

OTA

95TH CONGRESS
1ST SESSION

H. R. 3592

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 16, 1977

Mr. OTTINGER (for himself, Mr. BADILLO, Mr. BEDELL, Mr. CORRADA, Mr. DELLUMS, Mr. DUNCAN of Oregon, Mr. EDWARDS of California, Mr. GILMAN, Mr. HOWARD, Mr. HUGHES, Mr. JEFFORDS, Mr. KOSTMAYER, Mr. LEACH, Mr. LEHMAN, Mr. MIKVA, Mr. MOAKLEY, Mr. NEAL, Mr. RICHMOND, Mr. ROYBAL, Mr. SCHEUER, Mr. SIMON, Mr. STEERS, Mr. WALGREN, Mr. WAXMAN, and Ms. BURKE of California) introduced the following bill; which was referred to the Committee on Interstate and Foreign Commerce

A BILL

To provide for guidelines and strict liability in the development of research related to recombinant DNA.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*
3 That this Act may be cited as the "DNA Research Act of
4 1977".

FINDINGS

6 SEC. 2. The Congress finds that—

7 (1) research related to recombinant DNA is of
8 exceptional importance, with many potential benefits,

but also with major uncertainties regarding its possible effects on human beings and other organisms;

(2) research involving recombinant DNA may involve a high risk not only to those pursuing such research but to the population in general;

(3) it is essential in the public interest that the health and welfare of the Nation be protected by requiring that all research conducted with regard to recombinant DNA comply with strict standards of performance and safety; and

(4) all research with regard to recombinant DNA is either in interstate commerce or substantially affects such commerce and regulations by the Secretary of Health, Education, and Welfare as contemplated by this Act are necessary and proper to prevent and eliminate burdens on interstate commerce, to regulate such commerce effectively, and to protect the health and welfare of the Nation.

DEFINITIONS

SEC. 3. As used in this Act the term—

(1) “recombinant DNA” means molecules that consist of different segments of deoxyribonucleic acid which have been joined together in cell-free systems to infect and replicate in some host cell, either autonomously or on an integrated part of the host’s genome.

1 (2) "Secretary" means the Secretary of Health,
2 Education, and Welfare.

3 (3) "commerce" means—

4 (A) any activity which affects commerce be-
5 tween any State or territory and any place outside
6 thereof, and

7 (B) commerce within the District of Columbia
8 or within any territory.

9 ESTABLISHMENT OF GUIDELINES

10 SEC. 4. The Secretary shall promulgate guidelines for
11 research involving recombinant DNA within ninety days
12 after the date of enactment of this Act.

SLA

13 APPLICATION OF GUIDELINES

14 SEC. 5. The guidelines promulgated under section 4
15 shall apply to all research involving recombinant DNA that
16 is in or affects commerce, or that is carried on in any area
17 subject to the jurisdiction of the United States.

18 PATENT RESTRICTIONS

19 SEC. 6. Notwithstanding any other law, no patent shall
20 be granted on any procedure or organism which results from
21 research on recombinant DNA unless all applicable guide-
22 lines have been strictly adhered to, and full and complete
23 disclosure has been made with regard to such process or
24 organism.

1 CIVIL LIABILITY

2 SEC. 7. Persons carrying out research involving recom-
3 binant DNA shall be strictly liable, without regard to fault,
4 for all injury to persons or property caused by such research.

5 PROHIBITED ACTS

6 SEC. 8. No person shall solicit or accept, directly or in-
7 directly, any specimen for research which shall involve re-
8 combinant DNA or conduct such research unless there is in
9 effect a license for such research issued by the Secretary.

10 LICENSES

11 SEC. 9. (a) The Secretary is authorized to issue licenses
12 for research involving recombinant DNA.

13 (b) A license issued by the Secretary under this section
14 shall be valid for a period of one year, or such shorter period
15 as the Secretary may establish for any research project and
16 may be renewed in such manner as the Secretary may pre-
17 scribe.

18 (c) The Secretary may require payment of reasonable
19 fees for the insurance and renewal of licenses but the amount
20 of such fee shall not exceed an amount necessary to defray
21 the reasonable costs of reviewing and passing upon applica-
22 tions for licenses, and of enforcing guidelines.

23 (d) Licenses may contain such terms and conditions as
24 the Secretary finds are necessary and appropriate to carry
25 out the purposes of this Act.

APPLICATION REQUIREMENT

SEC. 10. A license shall not be issued by the Secretary unless—

(1) the application therefor contains or is accompanied by such information as the Secretary finds necessary; and

(2) the Secretary determines that such facility will be operated in accordance with the guidelines promulgated under section 4.

REVOCATION, SUSPENSION, OR LIMITATION

SEC. 11. A license issued by the Secretary may be revoked, suspended, or limited if the Secretary finds, after reasonable notice and opportunity for a hearing to the licensee, that such licensee—

(1) has been guilty of misrepresentation in obtaining a license;

(2) has engaged or attempted to engage or represented himself as entitled to perform any research or procedure or category of procedures not authorized by the license;

(3) has failed to comply with guidelines with respect to research facilities or personnel prescribed by the Secretary pursuant to this Act;

(4) has failed to comply with reasonable requests of the Secretary for any information or materials the

1 Secretary deems necessary to determine continued eli-
 2 gibility for its license or continued compliance with the
 3 Secretary's guidelines;

4 (5) has refused a request from the Secretary or any
 5 Federal officer or employee designated by the Secretary
 6 for permission to inspect the research facility and its
 7 operations and pertinent records at any reasonable time;
 8 or

9 (6) has violated or aided and abetted any violation
 10 of any provision of this section or of any guideline
 11 promulgated hereunder.

12 UNREASONABLE HAZARDS TO PUBLIC HEALTH

13 SEC. 12. Whenever the Secretary has reason to believe
 14 a continuation of any activity by a research facility licensed
 15 under this section would constitute a significant hazard to
 16 the public health, the Attorney General may, at the Secre-
 17 tary's request, bring suit in the name of the United States
 18 in the district court for the district in which such facility is
 19 situated to enjoin continuation of such activity and upon a
 20 proper showing, a temporary injunction or restraining order
 21 against continuation of such activity pending issuance of a
 22 final order may be granted without bond.

23 INSPECTION AUTHORITY

24 SEC. 13. (a) In order to enforce this Act, officers, em-
 25 ployees, or agents designated by the Secretary, upon pre-
 26 senting appropriate credentials to the owner, operator, or

7 setp
 it in the
 →

1 agent in charge of a facility engaged in research involving
2 recombinant DNA, are authorized—

3 (1) to enter, at reasonable times, any such research
4 facility; and

5 (2) to inspect, at reasonable times and in a reason-
6 able manner, such research facility and all equipment,
7 materials, containers, records, files, papers, processes,
8 controls, facilities, and other things therein, in order
9 to determine whether such research facility is being
10 operated in compliance with this Act, the guidelines
11 issued hereunder, and the terms of any license that
12 may have been issued with respect to such research
13 facility.

14 (b) Upon completion of any such inspection and prior
15 to leaving the premises, the officer, employee, or agent
16 making the inspection shall give to the owner, operator,
17 or agent in charge a report summarizing any conditions or
18 practices observed by him by which, in his judgment, indi-
19 cate a violation of this Act or any guideline or license
20 issued hereunder. He shall also prepare a written report
21 of his findings and send it to such owner, operator, or agent
22 within a reasonable time.

23 VIOLATION AND PENALTIES

24 SEC. 14. (a) Any person who wilfully violates any
25 provision of this Act or any guideline promulgated here-

1 under shall be guilty of a misdemeanor and shall, upon
2 conviction therefor, be subject to imprisonment for not more
3 than one year, or a fine of not more than \$10,000, or both.
4 For purposes of computing such fine, each day of a con-
5 tinuing violation shall be deemed a separate violation. In
6 addition, the court may order that the person or entity
7 convicted be ineligible for Federal funds, in whole or in part,
8 for a period of up to five years.

9 (b) No research facility employer shall discharge any
10 employee or otherwise discriminate against any employee
11 with respect to his compensation, terms, conditions, or
12 privileges of employment because the employee has—

13 (A) commenced, caused to be commenced, or is
14 about to commence or cause to be commenced a pro-
15 ceeding under this Act;

16 (B) testified or is about to testify in any such
17 proceeding; or

18 (C) assisted or participated in or is about to assist
19 or participate in such a proceeding or in any other
20 action to carry out the purposes of this Act.