

103^D CONGRESS
1ST SESSION

H. R. 1334

To amend the Public Health Service Act to establish a process to provide for reasonable prices for drugs, devices, and other tangible products made available to the public as a consequence of funding by the National Institutes of Health, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 11, 1993

Mr. WYDEN introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Public Health Service Act to establish a process to provide for reasonable prices for drugs, devices, and other tangible products made available to the public as a consequence of funding by the National Institutes of Health, 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,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Federal Research
5 Product Commercialization Act”.

1 **SEC. 2. ESTABLISHMENT OF PROCESS REGARDING REA-**
2 **SONABLE PRICES FOR PRODUCTS DEVEL-**
3 **OPED AS CONSEQUENCE OF FUNDING BY NA-**
4 **TIONAL INSTITUTES OF HEALTH.**

5 Part G of title IV of the Public Health Service Act
6 (42 U.S.C. 289 et seq.) is amended by inserting after sec-
7 tion 498 the following section:

8 “REASONABLE PRICES FOR PRODUCTS DEVELOPED WITH
9 ASSISTANCE OF INSTITUTES

10 “SEC. 498B. (a) IN GENERAL.—Subject to the provi-
11 sions of this section, for fiscal year 1994 and subsequent
12 fiscal years, a project of biomedical research relating to
13 the development of a drug, device, or other tangible prod-
14 uct may not be conducted or supported by any agency of
15 the National Institutes of Health unless there are in effect
16 such regulations issued by the Secretary as may be nec-
17 essary to ensure that, in the event the product is (in ac-
18 cordance with applicable law) to be made available to the
19 public, there is compliance with the following:

20 “(1) The research entity, in accordance with
21 this section, will ensure that the commercial parties
22 involved make the product available to the public at
23 a reasonable price, and that the commercial parties
24 pay to the National Institutes of Health royalties
25 reasonably related to the amounts expended by such
26 Institutes with respect to the product.

1 “(2) For purposes of paragraph (1), the re-
2 search entity will conduct a competitive process of
3 bidding in order to select entities to serve as com-
4 mercial parties regarding the product. With respect
5 to such bidding, a solicitation of applications con-
6 taining bids will be published in the Federal
7 Register.

8 “(3) Applicants under paragraph (2) will not be
9 approved by the research entity as commercial par-
10 ties regarding the project unless the following condi-
11 tions are met:

12 “(A) The application specifies a formula
13 for determining the price at which the product
14 will be made available to the public, and the
15 formula results in a price that is in accordance
16 with paragraph (1).

17 “(B) The application specifies the royalties
18 to be paid to the National Institutes of Health,
19 and the royalties are in accordance with para-
20 graph (1).

21 “(C) The application demonstrates that
22 the applicant possesses the appropriate bio-
23 medical and commercial expertise.

1 “(D) The application is in such form, is
2 made in such manner, and contains such other
3 information as the Secretary may require.

4 “(4)(A) Subject to subparagraph (B), in select-
5 ing commercial parties under paragraph (3), the re-
6 search entity will, if there are a sufficient number of
7 qualified applicants, approve such applications as
8 may be necessary to ensure that commercial parties
9 compete in making the product available to the
10 public.

11 “(B) The research entity will comply with sub-
12 paragraph (A) only to the extent not inconsistent
13 with paragraph (1).

14 “(5)(A) If there is an insufficient number of
15 qualified applicants to provide for competing com-
16 mercial parties, the research entity will, in approving
17 applications to provide for an exclusive arrangement
18 for making the product available to the public, re-
19 quire that the applicants negotiate prices and royal-
20 ties under paragraph (1) with the Secretary.

21 “(B) If an exclusive arrangement under sub-
22 paragraph (A) is to be made, the Secretary will
23 publish in the Federal Register a notice of such fact.

24 “(C) An exclusive arrangement under subpara-
25 graph (A) will not become legally binding until the

1 expiration of the 90-period beginning on the date on
2 which the notice required in subparagraph (B) with
3 respect to the arrangement is published in the
4 Federal Register.

5 “(b) APPLICABILITY.—Subsection (a) applies with re-
6 spect to a drug, device, or other tangible product only if
7 the project of research involved provides a material con-
8 tribution to achieving status as a drug, device, or other
9 product that, under applicable law, is permitted to be
10 made available to the public.

11 “(c) REQUIRED AGREEMENTS.—With respect to a
12 project of research described in subsection (a), regulations
13 under such subsection shall, in the case of the non-Federal
14 entities involved, impose the requirements of this section
15 as required agreements between such entities and the Na-
16 tional Institutes of Health, including (if the project is sup-
17 ported by such Institutes) imposing the requirements as
18 conditions of the receipt from such Institutes of the award
19 of the grant, cooperative agreement, or contract for the
20 conduct of the project. Conditions for such awards shall,
21 as necessary, include conditions governing the arrange-
22 ments that the research entity involved makes with enti-
23 ties to serve as commercial parties regarding the drug, de-
24 vice, or other tangible product involved, without regard to

1 whether the National Institutes of Health is a direct party
2 to such arrangements.

3 “(d) CONSULTATIONS REGARDING REGULATIONS.—
4 In issuing regulations pursuant to subsection (a), the Sec-
5 retary shall consult with the Director of NIH and with
6 the Administrator of the Health Care Financing Adminis-
7 tration.

8 “(e) DEFINITIONS.—For purposes of this section:

9 “(1) The term ‘commercial parties’ means the
10 parties that make available to the public a drug, de-
11 vice, or other tangible product.

12 “(2) The term ‘make available’, with respect to
13 the use by the public of a drug, device, or other
14 tangible product, means—

15 “(A) to manufacture the product; or

16 “(B) to sell or trade the product, or to
17 offer to sell or trade the product.

18 “(3) The term ‘product’ means a drug, device,
19 or other tangible product.

20 “(4)(A) The term ‘research entity’, with respect
21 to project of biomedical research described in sub-
22 section (a), means the entity with the principal prop-
23 erty interest in the results of the research, without
24 regard to whether the entity is the National Insti-
25 tutes of Health or a non-Federal entity.

1 “(B) An entity is a research entity under sub-
2 paragraph (A) without regard to whether the prop-
3 erty interest in the results of the project involved—

4 “(i) is directly in the drug, device, or other
5 product that is the subject of the project; or

6 “(ii) is only in findings that relate to the
7 product.”.

○