97TH CONGRESS
2D SESSION

H. R. 6245

To promote the development of nonanimal methods of research, experimentation, and testing, and to assure humane care of animals used in scientific research, experimentation, and testing.

IN THE HOUSE OF REPRESENTATIVES

APRIL 29, 1982

Mr. WALGREN (for himself, Mr. FUQUA, Mrs. HECKLER, Mr. BROWN of California, Mr. HOLLENBECK, Mr. ROE, Mr. LUNDINE, and Mr. DYMALLY) introduced the following bill; which was referred jointly to the Committees on Energy and Commerce and Science and Technology

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A BILL

To promote the development of nonanimal methods of research, experimentation, and testing, and to assure humane care of animals used in scientific research, experimentation, and testing.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SHORT TITLE

SECTION 1. This Act may be cited as the "Humane Care and Development of Substitutes for Animals in Research Act".

FINDINGS

SEC. 2. The Congress finds that—

(1) the humane care of animals used in scientific research and testing should be assured as part of a respect for life, and the public interest in this matter should be respected;

(2) methods of testing that reduce the number of animals in use have been developed which show promise of being faster, cheaper, and more accurate than traditional animal experiments for some purposes; and further opportunities exist for the development of these methods of testing;

(3) measures are needed to assure that where animal experimentation is necessary, treatment, care, and experimental methodology are such as to limit animal pain and distress to a minimum;

(4) institutional arrangements are needed to recognize the depth of public concern for protection of all life, and the expression of that concern in pressure for measures to limit pain and distress of laboratory animals, and to improve self-regulating measures which reflect this concern; and

(5) measures which help to meet public concern for laboratory animal welfare are important in assuring that significant areas of science, in which animal experimentation is crucial, such as research benefiting human health, will continue to develop as rapidly as possible.

TITLE I—DEVELOPMENT OF IMPROVED TESTING METHODS

NONANIMAL TESTING METHODS

SEC. 101. (a) The Secretary of Health and Human Services (hereafter in this Act referred to as the "Secretary") is authorized to make grants and contract awards—

(1) to sponsor research into, and development of, methods of research, experimentation, and testing which do not require the sacrifice of live animals or which reduce the numbers of live animals required or which produce less pain and distress in such animals than methods currently in use; and

(2) to establish the validity and reliability of such methods for the purpose of replacing methods currently in use.

(b) No award may be made under this section unless an application or proposal therefor has been assessed through applicable peer review procedures and approved by the Secretary. Such application or proposal shall be in such form, submitted in such manner, and contain such information, as the Secretary shall by regulation prescribe.

(c)(1) Each such application and proposal shall be reviewed by a special Advisory Panel to the Secretary comprised of—

(A) an executive secretary designated by the Secretary; and

(B) members who are recognized experts in fields such as the following: mathematical modeling; cell, tissue, and/or organ culture; statistical analysis; molecular toxicology; robotics and biomedical engineering; and clinical human and veterinary medicine.

(2) Such Advisory Panel shall meet no less than semiannually and shall make recommendations as it deems appropriate to the Secretary concerning specific opportunities (especially in the National Toxicology Program of the Department of Health and Human Services), or problems regarding research support of nonanimal testing.

(d) There are authorized to be appropriated to make grants under this section $10,000,000 for the fiscal year ending September 30, 1983, $15,000,000 for the fiscal year ending September 30, 1984, and $20,000,000 for the fiscal year ending September 30, 1985.

ADDITIONAL RESPONSIBILITIES OF SECRETARY

SEC. 102. (a) The Secretary shall direct the National Institutes of Health, the Food and Drug Administration, and the national toxicology program and shall consult with the

Environmental Protection Agency, and other appropriate regulatory and scientific research agencies to—

(1) promote the development of new and the evaluation of existing testing methods that do not require the use of animals and which will satisfy public health and safety concerns as well as regulatory requirements;

(2) promote the use of nonanimal methods of research, experimentation, and testing by seeking further cooperation in international regulatory research and development programs that would lead to more effective toxicology data systems; and

(3) assure the efficient use of current and future test data involving animal use by enhancing the capabilities and the integration of data storage and retrieval systems.

(b) The Secretary shall direct the national toxicology program to significantly increase its resources for research and development on new methodologies and validation of nonanimal methods or computer models, which could be more rapid, less expensive, and generate more useful toxicological information.

(c) The Secretary shall submit a report to the Speaker of the House and President of the Senate not later than two years after the date of enactment of this Act setting forth progress under this section, including new initiatives to

reduce animal use and increased emphasis on development of new methodologies by the national toxicology program.

TITLE II—FEDERAL RESEARCH GRANT REQUIREMENTS

GENERAL REQUIREMENTS

SEC. 201. No Federal agency shall, after the effective date of this title, conduct within any of its own research entities, or approve any research entity for the receipt of a Federal award for the conduct of research, experimentation, or testing, involving the use of animals unless—

(1) that research entity is accredited for such use in accordance with section 202; and

(2) that research entity has provided to the agency the assurances required under section 203.

ACCREDITATION

SEC. 202. (a) In order to be eligible to receive a Federal award for the conduct of research, experimentation, or testing, involving the use of animals, a research entity shall provide to a Federal agency evidence that it is accredited as qualified to engage in such use by a recognized accrediting agency approved by the Secretary under subsection (b) of this section. The Secretary shall, by regulation, prescribe the form and manner in which such evidence shall be presented.

(b) For the purpose of accrediting entities for the conduct of research, experimentation, or testing, involving the

use of animals, the Secretary shall designate (and shall at least once each five years review the designation of) a private agency or agencies which the Secretary has determined to—

(1) have the demonstrated capability to ascertain the qualifications, background, and experience of research entities in the use of animals for such purposes;

(2) have established a system for the initial accreditation of research entities, including a mechanism for the correction of items of noncompliance; and

(3) have established a system for the routine inspection, not less than once each three years, of laboratory animal facilities at any accredited research entity, such routine inspection to include a mechanism for the correction of items of noncompliance.

ASSURANCES REQUIRED FROM RESEARCH ENTITIES

SEC. 203. (a) In order to be eligible to receive a Federal award for the conduct of research, experimentation, or testing, involving the use of animals as required by section 201, a research entity shall provide to the responsible Federal agency a statement of assurances. Such statement shall be submitted at such time and in such manner and form as the agency may prescribe by regulation and shall demonstrate to the satisfaction of the agency—

(1) that the research entity has established an institutional animal care committee (hereinafter in this

section referred to as the "committee") composed of not fewer than three members who collectively possess sufficient expertise to assess the appropriateness of animal use in experimental research and of which—

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

(B) at least one member is not affiliated with the research entity or parent organization and who is responsible for representing the concerns of the surrounding local community regarding the welfare of the animal subjects; and

(C) not more than three members are from the same administrative unit of the research entity;

(2)(A) that such committee—

(i) will make inspections at least semiannually of all animal facilities of such research entity;

(ii) will review, as part of the inspection, research protocols in progress involving direct use of conscious animals, and the condition of research animals, for the purpose of evaluating these research protocols and practices for compliance with experimental design of the original approved proposal, and with accepted standards for appropriate treatment and care; and

(iii) will file with the responsible Federal agency certification that such inspections and reviews of research protocols have taken place, along with reports of any violations of assurances given pursuant to this section, deficiencies in animal care conditions, or deviations of experimental design from originally approved proposals in a manner affecting animal welfare; and

(B) that such inspection certification must be signed by a majority of the members of the committee, and that minority views shall be included in the reports if any members so desire, except that if either of the members designated in paragraph (a)(1)(A) or (B) of this section do not sign the majority report they shall be particularly notified of the opportunity to file a minority report and given reasonable time to do so.

(3) that the committee will maintain complete records of their inspection visits (including attendance of committee members), and other information pertinent to its activities, and that such records will be available for inspection by any authorized Federal agency;

(4) that each member of the committee will, as a condition of service on the committee, be responsible for notifying in writing the Animal and Plant Health

Inspection Service of the Department of Agriculture, the responsible Federal agency and the applicable accrediting agency (under section 202) of any seriously deficient animal care conditions requiring attention or animal care conditions which have been persistently neglected despite notification to the research entity; and

(5) that the committee will establish courses or sessions available annually for scientists, animal technicians, and other personnel involved with animal care and use by the research entity, which provide instruction or training in (A) the humane practice of animal maintenance and experimentation, and (B) the concept and availability of research or testing methods that minimize the use of animals or limit animal distress.

(b) In those cases where any animal care conditions have been persistently neglected despite notification to the research entity, the sponsoring Federal agency shall withhold Federal support for that project until such time as the deficiencies are shown to be corrected.

(c) The Secretary may waive the certification requirements under exceptional circumstance related to the needs for research results or special and unusual circumstances of the research entity.

COORDINATION

SEC. 204. (a) The Secretary shall facilitate agency compliance with the requirements of this title through the establishment of a clearinghouse for information regarding appropriate methods and research models which are in compliance with such requirement.

(b) There is authorized to be appropriated $30,000,000 in fiscal year 1983 for the purpose of assisting research entities, excluding those wholly owned and operated by the Federal Government, in improving animal care facilities in order to reach initial compliance with section 202(a) of this title.

DEFINITIONS

SEC. 205. For purposes of this title—

(1) the term "Federal agency" means an Executive agency as such term is defined in section 105 of title 5, United States Code, and the term "responsible Federal agency" with respect to any research entity means the agency from which the research entity has received a Federal award for the conduct of research, experimentation, or testing, involving the use of animals;

(2) the term "Federal award for the conduct of research, experimentation, or testing, involving the use of animals" means any mechanism (grant, contract, co-

operative agreement) under which Federal funds are provided to induce the conduct of such research;

(3) the term "animal" refers to any warm-blooded animal, that is, birds and mammals;

(4) the term "research entity" 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 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 on those animals; and

(5) "direct use of conscious animals" means any use that involves more than momentary minor pain or discomfort, or any procedure except where the animal is anesthetized throughout the entire course of that procedure.

EFFECTIVE DATE

SEC. 206. The provisions of this title shall apply to any institution in its entirety that receives an award for the conduct of research, experimentation, or testing, involving the use of animals approved by any Federal agency on or after a date which is three years after the date of enactment of this Act, except that regulations implementing this title may be issued prior to that date.

TITLE III—SPECIAL PROCEDURES

FEDERAL AGENCY REVIEW OF GRANT PROPOSALS

SEC. 301. No Federal agency shall, after the effective date of this title, approve any research entity for the receipt of a Federal award for the conduct of research, experimentation, or testing, involving the use of animals, unless the agency finds, as a result of its review of the scientific merit of the proposal, that the award proposal—

(1) includes, in any case involving the direct use of conscious animals, or chronic, long term invasive surgical procedures on animals, appropriate assurances that the services of a consulting doctor of veterinary medicine have been employed in the planning of such procedures;

(2) includes, in any case involving surgery or other invasive procedures on animals, appropriate assurances of the proper use of tranquilizers, analgesics and anaesthetics, including a full description of the substances, amount and frequency of use; and

(3) includes a justification for anticipated animal suffering in terms of demonstrable benefits of the research.

DEFINITIONS

SEC. 302. For the purposes of this title the terms "Federal agency", "research entity", "Federal award for the con-

duct of research, experimentation, or testing, involving the use of animals", "direct use of conscious animals", and "animals" have the meanings provided under section 205.

EFFECTIVE DATE

SEC. 303. The provisions of this title shall take effect one year after the date of enactment of this Act.

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AMENDMENT TO THE AMENDMENT

IN THE NATURE OF A SUBSTITUTE FOR H.R. 6245

OFFERED BY MR. SKEEN AND MR. WEBER

Immediately after section 303, insert the following new title:

TITLE IV -- AGRICULTURE EXEMPTION

Sec. 401. Nothing in this Act shall --

(1) be construed to apply to research, experimentation or testing intended to improve animal nutrition, health, breeding, management or production efficiency in horses, livestock or poultry used or intended for use as food or fiber, or for improving the quality or safety of food or fiber;