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95TH CONGRESS
1ST SESSION

H. R. 7897

IN THE HOUSE OF REPRESENTATIVES

JUNE 20, 1977

Mr. ROGERS (for himself, Mr. PREYER, Mr. SCHEUER, Mr. WAXMAN, Mr. FLORIO, Mr. MAGUIRE, Mr. MARKEY, Mr. OTTINGER, Mr. WALGREN, Mr. CARTER, Mr. MADIGAN, and Mr. SKUBITZ) introduced the following bill; which was referred to the Committee on Interstate and Foreign Commerce

A BILL

To amend the Public Health Service Act to regulate activities involving recombinant DNA, and for other purposes.

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 "Recombinant DNA Act".

TITLE I—REGULATION OF RECOMBINANT DNA ACTIVITIES

FINDINGS

SEC. 101. The Congress finds that—

(1) research and other activities involving recom-

"DISCLOSURE OF DATA

"SEC. 480. (a) (1) Any information reported to, or otherwise obtained by, the Secretary (or any representative of the Secretary) or any local biohazards committee under this part, which is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b) (4) of such section, shall not be disclosed, except that such information—

"(A) shall be disclosed by the Secretary to any officer or employee of the United States—

"(i) in connection with the official duties of such officer or employee under any law for the protection of health or the environment, or

"(ii) for specific law enforcement purposes;

"(B) shall be disclosed by the Secretary if the Secretary determines it necessary to protect health or the environment against an unreasonable risk of injury; or

"(C) may be disclosed by the Secretary when relevant in any proceeding under this part, except that disclosure in such a proceeding shall be made in such manner as to preserve confidentiality to the extent practicable without impairing the proceeding.

A research hypothesis, design, or protocol shall, for purposes of this paragraph, be considered to be information which is exempt from disclosure pursuant to subsection (a) of section

552 of title 5, United States Code, by reason of subsection (b) (4) of such section.

"(2) In any proceeding under subsection (a) of section 552 of title 5, United States Code, to obtain information the disclosure of which has been denied because of the provisions of paragraph (1) of this subsection, the Secretary or a local biohazards committee may not rely on subsection (b) (3) of such section 552 to sustain the Secretary's or committee's action.

"(b) Subsection (a) (1) does not prohibit the disclosure of any statement of an evaluation of risks submitted under section 475 (b) (5).

"(c) (1) In submitting data under this part, the individual or entity submitting the data may (A) designate the data which such individual or entity believes is entitled to confidential treatment under subsection (a) (1), and (B) submit each designated data separately from other data submitted under this part. A designation under this paragraph shall be made in writing and in such manner as the Secretary may prescribe.

"(2) (A) Except as provided in subparagraph (B), if the Secretary or a local biohazards committee proposes to release for inspection data which has been designated under paragraph (1) (A), the Secretary or committee shall notify, in writing and by certified mail, the individual or

entity which submitted such data of the intent to release such data. If the release of such data is to be made pursuant to a request made under section 552(a) of title 5, United States Code, such notice shall be given immediately upon approval of such request by the Secretary or committee. The Secretary or committee may not release such data until the expiration of thirty days after the individual or entity submitting such data has received the notice required by this subparagraph.

"(B) Subparagraph (A) shall not apply to the release of information under subparagraph (A), (B), or (C) of paragraph (1) of subsection (a), except that the Secretary may not release data under subparagraph (B) of such paragraph (1) unless the Secretary has notified each individual or entity who submitted such data of such release. Such notice shall be made in writing by certified mail at least fifteen days before the release of such data, except that if the Secretary determines that the release of such data is necessary to protect against an imminent, unreasonable risk of injury to health or the environment, such notice may be made by such means as the Secretary determines will provide notice at least twenty-four hours before such release is made.

"(d) Any officer or employee of the United States (including any member or employee of the Advisory Commit-

tee) or member or employee of a local biohazards committee or former officer or employee of the United States or former member or employee of such a committee, who by virtue of such employment or official position has obtained possession of, or has access to, material the disclosure of which is prohibited by subsection (a), and who knowing that disclosure of such material is prohibited by such subsection, willfully discloses the material in any manner to any person not entitled to receive it, shall be guilty of a misdemeanor and fined not more than $5,000 or imprisoned for not more than one year, or both. Section 1905 of title 18, United States Code, does not apply with respect to publishing, divulging, disclosing, making known, or making available information reported or otherwise obtained under this part.

"(e) Notwithstanding any limitation contained in this section or any other provision of law, all information reported to or otherwise obtained by the Secretary (or any representative of the Secretary) or by any local biohazards committee under this part shall be made available, upon written request of any duly authorized committee of the Congress, to such committee.

"(f) Each local biohazards committee shall be considered an agency for purposes of section 552 of title 5, United States Code.