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1. HISTORY

The animal research controversy has a long history and it seems to follow a 50-year cycle of waxing and waning. From 1850 to 1900, the controversy grew and required the serious attention of leaders of society toward the end of the century. From 1900 to 1950, the issue gradually disappeared from view as a significant societal problem. Then, from 1950 onward, it began to develop again and by the 1980s demanded the attention of politicians, scientists and the public. It is not clear whether the issue will begin to fade away again in the 21st century or if its new intellectual underpinnings will sustain it. However, the issues and arguments put forward in the 19th century are, with one exception, exactly the same as those we are dealing with today and they still remain largely unresolved. The one exception is the question of alternatives to animal use, which holds out the promise, in the view of its proponents, of having the fruits of research without having to bear the costs in animal pain, distress and death.

2. ANIMAL NUMBERS

The statistics on laboratory animal numbers in the United States are crude and relatively unreliable. In Europe, Britain has kept figures on laboratory animal use for over one hundred years and most countries in the European Union are now required to collect and report accurate statistics on animal use. These figures indicate that animal use has been falling in Europe since the late 1970s and early 1980s. For some countries, such as Switzerland and Great Britain, animal use has fallen by 50% from 1980 and 1975 respectively (to around one million animals in Switzerland and three million animals in Great Britain in 1992). For other countries, laboratory animal use has fallen by 20-40%.

In the U.S., the data on laboratory animal numbers are not as reliable. However, annual surveys were conducted in the 1960s by the National Academy of Science’s Institute for Laboratory Animal Resources (ILAR) up to 1971. From 1972, the U.S. Department of Agriculture (USDA) has kept statistics on dogs, cats, primates, rabbits, hamsters and guinea pigs. It is possible to track
the number of these six species used annually from around 1960 (one has to subtract the use by federal laboratories because of gaps and problems with the USDA annual reports). The data shows that of the six species, numbers peaked in the late sixties (at 2,063,846 average in 1968-9), and fell rapidly in the early seventies (1972-5 average was 1,581,983), then remained stable for the next fifteen years and began to fall again around 1990 (the 1990-93 average was 1,228,419).

Since 1968, the decline in the use of the six species has been around 40%. However, rats and mice are not included and they usually account for 80-85% of the laboratory animal total. The ILAR/USDA data do not reflect trends in mouse and rat numbers (ILAR did record mouse and rat use but the data only exist for the 1960s, 1971 and 1978 - a 40% decline was recorded between 1968 and 1978). Other more recent data, from the Department of Defense (DoD) and corporate laboratory records indicate that DoD mouse and rat use fell around 35% from 1983 to 1991 while corporate use fell by as much as 70% (Hoffman-La Roche) during the 1980s.

3. HOW MUCH ANIMAL PAIN & DISTRESS?

Public opinion polls and reaction to media stories indicate that when the public becomes concerned, it is primarily concerned with laboratory animal pain and distress. Even the painless killing of laboratory animals is perceived to carry a cost (particularly by those who work in research laboratories). However, we have very little data on the extent of animal pain and distress in research. The USDA requires registered laboratories to report their animal use (not including rats and mice) in three categories - research causing no pain/distress (category C), research causing pain/distress which is relieved by drugs (category D), and research causing pain and distress that is not relieved by drugs (category E). However, the USDA has never provided guidelines to help institutions decide how to classify their research (for example, if drugs are given to relieve pain for some, but not all of the time, should it be placed in category D or E?).
Nevertheless, the USDA returns indicate that 5-6% of all animal research is placed in category E, but there are very large differences among institutions and states. For example, Kansas reports that over 40% of its animals are used in category E research while many other states that use large numbers of animals report less than 1% of all their research in category E. Some corporations that do toxicity testing (where pain-relieving drugs are usually not used) report no animal use in category E. Many non-profit institutions are very reluctant to place animal research in category E because they believe they will be targeted by animal activists if they do. Thus, it is very probable that the USDA statistics under-report laboratory animal pain and distress, however mild some of it may be.

The only country that has collected systematic data on animal pain and distress is the Netherlands. Their 1990 Annual Report on animal experimentation notes that 53% of the animals experienced minor discomfort, 23% moderate discomfort, and 24% severe discomfort. About one fifth of the animals in this last category were given medication to alleviate pain. Examples of procedures that would place animals in the “severe” category are prolonged deprivation of food or water, some experimental infections, tumor research and LD50 testing.

Laboratory animal research causes less pain and distress than implied by animal protection literature but more animal pain and distress than claimed by research advocates.

4. REGULATORY STRUCTURES

Prior to 1970, animal research was largely unregulated in the United States. In 1966, the Laboratory Animal Welfare Act was passed to regulate dog and cat dealers but research institutions were not included. In theory at least, many institutions had animal care committees on their books at this time, but, if they functioned at all, they were mainly concerned with allocating space for research animals and setting the rates for maintaining animals in the facilities.
In 1970, the Laboratory Animal Welfare Act became the Animal Welfare Act and all institutions registered under the Act were required to follow regulations that governed the care of dogs, cats, primates, rabbits, hamsters and guinea pigs but how those animals were actually used remained outside the scope of the Act. Nonetheless, in response to rising public criticism, institutions began to address the question of how research animals should be used in experiments in addition to the routine care and housing they should receive. In 1981, the University of Southern California reworked its animal care committee and started to oversee how animals were used at the university. They even appointed a local animal activist to sit on the committee. Other institutions began to follow their lead.

In 1985, the Public Health Service (PHS) revised its animal use policy and required all institutions receiving its funds (mainly from the NIH) to establish animal care and use committees to review and approve animal research protocols. The new policy was based on the model of the Institutional review boards established in the 1970s to review research using human subjects. The new animal research committees began to grapple more and more with how animals should be used. Then, at the end of 1985, major amendments to the Animal Welfare Act were passed that required all registered research institutions (not just those receiving PHS funding) to establish Institutional Animal Care and Use Committees (IACUCs). The IACUC was required to review and approve animal research protocols prior to any animal research being conducted and to pay particular attention to reducing research animal pain and distress. In addition, the amendments required institutions to address the psychological well-being of primates and the exercise and socialization needs of laboratory dogs.

Today, those using laboratory animals in the United States have to conform to a wide range of housing and care standards and also have to address a variety of issues dealing with how the animals are used. In particular, if the animals are likely to experience pain and distress (even if alleviated by anesthetics or analgesics) the investigator has to demonstrate that he or she has looked for alternatives. IACUCs also pay much greater attention to the
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need to prevent pain and distress. However, there are still tensions about any interference with how animals are used and the boundaries of IACUC power to prevent particular research projects.

5. JUSTIFYING ANIMAL RESEARCH

Animal research is almost always justified in terms of its great utility in improving human and animal health, while the costs of such research in terms of animal harm and distress are considered to be small by comparison. Sometimes, it is also argued that animal research has played an important role in the development of basic knowledge about biology.

Although some critics argue that animal research has played no role in the advance of medical knowledge, such arguments are plainly wrong. There are many examples where animal research and testing have played an important part in the development of new knowledge or insights that have led to improvements in medical therapy. Some animal research projects have proved to be more important than others, but experience indicates that it is not possible to predict which research is likely to be more important than other research in building our understanding of human and animal biology and disease.

In the past ten to fifteen years, research advocates have begun to draw on more emotional arguments to prove that animal research is necessary, rather than simply listing the medical advances that are based on animal research. Patients who have benefited from modern medical technology have come forward as spokespersons to endorse the importance of animal research. This approach has been developed to counter the strong emotional arguments of the critics of animal research.

6. CRITICIZING ANIMAL RESEARCH

The critics of animal research have always employed emotion-laden images to protest the use of laboratory animals but, in the past twenty years, they have also developed a range of reason-based arguments that are grounded either in moral philosophy or...
that employ methods of argument and citation used in scientific discourse. By adopting a scientific style of argument, animal research critics are tapping into the authority and credibility that science enjoys in modern society. (However, simply adding references to an argument does not make it scientific, though it does allow greater scrutiny of the argument.)

Animal research is criticized on moral grounds either because animals are argued to have inherent moral rights that would prevent their use in research (rights-based arguments) or because animal research causes more animal harm and distress than benefits for humans and animals (utilitarian or consequentialist argument). The rights-based arguments do not necessarily hold that animals and humans have the same rights. The utilitarian argument is very similar to that used to justify animal research. The difference between the research advocates and the utilitarian critics is that the critics argue that animal research causes considerable animal pain and distress for little or no real benefit for the most part.

The critics have also put forward a range of technical arguments claiming that animal research is either not necessary or not as important as implied by the research advocates. These arguments may be summarized as:

i) better use of preventive medicine will eliminate the health problems that require animal research;

ii) public health and epidemiological research is far more important than animal research in improving public health;

iii) clinical research (i.e., human) has provided the key insights in advances in medical treatment and animal research has merely been employed to dramatize clinical findings; and

iv) the development of alternatives eliminates the need to use animals.

The importance of preventive medicine and of public health, epidemiological and clinical research is not in question in this debate. However, research advocates do not accept that the above
approaches are either being ignored or that they obviate the need for animal-based research. In addition, alternatives have not advanced to the point where they could replace all animal use.

There is plenty of room for legitimate and even interesting and constructive argument in debating the relative importance of animal research and its cost-benefit characteristics. Unfortunately, arguments are usually presented in relatively absolute terms and the research establishment has shown little interest in debating the technical merits of animal research with their critics for fear that it may give the critics what is perceived to be undeserved legitimacy.

7. ANIMAL TESTING

Laboratory animal use in testing is different from animal research because the main aim of testing is either to establish whether a product is safe for use (e.g. vaccines and biologicals) or to determine the level and type of toxicity associated with a new product (e.g. new drug testing). No hypothesis is being developed or tested in routine animal testing.

Animal testing accounts for between 10 and 20% of all laboratory animal use. Most test regimens for the toxicity or hazard (identifying safety) estimates of a chemical or product employ animals at some point. Such tests have been developed over the past sixty years because of a perceived public health need and because common laboratory animals are mammals, like humans, and are viewed as being sufficiently like humans to provide useful conclusions about human exposure.

In the past twenty years, criticisms of such tests have grown and have stimulated a widespread re-evaluation of the need for and role of animal testing. In addition, animal protection criticism and the rapid advance of biological technology have spurred interest in toxicity testing that does not use whole animals. Animal organs, animal or human cells, and computer modeling are some of the possible alternatives that are being explored.
In Europe, Japan and the United States, there are numerous projects to develop and validate alternatives for animal testing. Regulatory authorities are working to harmonize testing requirements and support the validation of alternatives. Industrial and academic toxicologists have largely accepted the need to develop, validate and implement alternatives. However, establishing hazard or safety is not easy and data from a laboratory mammal still provide a level of regulatory history and confidence that is not yet seen with the new alternative tests. As experience with the new alternative tests grows and as knowledge about toxic mechanisms continues to increase rapidly, so the need to perform animal tests will decline. However, animal testing will not disappear in the foreseeable future.

8. ANIMAL USE IN EDUCATION

Animals have traditionally been used in educational exercises to teach manual skills or to demonstrate known principles of biology or methods of research. Animal protection advocates oppose most use of animals in education because, they argue, the skills, principles and methods can now be taught just as effectively using models, computers or some other teaching aids. Research advocates resist this criticism because they see educational exercises using live and dead animals as essential in stimulating interest in biology, teaching the importance of biology and medical research and expanding biological literacy in general.

Currently, the debate over animal use in schools focuses on dissection and a student’s right to opt out of the laboratory without penalty. Several states have passed laws that specifically permit a student the right to choose. Research advocates are concerned about this because they perceive that if students are allowed to opt out of dissection, it challenges the school’s authority to teach what it considers necessary and how it should be taught and it also might lead to declining standards of biological literacy.

Ironically, both the country’s medical and veterinary schools are now allowing their students to opt out of animal laboratories if they so choose. Thirty-four of the 126 medical schools have no
animal laboratories and 61 of the remainder allow students to opt out of animal laboratories. More and more veterinary schools are allowing students to opt out of the surgery laboratory on purchased laboratory dogs and are teaching surgery skills via other means (e.g. student spay/neuter clinics on animals from a local humane society).

There is very little empirical data that either support or refute the contentions of either side. This is an issue where the firmness of the conclusion is inversely proportional to the amount of hard evidence supporting it. The evidence that is available supports the contention that factual (declarative) knowledge can be learned just as effectively from books, lectures and videotapes but that problem-solving skills (procedural knowledge) is much more effectively learned by performing laboratory exercises. In addition, unpublished research suggests that factual knowledge and values formation are unrelated.

9. ALTERNATIVES

The concept of alternatives developed from a 1959 book that suggested that researchers should seek to Replace animal use where possible, Reduce animal use where possible, and Refine animal research techniques so as to reduce animal pain and distress as much as possible. These "Three R's" now constitute what most people identify as "alternatives" although there is a tendency for both sides to focus on Replacement and ignore Reduction and Refinement.

As mentioned above, animal use has dropped by up to 50% in the past twenty years and it is generally considered that part (nobody knows how much) resulted from the promotion and adoption of the idea of alternatives. In addition, more attention is being given to reducing animal pain and distress in research.

In the United States, there is a certain amount of schizophrenia about the concept of alternatives. While corporate toxicologists and regulatory scientists have mostly accepted the term and are comfortable working to develop and implement alternatives,
academic scientists and their main funding source, the National Institutes of Health (NIH), and many research advocacy organizations reject the use of the term “alternatives” preferring to use such terms as “adjunct” and “complementary methods.” However, the Office for Protection from Research risks, which enforces PHS policy on animal research, does require attention to the three R’s (alternatives). Those who reject the term “alternatives” tend to see it as a Trojan horse planted by the animal protection movement that will lead to great harm for medical research if allowed to gain a foothold.

It appears as though most of the public who pay attention to this issue use the term “alternatives” and so do legislative bodies. The U.S. Congress recently mandated the NIH to develop a plan for promoting and implementing alternatives but, to date, only the National Institute of Environmental Health Sciences (which happens to be heavily involved in developing new toxicity-testing methods) has publicly embraced the term.

10. ROLE OF THE MEDIA

Scientific organizations have often suggested that animal activists have skillfully manipulated the media (thereby gaining an unfair advantage) because of the images of animals under experimentation that they have provided or because animal activists have particular public relations skills. It is true that animal images have a particular pull on the public (equal to human infants) but there is no evidence that animal protection organizations have any greater public relations skills than the scientific organizations who defend the use of animals.

Throughout the 1970s and the early 1980s, the general media’s coverage of animal protection issues was largely favorable to the animal groups. However, this began to change around 1985/86. One began to see more articles critical of the tactics and claims of the animal groups. The change was not the result of a re-appraisal by journalists but by more proactive and aggressive tactics by research advocates who decided that the animal rights threat warranted significant attention. Once they set their mind to
It, the scientific organizations and specialized groups formed to defend animal research could call on significant resources, including funding, sophisticated public relations skills and experience, many excellent contacts with the media, and high profile and respected spokespersons. The animal protection community is currently holding its own in the media battles but is having to work harder to do so.

It has sometimes been argued that the media converted the animal research controversy from a non-issue into a major story. However, it is not clear that the media have such power. In the 1930s and 1940s, the powerful Hearst newspaper chain adopted the antivivisection cause and yet, after two decades of campaigning against animal research, the public still favored animal research by an overwhelming margin. The media does not convert non-issues into major stories. Instead, skilled journalists have sensitive "news antennae" that sense the moods and concerns of the public before others do and develop stories that address those concerns. Thus, journalists do not make a public issue so much as articulate it when public concerns reach a certain level.

11. TACTICS AND STRATEGIES

A. Animal Protection

The animal protection groups have traditionally relied on "public education" and new legislation to change animal research practices. Public education initiatives were designed to inform the public about the "horrors" of animal research. Legislative initiatives would then be introduced to eliminate the problems and to regulate any remaining use of animals. With the growth of the movement, other tactics were developed and implemented.

High-profile campaigns succeeded against narrowly defined targets that were chosen to provide maximum advantage for the critics (e.g. cat sex experiments at the American Museum of Natural History, pig "torture" experiments sponsored by Amnesty International, and eye irritancy and lethal-dose testing by the cosmetic industry). Campaigns with more diffuse goals (e.g.
people for the ethical treatment of animals used undercover investigations and material stolen by the animal liberation front (alf) to expose research practices. they were particularly successful with two early cases - the exposes of the institute for behavioral research (the silver spring monkey saga) involving an undercover investigation (or infiltration depending on one's point of view) and the university of pennsylvania head-trauma laboratory, involving videotapes of the experiments on baboons stolen by the alf and later edited into a half-hour expose.

the use of stockholder resolutions as a way of bargaining with public corporations began in the 1980s and is now a common tactic.

animal protection organizations composed of and aimed at specific professions were established (e.g. physicians committee for responsible of medicine, association of veterinarians for animal rights, and psychologists for the ethical treatment of animals). these groups provided a source of expertise and credibility to the animal movement and also served as something of a counterbalance to the existing professional societies that supported animal research, though their membership is much smaller.

the animal protection "movement" also continued its legislative lobbying and public education but, with even more members and more money, was able to do both more effectively. many of the organizations hired washington lobbyists to represent their interests and the fund raising and public education mailings were distributed to a million or more constituents as opposed to a hundred thousand. both of these actions increased the political impact of the animal protection groups on capitol hill.

while the initial undercover investigations and break-ins by the alf were aimed specifically at exposing conditions in
animal research laboratories (i.e. the liberation of information),
there were also cases of vandalism (up to and including arson) and
anonymous threats were issued against research scientists and
their families. These tactics of intimidation led some research
advocates to categorize animal rights (and some animal welfare)
organizations as violent, anti-science groups and even as support­
ing terrorism. Such categorization began to have an impact, and
many of the establishment animal protection groups publically
criticized acts of vandalism and intimidation as being counter to
animal rights philosophy (i.e. no harm to any sentient being,
including humans). The boundaries of legitimate protest and civil
disobedience in animal protection campaigns remain to be defined
and articulated.

B. Research Advocates

Research advocacy and professional scientific and health
organizations tended to ignore the animal protection movement
until the early 1980s. A new research advocacy organization, the
(now National) Association for Biomedical Research, was started
in 1979 because existing organizations were perceived to be unable
to deal with the expanding animal protection movement. In July
of 1985, Margaret Heckler, Secretary of the Department of Health
and Human Services, suspended a grant to the University of
Pennsylvania head-trauma laboratory because of violations of
animal care and use policies. This was a wake-up call for the
research community which began to develop programs to counter
the animal rights movement.

The Association for Biomedical Research (which had many
corporate members) and the National Society for Medical Re­
search (which had many university and medical school members)
combined forces to form the National Association for Biomedical
Research. Many states either established state-based societies for
medical research or revived organizations that were active in the
early 1900s but had gradually fallen into a dormant state.

These groups developed a range of tactics and approaches.
They monitored state and federal legislatures and lobbied against
animal protection legislative initiatives. In Congress, they introduced and eventually got passed and signed into law an act making theft and destruction of property at a research facility a federal crime and subject to FBI jurisdiction. They developed numerous brochures and other materials for the public, including a rather successful series of posters. They supported the development of patients’ organizations to counter animal protection campaigns and emphasize the importance of animal research to the advance of medical knowledge. They also developed a variety of curricula and other materials aimed at school teachers and school children that are designed to confirm the importance of animal research and re-affirm how good laboratory animal housing and care are.

While research advocacy organizations like to argue that animal protection groups together have a very large annual budget to devote to campaigns against animal research, the playing field is more equal now than it was in the 1970s. While the national animal protection groups probably devote together around $15 million annually to the animal research issue, they often do not work together or co-ordinate their activities.

The research advocacy groups together currently devote around $5 million a year to support the need for animal research. However, these funds do not include the activities of the professional scientific and medical societies, of the National Institutes of Health or of the many corporations that are now actively engaged in the debate. Given the fact that the research establishment also has better access to the sources of power and the policy makers in America, the debate over animal research now would probably favor those who support the need to use animals in the laboratory.

It is likely that the balance of public opinion will begin to edge back towards greater support for the use of animals if current trends and tactics remain unchanged.

C. The "Troubled Middle"

Although it may appear from a quick survey of media
stories that the debate over animal research is hopelessly polarized, there are many scientists and interested members of the public who occupy what philosopher Strachan Donnelly has called the "troubled middle." In other words, they accept (with more or less reluctance) the need for animal research but they also acknowledge and worry about the moral challenges raised by the practice. This silent majority could be mobilized to participate in and support a constructive dialogue, leading to reasonable and effective public policy initiatives that would allow progress toward the elimination of animal pain and distress in research without placing unreasonable barriers in the quest for greater biological and medical understanding.

In England, Australia and a number of European countries a constructive dialogue has been developed around the "troubled middle" that involves both defenders and critics of animal research. In the U.S. such dialogue has been less visible but is nonetheless occurring. Representatives from pharmaceutical and household product companies have been working with representatives from some animal protection groups to support initiatives that would lead to the development and use of alternatives to some animal testing. Both defenders and critics of animal research have lobbied for more funding for enforcement of the Animal Welfare Act. In addition, as more people on each side develop a better understanding of the arguments of the other, chances for a meaningful and productive dialogue improve.

In the end, a credible public policy will have to be based on the meaningful inclusion of critics as well as defenders of animal research in policy formation and application.

12. PUBLIC POLICY SUGGESTIONS

A). An officially sanctioned forum should be established with representatives from major organizations and some independent analysts to determine how much reasonable common ground exists and to address specific assertions and claims by either side.

B). The USDA should develop a more extensive annual
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report form so that those involved in making and influencing public policy can have reliable data to support or refute arguments. In Europe, where such data are now becoming available because of a European Union directive, it is possible to identify trends and problem areas with some reliability.

C). Because of public concern about laboratory animal pain and distress, a more accurate assessment of the extent of animal pain and distress should be developed, and ways that such distress can be minimized should be systematically investigated. The development of accurate and trusted data would prevent exaggerated claims by both sides in the debate and would provide guidance in the areas where efforts to develop alternatives (to reduce animal pain and distress) would directly address an important public concern.

D). The new Applied Toxicology program authorized under the 1993 NIH Revitalization Act should be funded and built into a program that addresses new method (i.e. alternative) development, validation and implementation.

E). Scientific organizations should formally accept that the use of animals in research entails some costs in animal death and distress and should establish programs that specifically support efforts to minimize those costs. At the same time, animal protection groups should recognize that clinical (i.e. human), animal and non-animal research techniques have all played a significant role in the advance of biological knowledge and that removal of one of these three elements is likely to slow down the advance of biological knowledge.