1/19/83

SENATOR DOLE

JOHN GORDLEY/MARK SCANLAN

ANIMAL WELFARE BILL

We met with USDA and HHS officials on their opposition to the bill you introduced last session. USDA is reflecting the anxiety and near-paranoia of animal agriculture over the possible consequences of allowing even a minor "animal rights" bill to pass Congress. The National Institute of Health is opposed on the grounds that it feels the Animal Welfare Act is already being properly administered, and that it already has discretion to make most of the proposed changes in policy.

All agencies agree that it would be useful to develop a legislative compromise acceptable to the moderate animal welfare groups. However, farm organizations are sensitive to setting a precedent for laboratory animal care that will be later used in evaluating conditions for farm animals. Unless a philosophically-consistant position can be found that confines the issue to the use and treatment of research involving live animals, an animal welfare bill will be sharply opposed by farm interests.

In an effort to try to find a possible compromise, USDA, HHS, the Society for Animal Protection Legislation (Christine Stevens) and Congressman Walgren's office met Tuesday. Christine Stevens is mainly concerned with implementing a fool-proof method for checking on laboratory conditions and penalizing offenders. She believes that the agencies charged with these responsibilities are not prepared to discriminate between gradations of animal stress and suffering that would dictate not using live animals or using less onerous methods.

Christine does not hide the fact that the animal rights movement may be using the lab animal bill to get a foot in the door, or that subsequent efforts may try to include animals used in farm research. She is personally willing to confine the bill to scientific applications with an exemption for agriculture, but has no idea on how to allay industry fears about setting a precedent.

One approach would be to introduce a different bill that deletes all references to "animal rights" and emphasizes that conditions should be consistent with the potential value of the research in terms of human benefit. This principle would be more difficult to apply in farm situations. Another option would be to ask Christine to find another chief sponsor (your bill had ten) and for you to offer a less objectionable compromise on the floor.

Mark has drafted an alternative bill that deletes references to ethical practices, and can have Legislative Counsel prepare a new bill if appropriate.

A BILL:

To promote improved standards for the care of animals and to encourage the development of practical alternative methods of research, experimentation and testing for health purposes.

TITLE

"THE IMPROVED STANDARDS AND DEVELOPMENT OF ALTERNATIVES IN HEALTH RESEARCH ACT."

FINDINGS:

1) That standards for animal care exist for institutions involved in health research and that such standards, implemented on a uniform basis, will better serve the health research needs of society;

2) Alternative methods of research, testing and experimentation for health purposes have been developed which show promise of being faster, more cost effective and more accurate than traditional animal experiments for some purposes: and further opportunities exist for the development of these methods of testing;

3) Institutional arrangements are needed to recognize the depth of public concern for the protection of animal life and to improve self-regulating measures which reflect this concern; and

4) Measures which help meet the public concern for lab animal research are important in assuring that significant areas for science, in which animal experimentation is crucial, such as research benefiting human health, will continue to progress.

TITLE I

- Development of better testing methods -

NONANIMAL

Section 101

A) Secretary and NSF can make awards:

1) For sponsor research and development of alternatives testing which

o reduces the number of animals used

o does not require the use of animals or

o produce less pain

2) Establish the validity and reliability of such methods for the purpose of reducing the number of animals, or replacing animal research and test methods, where applicable.

B) Award money only if an application has been assessed through proper peer review procedures. Secretary will determine specifics of the proposal.

Section 102

A) Secretary shall direct certain agencies (EPA,FDA,NIH,NTP) to:

1) Promote development of and evaluation of present alternatives that reduce numbers or eliminate use of animals and that satisfy public concern for health, safety and regulations;

2) Promote alternatives in international regulatory research that yields better toxicology data systems;

3) Ensure the use of present and future animal test data by enhancing data storage and retrieval systems. (one alternative type - i.e. mathmatical modeling).

4) The Secretary will assess the implications of establishing a clearinghouse for information regarding appropriate methods and research models. Secretary shall include the status of establishing a clearinghouse in his report to the Congress. (102 (C)).

B) Secretary shall direct the National Toxicology Program to significantly increase its emphasis on new alternatives that are faster, more economical, more reliable and more useful.

C) Secretary shall report every 2 years to the House Speaker and Senate President indicating progress under Section 102.

TITLE II

General Requirements for Grants

Section 201

To receive federal grants research entities must:

o comply with Section 203.

o have an adopted set of standards for:

A) Acceptable care, treatment and research methods in experimental procedures including handling, housing, feeding, watering, sanitation, ventilation, shelter from extremes of weather, and exercise;

B) Comply with paragraphs 2-4 of Section 301.

STANDARDS

Section 202

A) (1) To receive money a facility must provide evidence it has met requirements to engage in such use as required under this title in (2) (B).

(2) Within one year the Secretary shall conduct a study to determine the economic impact od accreditation. Purpose: determine the costs of meeting standards comparable to NIH's Guide for the Care and Use of Lab Animals.

B) After completion, the Secretary shall issue regulations for implementing specific standards based on study/cost results. The Secretary can waive accreditation requirements that cause an undue economic hardship on an entity.

Section 203

A) To receive money an entity shall provide assurances that:

1) The entity has an animal study committee of at least 3 members to assess the proper care and treatment of research.

- Committee Structure -

A) One member must be a vet.

B) One member is not associated with the entity and is aware of community concerns. They will not release trade secrets.

C) No more than 3 members can be from the same administrative unit.

2) - will meet regularly with a quorum for formal action

- will inspect annually animal study areas and facilities

- will review research methods and practices used for live animals and their conditions. Purpose: to evaluate methods to ensure a minimum amount of pain

- will file that inspections have taken place along with reports of any violations

- a majority of the members will sign and minority views can be included. ~~If someone doesn't sign they may file a minority report~~.

3) Committee will maintain records of their inspection (including attendance of members) and other pertinent information. Records maintained for 3 years can be reviewed by the Federal agency.

4) Members may notify APHIS and others of bad practices, treatment, use, which have not been reported and which have persisted despite notification.

5) The committee may provide information they find helpful in encouraging alternatives and better animal care.

(b) Project money can be suspended if an entity doesn't make proper changes

(c) Whistle blower clause

(d) Secretary can waive accreditation requirements under:

- exceptional circumstances related to research needs.

DEFINITIONS

Section 204

o Large number: one hundred rodents, or 10 nonrodents ~~and~~ one nonhuman primate.

EFFECTIVE DATE

Section 205

- Law is binding within 3 years of enactment
- Regulations implementing title may be issued prior to 3 years.

TITLE III

Special Procedures

Federal Review of project proposals

Section 301

o Money only if after reviewing ~~the~~ scientific merit ~~of the proposal~~ that the proposals:

1) the research project justifies ~~research~~ in terms of beneficial results for the good of society;

2) when using conscious animals, insure that a consulting doctor or vet had approved the procedures;

3) when using conscious animals assure proper use of anesthetics, pre and post surgical nursing care. Assure withholding drugs will be only for a necessary period of time;

4) No animal shall be used in more than one major operation unless for research needs or exceptional circumstances.

John – we could say "entities will use appropriate guidelines as specified in NIH's Guide for the Care of Animals for surgical procedures"

EFFECTIVE DATE

Section 303

o This title - one year

Congressional Disapproval

Section 304

o Congress can reject a regulation within 60 days

TITLE IV

~~Farm~~ Exemptions

Section 401

- (a) Farm animals
- (b) National security cases or manned space flights