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108TH CONGRESS
1ST SESSION

H. R. 828

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

FEBRUARY 13, 2003

Mrs. MCCARTHY of New York (for herself, Mr. EMANUEL, Ms. NORTON, Mr. OWENS, and Mr. ISRAEL) introduced the following bill; which was referred to the Committee on Energy and Commerce

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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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Pharmaceutical Fiscal Accountability Act of 2003''.

SEC. 2. FINDINGS.

The Congress finds as follows:

(1) Prescription drug costs continue to rise, affecting all people in the United States.

(2) Generic drugs are approved by the Food and Drug Administration and offer a safe alternative to brand-name drugs.

(3) Access to generic drugs upon expiration of valid pharmaceutical patents can result in a cost-effective alternative to brand-name drugs.

(4) The generic version of a drug often enters the market at a cost that is 25 to 35 percent less than the cost of the brand-name version of the drug, and after a few years typically sells for about 50 percent of the cost of the brand-name version.

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

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

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

(1) in clause (iv)—

(A) by striking ''If the application'' and inserting ''Subject to clause (v), if the application''; and

(B) by striking ''continuing'' and inserting ''containing''; and

(2) by adding at the end the following:

''(v) If the application contains a certification described in subclause (IV) of paragraph (2)(A)(vii) for a drug, the Secretary shall treat the application as the first such application submitted under this subsection for that drug if every person that previously submitted an application containing such a certification for that drug—

''(I) fails to market the drug within 60 days after the Secretary approves the previously submitted application;

''(II) withdraws the previously submitted application;

''(III) changes, for any reason, the certification in the previously submitted application to a certification described in subclause (III) of paragraph (2)(A)(vii);

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

the patent that is the subject of the information within 60 days after the date on which the patent information is submitted; or

''(V) has engaged in conduct in violation of the antitrust laws (as the term 'antitrust laws' is defined in subsection (a) of the first section of the Clayton Act (15 U.S.C. 12(a)), except that such term includes section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent such section 5 applies to unfair methods of competition).''.

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

Section 402 of the Public Health Service Act (42 U.S.C. 282) is amended by adding at the end the following:

''(m)(1) The Director of NIH shall make awards of grants or contracts to designated small entities to support qualifying clinical research on the development of new drugs that, in the determination of such Director, have the potential to make a significant contribution to the prevention, diagnosis, or treatment of a disease.

''(2) For purposes of this subsection:

"(A) The term 'designated small entity' means a public or private entity (including a university or other educational institution) meeting the following conditions:

"(i) The entity has been granted an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act.

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

"(iii) The Director of NIH determines that the entity may lack the financial resources to complete the qualifying clinical research involved unless an award under paragraph (1) is made to the entity.

"(B) The term 'qualifying clinical research', with respect to a new drug, means the conduct of Phase 1 or Phase 2 studies within the meaning of section 312.21 of title 21, Code of Federal Regulations (or successor regulations).

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

ceding fiscal year is significantly less than amounts obligated by such Institutes for such fiscal year for clinical research on other diseases.

''(4) For the purpose of carrying out this subsection, there are authorized to be appropriated $750,000,000 for fiscal year 2004, and such sums as may be necessary for each subsequent fiscal year.''.

SEC. 5. CONTINGENT PAYMENT FOR NATIONAL INSTITUTES OF HEALTH SUPPORT FOR DEVELOPMENT OF NEW DRUGS.

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

''(n)(1) The Director of NIH may not award a grant or contract to an entity to support the development of a new drug, including any research related to such development, unless the entity involved agrees that, if the new drug with respect to which the award is made is approved under section 351 or under section 505 of the Federal Food, Drug, and Cosmetic Act, the entity will, for the effective patent period for which the new drug is in commercial distribution, pay to the Director of NIH an amount equal to 5 percent of the profits derived from sales of the new drug during such period. After consultation with such entity, the Director of NIH may establish a schedule of

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

''(2) Payments under paragraph (1) may be made directly by the entity involved or by an entity that has purchased the rights to the new drug involved or has received a license regarding the sale of the new drug.

''(3) Subject to the availability of appropriations, amounts paid to the Director of NIH under this subsection are available to the Director to award grants and contracts for the development of new drugs, and such amounts may remain available until expended.''.

SEC. 6. STUDY ON EFFECTS OF FEDERAL SUPPORT FOR RESEARCH AND DEVELOPMENT OF PRESCRIPTION DRUGS.

(a) STUDY.—The Comptroller General of the United States shall conduct a study and make findings and recommendations with respect to the effects of Federal funding used by Federal agencies to conduct or support research and development of prescription drugs, on the following:

(1) The overall cost of such research and development.

(2) The pricing of prescription drugs.

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

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

SEC. 7. STUDY ON PHARMACEUTICAL PATENT EXTENSIONS AND MARKET EXCLUSIVITY PERIODS.

(a) STUDY.—The Comptroller General of the United States shall conduct a study and make findings and recommendations on pharmaceutical patent extensions and market exclusivity periods under Federal law, including the effect of such extensions and periods on possible delays in the introduction of generic versions of prescription drugs.

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

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