

*Ag. Animal*

*Filing*

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**Congress of the United States**  
**House of Representatives**

Washington, D.C.  
September 12, 1967

COMMITTEES:  
INTERSTATE AND FOREIGN  
COMMERCE  
MERCHANT MARINE AND  
FISHERIES

SUBCOMMITTEES:  
PUBLIC HEALTH  
INVESTIGATIONS  
MERCHANT MARINE  
OCEANOGRAPHY  
COAST GUARD  
FISH AND WILDLIFE

Hon. Bob Dole  
243 Cannon Office Building

Inside Mail

RECEIVED

SEP 13 1967

BOB DOLE

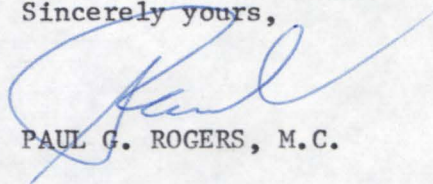
File: Legis-3 (C&D)

Dear Colleague:

I will welcome your support of this bill and will be pleased to answer any questions you may have concerning it. Please advise me if you wish to join in its sponsorship by the end of business on September 22nd so that I may make the necessary preparations for adding your name for introduction.

Kind regards and good wishes.

Sincerely yours,

  
PAUL G. ROGERS, M.C.

PGR:dm



September 12, 1967

Legis-3 (C&D)

Since meeting with leaders of some of the nation's leading humane organizations, there has been considerable comment throughout the nation regarding my laboratory animal bill.

Your office has contacted mine regarding correspondence from your constituents on my proposed bill. Because of this interest from your constituents on this matter, I thought you might be interested in co-sponsoring my bill.

Briefly, my bill would be an extension of PL 89-544, the humane animal bill which we passed last year. The present law does not cover the animal once it enters the research phase, which for all intents and purposes can be construed to mean the entire laboratory or research facility.

It establishes standards and regulations for care, treatment, and handling of animals using as a base those promulgated by PL 89-544 and provides for inspection of laboratories and research facilities.

The bill has the support of the nation's two largest humane organizations and the nation's largest state medical society, indeed a rare agreement of which I am very proud.

I sincerely believe that this is a sound piece of legislation which is entirely workable and satisfactory. The sponsorship of humane groups and the medical groups indicates that it will advance the cause of humane treatment for animals, and at the same time will not interfere with the use of animals in research.



A BILL  
TO REGULATE THE USE  
OF ANIMALS IN LABORATORIES

To amend the Public Health Service Act to provide special assistance for the improvement of laboratory animal research facilities; to establish standards for the humane care, handling, and treatment of laboratory animals in departments, agencies and instrumentalities of the United States and by recipients of grants, awards and contracts from the United States; to encourage the study and improvement of the care, handling, and treatment and the development of methods for minimizing pain and discomfort of laboratory animals used in biomedical activities; and to otherwise assure humane care, handling, and treatment of laboratory animals, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Humane Laboratory Animal Treatment Act of 1967."

DECLARATIONS OF POLICY

SEC. 2. The Congress hereby finds and declares that good health and high quality are essential in the laboratory animals used in the conduct of biomedical activities vital to the health and safety of the people of the United States, and that laboratory animals used in biomedical activities should be spared unnecessary pain and discomfort.



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#### DEFINITIONS

SEC. 3. For the purpose of this Act --

(a) The terms "department or agency" and "department and agency" mean any department, agency, or instrumentality of the United States, or of the District of Columbia;

(b) The term "Secretary" means the Secretary of Health, Education, and Welfare;

(c) The term "laboratory animal research facility" means any facility where laboratory animals are used or held for use in biomedical activities and which is either (1) owned, controlled, or used by a person engaged in biomedical activities who is a recipient of a grant or award from or has a contract with, or otherwise receives funds from any department or agency; or (2) which is owned, controlled, or used by any department or agency;

(d) The term "laboratory animal" means any living warm-blooded vertebrate animal which is used or intended for use in connection with biomedical activities;

(e) The term "biomedical activities" means research, testing, and education utilizing laboratory animals, except in elementary and secondary education, including research and testing with respect to the production and standardization of chemicals, detergents, pharmaceuticals, cosmetics and drugs;



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(f) The term "person" includes any individual, partnership, association, corporation (its affiliates and subsidiaries), trust, estate, firm, joint stock company, organization, educational or other institution, or legal entity;

(g) The term "accredited" means that a laboratory animal research facility has been inspected by the Secretary, or his agents designated pursuant to Section 5(a)(1), and has been certified by the Secretary as being in compliance with the provisions and policy of this Act and with the standards and regulations issued pursuant hereto and the policies and procedures approved by the facility's Committee on Animal Care and Utilization: Provided, That the physical plants of laboratory animal research facilities which, under contracts let prior to the date of enactment of this Act, have been brought into conformance with the standards for laboratories promulgated by the Secretary of Agriculture on February 24, 1967, shall be deemed to be approved for purposes of initial accreditation.

(h) The term "Committee on Animal Care and Utilization" means a committee composed of two or more biomedical scientists, at least one of whom shall be a veterinarian employed either on a full time or consultant basis, appointed by the laboratory animal research facility it serves, or by the organization or institution of which such facility is a part. The names of the members of this committee shall be on record with the Secretary.



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GRANTS FOR CONSTRUCTION OF LABORATORY ANIMAL RESEARCH  
FACILITIES

SEC. 4. Section 706(a) of the Public Health Service Act is amended by inserting immediately after "Grant made under this part" the following: "With respect to any facility other than a laboratory animal research facility"; and by inserting therein, after the phrase "the contemplated use of the facility for research, or research and related purposes," the following "other than use as a laboratory animal research facility," and by adding, at the end of such Section 706(a) the following: "In the case of a grant for construction of any facility which the Secretary determines is to be used (primarily or exclusively) as a laboratory animal research facility for research, or research and purposes related thereto (including research training), in the sciences related to health, such amount may not exceed 66 2/3 per centum of the necessary cost of construction as determined by the Secretary. In the case of a multipurpose facility which includes a laboratory animal research facility, such amount may not exceed 66 2/3 per centum of the part of the necessary cost of construction which the Secretary determines to be proportionate to the contemplated use of the facility as a laboratory animal research facility. The total of the grants under this part for any fiscal year for facilities consisting in whole or in part of laboratory animal research facilities may not exceed 25 per centum of the sums appropriated for grants under this part for such year."



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#### STANDARDS, REGULATIONS, AND ACCREDITATION

SEC. 5. (a) In order to effectuate the findings and declarations set forth in Section 2 of this Act, the Secretary shall prescribe and publish in the Federal Register standards and regulations, including minimum requirements, for the humane care, handling and treatment of laboratory animals, and for the accreditation of laboratory animal research facilities. In formulating such standards and regulations the Secretary shall consult with (1) departments and agencies which use laboratory animals or which make grants, awards, or contracts involving their use by the recipients of such grants, awards or contracts; (2) the National Academy of Sciences-National Research Council; (3) and such humane, scientific, and other organizations as he may select. Such standards and regulations shall conform to the requirements prescribed below:

(1) Every laboratory animal research facility shall be accredited and periodically inspected by the Secretary, or by his designated agents, who shall be professionally qualified employees of the Secretary, or a professional accrediting body, in order to determine if such facility is in compliance with the provisions and policy of this Act and the standards and regulations issued pursuant hereto and the policies and procedures approved by the facility's Committee on Animal Care and Utilization. The Secretary shall issue the certificates attesting to such accreditation;



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(2) Every laboratory animal research facility shall provide for the review and approval of policies and procedures governing the care, handling, treatment and use of laboratory animals in such facility, for the purpose of assuring that laboratory animals (a) are cared for and handled humanely in accordance with this Act and the standards and regulations promulgated thereunder by the Secretary; (b) are used in such facility only for legitimate scientific or educational purposes; (c) are cared for, handled, treated and used only by individuals qualified for their specific tasks and not found ineligible under section 6(e) of this Act; (d) and that sound and reasonable policies and procedures are followed to protect laboratory animals in such facility against unnecessary pain and suffering. Such review and approval shall be made by the Committee on Animal Care and Utilization for the facility. Commonly performed procedures need not be reviewed on an individual basis. Novel procedures and procedures likely to cause pain shall be reviewed individually;

(3) Commensurate with experimental needs and with the physiological functions under study, all biomedical activities likely to cause pain or discomfort greater than that attending anesthetization, shall be performed under adequate anesthesia. Exceptions to the use of such anesthesia shall be made only when anesthesia would defeat the objective of the biomedical activity, and then only with the express permission of the facility's Committee on Animal Care and Utilization;



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(4) When an operation is performed on any laboratory animal, conditions and care shall be observed during and after the operation, consistent with good surgical and veterinary practice, to minimize post-operative discomfort and infection, except when such procedures would defeat the objective of the biomedical activity, and then only with the express permission of the facility's Committee on Animal Care and Utilization;

(5) Commensurate with the experimental needs and with the physiological functions under study, each laboratory animal shall receive proper protection for its bodily comfort and each laboratory animal shall be humanely cared for, handled and treated, and properly fed, watered and housed;

(6) When mechanical, electrical or restraining devices are used, care shall be taken to protect the laboratory animal against unnecessary suffering and pain; and

(7) Records relating to the use and disposition of all laboratory animals and the proceedings of each Committee on Animal Care and Utilization, as provided for under subsection (2) of this section, shall be maintained in such form and in such manner as the Secretary may prescribe as to make possible the evaluation of compliance with the requirements of this Act.

(b) Initial standards and regulations under this section shall be prescribed by the Secretary as soon as reasonable but not later than one year from the date of enactment of this Act. The Secretary



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shall give due regard to any standards or regulations which may have been promulgated under the provisions of P.L. 89-544. Additions and amendments thereto may be prescribed from time to time as the Secretary determines.

#### COMPLIANCE

SEC. 6. On and after one year after the standards and regulations provided for in section 5 of this Act are published in the Federal Register --

(a) Every laboratory animal research facility shall (1) comply with the provisions and policy of this Act and the standards and regulations issued pursuant thereto and the policies and procedures approved by the facility's Committee on Animal Care and Utilization; (2) permit such inspections by the Secretary, or his agents designated pursuant to Section 5(a)(1), as may be prescribed in such regulations or as the Secretary deems necessary in order to determine whether such facility is in compliance with the provisions and policy of this Act and the standards and regulations issued pursuant hereto and the policies and procedures approved by the facility's Committee on Animal Care and Utilization; and (3) file such reports as may be prescribed by the regulations: Provided, That the Secretary may grant extensions of time to such laboratory animal research facilities for compliance with those standards and regulations which depend upon obtaining additional funds for construction or renovation of facilities or purchase of new equipment, if the Secretary determines that there is evidence that the



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laboratory animal research facility is making reasonable effort to obtain such funds and will meet such standards and regulations within a reasonable time. In such cases the Secretary, or his agents designated pursuant to Section 5(a)(1), shall provisionally accredit such laboratory animal research facilities and the laboratory animal research facility shall comply with all other standards and regulations which do not depend upon obtaining such additional funds. The Secretary shall issue the certificates attesting to such provisional accreditation.

(b) If the Secretary determines that a laboratory animal research facility has failed to comply with any of the provisions or policy of this Act, or any of the standards and regulations issued pursuant hereto or the policies and procedures approved by the facility's Committee on Animal Care and Utilization (except those standards and regulations especially provided for in subsection (a) of this section), he shall notify the Committee on Animal Care and Utilization of the laboratory animal research facility, specifying the nature of such non-compliance and the time within which the noncompliance must be remedied.

(c) Any laboratory animal research facility not owned or controlled by a department or agency which knowingly fails to obey after a reasonable period of time, as determined by the Secretary, a notice of noncompliance issued by the Secretary under this section shall (1) be subject to a civil penalty of up to \$500 for each offense, and each day during which such failure continues shall be deemed a separate



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offense; and (2) be ineligible to receive or use funds from a department or agency under a grant, award or contract made after the effective date of the standards and regulations issued pursuant to this Act, and shall remain so ineligible until such time as the Secretary determines that such laboratory animal research facility is in compliance with the provisions and policy of this Act and the standards and regulations issued pursuant hereto and the policies and procedures approved by the facility's Committee on Animal Care and Utilization: Provided, That the Secretary may limit such ineligibility to receive or use such funds in any given case of noncompliance to the particular grant, award, or contract in connection with which such noncompliance occurred.

(d) If any laboratory animal research facility owned or controlled by a department or agency knowingly fails to obey a notice of noncompliance issued by the Secretary under this section, the Secretary shall give public notice of such noncompliance in the Federal Register.

(e) The individual who conducts or supervises any biomedical activity involving the use of any laboratory animal protected by this Act shall be deemed accountable for such animal during the period of such activity and the period of its post-operative care, and shall, during such periods, ensure compliance with the provisions and policy of this Act, the standards and regulations issued pursuant hereto, and the policies and procedures approved by the facility's Committee on Animal Care and Utilization. Any such individual who, after



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opportunity for agency hearing, has been found by the Secretary to be guilty of violating any such requirements shall be (1) ineligible to use laboratory animals in any laboratory animal research facility and (2) be ineligible to receive a grant, award or contract from the United States involving the use of laboratory animals. The Secretary shall prescribe by regulation the conditions under which such an individual may have such eligibility restored.

#### JUDICIAL REVIEW

SEC. 7. (a) Any person aggrieved by any action of the Secretary under this Act shall be entitled to a judicial review of the basis for such determination by filing a written petition for an order setting aside that determination in the United States Court of Appeals for the District of Columbia or in the court of appeals of the United States for the judicial circuit in which such party resides and serving a true copy of the petition upon the Secretary, within sixty days after notice of such determination. The Secretary thereupon shall certify and file in the court a true and correct transcript of the entire record of the proceedings upon which the determination was based, including all evidence taken and the findings and conclusions made by the Secretary thereon. The court shall have jurisdiction to hear and determine any such petition, and shall have power to affirm, modify, or set aside the determination of the Secretary. In any such review, the findings of fact made by the Secretary, if supported by substantial evidence, shall be conclusive. If the petitioner shall



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apply to the court for leave to adduce additional evidence, and shall show to the satisfaction of the court that such additional evidence is material, the court may order such additional evidence to be taken by the Secretary and to be considered in such manner and upon such terms and conditions as the court may deem proper. The Secretary may modify his findings as to the facts by reason of the additional evidence so taken, and he shall file such modified or new findings, and recommendations, if any, which, if supported by substantial evidence, shall be conclusive with respect to action in the matter under consideration. The judgment and decree of the court shall be final, except that it shall be subject to review by the Supreme Court upon certiorari, as provided in section 1254 of title 28, United States Code.

(b) Any determination made by the Secretary under this Act shall become final --

(1) upon the expiration of the time allowed for filing a petition for judicial review, if no such petition has been duly filed within such time;

(2) upon the expiration of the time allowed for filing a petition for certiorari if the determination of the Secretary has been affirmed or the petition for judicial review has been dismissed by a United States court of appeals, and no petition for certiorari has been duly filed;

(3) upon the denial of a petition for certiorari, if the determination of the Secretary has been affirmed or the petition for review has been dismissed by a United States court of appeals; or



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(4) upon the expiration of ten days from the date of issuance of the mandate of the Supreme Court, if such Court directs that the determination of the Secretary be affirmed or that the petition for review be dismissed.

#### FINANCIAL ASSISTANCE

SEC. 8. (a) The Secretary shall encourage research, promote, and make such funds available as Congress may appropriate for promoting the efficient and humane care, handling, treatment, and use of laboratory animals through the training of personnel in laboratory animal care and use; the improvement and development of laboratory animal methods and techniques; the development of instruments; the improvement and development of humane methods for the care, handling, treatment and use of laboratory animals; the diagnosis, study and control of laboratory animal disease; the study and definition of more efficient biological models; the development and maintenance of unique and valuable colonies of research animals; the improved operation of institutional laboratory animal resources; the reduction of pain to laboratory animals; the use of the least sensitive or non-sentient biological models commensurate with particular experimental purposes; and the effective retrieval and use of scientific information.

(b) The Secretary is authorized to make, on such terms and conditions as he may deem appropriate, grants to or contracts with any professional accrediting body approved by him, to assist in



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meeting the costs of such body in carrying out the function of accreditation provided for in this Act.

#### TECHNICAL ASSISTANCE AND DISSEMINATION OF INFORMATION

SEC. 9. The Secretary shall collect and make available through publications, conferences, films, demonstrations and other appropriate means, information relating to the humane care, handling, treatment and use of laboratory animals used for biomedical activities, including, but not limited to, the proper use of anesthesia, design and analysis of experiments, selection of the biological model, and the effective use of informational tools, and, insofar as possible, shall provide technical assistance with respect to the means of providing and training the personnel necessary to assure such humane care, handling, treatment and use of laboratory animals to departments or agencies, persons, laboratory animal research facilities, and other entities.

#### SAVINGS CLAUSE

SEC. 10. If any provision of this Act or the application thereof to any person, department or agency, or to any circumstance shall be held invalid, the remainder of the Act and the application of any such provision to persons, departments or agencies, or circumstances other than those as to which it is held invalid, shall not be affected thereby.



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#### RULES AND REGULATIONS

SEC. 11. The Secretary is authorized to promulgate such standards, rules, regulations and orders as he may deem necessary in order to effectuate the policy and purposes of this Act.

#### AMENDMENTS TO PUBLIC LAW 89-544

SEC. 12. (a) Section 13 of Public Law 89-544 (80 Stat. 352) is amended by striking out "and research facilities"; and by striking out "during actual research or experimentation by a research facility as determined by such research facility" and inserting in lieu thereof "by a research facility."

(b) Section 14 of Public Law 89-544 is repealed.

(c) Section 15 of Public Law 89-544 is amended by repealing subsection (a) thereof, and by striking out "(b)".

(d) Section 16 of Public Law 89-544 is amended by striking out "or research facility"; and by striking out "(1)" and all that follows through the end thereof and inserting in lieu thereof the following: "such animals are held by a dealer."

(e) Section 18 of Public Law 89-544 is amended by striking out "during actual research or experimentation by a research facility as determined by such research facility" and inserting in lieu thereof "by a research facility."



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(f) Public Law 89-544 is amended by redesignating sections 15, 16, 17, 18, 19, 20, 21, 22, 23, and 24 thereof as sections 14, 15, 16, 17, 18, 19, 20, 21, 22, and 23, respectively.

(g) This section shall take effect two years after the date of enactment of this Act.



T.W.A - Mia Justice

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Spoken Order, etc - Bea

- Ray Miller Residence - Friday  
↓ Moscow

- Ly - Chisel - George Deen  
- 2487

- Justice Trading Service