

105TH CONGRESS  
1ST SESSION

# H. R. 1727

To amend the Federal Food, Drug, and Cosmetic Act to allow for additional deferred effective dates for approval of applications under the new drugs provisions, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

MAY 22, 1997

Mr. GREENWOOD (for himself, Mr. WAXMAN, Mr. BURR of North Carolina, Mr. UPTON, Mrs. JOHNSON of Connecticut, Mr. KLUG, Mr. FRANKS of New Jersey, Ms. LOFGREN, Ms. PRYCE of Ohio, Mr. TOWNS, Ms. DEGETTE, Mr. BOUCHER, Mr. FALEOMAVAEGA, Mr. HORN, and Ms. SLAUGHTER) introduced the following bill; which was referred to the Committee on Commerce

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act to allow for additional deferred effective dates for approval of applications under the new drugs provisions, 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 “Better Pharma-  
5 ceuticals for Children Act”.

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1 **SEC. 2. FINDINGS.**

2 Congress finds that—

3 (1) children are the future of the Nation and  
4 the preservation and improvement of child health is  
5 in the national interest;

6 (2) the preservation and improvement of child  
7 health may require the use of pharmaceutical prod-  
8 ucts;

9 (3) children may metabolize drugs differently  
10 from adults and may require smaller doses or dif-  
11 ferent forms of administration of the drugs;

12 (4) the testing of drugs for safety and  
13 pharmacokinetics is necessary to ensure that the  
14 drugs are safe and effective for use by children;

15 (5) it is estimated that 4 out of 5 drugs on the  
16 market in the United States have not been approved  
17 for use by children;

18 (6) many other drugs are not manufactured in  
19 a form that permits young children to use such  
20 drugs and consequently untested and unapproved  
21 forms are often employed;

22 (7) many of these drugs are nonetheless widely  
23 used by children or hold promise for use by children,  
24 despite the lack of approval, dosage, labeling, or for-  
25 mulation;

1           (8) this Act is intended to encourage manufac-  
2           turers to perform such research, to develop informa-  
3           tion about the safe and appropriate use of such  
4           drugs, and to label and formulate such drugs for use  
5           by children;

6           (9) the National Institutes of Health, acting  
7           through the Pediatric Pharmacology Research Unit  
8           (PPRU) Network, has initiated research on appro-  
9           priate pediatric indications for drugs that have not  
10          been approved for use by children;

11          (10) the PPRU Network has performed such  
12          research with both public funding and private con-  
13          tracts with industry;

14          (11) the Better Pharmaceuticals for Children  
15          Act, if enacted, will provide a range of private con-  
16          tractual opportunities for the PPRU Network to  
17          work with industry on research involving drugs that  
18          are protected by some form of patent or exclusivity  
19          and that are candidates for protection under this  
20          Act;

21          (12) there will, nonetheless, remain a number of  
22          drugs that are in widespread use, and that have not  
23          been approved for use by children, but that are not  
24          protected by some form of patent or exclusivity, and

1       thus are not candidates for protection under this  
2       Act;

3               (13) if this Act is enacted, the PPRU Network  
4       will continue to be well suited to continue to use  
5       public funds and such private funds as may be avail-  
6       able to conduct research on such drugs for pediatric  
7       use; and

8               (14) if this Act is enacted, the safety and effec-  
9       tiveness of the use of pharmaceuticals by children  
10       will be improved and the health of the children of  
11       this Nation will benefit.

12 **SEC. 3. PEDIATRIC STUDIES MARKETING EXCLUSIVITY.**

13       Chapter V of the Federal Food, Drug, and Cosmetic  
14       Act (21 U.S.C. 351 et seq.) is amended by inserting after  
15       section 505 the following new section:

16 **“SEC. 505A. PEDIATRIC STUDIES OF DRUGS.**

17       “(a) MARKET EXCLUSIVITY FOR NEW DRUGS.—If,  
18       prior to approval of an application that is submitted under  
19       section 505(b)(1) the Secretary determines that informa-  
20       tion relating to the use of a drug in the pediatric popu-  
21       lation may produce health benefits in that population, the  
22       Secretary makes a written request for pediatric studies  
23       (which may include a time frame for completing such stud-  
24       ies), and such studies are completed within any such time  
25       frame and the reports thereof submitted in accordance

1 with subsection (d)(2) or completed within any such time  
2 frame and the reports thereof are accepted in accordance  
3 with subsection (d)(3)—

4 “(1)(A) the period during which an application  
5 may not be submitted under subsections  
6 (c)(3)(D)(ii) and (j)(4)(D)(ii) of section 505 shall be  
7 five years and six months rather than five years, and  
8 the references in subsections (c)(3)(D)(ii) and  
9 (j)(4)(D)(ii) of section 505 to four years, to forty-  
10 eight months, and to seven and one-half years shall  
11 be deemed to be four and one-half years, fifty-four  
12 months, and eight years, respectively; or

13 “(B) the period of market exclusivity under  
14 subsections (c)(3)(D) (iii) and (iv) and (j)(4)(D) (iii)  
15 and (iv) of section 505 shall be three years and six  
16 months rather than three years; and

17 “(2)(A) if the drug is the subject of—

18 “(i) a listed patent for which a certification  
19 has been submitted under section  
20 505(b)(2)(A)(ii) or section (j)(2)(A)(vii)(II) and  
21 for which pediatric studies were submitted prior  
22 to the expiration of the patent (including any  
23 patent extensions), or

24 “(ii) a listed patent for which a certifi-  
25 cation has been submitted under section

1           505(b)(2)(A)(iii)                   or           section  
2           505(j)(2)(A)(vii)(III),  
3       the period during which an application may not be  
4       approved under section 505(c)(3) or section  
5       505(j)(4)(B) shall be extended by a period of six  
6       months after the date the patent expires (including  
7       any patent extensions); or

8           “(B) if the drug is the subject of a listed patent  
9       for which a certification has been submitted under  
10       section 505(b)(2)(A)(iv)           or           section  
11       505(j)(2)(A)(vii)(IV), and in the patent infringement  
12       litigation resulting from the certification the court  
13       determines that the patent is valid and would be in-  
14       fringed, the period during which an application may  
15       not be approved under section 505(c)(3) or section  
16       505(j)(4)(B) shall be extended by a period of six  
17       months after the date the patent expires (including  
18       any patent extensions).

19       “(b) SECRETARY TO DEVELOP LIST OF DRUGS FOR  
20       WHICH ADDITIONAL PEDIATRIC INFORMATION MAY BE  
21       BENEFICIAL.—Not later than 180 days after the date of  
22       enactment of this section, the Secretary, after consultation  
23       with experts in pediatric research (such as the American  
24       Academy of Pediatrics, the Pediatric Pharmacology Re-  
25       search Unit Network, and the United States Pharma-

1 copoeia) shall develop, prioritize and publish an initial list  
2 of approved drugs for which additional pediatric informa-  
3 tion may produce health benefits in the pediatric popu-  
4 lation. The Secretary shall annually update the list.

5 “(c) MARKET EXCLUSIVITY FOR ALREADY-MAR-  
6 KETED DRUGS.—If the Secretary makes a written request  
7 for pediatric studies (which may include a time frame for  
8 completing such studies) concerning a drug identified in  
9 the list described in subsection (b) to the holder of an ap-  
10 proved application under section 505(b)(1) for the drug,  
11 the holder agrees to the request, and the studies are com-  
12 pleted within any such time frame and the reports thereof  
13 submitted in accordance with subsection (d)(2) or com-  
14 pleted within any such time frame and the reports thereof  
15 accepted in accordance with subsection (d)(3)—

16 “(1)(A) the period during which an application  
17 may not be submitted under subsections  
18 (c)(3)(D)(ii) and (j)(4)(D)(ii) of section 505 shall be  
19 five years and six months rather than five years, and  
20 the references in subsections (c)(3)(D)(ii) and  
21 (j)(4)(D)(ii) of section 505 to four years, to forty-  
22 eight months, and to seven and one-half years shall  
23 be deemed to be four and one-half years, fifty-four  
24 months, and eight years, respectively; or

1           “(B) the period of market exclusivity under  
2 subsections (c)(3)(D) (iii) and (iv) and (j)(4)(D) (iii)  
3 and (iv) of section 505 shall be three years and six  
4 months rather than three years; and

5           “(2)(A) if the drug is the subject of—

6           “(i) a listed patent for which a certification  
7 has been submitted under section  
8 505(b)(2)(A)(ii) or (j)(2)(A)(vii)(II) and for  
9 which pediatric studies were submitted prior to  
10 the expiration of the patent (including any pat-  
11 ent extensions), or

12           “(ii) a listed patent for which a certifi-  
13 cation has been submitted under section  
14 505(b)(2)(A)(iii) or section  
15 505(j)(2)(A)(vii)(III),

16 the period during which an application may not be  
17 approved under section 505(c)(3) or section  
18 505(j)(4)(B) shall be extended by a period of six  
19 months after the date the patent expires (including  
20 any patent extensions); or

21           “(B) if the drug is the subject of a listed patent  
22 for which a certification has been submitted under  
23 section 505(b)(2)(A)(iv) or section  
24 505(j)(2)(A)(vii)(IV), and in the patent infringement  
25 litigation resulting from the certification the court

1 determines that the patent is valid and would be in-  
2 fringed, the period during which an application may  
3 not be approved under section 505(c)(3) or section  
4 505(j)(4)(B) shall be extended by a period of six  
5 months after the date the patent expires (including  
6 any patent extensions).

7 “(d) CONDUCT OF PEDIATRIC STUDIES.—

8 “(1) AGREEMENT FOR STUDIES.—The Sec-  
9 retary may, pursuant to a written request for stud-  
10 ies, after consultation with—

11 “(A) the sponsor of an application for an  
12 investigational new drug under section 505(i),

13 “(B) the sponsor of an application for a  
14 drug under section 505(b)(1), or

15 “(C) the holder of an approved application  
16 for a drug under section 505(b)(1),

17 agree with the sponsor or holder for the conduct of  
18 pediatric studies for such drug.

19 “(2) WRITTEN PROTOCOLS TO MEET THE  
20 STUDIES REQUIREMENT.—If the sponsor or holder  
21 and the Secretary agree upon written protocols for  
22 the studies, the studies requirement of subsection  
23 (a) or (c) is satisfied upon the completion of the  
24 studies and submission of the reports thereof in ac-  
25 cordance with the original written request and the

1 written agreement referred to in paragraph (1). Not  
2 later than 60 days after the submission of the report  
3 of the studies, the Secretary shall determine if such  
4 studies were or were not conducted in accordance  
5 with the original written request and the written  
6 agreement and reported in accordance with the re-  
7 quirements of the Secretary for filing and so notify  
8 the sponsor or holder.

9 “(3) OTHER METHODS TO MEET THE STUDIES  
10 REQUIREMENT.—If the sponsor or holder and the  
11 Secretary have not agreed in writing on the proto-  
12 cols for the studies, the studies requirement of sub-  
13 section (a) or (c) is satisfied when such studies have  
14 been completed and the reports accepted by the Sec-  
15 retary. Not later than 90 days after the submission  
16 of the reports of the studies, the Secretary shall ac-  
17 cept or reject such reports and so notify the sponsor  
18 or holder. The Secretary’s only responsibility in ac-  
19 cepting or rejecting the reports shall be to deter-  
20 mine, within the 90 days, whether the studies fairly  
21 respond to the written request, whether such studies  
22 have been conducted in accordance with commonly  
23 accepted scientific principles and protocols, and  
24 whether such studies have been reported in accord-

1           ance with the requirements of the Secretary for fil-  
2           ing.

3           “(e) DELAY OF EFFECTIVE DATE FOR CERTAIN AP-  
4           PLICATIONS; PERIOD OF MARKET EXCLUSIVITY.—If the  
5           Secretary determines that the acceptance or approval of  
6           an application under section 505(b)(2) or 505(j) for a  
7           drug may occur after submission of reports of pediatric  
8           studies under this section, which were submitted prior to  
9           the expiration of the patent (including any patent exten-  
10          sion) or market exclusivity protection, but before the Sec-  
11          retary has determined whether the requirements of sub-  
12          section (d) have been satisfied, the Secretary shall delay  
13          the acceptance or approval under section 505(b)(2) or  
14          505(j), respectively, until the determination under sub-  
15          section (d) is made, but such delay shall not exceed 90  
16          days. In the event that requirements of this section are  
17          satisfied, the applicable period of market exclusivity re-  
18          ferred to in subsection (a) or (c) shall be deemed to have  
19          been running during the period of delay.

20          “(f) NOTICE OF DETERMINATIONS ON STUDIES RE-  
21          QUIREMENT.—The Secretary shall publish a notice of any  
22          determination that the requirements of subsection (d)  
23          have been met and that submissions and approvals under  
24          section 505(b)(2) or (j) for a drug will be subject to the  
25          provisions of this section.

1       “(g) DEFINITIONS.—As used in this section, the term  
2 ‘pediatric studies’ or ‘studies’ means at least one clinical  
3 investigation (that, at the Secretary’s discretion, may in-  
4 clude pharmacokinetic studies) in pediatric age-groups in  
5 which a drug is anticipated to be used.

6       “(h) LIMITATION.—The holder of an approved appli-  
7 cation for a new drug that has already received six months  
8 of market exclusivity under subsection (a) or subsection  
9 (c) may, if otherwise eligible, obtain six months of market  
10 exclusivity under subsection (c)(1)(B) for a supplemental  
11 application, except that the holder is not eligible for exclu-  
12 sivity under subsection (c)(2).”

13       “(i) SUNSET.—No period of market exclusivity shall  
14 be granted under this section based on studies commenced  
15 after January 1, 2004. The Secretary shall conduct a  
16 study and report to Congress not later than January 1,  
17 2003 based on the experience under the program. The  
18 study and report shall examine all relevant issues, includ-  
19 ing—

20               “(1) the effectiveness of the program in improv-  
21 ing information about important pediatric uses for  
22 approved drugs;

23               “(2) the adequacy of the incentive provided  
24 under this section;

25               “(3) the economic impact of the program; and

1           “(4) any suggestions for modification that the  
2           Secretary deems appropriate.”.

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