

# Coalition For Animals & Animal Research

## CFAAR Arizona Newsletter

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To join the Arizona CFAAR, please fill out the membership form on the back page. Donations purchase our newsletter and educational materials. A year's subscription is included with your contribution.

### CFAAR: Who We Are

CFAAR is a nonprofit educational organization which formed in response to activists who were attempting to discredit animal research and animal researchers in 1988. Several local CFAAR chapters have since sprung up across the country. These groups share the following objectives:

- 1) To **organize** students, faculty, and staff at institutions where animal research is performed so effective letter writing campaigns can be initiated quickly.
- 2) To **educate** the public, in general, and the campus, in particular, about the true nature of animal research and animal researchers.
- 3) To **support** responsible and humane use of animals in biomedical research.

The first of these objectives will be the primary function of the group. As legislation is introduced that affects animal research, we need to respond so our representatives know exactly how we, the people, want them to vote. Accordingly, through our newsletter, we will help inform you about legislation and other "happenings" concerning attacks on animal research. Our goal is to make it as easy as possible to contact your Washington, D.C. representatives.

The key to the effectiveness of this organization is you! We need your willingness to write an occasional letter, perhaps talk with a school group and, of course, give a few dollars to cover the cost of printing the newsletter and educational materials.

**HELP SUPPORT CFAAR  
SO WE CAN SUPPORT YOU**

### Regulations Covering Federally Funded Research

All medical research funded by the U.S. Government must comply with the U.S. *Government Principles of Utilization and Care of Vertebrate Animals*. This includes research being conducted by, as well as funded by, any governmental agency. These principles are fairly broad statements about the care and use of laboratory animals, designed to give each agency a basic guide, or outline, from which to construct their own, more detailed policies. As an example, one of the principles state "The living conditions of animals should be appropriate for their species and contribute to their health and comfort." To insure that all research is being performed under their jurisdiction complies with this, each agency then defines what are the appropriate living conditions (cage size, climatic conditions, etc.).

The vast majority of medical research in this country is funded by the U.S. Public Health Service (PHS) through the National Institutes of Health (NIH). The NIH *Guide for the Care and Use of Laboratory Animals* sets forth detailed standards for laboratory animals used in medical research. The *Public Health Service Policy on Humane Care and Use of Laboratory Animals* establishes the means for insuring compliance with the Guide.

### The Public Health Service Policy On Humane Care And Use Of Laboratory Animals

The PHS Policy requires each institution receiving PHS funding to establish an Institutional Animal Care Use Committee (IACUC) to enforce the requirements set forth in the Guide. This Committee is to be comprised of a minimum of five individuals of which one member must be a veterinarian specializing in laboratory animal medicine and one member must be a representative of the community (someone not affiliated with the institution).

Before any research grant proposal can be submitted to the NIH, it must be reviewed and approved by the Committee to determine, among other things, if the use of animals is justified (could the experiment be performed using "alternative" methods?), if so are the numbers and types of animals to be used appropriate, will the procedures cause the animals pain or distress and if so what pain relieving medication is going to be used.

The Committee also must inspect the research facility on a regular basis to determine compliance with the Policy and the Guide. If noncompliance is found in any area, the Committee is required to report such to the NIH. They also must approve any instance of the withholding of pain relieving medication. The NIH conducts unannounced site visits to insure the institution is operating within the requirements listed in the Policy and the Guide.

### **Guide For The Care And Use Of Laboratory Animals**

The Guide is eighty pages of small print containing specific requirements on personnel qualifications; animal procurement, housing, feeding, bedding, sanitation, disease control, surgery and post surgical care, use of anesthesia and pain killers and euthanasia procedures; and building construction requirements. The Guide is very specific in all of these areas. For example, it describes the type of paint which is allowable on wall, ceilings and floors, sizes of corridors, sizes of animal cages (rats under 100 grams must be housed in cages with a minimum of 17 square inches of floor space per animal with a cage height of at least 7 inches), to name but a few.

The Guide requires that anesthetics and/or pain killing drugs be used during any procedure which could be painful or cause distress for the laboratory animal unless such drugs would defeat the purpose of the experiment (such as in research into pain itself). In such a situation, special approval for withholding pain medication must be obtained and special reports must be filed. Noncompliance with the Guide could result in the NIH withdrawing funding for specific projects or from the entire institution until violations are satisfactorily corrected.

Federal law now requires research facilities receiving PHS funding to comply not only

with the Federal Animal Welfare Act, but also with the PHS Policy and the NIH Guide.

The NIH Guide covers research facilities receiving federal funding and includes all animals regardless of species.

### **Other Federal Agencies' Policies**

Although the PHS is by far the largest grantor of federal medical research grants, there are other federal departments and agencies which conduct animal experimentation within federal facilities and/or support extramural research using animals. Many require that the NIH Guide be adhered to, others (such as the Food and Drug Administration and the Environmental Protection Agency) have established their own policies, and a few others which do very little animal testing simply incorporate the U.S. Government Principles.

(iiFARsighted Report, Vol 2, No 2)

### **Are There Alternatives To Animal Research?**

This is a question being frequently asked these days which unfortunately is causing a good deal of confusion to the general public because the only truthful answer is "yes and no", depending on the "scope" one is examining.

In the broad, overall scope there is not an alternative to using animals in research - their use is absolutely essential. But in a narrow, tightly focused scope, there are non-animal research methods which can be used as alternatives to live animals in certain individual experiments and tests. It's kind of like the question "Are there alternatives to factory workers?" No, a factory can not operate without workers, but yes, there are alternatives, such as computer driven spot welders, which can replace some of the workers in certain jobs. Actually, the term "alternatives" is inappropriate when discussing the general topic of animal research because in medical research, as in the example of factory workers, the "alternatives" are actually supplements allowing the overall objectives to be reached more efficiently, rather than substitutes aimed at eliminating animals or workers.

Being supplements, there is an incredible amount of interplay between non-animal and live animal research methods. When looking for

answers to questions, researchers always use the most appropriate means. In most cases this involves several steps, ranging from studying scientific journals, to computer analysis of existing data, to in-vitro cell cultures, to in-vivo research using animals, to clinical trials on humans.

Non-animal research methods are proving to be particularly useful in three areas of medical research; basic research, pharmacology and toxicology. As the name implies, basic research is where scientists learn the basics of how the body, body systems, and the disease process works. For instance, molecular biologists are discovering new information on how body cells function. This information is proving valuable to research in pinpointing the causes of cancer, a disease where cells grow uncontrolled because of a mechanism not yet fully understood. Researchers are using cell and tissue cultures of cancer tumors removed from humans and animals in these studies.

Basic researchers also use computers to generate new theories and hypotheses. They may, for example, put into a computer information about the chemistry and metabolism of the liver. The computer would then analyze this information and may postulate that a previously unknown enzyme could exist. It may even be able to suggest what the chemical structure and function of that enzyme may be. Researchers can now examine the chemistry and metabolism of the liver itself in animals where the liver is operating normally & interacting with other metabolic systems of the body to determine whether or not that enzyme does exist, and how in fact it works.

Pharmacological research uses computers to analyze existing data and perhaps suggest a chemical compound which may provide the desired results. If the research is looking for a drug to react with a certain portion of the brain, for example, it can then be tested on brain cells and/or tissues in culture to see if it has the desired effect. If these tests are successful, the drug is then tested in several animal species. This step is essential for several reasons. Drugs that are effective in culture may not work at all in complete living systems because they may not be able to pass from the blood stream to the brain, or they may be inactivated so rapidly by the liver or kidneys that effective concentrations of the drug do not reach the brain. A more dangerous

possibility is that the drug itself may cause severe damage to other vital tissues of organs.

Toxicologists use computer "pattern recognition" programs to compare a suspected toxin's characteristics to those of compounds known to be toxic. If the program shows a relationship with a known toxin, the investigation can oftentimes stop. If the program does not indicate any relationship to known toxins, the compound would then be tested in cell cultures and animals to determine toxicity, and if proven to be toxic in these tests, that data would be added to the computer program's data base. Pattern recognition screening is increasingly reducing the number of suspected toxins which require testing on live animals. However, as the number of possible chemical combinations is practically infinite, new compounds will continually be discovered for which there is no previous knowledge, thereby requiring additional animal testing.

In the area of detecting possible cancer-causing properties of compounds, the Ames test is but one example of a useful cell culture technique. By observing a substance after it is introduced into a bacteria culture, it is possible to determine with accuracy whether or not the substance is a "mutagen." From animal research, we know that mutagens frequently cause cancer, so the Ames test is widely used first stage screening procedure for drugs and chemical testing. If the test shows the compound to be a mutagen, it is then tested in animals to determine if that particular mutagen will actually cause cancer.

As you can see, there are several non-animal research methods making great contributions to medical research. But like all individual procedures, alternatives by themselves cannot provide all the answers, no more so than simply reading text books or conducting research solely on animals. It is the whole system – the interplay between all of the procedures researchers use – that gives us the cures, treatments and preventative measures we so desperately need.

(iiFARsighted Report Vol.2, No. 3)

### **New Hemophilia Drug Approved By FDA**

According to a recent Associated Press report, the Baxter Healthcare Corp., of Glendale,

Cal., recently announced the Food and Drug Administration (FDA) has approved marketing of a drug for hemophilia that is made in the laboratory instead of being extracted from human blood.

Marketed under the brand name Recombinate Antihemophilic Factor, Baxter Healthcare Corp. officials told iiFar hemophiliac dogs and mice were crucial in the testing and development of the drug.

It is a laboratory-made version of the human blood clotting factor VIII, used in the treatment of hemophilia A, the most common form of hemophilia. Because the drug is produced artificially, patients taking it will not face the risk of contracting blood-borne disease.

(iiFARsighted Report 1/93, Vol 7 No 1)

### **Herpes Virus Helps Repair Brain Cells**

Researchers at the Wistar Institute of Anatomy and Biology and the University of Pennsylvania reported in the August Nature Genetics that they were able to transfer a necessary enzyme to the brain cells of mice using herpes virus as a transfecting agent. The animals were suffering from Sly disease, an inherited malady caused by enzyme deficiency that also occurs in humans.

Sly disease is one of the so-called MPS group of inherited diseases; mice and dogs are susceptible and show disease syndromes similar to humans'. According to one of the researchers, Nigel Fraser, "The herpes virus is uniquely able to transfer genetic material to a brain cell without killing it because the virus is latent."

(Lab Animal, Vol 21, No 9, Oct. 1992)

### **Federal Judge Orders Rewrite Of Portions Of USDA Animal Welfare Standards**

US Department of Agriculture (USDA) rules dealing with dogs and nonhuman primates were struck down on Thursday, February 25, by U.S. District Judge Charles S. Richey. USDA has been directed to promulgate new regulations, subject to public notice and comment, without unnecessary delay. Agriculture has at least 30 days to decide whether to appeal the decision.

This action results from a May 1991 lawsuit against USDA, the Department of Health and Human Services (HHS) and the Office of Management and Budget (OMB). The Animal Legal Defense Fund (ALDF), the Society for Animal Protective Legislation, Inc. (SAPL) and others sought to have certain sections of new animal welfare standards declared unlawful and, therefore, revised. The activist suit specifically named sections of the regulations finalized in February 1991 dealing with primary enclosures for dogs, cats and primates and research facility plans for dog exercise and promoting the psychological well-being of non-human primates (Sections 3.6(b)(1), 3.6(c)(1), 3.6(d), 3.8, 3.80(b)(1), 3.8(b)(2), 3.8(c) and 3.81 of Part 3 of the Animal Welfare Standards). Judge Richey's opinion does not specify exact sections to be revised, but it discusses only dog and primate treatment issues.

Basically, the judge concluded the 1991 regulations violate the federal Administrative Procedures Act in that they:

- do not provide minimum standards intended by Congress;
- are arbitrary and capricious because nonhuman primate group housing and minimum cage size requirements, as well as dog exercise requirements, are inconsistent with the USDA's original findings;
- unlawfully delay compliance in some cases until February 1994;
- permit the use of special (innovative) cages to avoid compliance with the Animal Welfare Act.

The decision disagreed with the plaintiffs' position on just one point. The court found that written plans developed and kept by research facilities to comply with the Animal Welfare Act are not federal "agency records" and, therefore, are not subject to public disclosure under the federal Freedom of Information Act.

Judge Richey seemed to have based his opinion on the plaintiffs' arguments, but also on what he calls "original findings" made by USDA. References are made to the 1989 statements published with proposed standards. For example, the following USDA statements are used:

“...the consensus of its veterinarians with training and experience in the care of dogs is that 30 minutes of daily exercise is a reasonable minimum for maintenance of a dog’s health and well-being.” (54 Federal Register 10905 (1989))

“...agency and the commentators on the proposed guidelines agreed that the social deprivation is psychologically debilitating to nonhuman primates and that group housing for nonhuman primates was the best way to avoid this problem.” (54 Federal Register 10837 (1989))

Having interpreted from those statements that scientifically valid, absolute standards should be required, the Judge faulted USDA for not doing so. Commenting on one point, he said the standards “may well be based more on the almighty dollar than the welfare of animals.”

A suggested letter to Agriculture Secretary Espy follows.

The Honorable Mike Espy  
Secretary, US Department of Agriculture  
Administration Building, Room 200 A  
14<sup>th</sup> Street and Independence Ave, SW  
Washington, DC 20250

Dear Mr. Secretary: In the absence of other departmental staff, this matter of critical importance must be brought directly to your attention.

We urge the Department of Agriculture to appeal the decision made February 25, 1993 by District Court Judge Charles R. Richey in Animal Legal Defense Fund, et al. v. The Secretary of Agriculture et al. This decision sets aside portions of the animal welfare standards finalized on February 15, 1991 (9 C.F.R. Part 3). The Department has been directed to promulgate new regulations in compliance with the Court’s order.

In adopting the existing performance-based animal welfare standards, the Department wisely decided that flexibility is necessary for research facilities to best care for their laboratory animals. After careful deliberation, USDA correctly recognized that the valid scientific information necessary to adopt exact requirements appropriate for every individual animal, in every research setting, does not exist. Based on currently available scientific data, the “minimum requirements” the court wants

established for all dogs or non-human primates would be very minimal indeed. Animal well-being is much better protected under the individualized written plans which USDA now requires each research facility to produce, follow and update as better information regarding animals’ needs become known.

Please do whatever is necessary to preserve our existing performance based standards. Should you or your staff need additional information or have any questions, please call upon me or the National Association for Biomedical Research.

Thank you for your consideration of this important issue.

Sincerely, (Your Name)

(NABR *ALERT*, Vol XV, No 2, 3/1/93)

**Be Sure To Send A Copy To Our Representatives!**

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