

105TH CONGRESS
1ST SESSION

S. 713

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.

IN THE SENATE OF THE UNITED STATES

MAY 7, 1997

Mr. DODD (for himself and Mr. DEWINE) introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

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”.

6 **SEC. 2. FINDINGS.**

7 Congress finds that—

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

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

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

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

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

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

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

24 (8) this Act is intended to encourage manufac-
25 turers to perform such research, to develop informa-

1 tion about the safe and appropriate use of such
2 drugs, and to label and formulate such drugs for use
3 by children;

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

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

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

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

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

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

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

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

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

15 “(a) MARKET EXCLUSIVITY FOR NEW DRUGS.—If,
 16 prior to approval of an application that is submitted under
 17 section 505(b)(1) the Secretary determines that informa-
 18 tion relating to the use of a drug in the pediatric popu-
 19 lation may produce health benefits in that population, the
 20 Secretary makes a written request for pediatric studies
 21 (which may include a time frame for completing such stud-
 22 ies), and such studies are completed within any such time
 23 frame and the reports thereof submitted in accordance
 24 with subsection (d)(2) or completed within any such time

1 frame and the reports thereof are accepted in accordance
2 with subsection (d)(3)—

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

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

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

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

23 “(ii) a listed patent for which a certifi-
24 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

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

“(d) CONDUCT OF PEDIATRIC STUDIES.—

“(1) AGREEMENT FOR STUDIES.—The Secretary may, pursuant to a written request for studies, after consultation with—

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

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

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

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

“(2) WRITTEN PROTOCOLS TO MEET THE STUDIES REQUIREMENT.—If the sponsor or holder and the Secretary agree upon written protocols for the studies, the studies requirement of subsection (a) or (c) is satisfied upon the completion of the studies and submission of the reports thereof in accordance 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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