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116TH CONGRESS
1ST SESSION

H. R. 1209

To amend the Public Health Service Act to ensure that non-animal methods are prioritized, where applicable and feasible, in proposals for all research to be conducted or supported by the National Institutes of Health, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 13, 2019

Ms. ROYBAL-ALLARD (for herself and Mr. CALVERT) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Public Health Service Act to ensure that non-animal methods are prioritized, where applicable and feasible, in proposals for all research to be conducted or supported by the National Institutes of Health, and for other purposes.

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

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Humane and Existing Alternatives in Research and Testing Sciences Act of 2019'' or the ''HEARTS Act of 2019''.

SEC. 2. FINDINGS.

Congress finds the following:

(1) The National Institutes of Health has supported life-saving research that has greatly improved the health and well-being not only of Americans but also of people around the world.

(2) Much of this research has relied on animals. It is estimated that between 17 million and 22 million animals are used annually in the United States in research, education, and testing.

(3) At the same time, however, a great deal of research that utilized animal studies yielded no benefits for humans. For example, according to NIH itself, ''approximately 30 percent of promising medications have failed in human clinical trials because they are found to be toxic despite promising pre-clinical studies in animal models. About 60 percent of candidate drugs fail due to lack of efficacy''.

(4) The laboratory use of animals has also long been an issue of public concern because animals will, in most cases, experience fear, pain, disease or surgery, and early death.

(5) Much more has become known about the unsuitability of animal models for studying human disease and many more humane, cost-effective, and

scientifically suitable non-animal methods are available.

(6) Under the system of oversight established by the Animal Welfare Act (Public Law 89–544), researchers are supposed to consider alternatives to animal use or painful procedures and should not unnecessarily duplicate previous experiments. However, oversight is generally weak and little heed is paid to the use of non-animal methods or the avoidance of duplication, thereby unnecessarily subjecting animals to pain, suffering, and death.

(7) A system of active incentives is needed to encourage researchers to utilize humane, cost-effective, and scientifically suitable non-animal methods.

SEC. 3. ANIMALS IN RESEARCH.

Section 495 of the Public Health Service Act (42 U.S.C. 289d) is amended to read as follows:

"SEC. 495. ANIMALS IN RESEARCH.

''(a) IN GENERAL.—The Secretary, acting through the Director of NIH, shall, with respect to all research conducted or supported by the National Institutes of Health, do the following:

''(1) Establish a system of meaningful incentives to encourage the use of existing humane and

scientifically satisfactory non-animal methods in research proposals.

''(2) Ensure that, before any research involving the use of animals is approved or performed—

''(A) all scientifically satisfactory non-animal methods for obtaining the results sought have been fully evaluated; and

''(B) a detailed explanation and an analysis of the harms and benefits of such use of animals have been completed.

''(3) Ensure that—

''(A) research proposals are reviewed by at least one person who has expertise in non-animal research methods; and

''(B) reviewers of the research proposals have access to a reference librarian with expertise in evaluating the adequacy of the searches for non-animal methods described in the research proposals.

''(4) Establish and maintain research proposal guidelines for the following:

''(A) Conducting thorough searches for non-animal alternatives to the use of animals for biomedical and behavioral research.

''(B) Carrying out analyses of the harms and benefits of the use of animals in proposed research to assess whether the harms that would be caused to animals in terms of suffering, pain, and distress are justified by the expected outcomes, taking into account ethical considerations and the expected benefits to human beings, animals, or the environment.

''(5) Establish and maintain animal care guidelines for the following:

''(A) The proper care of animals to be used in biomedical and behavioral research.

''(B) The proper treatment of animals while being used in such research. Guidelines under this paragraph shall require—

''(i) the appropriate use of tranquilizers, analgesics, anesthetics, paralytics, and euthanasia for animals in such research; and

''(ii) appropriate pre-surgical and post-surgical veterinary medical and nursing care for animals in such research.

Such guidelines shall not be construed to prescribe methods of research.

"(C) The organization and operation of animal care committees in accordance with subsection (b).

"(b) ANIMAL CARE COMMITTEES.—

"(1) IN GENERAL.—The guidelines under subsection (a)(5)(C) shall require animal care committees at each entity which conducts biomedical and behavioral research with funds provided under this Act (including the National Institutes of Health and the national research institutes) to assure compliance with the guidelines established under subsection (a)(5).

"(2) APPOINTMENT OF MEMBERS.—Each animal care committee shall—

"(A) be appointed by the chief executive officer of the entity for which the committee is established;

"(B) be composed of not fewer than three members; and

"(C) include at least one individual who has no association with such entity and at least one doctor of veterinary medicine.

"(3) REQUIREMENTS.—Each animal care committee of a research entity shall—

''(A) review the care and treatment of animals in all animal study areas and facilities of the research entity at least semiannually to evaluate compliance with applicable guidelines established under subsection (a)(5) for appropriate animal care and treatment;

''(B) keep appropriate records of reviews conducted under subparagraph (A); and

''(C) for each review conducted under subparagraph (A), file with the Director of NIH at least annually—

''(i) a certification that the review has been conducted; and

''(ii) reports of any violations of the guidelines under subsection (a)(5) or assurances required under paragraph (1) which were observed in such review and which have continued after notice by the committee to the research entity involved of the violations.

''(4) MINORITY VIEWS.—Reports filed under paragraph (3)(C) shall include any minority views filed by members of the committee.

''(c) APPLICATIONS AND CONTRACTS.—

''(1) CONTENTS.—The Director of NIH shall require each applicant for a grant, contract, or cooperative agreement involving research on animals which is administered by the National Institutes of Health or any national research institute to include in its application or contract proposal—

''(A) assurances satisfactory to the Director of NIH that—

''(i) the applicant meets the requirements under paragraphs (2), (3), (4), and (5) of subsection (a) and has an animal care committee which meets the requirements of subsection (b); and

''(ii) scientists, animal technicians, and other personnel involved with animal care, treatment, and use by the applicant have available to them instruction or training in—

''(I) the humane practice of animal maintenance and experimentation; and

''(II) the concept, availability, and use of research or testing methods that replace the use of animals,

limit the use of animals, or limit animal distress;

''(B) a statement of the reasons for the use of animals in the research to be conducted with funds provided under such grant or contract;

''(C) a statement of assurance that a scientifically satisfactory non-animal method of obtaining the result sought is not available; and

''(D) an analysis of the harms and benefits of the use of animals in the proposed research assessing whether the harms that would be caused to animals in terms of suffering, pain, and distress is justified by the expected outcomes, taking into account ethical considerations and the expected benefits to human beings, animals, or the environment.

''(2) REGULATORY PROCESS.—Notwithstanding subsection (a)(2) of section 553 of title 5, United States Code, regulations under this subsection shall be promulgated in accordance with the notice and comment requirements of such section.

''(d) SUSPENSION OR REVOCATION.—If the Director of NIH determines that—

''(1) the conditions of animal care, treatment, or use in an entity which is receiving a grant, contract, or cooperative agreement involving research on animals under this title do not meet applicable guidelines established under subsection (a)(5);

''(2) the entity has been notified by the Director of NIH of such determination and has been given a reasonable opportunity to take corrective action; and

''(3) no action has been taken by the entity to correct such conditions,

the Director of NIH shall suspend or revoke such grant, contract, or cooperative agreement under such conditions as the Director determines appropriate.

''(e) PROTECTION OF CERTAIN INFORMATION.—No guideline or regulation promulgated under subsection (a)(5) or (c) may require a research entity to disclose publicly trade secrets or commercial or financial information which is privileged or confidential.''.

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