

THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 2201

Session of
1978

INTRODUCED BY MANDERINO, RAPPAPORT, BERSON, MEBUS, FREIND,
SCIRICA, DiCARLO, KELLY, ITKIN, O'DONNELL, McLANE AND
D. R. WRIGHT, APRIL 3, 1978

REFERRED TO COMMITTEE ON HEALTH AND WELFARE, APRIL 3, 1978

AN ACT

1 Requiring that laboratories and persons doing experimental work
2 with recombinant DNA register with the Department of Health
3 and follow regulations prescribed by the National Institute
4 of Health; establishing a committee to provide guidelines for
5 the safe operation of such laboratories and experiments;
6 providing the Secretary of Health with the power to suspend
7 or revoke licenses; and establishing the responsibility for
8 such research.

9 The General Assembly of the Commonwealth of Pennsylvania
10 hereby enacts as follows:

11 Section 1. This act shall be known and may be cited as the
12 "Safety in Recombinant DNA Research Act."

13 Section 2. Recombinant DNA research is a scientific tool of
14 enormous potential but also of potential deadly peril. Many of
15 the hazards of this research--sometimes known as "genetic
16 tinkering"--are unknown.

17 The possibility that new forms of life can be created by
18 genetic manipulation places biologists at a threshold similar to
19 that of physicists when they first split the atom.

20 The Federal Government has noted the dangers of recombinant

1 DNA research by having the National Institute of Health draw up
2 regulations for the safety of such experiments. However, these
3 regulations apply only to laboratories receiving Federal funds.

4 There is the possibility that other laboratories, not covered
5 by Federal regulations, are conducting or are capable of
6 conducting recombinant DNA experiments.

7 There is no reasonable alternative to regulation by the
8 Commonwealth to insure that experimental DNA research has no ill
9 effects on the general public and the environment.

10 Section 3. The following words and phrases when used in this
11 act shall have, unless the context clearly indicates otherwise,
12 the meanings given to them in this section:

13 "Person." An individual, partnership, association,
14 corporation, private institution, governmental entity,
15 educational institution or a similar body.

16 "Recombinant DNA research." Research of molecules that
17 consist of segments of deoxyribonucleic acid from different
18 organisms which are joined in cell-free systems and which have
19 the capacity to infect and replicate in some host cell, either
20 autonomously or as an integrated part of the host genome.

21 "Secretary." The Secretary of Health.

22 Section 4. (a) The secretary shall issue licenses for
23 research involving recombinant DNA to persons providing they
24 meet the following conditions:

25 (1) the secretary determines that the facilities for
26 recombinant DNA research will be operated in accordance with
27 the National Institute of Health guidelines; and

28 (2) the application contains or is accompanied by such
29 information as the secretary finds sufficient to determine
30 compliance with the National Institute of Health guidelines

1 concerning recombinant DNA research.

2 (b) The license issued by the secretary shall be valid for a
3 period of one year and may be renewed in such manner as
4 prescribed by the secretary.

5 (c) The secretary may require the payment of a reasonable
6 fee for the issuance or renewal of a license but such payment
7 shall not exceed an amount necessary to defray the reasonable
8 costs of issuing such license and making investigation in
9 issuing such license.

10 (d) Licenses may contain such terms and conditions as the
11 secretary finds are necessary and appropriate to carry out the
12 purposes of this act.

13 (e) In the case of persons already required to comply with
14 the National Institute of Health guidelines on recombinant DNA
15 research, evidence of such compliance submitted on the form
16 supplied by the National Institute of Health will be sufficient
17 to qualify a person for the license required under this act.

18 (f) A license issued by the secretary may be revoked,
19 suspended or limited by the secretary if he finds after
20 reasonable notice and opportunity for a hearing that such
21 licensee:

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

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

27 (3) has failed to comply with the National Institute of
28 Health guidelines with respect to research facilities or
29 personnel;

30 (4) has willfully failed to comply with reasonable

1 requests of the secretary for any information or materials
2 the secretary deems necessary to determine continued
3 eligibility for its license or continued compliance with the
4 National Institute of Health guidelines;

5 (5) has refused a request from the secretary or an agent
6 of the secretary for permission to inspect the research
7 facilities and the operations and pertinent records at any
8 reasonable time;

9 (6) has willfully violated or aided and abetted any
10 violation of any provision of this act; or

11 (7) has failed to correct any violation of this act
12 within 30 days after written notice of such violation.

13 Section 5. The secretary shall appoint a Biohazards Safety
14 Committee of seven persons, one of whom shall be the secretary
15 and two other members of the general public. The other four
16 members shall be experts in such fields as biology,
17 microbiology, virology, epidemiology, medicine or environmental
18 health. This committee shall have the following duties:

19 (1) promulgate such regulations as deemed necessary for
20 the implementation of this act;

21 (2) review all proposals for licenses for compliance
22 with the National Institute of Health guidelines and to make
23 recommendations as to licensure to the secretary;

24 (3) hold public hearings, either to obtain or to
25 dispense information, at such times and places as the
26 committee shall determine; and

27 (4) conduct such visits and inspections as necessary to
28 determine compliance with this act.

29 Section 6. Persons carrying out recombinant DNA research
30 shall comply with the "Recombinant DNA Research Guidelines"

1 adopted by the National Institute of Health and any subsequent
2 modification.

3 Section 7. Persons carrying out research involving
4 recombinant DNA research shall be liable for all damage or
5 injury to persons or property caused by such research.

6 Section 8. Confidentiality shall be maintained on research
7 proposals and proprietary information submitted to the Secretary
8 of the Biohazards Committee under this act.

9 Section 9. In order to enforce this act, members of the
10 Biohazards Committee or agents of the committee or of the
11 secretary, upon presentation of appropriate credentials to the
12 owner, operator or agent in charge of a facility engaged in
13 research involving recombinant DNA, are authorized:

14 (1) to enter, at reasonable times, any such research
15 facility;

16 (2) to inspect, at reasonable times and in a reasonable
17 manner, such research facilities and any equipment,
18 materials, containers, records, files, papers, processes,
19 controls, facilities and other things therein pertaining to
20 recombinant DNA research, in order to determine whether such
21 facility is being operated in compliance with this act, the
22 guidelines of the National Institute of Health, the
23 guidelines issued under this act and the terms under which
24 the license may have been issued; and

25 (3) to issue such report or reports as may be necessary
26 following such inspection and to communicate such report to
27 the owner, operator or agent in charge of the research
28 facility; such report shall be in writing, although
29 preliminary oral reports may be made, and shall summarize any
30 violation of this act, the guidelines issued by the National

1 Institute of Health or under this act, or of the conditions
2 under which the license was issued.

3 Section 10. (a) In case of violation of this act or if the
4 secretary shall determine that such activity in recombinant DNA
5 research shall constitute a significant hazard to the public
6 health or safety, the Attorney General of the Commonwealth shall
7 bring suit in the county in which the violation is alleged to
8 enjoin the continuation of such activity and upon a proper
9 showing a temporary injunction or restraining order shall be
10 issued pending the issuance of a final order.

11 (b) Any person that willfully engaged in recombinant DNA
12 research without a license or in violation of the conditions of
13 a license shall be liable for a civil penalty not to exceed
14 \$1,000 for each violation; each day such violation continues
15 shall constitute a separate violation.

16 Section 11. This act shall take effect in 60 days and shall
17 remain in force for a period of six years.