

95TH CONGRESS  
1ST SESSION

# H. R. 7897

File - SC119  
Mr. Woodrow  
Re. Director  
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see asterisk  
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## 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.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

### SHORT TITLE

4 SECTION 1. This Act may be cited as the "Recombinant  
5 DNA Act".

### 6 TITLE I—REGULATION OF RECOMBINANT DNA 7 ACTIVITIES

#### 8 FINDINGS

9 SEC. 101. The Congress finds that—

10 (1) research and other activities involving recom-

## "DISCLOSURE OF DATA

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"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

1 552 of title 5, United States Code, by reason of subsection  
2 (b) (4) of such section.

3 “(2) In any proceeding under subsection (a) of section  
4 552 of title 5, United States Code, to obtain information the  
5 disclosure of which has been denied because of the provisions  
6 of paragraph (1) of this subsection, the Secretary or a local  
7 biohazards committee may not rely on subsection (b) (3) of  
8 such section 552 to sustain the Secretary's or committee's  
9 action.

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

13 “(c) (1) In submitting data under this part, the indi-  
14 vidual or entity submitting the data may (A) designate the  
15 data which such individual or entity believes is entitled to  
16 confidential treatment under subsection (a) (1), and (B)  
17 submit each designated data separately from other data sub-  
18 mitted under this part. A designation under this paragraph  
19 shall be made in writing and in such manner as the Secretary  
20 may prescribe.

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

1 entity which submitted such data of the intent to release  
2 such data. If the release of such data is to be made pursu-  
3 ant to a request made under section 552 (a) of title 5,  
4 United States Code, such notice shall be given immediately  
5 upon approval of such request by the Secretary or commit-  
6 tee. The Secretary or committee may not release such data  
7 until the expiration of thirty days after the individual or  
8 entity submitting such data has received the notice required  
9 by this subparagraph.

10 " (B) Subparagraph (A) shall not apply to the release  
11 of information under subparagraph (A), (B), or (C) of  
12 paragraph (1) of subsection (a), except that the Secretary  
13 may not release data under subparagraph (B) of such  
14 paragraph (1) unless the Secretary has notified each in-  
15 dividual or entity who submitted such data of such release.  
16 Such notice shall be made in writing by certified mail at least  
17 fifteen days before the release of such data, except that if  
18 the Secretary determines that the release of such data is nec-  
19 essary to protect against an imminent, unreasonable risk of  
20 injury to health or the environment, such notice may be made  
21 by such means as the Secretary determines will provide  
22 notice at least twenty-four hours before such release is made.

23 " (d) Any officer or employee of the United States (in-  
24 cluding any member or employee of the Advisory Commit-

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

15       “(e) Notwithstanding any limitation contained in this  
16 section or any other provision of law, all information reported  
17 to or otherwise obtained by the Secretary (or any represent-  
18 ative of the Secretary) or by any local biohazards committee  
19 under this part shall be made available, upon written request  
20 of any duly authorized committee of the Congress, to such  
21 committee.

22       “(f) Each local biohazards committee shall be consid-  
23 ered an agency for purposes of section 552 of title 5, United  
24 States Code.