

104TH CONGRESS
2D SESSION

H. R. 4270

To require reporting on research and development expenditures for drugs approved for marketing, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 27, 1996

Mr. SANDERS introduced the following bill; which was referred to the Committee on Commerce

A BILL

To require reporting on research and development expenditures for drugs approved for marketing, 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 “Health Care Research
5 and Development and Consumer Protection Act”.

6 **SEC. 2. FINDINGS.**

7 The Congress makes the following findings:

8 (1) Public health needs are advanced by the de-
9 velopment and distribution of new drug therapies

1 (2) The public interest in the development of
2 new drug therapies is parallel to the public interest
3 in controlling public and private health care costs.

4 (3) The Federal Government needs mechanisms
5 to ensure that portions of revenues from the sale of
6 drugs to consumers are reinvested in the research
7 and development of new technologies.

8 (4) The Federal Government is the single larg-
9 est supporter of biomedical research in the world,
10 spending \$33 billion in 1994 alone for biomedical
11 and related health research.

12 (5) The Federal Government provides 80 per-
13 cent of the monies spent each year for fundamental
14 biomedical research at universities, medical schools,
15 and other non-profit institutions.

16 (6) Of all the cancer drugs developed since the
17 founding of the National Cancer Institute's new
18 drug program in 1955 and approved for marketing
19 by the Food and Drug Administration through
20 1992, 34 of 37 cancer drugs, or 92 percent, were de-
21 veloped with taxpayer funds.

22 (7) The public should not have to pay twice for
23 health care inventions, first as taxpayers and second
24 as consumers.

1 (8) The Department of Health and Human
2 Services has the responsibility for funding basic bio-
3 medical research, for funding medical treatment
4 through the programs under titles XVIII and XIX
5 of the Social Security Act, for providing direct medi-
6 cal care, and, more generally, for protecting the
7 health and safety of the public, it is incumbent upon
8 the Secretary of Health and Human Services to re-
9 quire a reasonable relationship between the pricing
10 of drugs, the public investment in those drugs, and
11 the health and safety needs of the public.

12 (9) The Department of Health and Human
13 Services, academic researchers, and the general pub-
14 lic have the right to know, but lack the necessary in-
15 formation about, information about the actual costs
16 for drug development, the general revenues gen-
17 erated from the sale of pharmaceutical drugs, and
18 the taxpayer's investment in new drug development.

19 (10) The Department of Health and Human
20 Services lacks the necessary information to make ap-
21 propriate decisions about the reasonableness of drug
22 prices or the impact of its policies on research and
23 development of new medical technologies.

1 **SEC. 3. REPORT ON RESEARCH OF THE FEDERAL GOVERN-**
2 **MENT.**

3 (a) INVOLVEMENT OF THE FEDERAL GOVERN-
4 MENT.—For each drug for which an application under sec-
5 tion 505, 507, or 512 of the Federal Food, Drug, and
6 Cosmetic Act has been approved the following shall be re-
7 ported to the Secretary of Health and Human Services:

8 (1) Each patent, cooperative research and de-
9 velopment agreement under section 12 of the Ste-
10 venson-Wydler Technology Innovation Act of 1980,
11 or other contractual agreement with the Federal
12 Government which contributed to the development of
13 the drug. The dollar amount of Federal funds ex-
14 pended, the agency of the Federal Government
15 which provided such funds, the dates of any contrac-
16 tual agreements, and the nature of the research and
17 development activity shall be included in the report.

18 (2) Each grant, contract, or other funding
19 mechanism of the Federal Government which was
20 used to support research or development activities
21 with respect to the drug, including any grant or con-
22 tract by the Federal Government to an institution of
23 higher education or other non profit institution or
24 other funds expended by the Federal Government on
25 research and development which directly contributed
26 to the development of the drug. The dollar amount

1 of Federal funds expended, the agency of the Fed-
2 eral Government which provided such funds, the
3 dates of any contractual agreements, and the nature
4 of the research and development activity shall be in-
5 cluded in the report.

6 The Secretary shall make such report available to the pub-
7 lic.

8 (b) RESEARCH AND DEVELOPMENT.—

9 (1) IN GENERAL.—For each drug for which an
10 application under section 505, 507, or 512 of the
11 Federal Food, Drug, and Cosmetic Act has been ap-
12 proved the total amount expended for each type of
13 research and development of the drug in each cal-
14 endar year, including pre-clinical research and phase
15 I, II, and III clinical trials, the entity which made
16 the expenditures, and the amount provided by the
17 Federal Government shall be reported to the Sec-
18 retary of Health and Human Services.

19 (2) PUBLIC DISCLOSURE OF DATA.—If a drug
20 is protected under section 527(a) of the Federal
21 Food, Drug, and Cosmetic Act or under a patent,
22 the material reported under paragraph (1) for such
23 drug shall be made available by the Secretary to the
24 public. If a drug is not protected under such section
25 or a patent, the Secretary shall make the report

1 available to the public in a form which does not
2 identify individual entities.

3 **SEC. 4. REASONABLE PRICE AGREEMENT.**

4 (a) IN GENERAL.—If any Federal agency or any non-
5 profit entity undertakes federally funded health care re-
6 search and development and is to convey or provide a pat-
7 ent or other exclusive right to use such research and devel-
8 opment for a drug or other health care technology, such
9 agency or entity shall not make such conveyance or pro-
10 vide such patent or other right until the person who will
11 receive such patent or other right first agrees to a reason-
12 able pricing agreement with the Secretary of Health and
13 Human Services or the Secretary makes a determination
14 that the public interest is served by a waiver of the reason-
15 able pricing agreement provided in accordance with sub-
16 section (b).

17 (b) WAIVER.—No waiver shall take effect under sub-
18 section (a) before the public is given notice of the proposed
19 waiver and provided a reasonable opportunity to comment
20 on the proposed waiver. A decision to grant a waiver shall
21 set out the Secretary's finding that such a waiver is in
22 the public interest.

1 **SEC. 5. PURCHASE OF DRUGS DEVELOPED WITH TAXPAYER**
2 **SUPPORT.**

3 For any drug approved for marketing by the Food
4 and Drug Administration which was developed with sig-
5 nificant Federal support, the Secretary of Health and
6 Human Services shall review the price of the drug for pur-
7 poses of determining a reasonable price for Federal reim-
8 bursements under the programs under titles XVIII and
9 XIX of the Social Security Act and other Federal pro-
10 grams that elect to participate in the Secretary's reason-
11 able pricing program, In determining a reasonable price
12 for a drug, the Secretary shall consider—

13 (1) the public interest in continued health care
14 research and development,

15 (2) the contribution of the person marketing
16 such drug to the drug research and development ex-
17 penses, including the amount, timing, and risk of in-
18 vestment in such research and development,

19 (3) the contribution of the Federal Government
20 to the research and development of such drug, in-
21 cluding the amount, timing, and risk of investment
22 in such research and development,

23 (4) the therapeutic value of such drug,

24 (5) the number of patients who are expected to
25 purchase such drug,

1 (6) the cost of producing and marketing of such
2 drug,

3 (7) the cost of therapies which are similar to
4 the therapy using such drug, and

5 (8) other relevant factors.

6 **SEC. 6. MATERIAL TRANSFER AGREEMENT.**

7 If in connection with research and development for
8 health care technologies, the Secretary of Health and
9 Human Services determines that the public interest will
10 be advanced by the ability of the Secretary to conduct re-
11 search on biological substances or other materials, the
12 Secretary shall have the authority to compel the owner of
13 such substances or materials to provide the Secretary with
14 such substances or materials in accordance with a mate-
15 rials transfer agreement. The agreement shall—

16 (1) provide the owner of such substances or ma-
17 terials compensation for the costs incurred in mak-
18 ing the transfer to the Secretary;

19 (2) define the terms and conditions under which
20 the Secretary may use the materials;

21 (3) not grant rights in intellectual property or
22 rights for commercial purposes; and

23 (4) require that the material be used for re-
24 search purposes only.

1 **SEC. 7. PROMOTION OF RESEARCH AND DEVELOPMENT.**

2 (a) ACCOUNT.—Any person engaged in the manufac-
3 ture of drugs for introduction into interstate commerce
4 shall, in accordance with subsection (b), establish for each
5 drug an account for funds to be reinvested in research
6 and development for health care technologies.

7 (b) REINVESTMENT IN RESEARCH AND DEVELOP-
8 MENT.—To insure that adequate funds are being made
9 available for research and development of new health care
10 technologies, the Secretary of Health and Human Services
11 shall establish for persons engaged in the manufacture of
12 drugs for introduction into interstate commerce the mini-
13 mum amount such person should make available for re-
14 search and development of its new health care technologies
15 based upon a percentage of sales revenue for that drug.
16 The Secretary may require different percentages for mini-
17 mum reinvestment for different classes of drugs based
18 upon patient protection, orphan drug status, or magnitude
19 of sales.

20 (c) ADDITIONAL RULES.—The Secretary shall adopt
21 regulations concerning qualifying research and develop-
22 ment expenditures and the reporting requirements for per-
23 sons who are subject to subsections (a) and (b).

24 **SEC. 8. REPORTS ON SALES.**

25 Any person engaged in the manufacture and sale of
26 drugs approved under section 505, 507, or 512 of the Fed-

1 eral Food, Drug, and Cosmetic Act shall report to the
2 Health Care Financing Administration the total number
3 of each drug it has sold and the total revenue it has re-
4 ceived from such sales, including sales made outside the
5 United States.

6 **SEC. 9. GOVERNMENT EXPENDITURE ON PRESCRIPTION**
7 **DRUGS.**

8 The Secretary of Health and Human Services shall
9 report to the Congress annually on the estimate of the
10 amount of money the Federal government expends, di-
11 rectly or through reimbursement, for the purchase of pre-
12 scription drugs, including an estimate of the amount of
13 money expended each year on drugs which were developed
14 with significant Federal support.

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