standards," the district court went on to hold that he had "unlawfully withheld and unreasonably delayed" action in violation of the APA; it ordered the Secretary to "commence appropriate rulemaking procedures" and promulgate standards. 943 F.Supp. at 59-60. Our holding here moots this theory and accordingly we vacate that portion of the order.

It of course remains possible that the engineering and performance standards chosen by the Secretary are not enough to meet the mandate of "minimum requirements." We assess this issue under the familiar doctrine that if Congress has spoken to the precise question at issue, we must "give effect to the unambiguously expressed intent of Congress," but if Congress has not, we defer to a permissible agency construction of the statute. *Chevron U.S.A. Inc. v. NRDC*, 467 U.S. 837, 842-43, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984).

Here *Jurnove's* Exhibit A (and indeed his only serious example) is the Secretary's handling of primates' "social grouping." In 1989 the Secretary proposed to include a requirement of group housing for primates, saying that he intended to emphasize that nonhuman primates must be grouped in a primary enclosure with compatible members of their species or with other nonhuman primate species, either in pairs, family groups, or other compatible social groupings, whenever possible and consistent with providing for the nonhuman primates' health, safety, and well-being, unless social grouping is prohibited by an animal care and use procedure and approved by the facility's Committee. 54 Fed.Reg. 10822, 10917 (1989). This proposal was based on evidence that "nonhuman primates are social beings in nature and require contact with other nonhuman primates for their psychological well-being," and that "[s]ocial deprivation is regarded by the scientific community as psychologically debilitating to social animals." *Id.*

The final rule, of course, refrained from imposing such a general group housing requirement. *Jurnove* (stating his case in the best light) would tie the agency to its 1989 proposal on two theories: He argues first under *Chevron* that because of this finding

any interpretation of the statute not recognizing social grouping as one of the “minimum requirements” could not be a reasonable interpretation of the statute. And second he claims that the Secretary’s decision was arbitrary and capricious because he failed to explain it adequately, in violation of the Administrative Procedure Act and the principles set out in *Motor Vehicle Mfrs. Ass’n v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 43, 103 S.Ct. 2856, 77 L.Ed.2d 443 (1983).

The Secretary’s 1989 proposal was at odds with comments already in the record. For example, comments of the American Psychological Association had noted the wide disparities in social behavior among primates, with some forming large troops of 50 to 100 or more, others living in small groups of 10 to 20, and still others spending their lives in almost solitary isolation or as pairs in the wild. The 1989 proposal itself then generated new opposing comments, most notably from the University of Chicago, which pointed out that group housing “can significantly increase the incidence of trauma, the spread of upper respiratory and gastrointestinal diseases and more recently has been responsible for the outbreak of Simian Acquired Immune Deficiency Syndrome.” Moreover, according to these comments, an image of nonhuman primates blissfully coexisting in groups is a substantially incomplete depiction of species-typical behavior. Again, as the University of Chicago informed the Secretary: “Even in compatible groups in no specific distress, species typical activities include threatening, chasing, fighting, wounding, hair-pulling, food competition, dominance challenges and reversals, and displacement of subordinate animals from food, water and shelter. Such activity can threaten the animals’ health and well-being.”

The Secretary took account of such comments, just as the designers of “notice and comment” rulemaking intended. He pointed to expressions of concern that “social grouping would endanger the animal’s [sic] welfare by increasing noise and fighting,” 55 Fed.Reg. at 33491, and to contentions that differences among species (there are, recall, over 240) required “discretion be used in deciding whether to employ group housing,” *id.* Although it is true (as the district court noted and *Jurnove* here argues) that even in the final rulemaking the Secretary observed that “[i]n general, housing in groups promotes psychological well-being more assuredly than does individual housing,” 943 F.Supp. at 60 (quoting 56 Fed.Reg. at 6472-73), that generality was obviously qualified by the remarks just quoted. Thus the Secretary proposed a new regulation on social grouping:

The environment enhancement plan must include specific provisions to address the social needs of nonhuman primates of species known to exist in social groups in nature. Such specific provisions must be in accordance with currently accepted professional standards, as cited in appropriate professional journals or reference guides, and as directed by the attending veterinarian.

55 Fed.Reg. at 33525; 9 C.F.R. § 3.81(a) (final rule same). The regulation then offers “exceptions” to the social needs provision if the primate is vicious or debilitated, if it carries contagious diseases, or if its potential companions are not compatible. *Id.* § 3.81(a)(1)-(3). Even though social grouping is no longer formally mandated (facilities must only produce a “specific” plan for action that addresses “social needs”), the Secretary rightly argues that the enumeration of the “exceptions” makes social grouping the “norm.”

It is difficult to discern what difference use of the district court’s preferred method (a requirement subject to exceptions) would make. Given the Secretary’s amply supported findings, the exceptions would necessarily have been at a rather broad level of

an “environment enhancement plan for primates” at each facility, but the standards contain few solid criteria on which an inspector can judge the content of the plan as “in compliance” or “out of compliance.” The regulations state that the plan must address social grouping, enrichment of the physical environment, special considerations, and restraint devices, but what is required in order to address these in a minimally compliant manner is unclear. Some inspectors said they had the impression that the only legally necessary condition for compliance was the existence of the document itself, regardless of its contents. A few commented that once the facility’s attending veterinarian approved a plan, it was problematic to enforce additional requirements, even if that plan was very poor.

A few inspectors expressed the concern that without adequately specified criteria and only a notion of an abstract endpoint to achieve (psychological well-being, which can not be directly or unequivocally measured), facilities are free to try, or NOT try, anything—including a very behaviorally restrictive, barren environment. No one, including inspectors, would have any basis for criticism, until there is proof of “poor performance.” Unfortunately, there is no agreement on what “poor performance” looks like. There might be virtually no performance parameter or outcome that could be proven to have been caused by an inadequate environment.

2. Lack of Enforceability

APHIS Animal Care employees recognize that there is a legal question concerning the enforceability of performance standards. Some inspectors said they could recognize a plan that was not in accordance with professional literature or was not “adequate to promote psychological well-being.” However, they had concerns about Agency support for particular interpretations or judgement because of the vague language and nature of the performance standard.

3. Minimalistic and One-Sided Enhancement Programs

A common refrain among inspectors was that too many enhancement programs consisted of only one or two types of enrichment, such as feeding of treats or provision with a simple rubber toy, in an otherwise barren, stimulus-poor environment. There is agreement that acceptable enhancement programs should stimulate a variety of normal activities and meet all major areas of behavioral need in a species-typical manner, rather than concentrate on a few limited aspects of behavior (Olfert *et. al.* 1993, Poole 1991b). Many employees supported the idea that enhancement programs be required to address several different aspects of a primate’s environment and behavior, beyond the superficial breakdown given in 9 CFR §3.81 (“social,” “physical,” and “special”). The team received many helpful suggestions on this issue.

4. Questionable Implementation of the Facility Plans

Another problem has been the difficulty in proving actual implementation of an enhancement plan. Animal Care inspectors recommended facilities be required to provide better documentation of implementation.

5. Low Levels of Appropriate Social Grouping

Some Animal Care inspectors felt that there were too many singly housed primates. This is especially true at research facilities and among small licensed exhibitors. Inspectors who inspected public exhibits with singly housed chimpanzees said that the reasons most frequently given for housing these animals singly were that the exhibitor: preferred to have only one chimpanzee at a time; considered them more tractable

when single-caged; was ill-equipped to permit socialization of one single-caged chimpanzee with another; and/or was unwilling to transfer or loan a single chimp to other facility, even one equipped to provide a socially enriched environment. All of these reasons reflect convenience for the owner(s), not primary consideration for the psychological needs of the animals.

6. Practices that Perpetuate Socially Incompetent Individuals or Abnormal Behavior

Animal Care inspectors were concerned that dealers involved in the pet trade continue to remove infants from their care-giving parent(s) at an inappropriately early age, for reasons other than medical necessity. These practices are known to produce socially incompetent adults and contribute to the low levels of social grouping already identified.

7. Poorly Furnished Environments

Inspectors reported facilities with cages that did not have a single elevated perch, shelf, or similar structure. Inspectors said they often did not cite the above situations as noncompliant in inspection reports, although they believed the situations were not in accordance with the intent of the Animal Welfare Act, because they believed the Agency could not or would not support them.

Inspectors mentioned other problems with enhancement plans. Some plans are static, not updated to reflect whether they are working effectively. Some are not updated to be consistent with changes in the facility's population and use of animals. Some plans do not consider variation in individual animals' personalities and rearing histories. Others fail to avoid latent effects of harmful housing or rearing conditions. Inspectors said some facilities solve the problem of abnormal or psychological distress-related behavior by simply selling or transferring the primates to other parties. Facilities that sell or transfer primates after relatively short periods of use have little motivation to concern themselves with cumulative or latent effects on the behavior of their primates because these behaviors will be manifested at another facility.

The urgency of these problems or issues raised by their colleagues motivated the members of the Primate Environment Enhancement Team to move forward with the design of a conceptual model and policy. Another factor they had to consider was how to promote psychological well-being for nonhuman primates in the context of the larger political environment. A strategy had to be developed to fulfill the original intent and language of the Animal Welfare Act, while considering the response of the community affected by any new policy, the approach of other nations and societies also facing similar problems, and the difficulties inherent in scientifically measuring psychological well-being. These topics are discussed in Chapter II.

Questions & Notes

1. Why does an agency contest a law suit that claims that the regulations are inadequate while at the same time writes a report showing how inadequately their own field people believe the regulations are?
2. It should be noted that this report does not suggest new regulations, being unwilling (perhaps politically unable) to give up the performance standard approach.

3. What is the legal impact of having a published agency policy? As of the summer of 2003 the agency had not moved to adopt any new guidelines for primates. The Animal Legal Defense Fund, the Animal Welfare Institute and other plaintiffs filed a federal suit to force final agency action on the proposal. Eighteen years after the adoption of the law, uncertainty continues.
4. If you had a clean slate upon which to draft a regulation to implement the law of the AWA – “a physical environment adequate to promote the psychological well-being of primates” – how would you approach the issue?

The report above goes into considerable detail concerning the specifics of this issue and the reader is referred to the report for additional information.

In conjunction with the release of the above report, a policy was proposed and published, Animal and Plant Health Inspection Service, Draft Policy on Environment Enhancement for Nonhuman Primates, Federal Register: July 15, 1999 (Volume 64, Number 135) page 38145-38150 [Proposed Rules] [Docket No. 98-121-1]. But this was a policy for “guidance” not proposed new regulations, and has yet to be finalized into a formal policy of the agency.

Section 3

Institutional Animal Care Committees

A growing criticism of the AWA during the early 1980’s was the infrequency of USDA inspections generally, and specifically those of research facilities. A once-a-year walk-through by a federal inspector was not sufficient to protect the interests of the animals in a laboratory. At that time, it was becoming apparent that there were many animal welfare issues upon which research facilities also needed to focus. Given the reluctance of Congress to have the federal government impose itself upon research facilities, the lack of resources to provide for extensive USDA inspections, and the desire that scientific research remain self-directed, the 1985 amendments provided a new approach. They required the creation of a committee, which by its very nature would become a local focal point for most research animal care and welfare issues. With this action, Congress brought these concerns out of the dark secrecy of a research facility and into at least a semipublic view. This committee is also supposed to be the federal government’s watchdog in the laboratories by conducting a minimum of two inspections annually, with reports available to the federal government. The provisions of Sec 13(b) deal with three topics: the creation of the committee, the duties of the committee, and the responses required to negative reports by the committee (see Appendix B for full text of Sec. 13(b)).

Committee Creation

The idea of creating a local-level review committee was not new with the AWA’s 1985 amendments as a number of universities had previously created them. Also during 1985, a revised National Institutes of Health Guideline for grant recipient institutions was released which included provisions for an animal care and use committee. Finally, when the funding authorization statutes for the NIH were redrafted and passed by Congress during 1985, for the first time an institution receiving NIH funds had to have an animal care committee. While these statutory provisions are not as detailed as those under the AWA, they are roughly equivalent in their creation of a review committee and its responsibilities. Presumably one committee per facility will satisfy both

statutory requirements.

Returning to Sec. 13(b) of the AWA:

(1)...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.

While the power to appoint the committee members clearly rests with the chief executive officer of each research facility, there are two broad parameters within which the appointments must be made. First, the appointees must have knowledge about animal care. The second is a mandate that the members of the committee "shall represent society's concerns regarding the welfare of animals used at such facility." These words are more reflective of Congressional intent than of mandatory action.

In addition, Congress also provided specific requirements for two of the members of the Committee.

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

Congress is obviously seeking to obtain some balance of views on these committees. Animal rights/welfare organizations fought for a public member very strongly; their hope being that a public voice on the committee could help eliminate some of the animal welfare problems in research facilities. Whether or not this occurs, depends entirely upon whom the research facilities appoint as the public members. If an appointment authority does not seek out knowledgeable promoters of animal protection, from local humane societies for example, then the public member could qualify under the statute but be totally ineffective as a strong minority voice for the interests of the animals.

It is doubtful that most committees will only have the minimum number of three members. Five or more members is a more likely number, further diminishing the vote of the one public member. The only restriction of committees of larger than three is that no more than three can be from the same administrative unit of the research facility. Thus, the medical school of a university could not hold more than three positions on a seven member committee.

Duties of the Committee

The primary statutory responsibility of the committee is to engage in inspections of the research facility at least twice a year. The language in this paragraph makes it clear

that the committee is not limited to reviewing the housing conditions of an animal research facility, but also to the research areas as well. The purpose of the inspection is “to ensure compliance...To minimize pain and distress to animals.” Under this provision the members of the committee have the right to inquire about and observe any painful or distressful procedures or conditions within the facility, whether or not they are part of a pre-existing protocol.

Under Sec. 13(a)(3)(F), the committee is also the recipient of reports from any principal investigator who has drafted a protocol which will violate one or more of the animal care provisions of Sec. 13 (a)(3). The AWA does not state what the committee should do with such a report. While there is no federal authority for the committee to veto a proposed exception to the care standards, at a minimum the committee could provide a forum of discussion. Additionally, the research institution itself could empower the committee with overriding authority.

When the Committees are operational, a key legal question is whether the meetings of the Committee are open to the public, and whether the documents generated by the Committee are subject to disclosure under the rules of the Freedom of Information Act. First, almost all cases would be governed by state law and not the federal law because even though a federal law is involved; the organizations are either private or state affiliated. The quick answer to the question is that it depends; different state courts have provided different answers, and the laws have different rules under various state Open Meetings Acts and state Freedom of Information Acts. A few of the key issues under these acts concern whether a Committee of a University is subject to the state law governing the operations of government agencies? Also at issue is whether or not a researcher’s proposal is subject to public disclosure? See, **Citizens for Alternatives to Animal Labs, Inc. v. Board of Trustees of State University of New York**, 92 NY2d 357, 703 NE2d 1218 (1998); **Medlock v. Board of Trustees of University of Massachusetts**, 31 Mass. App. Ct. 495, 580 NE2d 387 (1991). The Court of Appeals of Texas held that the institutional animal care committee was not subject to the Texas Open meetings Act. **Animal Connection of Texas v. The University of Texas Southwestern Medical Center at Dallas**, 2002 WL 1397427, Tex.App.-Dallas, June 28, 2002.

Section 4

Other Laboratory Animal Standards

The National Institute of Health is one of the largest funders of animal research in the United States. They have a set of guidelines for the use of animals in research that is independent of the AWA and its regulations. Compliance with these guidelines is required for receiving a grant. See, NIH’s 230 page “Guide for the Care and Use of Laboratory Animals,” available at <http://oacu.od.nih.gov>. It should be noted that unlike the AWA “rats, birds and mice” are not exempt from the provision of the guideline.

The NIH will do inspections of animal conditions when issues arise, but they are not set up, as is the USDA under the AWA, for regular inspections and reports. A third organization exist which bridges the gap between the NIH Guide and the need for determination of compliance. This private voluntary organization is known as the AAALAC. The following is from their website:

What is AAALAC?

entists, CDC officials said.

In an inspection last year, the group found a range of problems with the way the CDC handles lab animals that prompted it to consider revoking the CDC's accreditation. Among the findings:

- Faulty sipper tubes left some monkeys with no access to water, leading to the dehydration death of an owl monkey and a rhesus monkey in 2004.
- A rhesus monkey was mistakenly killed in 2005 because of record-keeping and communications problems.
- Three rhesus monkeys were given a deadly combination of anesthetic and analgesic medications. The doses were consistent with published guidelines, but it killed the monkeys, leading to the CDC adopting new standards.
- Veterinarians had difficulty getting access to lab animals.
- There was a shortage of staffers to care for the animals.
- CDC staff denied access to some animal medical records, and other records were incomplete or never kept.
- Many cages were overcrowded with rodents and rabbits, and some animals were too large for their cages.
- Sanitation equipment breakdowns caused a back-up of soiled cages.

The AAALAC's report prompted the CDC to transfer oversight of its lab animal care to the director's office and add nearly 20 animal care staffers, CDC officials said Thursday. The agency has about 6,000 rodents and several hundred other animals, including bats, rabbits and monkeys, at its three Atlanta campuses.

The CDC's director, Dr. Julie Gerberding, said she was appalled when she learned about the problems last year, and vowed to make dramatic reforms. "We made a commitment ... that we're going to be an exemplar of excellence in animal care," she said.

A special \$3 million appropriation from Congress this year enabled the agency to make a number of facility upgrades, including the purchase of a cage-washing machine that costs nearly \$1.5 million.

The agency has also phased in an electronic records system, beefed up training and added veterinarians and other staff.

The AAALAC performed a follow-up inspection last month and will decide on the CDC's accreditation status in January.

Questions & Notes

1. Why did the above happen as a result of the actions of the AAALAC rather than the USDA and the obligations under the AWA? Did all of the problems cited violate the regulations of the AWA? Remember that rats are not covered under AWA but primates clearly are.
2. After considering all of the above information about animals in science labs, do you think our social duty to animals has been fully implemented by the

in species becomes more pronounced and obtuse; it becomes more of a challenge to interpret a particular animal's perception of pain. We have more personal experience and knowledge about a dog than we do of an octopus. Pain is a subjective interpretation of the response to negative stimuli. It is not something that can be measured by an exact scientific method, but it can be inferred by reasonable conjecture.

A few definitions of terms from AWA relating to the relief of pain:

Analgesic: a drug that relieves pain without the loss of consciousness; absence of pain or a noxious stimulation.

A drug that is described as having analgesic properties is a drug that relieves pain.

Examples: opium, morphine, aspirin, Tylenol

Tranquilizer [in veterinary medicine this word is used interchangeably with: **ataractics, neuroleptics, sedatives**]

Refers to a drug that calms or quiets a patient. The drug promotes sleep but does not induce sleep even at high doses. It is frequently used as a pre-anesthetic so less general anesthetic is needed. May or may not have any analgesic effects.

Major Tranquilizers: (neuroleptics, antipsychotic agents) used to stabilize mood and reduce anxiety, tension, and hyperactivity. Helps to control agitation and aggression.

Example: acepromazine

Minor Tranquilizers: Antianxiety

Example: diazepam (valium)

Anesthetics: a drug that causes loss of feeling or sensation; used to abolish the sensation of pain and achieve adequate muscle relaxation. Some cause CNS stimulation.

Local Anesthetic: blocks nerve transmission in the area it is administered to. It causes an area or region of the body to be insensitive to painful stimuli. Does not cause unconsciousness.

Example: novacaine

Injectable Anesthetic: barbiturates

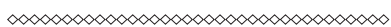
Dissociative Anesthetic: analgesia and superficial sleep. Name describes the state produced by these drugs. It is a good somatic analgesic, poor visceral analgesic, and poor muscle relaxant.

Example: ketamine (street drug: "Special K")

Inhalant Anesthetic: analgesia and unconsciousness are produced when concentrations reach a specific level in the brain and spinal cord.

Examples: halothane, isoflurane

Paralytic: loss or impairment of motor function



Appendix B: Provisions of AWA

§2143. Humane standards for animals transported in commerce [Sec. 13]

(a) Promulgation of standards, rules, regulations, and orders; research facilities; State authority.

(1) The Secretary shall promulgate standards to govern the humane handling, care, treatment, and transportation of animals by dealers, research facilities, and exhibitors.

(2) The standards described in paragraph (1) shall include minimum requirements –

(A) for handling, housing, feeding, watering, sanitation, ventilation, shelter from extremes of weather and temperatures, adequate veterinary care, and separation by species where the Secretary finds necessary for humane handling, care, or treatment of animals; and

(B) for exercise of dogs, as determined by an attending veterinarian in accordance with general standards promulgated by the Secretary, and for a physical environment adequate to promote the psychological well-being of primates.

(3) In addition to the requirements under paragraph (2), the standards described in paragraph (1) shall, with respect to animals in research facilities, include requirements –

(A) for animal care, treatment, and practices in experimental procedures to ensure that animal pain and distress are minimized, including adequate veterinary care with the appropriate use of anesthetic, analgesic, tranquilizing drugs, or euthanasia;

(B) that the principal investigator considers alternatives to any procedure likely to produce pain to or distress in an experimental animal;

(C) in any practice which could cause pain to animals –

(i) that a doctor of veterinary medicine is consulted in the planning of such procedures;

(ii) for the use of tranquilizers, analgesics, and anesthetics;

(iii) for pre-surgical and post-surgical care by laboratory workers, in accordance with established veterinary medical and nursing procedures;

(iv) against the use of paralytics without anesthesia; and

(v) that the withholding of tranquilizers, anesthesia, analgesia, or euthanasia when scientifically necessary shall continue for only the necessary period of time;

(D) that no animal is used in more than one major operative experiment from which it is allowed to recover except in cases of –

(i) scientific necessity; or

(ii) other special circumstances as determined by the Secretary; and

(E) that exceptions to such standards may be made only when specified by research protocol and that any such exception shall be detailed and explained in

a report outlined under paragraph (7) and filed with the Institutional Animal Committee.

(4) The Secretary shall also promulgate standards to govern the transportation in commerce, and the handling, care, and treatment in connection therewith, by intermediate handlers, air carriers, or other carriers, of animals consigned by any dealer, research facility, exhibitor, operator of an auction sale, or other person, or any department, agency, or instrumentality of the United States or of any State or local government, for transportation in commerce. The Secretary shall have authority to promulgate such rules and regulations as he determines necessary to assure humane treatment of animals in the course of their transportation in commerce including requirements such as those with respect to containers, feed, water, rest, ventilation, temperature, and handling.

(5) In promulgating and enforcing standards established pursuant to this section, the Secretary is authorized and directed to consult experts, including outside consultants where indicated.

(6) (A) Nothing in this Act –

(i) except as provided in paragraphs [paragraph] (7) of this subsection, shall be construed as authorizing the Secretary 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;

(ii) except as provided [in] subparagraphs (A) and (C)(ii) through (v) of paragraph (3) and paragraph (7) of this subsection, shall be construed as authorizing the Secretary to promulgate rules, regulations, or orders with regard to the performance of actual research or experimentation by a research facility as determined by such research facility; and

(iii) shall authorize the Secretary, during inspection, to interrupt the conduct of actual research or experimentation.

(B) No rule, regulation, order, or part of this Act shall be construed to require a research facility to disclose publicly or to the Institutional Animal Committee during its inspection, trade secrets or commercial or financial information which is privileged or confidential.

(7) (A) The Secretary shall require each research facility to show upon inspection, and to report at least annually, that the provisions of this Act are being followed and that professionally acceptable standards governing the care, treatment, and use of animals are being followed by the research facility during actual research or experimentation.

(B) In complying with subparagraph (A), such research facilities shall provide –

(i) information on procedures likely to produce pain or distress in any animal and assurances demonstrating that the principal investigator considered alternatives to those procedures;

(ii) assurances satisfactory to the Secretary that such facility is adhering to the standards described in this section; and

(iii) an explanation for any deviation from the standards promulgated under this section.

(8) Paragraph (1) shall not prohibit any State (or a political subdivision of such State) from promulgating standards in addition to those standards promulgated by the Secretary under paragraph (1).

§2143(b) Research facility Committee; establishment, membership, functions, etc.

(1) The Secretary shall require that each research facility establish at least one Committee. 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.

(2) A quorum shall be required for all formal actions of the Committee, including inspections under paragraph (3).

(3) The Committee shall inspect at least semiannually all animal study areas and animal facilities of such research facility and review as part of the inspection –

(A) practices involving pain to animals, and

(B) the condition of animals, to ensure compliance with the provisions of this Act to minimize pain and distress to animals. Exceptions to the requirement of inspection of such study areas may be made by the Secretary if animals are studied in their natural environment and the study area is prohibitive to easy access.

(4) (A) The Committee shall file an inspection certification report of each inspection at the research facility. Such report shall –

(i) be signed by a majority of the Committee members involved in the inspection;

(ii) include reports of any violation of the standards promulgated, or assurances required, by the Secretary, including any deficient conditions of animal care or treatment, any deviations of research practices from originally approved proposals that adversely affect animal welfare, any notification to the facility regarding such conditions, and any corrections made thereafter;

- (iii) include any minority views of the Committee; and
- (iv) include any other information pertinent to the activities of the Committee.

(B) Such report shall remain on file for at least three years at the research facility and shall be available for inspection by the Animal and Plant Health Inspection Service and any funding Federal agency.

(C) In order to give the research facility an opportunity to correct any deficiencies or deviations discovered by reason of paragraph (3), the Committee shall notify the administrative representative of the research facility of any deficiencies or deviations from the provisions of this Act. If, after notification and an opportunity for correction, such deficiencies or deviations remain uncorrected, the Committee shall notify (in writing) the Animal and Plant Health Inspection Service and the funding Federal agency of such deficiencies or deviations.

(5) The inspection results shall be available to Department of Agriculture inspectors for review during inspections. Department of Agriculture inspectors shall forward any Committee inspection records which include reports of uncorrected deficiencies or deviations to the Animal and Plant Health Inspection Service and any funding Federal agency of the project with respect to which such uncorrected deficiencies and deviations occurred.

(c) Federal research facilities; establishment, composition, and responsibilities of Federal Committee. In the case of Federal research facilities, a Federal Committee shall be established and shall have the same composition and responsibilities provided in subsection (b), except that the Federal Committee shall report deficiencies or deviations to the head of the Federal agency conducting the research rather than to the Animal and Plant Health Inspection Service. The head of the Federal agency conducting the research shall be responsible for —

- (1) all corrective action to be taken at the facility; and
- (2) the granting of all exceptions to inspection protocol.

(d) Training of scientists, animal technicians, and other personnel involved with animal care and treatment of research facilities. Each research facility shall provide for the training of scientists, animal technicians, and other personnel involved with animal care and treatment in such facility as required by the Secretary. Such training shall include instruction on —

- (1) the humane practice of animal maintenance and experimentation;
- (2) research of testing methods that minimize or eliminate the use of animals or limit animal pain or distress;
- (3) utilization of the information service at the National Agricultural Library, established under subsection (e); and
- (4) methods whereby deficiencies in animal care and treatment should be reported.

(e) Establishment of information service at National Agricultural Library; service functions. The Secretary shall establish an information service at the National Agricultural Library. Such service shall, in cooperation with the National Library of Medicine, pro-

In his book, *The New Priesthood*, Ralph E. Lapp describes science slightly differently:

the goals of science focus upon the exploration of the unknown and the enlargement of knowledge. Very often the greatest discoveries come when a man sees relationships between things which no one recognized before—or sees these in a new light. But usually science expands into the unknown like a huge amoeba, moving first this way and then that, seeking the virgin and the fertile. Its goals are determined by opportunity and chance, and sometimes design.

Finally, J. Bronowski, arguing that science at its highest level is an extremely creative human process, has offered the following definition:

All science is the search for unity in hidden likenesses ...

The scientist looks for order in the appearances of nature by exploring such likenesses ...

The progress of science is the discovery at each step of a new order which gives unity to what had long seemed unlike. Faraday did this when he closed the link between electricity and magnetism. Clark Maxwell did it when he linked both the light. Einstein linked time with space, mass with energy, and the path of light past the sun with the flight of a bullet ... J. Bronowski, **Science and Human Value** (1965).

As can be seen in the above definitions, science is the search for knowledge of how and why the universe around us functions. The process by which this knowledge is acquired is as complex as, and indeed might be considered parallel to, the development of the human mind. At times the process involves merely mechanical data gathering or tedious computation, but like art, it is also a creative process in which the scientist, like the artist, seeks to provide some new insight or a different, broader, perspective of nature.

In addition, science is a social activity. The growth of scientific knowledge is heavily dependent upon the interchange of ideas among scientists, both contemporaries and predecessors. The scientist who makes a “breakthrough” not only “stands on the shoulders of giants, and hence can see a little farther,” but he perceives reality subject to all of the strengths and weaknesses of his colleagues.

How does one know if an activity is that of science? The following represents some of the key attributes:

1. uses a suitable method for describing its subject matter; e.g., mathematics, words, diagrams, or symbols;
2. uses an existing method systematizing or classifying the material to be described, or creates a new method for doing so; e.g., classifying plants into species on the basis of particular features, or naming and classifying subatomic particles;
3. uses hypotheses for the purpose of predicting or accounting for the occurrence of natural phenomena;
4. uses experimentation, as previously defined, to test hypotheses. Experimentation should include:
 - (a) planning objectives and procedures,

- (b) [having the] potential for recognizing error and minimizing it by proper design
- (c) gathering data and insuring its uniformity,
- (d) analyzing the data, and interpreting the data and drawing conclusions based on the data.