

107TH CONGRESS  
2D SESSION

# H. R. 4998

To amend the Federal Food, Drug, and Cosmetic Act to allow certain applicants for approval of a generic drug to be eligible for a 180-day period of protection from competition, and for other purposes.

---

## IN THE HOUSE OF REPRESENTATIVES

JUNE 21, 2002

Mrs. McCARTHY of New York introduced the following bill; which was referred to the Committee on Energy and Commerce

---

## A BILL

To amend the Federal Food, Drug, and Cosmetic Act to allow certain applicants for approval of a generic drug to be eligible for a 180-day period of protection from competition, 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 “Pharmaceutical Fiscal

5       Accountability Act of 2002”.

6       **SEC. 2. FINDINGS.**

7       The Congress finds as follows:

6 (3) Access to generic drugs upon expiration of  
7 valid pharmaceutical patents can result in a cost-ef-  
8 fective alternative to brand-name drugs.

14 (5) Enhancing competition between generic and  
15 brand-name drug manufacturers can reduce the cost  
16 of prescription drugs.

17 SEC. 3. 180-DAY GENERIC DRUG EXCLUSIVITY FOR CERTAIN  
18 SUBSEQUENT APPLICANTS.

19 Section 505(j)(5)(B) of the Federal Food, Drug, and  
20 Cosmetic Act (21 U.S.C. 355(j)(5)(B)) is amended—

21 (1) in clause (iv) —

22 (A) by striking “If the application” and in-  
23 serting “Subject to clause (v), if the applica-  
24 tion”; and

(B) by striking “continuing” and inserting  
“containing”; and

3 (2) by adding at the end the following:

4                   “(v) If the application contains a certification  
5                   described in subclause (IV) of paragraph (2)(A)(vii)  
6                   for a drug, the Secretary shall treat the application  
7                   as the first such application submitted under this  
8                   subsection for that drug if every person that pre-  
9                   viously submitted an application containing such a  
10                   certification for that drug—

11                   “(I) fails to market the drug within 60  
12 days after the Secretary approves the previously  
13 submitted application;

16                   “(III) changes, for any reason, the certifi-  
17                   cation in the previously submitted application to  
18                   a certification described in subclause (III) of  
19                   paragraph (2)(A)(vii);

20                             “(IV) in a case in which, after the date on  
21                             which the previous application was submitted,  
22                             new patent information is submitted for the  
23                             drug under subsection (c)(2) for a patent for  
24                             which certification is required under subclause  
25                             (IV) of paragraph (2)(A)(vii), fails to challenge

1           the patent that is the subject of the information  
2           within 60 days after the date on which the pat-  
3           ent information is submitted; or

4           “(V) has engaged in conduct in violation of  
5           the antitrust laws (as the term ‘antitrust laws’  
6           is defined in subsection (a) of the first section  
7           of the Clayton Act (15 U.S.C. 12(a)), except  
8           that such term includes section 5 of the Federal  
9           Trade Commission Act (15 U.S.C. 45) to the  
10           extent such section 5 applies to unfair methods  
11           of competition).”.

12 **SEC. 4. NATIONAL INSTITUTES OF HEALTH; AWARDS TO**  
13           **DESIGNATED SMALL ENTITIES FOR PHASE 1**  
14           **OR 2 CLINICAL STUDIES ON DEVELOPMENT**  
15           **OF NEW DRUGS.**

16           Section 402 of the Public Health Service Act (42  
17 U.S.C. 282) is amended by adding at the end the fol-  
18 lowing:

19           “(m)(1) The Director of NIH shall make awards of  
20 grants or contracts to designated small entities to support  
21 qualifying clinical research on the development of new  
22 drugs that, in the determination of such Director, have  
23 the potential to make a significant contribution to the pre-  
24 vention, diagnosis, or treatment of a disease.

25           “(2) For purposes of this subsection:

1           “(A) The term ‘designated small entity’ means  
2           a public or private entity (including a university or  
3           other educational institution) meeting the following  
4           conditions:

5           “(i) The entity has been granted an ex-  
6           emption under section 505(i) of the Federal  
7           Food, Drug, and Cosmetic Act.

8           “(ii) Qualifying clinical research is being or  
9           will be conducted pursuant to such exemption.

10           “(iii) The Director of NIH determines that  
11           the entity may lack the financial resources to  
12           complete the qualifying clinical research in-  
13           volved unless an award under paragraph (1) is  
14           made to the entity.

15           “(B) The term ‘qualifying clinical research’,  
16           with respect to a new drug, means the conduct of  
17           Phase 1 or Phase 2 studies within the meaning of  
18           section 312.21 of title 21, Code of Federal Regula-  
19           tions (or successor regulations).

20           “(3) In supporting qualifying clinical research under  
21           paragraph (1) for a fiscal year, the Director of NIH shall  
22           give priority to the development of any new drug described  
23           in such paragraph that is being developed for a disease  
24           for which the amount of funds for clinical research obli-  
25           gated by the National Institutes of Health for the pre-

1 ceding fiscal year is significantly less than amounts obli-  
2 gated by such Institutes for such fiscal year for clinical  
3 research on other diseases.

4 “(4) For the purpose of carrying out this subsection,  
5 there are authorized to be appropriated \$750,000,000 for  
6 fiscal year 2003, and such sums as may be necessary for  
7 each subsequent fiscal year.”.

8 **SEC. 5. CONTINGENT PAYMENT FOR NATIONAL INSTITUTES**  
9 **OF HEALTH SUPPORT FOR DEVELOPMENT OF**  
10 **NEW DRUGS.**

11 Section 402 of the Public Health Service Act (42  
12 U.S.C. 282) (as amended by section 4) is further amended  
13 by adding at the end the following:

14 “(n)(1) The Director of NIH may not award a grant  
15 or contract to an entity to support the development of a  
16 new drug, including any research related to such develop-  
17 ment, unless the entity involved agrees that, if the new  
18 drug with respect to which the award is made is approved  
19 under section 351 or under section 505 of the Federal  
20 Food, Drug, and Cosmetic Act, the entity will, for the ef-  
21 fective patent period for which the new drug is in commer-  
22 cial distribution, pay to the Director of NIH an amount  
23 equal to 5 percent of the profits derived from sales of the  
24 new drug during such period. After consultation with such  
25 entity, the Director of NIH may establish a schedule of

- 1 periodic payments to meet the obligation of the entity
- 2 under the preceding sentence.

3       “(2) Payments under paragraph (1) may be made di-  
4 rectly by the entity involved or by an entity that has pur-  
5 chased the rights to the new drug involved or has received  
6 a license regarding the sale of the new drug.

7       “(3) Subject to the availability of appropriations,  
8 amounts paid to the Director of NIH under this sub-  
9 section are available to the Director to award grants and  
10 contracts for the development of new drugs, and such  
11 amounts may remain available until expended.”.

12 SEC. 6. STUDY ON EFFECTS OF FEDERAL SUPPORT FOR RE-  
13 SEARCH AND DEVELOPMENT OF PRESCRIP-  
14 TION DRUGS.

15 (a) STUDY.—The Comptroller General of the United  
16 States shall conduct a study and make findings and rec-  
17 ommendations with respect to the effects of Federal fund-  
18 ing used by Federal agencies to conduct or support re-  
19 search and development of prescription drugs, on the fol-  
20 lowing:

21 (1) The overall cost of such research and devel-  
22 opment.

## 23 (2) The pricing of prescription drugs.

24 (b) REPORT.—Not later than 1 year after the date  
25 of the enactment of this Act, the Comptroller General of

1 the United States shall submit to the Congress a report  
2 on the study, findings, and recommendations required by  
3 subsection (a).

4 **SEC. 7. STUDY ON PHARMACEUTICAL PATENT EXTENSIONS**

5 **AND MARKET EXCLUSIVITY PERIODS.**

6 (a) STUDY.—The Comptroller General of the United  
7 States shall conduct a study and make findings and rec-  
8 ommendations on pharmaceutical patent extensions and  
9 market exclusivity periods under Federal law, including  
10 the effect of such extensions and periods on possible delays  
11 in the introduction of generic versions of prescription  
12 drugs.

13 (b) REPORT.—Not later than 1 year after the date  
14 of the enactment of this Act, the Comptroller General of  
15 the United States shall submit to the Congress a report  
16 on the study, findings, and recommendations required by  
17 subsection (a).

