

## Union Calendar No. 167

107<sup>TH</sup> CONGRESS  
1<sup>ST</sup> SESSION

# H. R. 2887

[Report No. 107-277]

To amend the Federal Food, Drug, and Cosmetic Act to improve the safety and efficacy of pharmaceuticals for children.

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### IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 13, 2001

Mr. GREENWOOD (for himself, Ms. ESHOO, Mr. UPTON, Mr. WYNN, Mr. BUYER, Mr. RUSH, Mr. BRADY of Pennsylvania, Ms. ROYBAL-ALLARD, and Ms. LOFGREN) introduced the following bill; which was referred to the Committee on Energy and Commerce

NOVEMBER 9, 2001

Additional sponsors: Mrs. ROUKEMA, Mr. SMITH of New Jersey, Mr. RANGEL, Mr. FRANK, Mr. FATTAH, Ms. WOOLSEY, Mr. WHITFIELD, Mr. OWENS, Mrs. MORELLA, Mr. DOOLEY of California, Mr. MCGOVERN, Mr. LANTOS, Mr. CAPUANO, and Mr. KIND

NOVEMBER 9, 2001

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in italics]

[For text of introduced bill, see copy of bill as introduced on September 13, 2001]

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act to improve the safety and efficacy of pharmaceuticals for children.

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 “Best Pharmaceuticals*  
5 *for Children Act”.*

6 **SEC. 2. PEDIATRIC STUDIES OF ALREADY-MARKETED**  
7 **DRUGS.**

8        *(a) IN GENERAL.—Section 505A of the Federal Food,*  
9 *Drug, and Cosmetic Act (21 U.S.C. 355a) is amended—*

10            *(1) by striking subsection (b); and*

11            *(2) by redesignating subsections (c) through*  
12 *through (k) as subsections (b) through (j), respectively.*

13        *(b) CONFORMING AMENDMENTS.—Section 505A of the*  
14 *Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a)*  
15 *is amended in subsection (b) (as redesignated by subsection*  
16 *(a)(2) of this section)—*

17            *(1) by inserting after “the Secretary” the fol-*  
18 *lowing: “determines that information relating to the*  
19 *use of an approved drug in the pediatric population*  
20 *may produce health benefits in that population and”;*  
21 *and*

22            *(2) by striking “concerning a drug identified in*  
23 *the list described in subsection (b)”.*

1 **SEC. 3. RESEARCH FUND FOR THE STUDY OF DRUGS LACK-**  
2 **ING EXCLUSIVITY.**

3 *Part B of title IV of the Public Health Service Act*  
4 *(42 U.S.C. 284 et seq.) is amended—*

5 *(1) by redesignating the second section 409C (re-*  
6 *lating to clinical research) as section 409G;*

7 *(2) by redesignating the second section 409D (re-*  
8 *lating to enhancement awards) as section 409H; and*

9 *(3) by adding at the end the following:*

10 **“SEC. 409I. PROGRAM FOR PEDIATRIC STUDIES OF DRUGS**  
11 **LACKING EXCLUSIVITY.**

12 *“(a) LIST OF DRUGS LACKING EXCLUSIVITY FOR*  
13 *WHICH PEDIATRIC STUDIES ARE NEEDED.—*

14 *“(1) IN GENERAL.—Not later than 1 year after*  
15 *the date of enactment of this section, the Secretary,*  
16 *acting through the Director of the National Institutes*  
17 *of Health and in consultation with the Commissioner*  
18 *of Food and Drugs and experts in pediatric research,*  
19 *shall develop, prioritize, and publish an annual list*  
20 *of approved drugs for which—*

21 *“(A)(i) there is an approved application*  
22 *under section 505(j) of the Federal Food, Drug,*  
23 *and Cosmetic Act;*

24 *“(ii) there is a submitted application that*  
25 *could be approved under the criteria of section*

1           505(j) of the Federal Food, Drug, and Cosmetic  
2           Act;

3           “(iii) there is no patent protection or mar-  
4           ket exclusivity protection under the Federal  
5           Food, Drug, and Cosmetic Act; or

6           “(iv) there is, under section 505A(c)(4)(C)  
7           of the Federal Food, Drug, and Cosmetic Act, a  
8           referral for inclusion on such list; and

9           “(B) additional studies are needed to assess  
10          the safety and effectiveness of the use of the drug  
11          in the pediatric population.

12          “(2) CONSIDERATION OF AVAILABLE INFORMA-  
13          TION.—In developing the list under paragraph (1),  
14          the Secretary shall consider, for each drug on the  
15          list—

16               “(A) the availability of information con-  
17               cerning the safe and effective use of the drug in  
18               the pediatric population;

19               “(B) whether additional information is  
20               needed;

21               “(C) whether new pediatric studies con-  
22               cerning the drug may produce health benefits in  
23               the pediatric population; and

24               “(D) whether reformulation of the drug is  
25               necessary;

1           “(b) *CONTRACTS FOR PEDIATRIC STUDIES.*—*The Sec-*  
2 *retary shall award contracts to entities that have the exper-*  
3 *tise to conduct pediatric clinical trials (including qualified*  
4 *universities, hospitals, laboratories, contract research orga-*  
5 *nizations, federally funded programs such as pediatric*  
6 *pharmacology research units, other public or private insti-*  
7 *tutions, or individuals) to enable the entities to conduct pe-*  
8 *diatric studies concerning one or more drugs identified in*  
9 *the list described in subsection (a).*

10           “(c) *PROCESS FOR CONTRACTS AND LABELING*  
11 *CHANGES.*—

12                   “(1) *WRITTEN REQUEST TO HOLDERS OF AP-*  
13 *PROVED APPLICATIONS FOR DRUGS LACKING EXCLU-*  
14 *SIVITY.*—

15                           “(A) *IN GENERAL.*—*The Commissioner of*  
16 *Food and Drugs, in consultation with the Direc-*  
17 *tor of National Institutes of Health, may issue a*  
18 *written request (which shall include a timeframe*  
19 *for negotiations for an agreement) for pediatric*  
20 *studies concerning a drug identified in the list*  
21 *described in subsection (a) to all holders of an*  
22 *approved application for the drug under section*  
23 *505 of the Federal Food, Drug, and Cosmetic*  
24 *Act. Such a written request shall be made in a*  
25 *manner equivalent to the manner in which a*

1           *written request is made under subsection (a) or*  
2           *(b) of section 505A of the Federal Food, Drug,*  
3           *and Cosmetic Act, including with respect to in-*  
4           *formation provided on the pediatric studies to be*  
5           *conducted pursuant to the request.*

6           “(B) *PUBLICATION OF REQUEST.—If the*  
7           *Commissioner of Food and Drugs does not re-*  
8           *ceive a response to a written request issued*  
9           *under subparagraph (A) within 30 days of the*  
10           *date on which a request was issued, the Sec-*  
11           *retary, acting through the Director of National*  
12           *Institutes of Health and in consultation with the*  
13           *Commissioner of Food and Drugs, shall publish*  
14           *a request for contract proposals to conduct the*  
15           *pediatric studies described in the written request.*

16           “(C) *DISQUALIFICATION.—A holder that re-*  
17           *ceives a first right of refusal shall not be entitled*  
18           *to respond to a request for contract proposals*  
19           *under subparagraph (B).*

20           “(D) *GUIDANCE.—Not later than 270 days*  
21           *after the date of enactment of this section, the*  
22           *Commissioner of Food and Drugs shall promul-*  
23           *gate guidance to establish the process for the sub-*  
24           *mission of responses to written requests under*  
25           *subparagraph (A).*

1           “(2) *CONTRACTS.*—A contract under this section  
2           may be awarded only if a proposal for the contract  
3           is submitted to the Secretary in such form and man-  
4           ner, and containing such agreements, assurances, and  
5           information as the Secretary determines to be nec-  
6           essary to carry out this section.

7           “(3) *REPORTING OF STUDIES.*—

8           “(A) Upon completion of a pediatric study  
9           in accordance with a contract awarded under  
10          this section, a report concerning the study shall  
11          be submitted to the Director of National Insti-  
12          tutes of Health and the Commissioner of Food  
13          and Drugs. The report shall include all data gen-  
14          erated in connection with the study.

15          “(B) *AVAILABILITY OF REPORTS.*—Each re-  
16          port submitted under subparagraph (A) shall be  
17          considered to be in the public domain, and shall  
18          be assigned a docket number by the Commis-  
19          sioner of Food and Drugs. An interested person  
20          may submit written comments concerning such  
21          pediatric studies to the Commissioner of Food  
22          and Drugs, and the written comments shall be-  
23          come part of the docket file with respect to each  
24          of the drugs.

1           “(C) *ACTION BY COMMISSIONER.*—*The Com-*  
2           *missioner of Food and Drugs shall take appro-*  
3           *priate action in response to the reports submitted*  
4           *under subparagraph (A) in accordance with*  
5           *paragraph (4).*

6           “(4) *REQUEST FOR LABELING CHANGES.*—*Dur-*  
7           *ing the 180-day period after the date on which a re-*  
8           *port is submitted under paragraph (3)(A), the Com-*  
9           *missioner of Food and Drugs shall—*

10           “(A) *review the report and such other data*  
11           *as are available concerning the safe and effective*  
12           *use in the pediatric population of the drug stud-*  
13           *ied;*

14           “(B) *negotiate with the holders of approved*  
15           *applications for the drug studied for any label-*  
16           *ing changes that the Commissioner of Food and*  
17           *Drugs determines to be appropriate and requests*  
18           *the holders to make; and*

19           “(C)(i) *place in the public docket file a copy*  
20           *of the report and of any requested labeling*  
21           *changes; and*

22           “(ii) *publish in the Federal Register a sum-*  
23           *mary of the report and a copy of any requested*  
24           *labeling changes.*

1           “(5) *DISPUTE RESOLUTION.*—If, not later than  
2           the end of the 180-day period specified in paragraph  
3           (4), the holder of an approved application for the  
4           drug involved does not agree to any labeling change  
5           requested by the Commissioner of Food and Drugs  
6           under that paragraph—

7                   “(A) the Commissioner of Food and Drugs  
8                   shall immediately refer the request to the Pedi-  
9                   atric Advisory Subcommittee of the Anti-Infec-  
10                  tive Drugs Advisory Committee; and

11                  “(B) not later than 90 days after receiving  
12                  the referral, the Subcommittee shall—

13                          “(i) review the available information  
14                          on the safe and effective use of the drug in  
15                          the pediatric population, including study  
16                          reports submitted under this section; and

17                          “(ii) make a recommendation to the  
18                          Commissioner of Food and Drugs as to ap-  
19                          propriate labeling changes, if any.

20           “(6) *FDA DETERMINATION.*—Not later than 30  
21           days after receiving a recommendation from the Sub-  
22           committee under paragraph (5)(B)(ii) with respect to  
23           a drug, the Commissioner of Food and Drugs shall  
24           consider the recommendation and, if appropriate,  
25           make a request to the holders of approved applica-

1        *tions for the drug to make any labeling change that*  
2        *the Commissioner of Food and Drugs determines to be*  
3        *appropriate.*

4               “(7) *FAILURE TO AGREE.*—*If a holder of an ap-*  
5        *proved application for a drug, within 30 days after*  
6        *receiving a request to make a labeling change under*  
7        *paragraph (6), does not agree to make a requested la-*  
8        *beling change, the Commissioner may deem the drug*  
9        *to be misbranded under the Federal Food, Drug, and*  
10       *Cosmetic Act.*

11               “(8) *RECOMMENDATION FOR FORMULATION*  
12        *CHANGES.*—*If a pediatric study completed under pub-*  
13        *lic contract indicates that a formulation change is*  
14        *necessary and the Secretary agrees, the Secretary*  
15        *shall send a nonbinding letter of recommendation re-*  
16        *garding that change to each holder of an approved*  
17        *application.*

18               “(d) *CONFIDENTIAL COMMERCIAL INFORMATION;*  
19        *TRADE SECRETS.*—*Nothing in this section requires or au-*  
20        *thorizes the use or disclosure of confidential commercial in-*  
21        *formation or trade secrets.*

22               “(e) *AUTHORIZATION OF APPROPRIATIONS.*—

23               “(1) *IN GENERAL.*—*For the purpose of carrying*  
24        *out this section, there are authorized to be appro-*  
25        *priated \$200,000,000 for fiscal year 2002, and such*

1        *sums as may be necessary for each of the fiscal years*  
2        *2003 through 2007.*

3                *“(2) AVAILABILITY.—Any amount appropriated*  
4        *under paragraph (1) shall remain available to carry*  
5        *out this section until expended.”.*

6        **SEC. 4. WRITTEN REQUEST TO HOLDERS OF APPROVED AP-**  
7                        **PLICATIONS FOR DRUGS THAT HAVE MARKET**  
8                        **EXCLUSIVITY.**

9        *Section 505A of the Federal Food, Drug, and Cosmetic*  
10        *Act (21 U.S.C. 355a) is amended in subsection (c) (as reded-*  
11        *ignated by section 2(a)(2) of this Act) by adding at the end*  
12        *the following:*

13                *“(4) WRITTEN REQUEST TO HOLDERS OF AP-*  
14        *PROVED APPLICATIONS FOR DRUGS THAT HAVE MAR-*  
15        *KET EXCLUSIVITY.—*

16                        *“(A) REQUEST AND RESPONSE.—If the Sec-*  
17        *retary makes a written request for pediatric*  
18        *studies under subsection (b) to the holder of an*  
19        *application approved under section 505(b)(1),*  
20        *the holder, not later than 180 days after receiv-*  
21        *ing the written request, shall respond to the Sec-*  
22        *retary as to the intention of the holder to act on*  
23        *the request by—*

1           “(i) *indicating when the pediatric*  
2 *studies will be initiated, if the holder agrees*  
3 *to the request; or*

4           “(ii) *indicating that the holder does*  
5 *not agree to the request.*

6           “(B) *NO AGREEMENT TO REQUEST.—*

7           “(i) *REFERRAL.—If the holder does not*  
8 *agree to a written request within the time*  
9 *period specified in subparagraph (A), and*  
10 *if the Secretary determines that there is a*  
11 *continuing need for information relating to*  
12 *the use of the drug in the pediatric popu-*  
13 *lation (including neonates as appropriate),*  
14 *the Secretary shall refer the drug to the*  
15 *Foundation for Pediatric Research estab-*  
16 *lished under section 499A of the Public*  
17 *Health Service Act (referred to in this para-*  
18 *graph as the ‘Foundation’) for consideration*  
19 *for the conduct of the pediatric studies de-*  
20 *scribed in the written request.*

21           “(ii) *PUBLIC NOTICE.—The Secretary*  
22 *shall give public notice of a referral under*  
23 *clause (i), including notice of the name of*  
24 *the drug, the name of the manufacturer,*  
25 *and the indication to be studied.*

1           “(C) *LACK OF FUNDS.*—If, on referral of a  
2           drug under subparagraph (B)(i), the Foundation  
3           certifies to the Secretary that the Foundation  
4           does not have funds available to conduct the re-  
5           quested studies, the Secretary shall refer the drug  
6           for inclusion on the list established under section  
7           409I of the Public Health Service Act for the  
8           conduct of the studies.

9           “(D) *CONFIDENTIAL COMMERCIAL INFORMA-*  
10          *TION; TRADE SECRETS.*—Nothing in this para-  
11          graph requires or authorizes the use or disclosure  
12          of confidential commercial information or trade  
13          secrets.

14          “(E) *NO REQUIREMENT TO REFER.*—Noth-  
15          ing in this subsection shall be construed to re-  
16          quire that every declined written request shall be  
17          referred to the Foundation.”.

18   **SEC. 5. TIMELY LABELING CHANGES FOR DRUGS GRANTED**

19                   **EXCLUSIVITY; DRUG FEES.**

20          (a) *ELIMINATION OF USER FEE WAIVER FOR PEDI-*  
21          *ATRIC SUPPLEMENTS.*—Section 736(a)(1) of the Federal  
22          Food, Drug, and Cosmetic Act (21 U.S.C. 379h(a)(1)) is  
23          amended—

24                  (1) by striking subparagraph (F); and

1           (2) *by redesignating subparagraph (G) as sub-*  
2 *paragraph (F).*

3           ***(b) LABELING CHANGES.—***

4           ***(1) DEFINITION OF PRIORITY SUPPLEMENT.—***  
5 *Section 201 of the Federal Food, Drug, and Cosmetic*  
6 *Act (21 U.S.C. 321) is amended by adding at the end*  
7 *the following:*

8           ***“(kk) PRIORITY SUPPLEMENT.—The term ‘priority*  
9 *supplement’ means a drug application referred to in section*  
10 *101(4) of the Food and Drug Administration Moderniza-*  
11 *tion Act of 1997 (111 Stat. 2298).”.***

12           ***(2) TREATMENT AS PRIORITY SUPPLEMENTS.—***  
13 *Section 505A of the Federal Food, Drug, and Cos-*  
14 *metic Act (21 U.S.C. 355a), as amended by section*  
15 *2(a)(2) of this Act, is amended by adding at the end*  
16 *the following:*

17           ***“(k) LABELING SUPPLEMENTS.—***

18           ***“(1) PRIORITY STATUS FOR PEDIATRIC SUPPLE-***  
19 *MENTS.—Any supplement to an application under*  
20 *section 505 proposing a labeling change pursuant to*  
21 *a report on a pediatric study under this section—*

22           ***“(A) shall be considered to be a priority***  
23 *supplement; and*

1           “(B) shall be subject to the performance  
2           goals established by the Commissioner for pri-  
3           ority drugs.

4           “(2) *DISPUTE RESOLUTION.*—If the Commis-  
5           sioner determines that an application with respect to  
6           which a pediatric study is conducted under this sec-  
7           tion is approvable and that the only open issue for  
8           final action on the application is the reaching of an  
9           agreement between the sponsor of the application and  
10          the Commissioner on appropriate changes to the label-  
11          ing for the drug that is the subject of the  
12          application—

13           “(A) not later than 180 days after the date  
14          of submission of the application—

15           “(i) the Commissioner shall request  
16          that the sponsor of the application make  
17          any labeling change that the Commissioner  
18          determines to be appropriate; and

19           “(ii) if the sponsor of the application  
20          does not agree to make a labeling change re-  
21          quested by the Commissioner by that date,  
22          the Commissioner shall immediately refer  
23          the matter to the Pediatric Advisory Sub-  
24          committee of the Anti-Infective Drugs Advi-  
25          sory Committee;

1           “(B) not later than 90 days after receiving  
2 the referral, the Pediatric Advisory Sub-  
3 committee of the Anti-Infective Drugs Advisory  
4 Committee shall—

5                   “(i) review the pediatric study reports;

6                   and

7                   “(ii) make a recommendation to the  
8 Commissioner concerning appropriate label-  
9 ing changes, if any;

10           “(C) the Commissioner shall consider the  
11 recommendations of the Pediatric Advisory Sub-  
12 committee of the Anti-Infective Drugs Advisory  
13 Committee and, if appropriate, not later than 30  
14 days after receiving the recommendation, make a  
15 request to the sponsor of the application to make  
16 any labeling change that the Commissioner de-  
17 termines to be appropriate; and

18           “(D) if the sponsor of the application, with-  
19 in 30 days after receiving a request under sub-  
20 paragraph (C), does not agree to make a labeling  
21 change requested by the Commissioner, the Com-  
22 missioner may deem the drug that is the subject  
23 of the application to be misbranded.”.

1 **SEC. 6. OFFICE OF PEDIATRIC THERAPEUTICS.**

2 (a) *ESTABLISHMENT.*—*The Secretary of Health and*  
3 *Human Services shall establish an Office of Pediatric*  
4 *Therapeutics within the Office of the Commissioner of Food*  
5 *and Drugs.*

6 (b) *DUTIES.*—*The Office of Pediatric Therapeutics*  
7 *shall be responsible for oversight and coordination of all ac-*  
8 *tivities of the Food and Drug Administration that may*  
9 *have any effect on a pediatric population or the practice*  
10 *of pediatrics or may in any other way involve pediatric*  
11 *issues.*

12 (c) *STAFF.*—*The staff of the Office of Pediatric Thera-*  
13 *peutics shall include—*

14 (1) *employees of the Department of Health and*  
15 *Human Services who, as of the date of enactment of*  
16 *this Act, exercise responsibilities relating to pediatric*  
17 *therapeutics;*

18 (2) *1 or more additional individuals with exper-*  
19 *tise concerning ethical issues presented by the conduct*  
20 *of clinical research in the pediatric population; and*

21 (3) *1 or more additional individuals with exper-*  
22 *tise in pediatrics who shall consult and collaborate*  
23 *with all components of the Food and Drug Adminis-*  
24 *tration concerning activities described in subsection*  
25 *(b).*

1 **SEC. 7. NEONATES.**

2 *Section 505A of the Federal Food, Drug, and Cosmetic*  
3 *Act (21 U.S.C. 355a) is amended in subsection (f) (as reded-*  
4 *ignated by section 2(a)(2) of this Act) by inserting “(includ-*  
5 *ing neonates in appropriate cases)” after “pediatric age*  
6 *groups”.*

7 **SEC. 8. SUNSET.**

8 *Section 505A of the Federal Food, Drug, and Cosmetic*  
9 *Act (21 U.S.C. 355a) is amended by striking subsection (i)*  
10 *(as redesignated by section 2(a)(2) of this Act) and insert-*  
11 *ing the following:*

12 *“(i) SUNSET.—A drug may not receive any 6-month*  
13 *period under subsection (a) or (b) unless—*

14 *“(1) on or before October 1, 2007, the Secretary*  
15 *makes a written request for pediatric studies of the*  
16 *drug;*

17 *“(2) on or before October 1, 2007, an approvable*  
18 *application for the drug is submitted under section*  
19 *505(b)(1); and*

20 *“(3) all requirements of this section are met.”.*

21 **SEC. 9. DISSEMINATION OF PEDIATRIC INFORMATION.**

22 *Section 505A of the Federal Food, Drug, and Cosmetic*  
23 *Act, as amended by section 5(b)(2) of this Act, is amended*  
24 *by adding at the end the following:*

25 *“(l) DISSEMINATION OF PEDIATRIC INFORMATION.—*

1           “(1) *IN GENERAL.*—Not later than 180 days  
 2           after the date of submission of a report on a pediatric  
 3           study under this section, the Commissioner shall make  
 4           available to the public a summary of the medical and  
 5           clinical pharmacology reviews of pediatric studies  
 6           conducted for the supplement, including by publica-  
 7           tion in the Federal Register.

8           “(2) *EFFECT OF SUBSECTION.*—Nothing in this  
 9           subsection alters or amends in any way section 552  
 10          of title 5 or section 1905 of title 18, United States  
 11          Code.”.

12 **SEC. 10. CLARIFICATION OF INTERACTION OF MARKET EX-**  
 13                                   **CLUSIVITY UNDER SECTION 505A OF THE**  
 14                                   **FEDERAL FOOD, DRUG, AND COSMETIC ACT**  
 15                                   **AND MARKET EXCLUSIVITY AWARDED TO AN**  
 16                                   **APPLICANT FOR APPROVAL OF A DRUG**  
 17                                   **UNDER SECTION 505(j) OF THAT ACT.**

18          Section 505A of the Federal Food, Drug, and Cosmetic  
 19          Act, as amended by section 9 of this Act, is amended by  
 20          adding at the end the following:

21          “(m) *CLARIFICATION OF INTERACTION OF MARKET*  
 22          *EXCLUSIVITY UNDER THIS SECTION AND MARKET EXCLU-*  
 23          *SIVITY AWARDED TO AN APPLICANT FOR APPROVAL OF A*  
 24          *DRUG UNDER SECTION 505(j).*—

1           “(1) *IN GENERAL.*—If a 180-day period under  
2           section 505(j)(5)(B)(iv) overlaps with a 6-month ex-  
3           tension under this section, so that the applicant for  
4           approval of a drug under section 505(j) entitled to the  
5           180-day period under that section loses a portion of  
6           the 180-day period to which the applicant is entitled  
7           for the drug, the 180-day period shall be extended—

8                   “(A) if the 180-day period would, but for  
9                   this subsection, expire after the 6-month exten-  
10                  sion, by the number of days of the overlap; or

11                  “(B) if the 180-day period would, but for  
12                  this subsection, expire during the 6-month exten-  
13                  sion, by 6 months.

14           “(2) *EFFECT OF SUBSECTION.*—Under no cir-  
15           cumstances shall application of this section result in  
16           an applicant for approval of a drug under section  
17           505(j) being enabled to commercially market the drug  
18           to the exclusion of a subsequent applicant for ap-  
19           proval of a drug under section 505(j) for more than  
20           180 days.”.

21 **SEC. 11. PROMPT APPROVAL OF GENERIC DRUGS WHEN PE-**

22 **DIATRIC INFORMATION ADDED TO LABELING.**

23           (a) *IN GENERAL.*—Section 505A of the Federal Food,  
24           Drug, and Cosmetic Act, as amended by section 10 of this

1 *Act, is amended by adding at the end the following sub-*  
2 *section:*

3       “(n) *PROMPT APPROVAL OF GENERIC DRUGS WHEN*  
4 *PEDIATRIC INFORMATION ADDED TO LABELING.—*

5               “(1) *IN GENERAL.—A drug for which an appli-*  
6 *cation has been submitted or approved under section*  
7 *505(j) and which otherwise meets all other applicable*  
8 *requirements under that section shall be considered el-*  
9 *igible for approval and shall not be considered mis-*  
10 *branded under section 502 even when its labeling*  
11 *omits a pediatric indication or other aspect of label-*  
12 *ing pertaining to pediatric use that is protected by*  
13 *patent or by market exclusivity pursuant to clause*  
14 *(iii) or (iv) of section 505(j)(5)(D).*

15               “(2) *LABELING OF GENERIC DRUG.—Notwith-*  
16 *standing the provisions of clause (iii) or (iv) of sec-*  
17 *tion 505(j)(5)(D), the Secretary may require that the*  
18 *labeling of a drug approved under section 505(j) that*  
19 *omits pediatric labeling pursuant to paragraph (1)*  
20 *include—*

21                       “(A) *a statement that the drug is not la-*  
22 *beled for the protected pediatric use; and*

23                       “(B) *any warnings against unsafe pediatric*  
24 *use that the Secretary considers necessary.*

1           “(3) *RULE OF CONSTRUCTION.*—Paragraphs 1  
2           and 2 of this subsection do not affect—

3                   “(A) *the availability or scope of exclusivity*  
4                   *under this section;*

5                   “(B) *the availability or scope of exclusivity*  
6                   *under section 505 for pediatric formulations; or*

7                   “(C) *except as expressly provided in para-*  
8                   *graph (1) and (2), the operation of section 505.”.*

9           (b) *EFFECTIVE DATE.*—*The amendments made by sub-*  
10 *section (a) take effect on the date of the enactment of this*  
11 *Act, including with respect to applications under section*  
12 *505(j) of the Federal Food, Drug, and Cosmetic Act that*  
13 *are approved or pending on that date.*

14 **SEC. 12. ADVERSE-EVENT REPORTING.**

15           (a) *TOLL-FREE NUMBER IN LABELING.*—*Not later*  
16 *than one year after the date of the enactment of this Act,*  
17 *the Secretary of Health and Human Services shall promul-*  
18 *gate a final rule requiring that the labeling of each drug*  
19 *for which an application is approved under section 505 of*  
20 *the Federal Food, Drug, and Cosmetic Act (regardless of*  
21 *the date on which approved) include the toll-free number*  
22 *maintained by the Secretary for the purpose of receiving*  
23 *reports of adverse events regarding drugs. With respect to*  
24 *the final rule:*

1           (1) *The rule shall provide for the implementation*  
2 *of such labeling requirement in a manner that the*  
3 *Secretary considers to be most likely to reach the*  
4 *broadest consumer audience.*

5           (2) *In promulgating the rule, the Secretary shall*  
6 *seek to minimize the cost of the rule on the pharmacy*  
7 *profession.*

8           (3) *The rule shall take effect not later than 60*  
9 *days after the date on which the rule is promulgated.*

10       **(b) DRUGS WITH PEDIATRIC MARKET EXCLUSIVITY.—**

11           (1) *IN GENERAL.—During the one-year begin-*  
12 *ning on the date on which a drug receives a period*  
13 *of market exclusivity under 505A of the Federal Food,*  
14 *Drug, and Cosmetic Act, any report of an adverse*  
15 *event regarding the drug that the Secretary of Health*  
16 *and Human Services receives shall be referred to the*  
17 *Office of Pediatric Therapeutics established under sec-*  
18 *tion 6 of this Act. In considering the report, the Di-*  
19 *rector of such Office shall provide for the review of the*  
20 *report by the Pediatric Advisory Subcommittee of the*  
21 *Anti-Infective Drugs Advisory Committee, including*  
22 *obtaining any recommendations of such Sub-*  
23 *committee regarding whether the Secretary should*  
24 *take action under the Federal Food, Drug, and Cos-*  
25 *metic Act in response to the report.*

1           (2) *RULE OF CONSTRUCTION.*—Paragraph (1)  
2           *may not be construed as restricting the authority of*  
3           *the Secretary of Health and Human Services to con-*  
4           *tinue carrying out the activities described in such*  
5           *paragraph regarding a drug after the one-year period*  
6           *described in such paragraph regarding the drug has*  
7           *expired.*

8 **SEC. 13. FOUNDATION FOR PEDIATRIC RESEARCH.**

9           *Title IV of the Public Health Service Act (42 U.S.C.*  
10          *281 et seq.) is amended by adding at the end the following*  
11          *part:*

12                   **“PART J—FOUNDATION FOR PEDIATRIC**  
13                                   **RESEARCH**

14 **“SEC. 499A. ESTABLISHMENT AND DUTIES OF FOUNDATION.**

15           “(a) *IN GENERAL.*—*The Secretary, acting through the*  
16          *Director of NIH and in consultation with the Commissioner*  
17          *of Food and Drugs, shall establish a nonprofit corporation*  
18          *to be known as the Foundation for Pediatric Research (here-*  
19          *after in this section referred to as the ‘Foundation’). The*  
20          *Foundation shall not be an agency or instrumentality of*  
21          *the United States Government.*

22           “(b) *PURPOSE OF FOUNDATION.*—*The purpose of the*  
23          *Foundation shall be to collect funds and award grants for*  
24          *research on drugs listed by the Secretary pursuant to sec-*  
25          *tion 409I(a)(1)(A).*

1       “(c) *CERTAIN ACTIVITIES OF FOUNDATION.*—

2               “(1) *IN GENERAL.*—*In carrying out subsection*  
3 *(b), the Foundation may solicit and accept gifts,*  
4 *grants, and other donations, establish accounts, and*  
5 *invest and expend funds in support of a program to*  
6 *encourage donations for the conduct of studies of*  
7 *drugs referred to in subsection (b).*

8               “(2) *FEEES.*—*The Foundation may assess fees for*  
9 *the provision of professional, administrative and*  
10 *management services by the Foundation in amounts*  
11 *determined reasonable and appropriate by the Execu-*  
12 *tive Director.*

13               “(3) *AUTHORITY OF FOUNDATION.*—*The Founda-*  
14 *tion shall be the sole entity responsible for carrying*  
15 *out the activities described in this subsection.*

16       “(d) *BOARD OF DIRECTORS.*—

17               “(1) *COMPOSITION.*—

18                       “(A) *The Foundation shall have a Board of*  
19 *Directors (hereafter referred to in this section as*  
20 *the ‘Board’), which shall be composed of ex offi-*  
21 *cio and appointed members in accordance with*  
22 *this subsection. Appointed members of the Board*  
23 *shall be the voting members.*

24                       “(B) *The ex officio members of the Board*  
25 *shall be—*

1           “(i) the Chairman and ranking minor-  
2           ity member of the Subcommittee on Health  
3           (Committee on Energy and Commerce) or  
4           their designees, in the case of the House of  
5           Representatives;

6           “(ii) the Chairman and ranking mi-  
7           nority member of the Committee on Health,  
8           Education, Labor and Pensions or their  
9           designees, in the case of the Senate;

10          “(iii) the Director of NIH; and

11          “(iv) the Commissioner of Food and  
12          Drugs.

13          “(C) The *ex officio* members of the Board  
14          under subparagraph (B) shall appoint to the  
15          Board 11 individuals from among a list of can-  
16          didates to be provided by the National Academy  
17          of Science. Of such appointed members—

18               “(i) 5 shall be representative of the ex-  
19               perts in pediatric medicine and research  
20               field;

21               “(ii) 1 shall be a biomedical ethicist;  
22               and

23               “(iii) 5 shall be representatives of the  
24               general public, which may include rep-  
25               resentatives of affected industries.

1           “(D)(i) Not later than 30 days after the  
2 date of the enactment of the Best Pharma-  
3 ceuticals for Children Act, the Director of NIH  
4 shall convene a meeting of the *ex officio* members  
5 of the Board to—

6           “(I) incorporate the Foundation and  
7 establish the general policies of the Founda-  
8 tion for carrying out the purposes of sub-  
9 section (b), including the establishment of  
10 the bylaws of the Foundation; and

11           “(II) appoint the members of the  
12 Board in accordance with subparagraph  
13 (C).

14           “(i) Upon the appointment of the members  
15 of the Board under clause (i)(II), the terms of  
16 service of the *ex officio* members of the Board as  
17 members of the Board shall terminate.

18           “(E) The agreement of not less than three-  
19 fifths of the members of the *ex officio* members of  
20 the Board shall be required for the appointment  
21 of each member to the initial Board.

22           “(F) No employee of the National Institutes  
23 of Health shall be appointed as a member of the  
24 Board.

25           “(2) CHAIR.—

1           “(A) *The ex officio members of the Board*  
2           *under paragraph (1)(B) shall designate an indi-*  
3           *vidual to serve as the initial Chair of the Board.*

4           “(B) *Upon the termination of the term of*  
5           *service of the initial Chair of the Board, the ap-*  
6           *pointed members of the Board shall elect a mem-*  
7           *ber of the Board to serve as the Chair of the*  
8           *Board.*

9           “(3) *TERMS AND VACANCIES.—*

10           “(A) *The term of office of each member of*  
11           *the Board appointed under paragraph (1)(C)*  
12           *shall be 5 years, except that the terms of offices*  
13           *for the initial appointed members of the Board*  
14           *shall expire as determined by the ex officio mem-*  
15           *bers and the Chair.*

16           “(B) *Any vacancy in the membership of the*  
17           *Board shall be filled in the manner in which the*  
18           *original position was made and shall not affect*  
19           *the power of the remaining members to execute*  
20           *the duties of the Board.*

21           “(C) *If a member of the Board does not*  
22           *serve the full term applicable under subpara-*  
23           *graph (A), the individual appointed to fill the*  
24           *resulting vacancy shall be appointed for the re-*

1           *mainder of the term of the predecessor of the in-*  
2           *dividual.*

3           “(D) *A member of the Board may continue*  
4           *to serve after the expiration of the term of the*  
5           *member until a successor is appointed.*

6           “(4) *COMPENSATION.—Members of the Board*  
7           *may not receive compensation for service on the*  
8           *Board. Such members may be reimbursed for travel,*  
9           *subsistence, and other necessary expenses incurred in*  
10          *carrying out the duties of the Board, as set forth in*  
11          *the bylaws issued by the Board.*

12          “(5) *MEETINGS AND QUORUM.—A majority of*  
13          *the members of the Board shall constitute a quorum*  
14          *for purposes of conducting the business of the Board.*

15          “(6) *CERTAIN BYLAWS.—*

16                 “(A) *In establishing bylaws under this sub-*  
17                 *section, the Board shall ensure that the following*  
18                 *are provided for:*

19                         “(i) *Policies for the selection of the offi-*  
20                         *cers, employees, and agents of the Founda-*  
21                         *tion.*

22                         “(ii) *Policies, including ethical stand-*  
23                         *ards, for the acceptance, solicitation, and*  
24                         *disposition of donations and grants to the*  
25                         *Foundation and for the disposition of the*

1           *assets of the Foundation. Policies with re-*  
2           *spect to ethical standards shall ensure that*  
3           *officers, employees and agents of the Foun-*  
4           *ation (including members of the Board)*  
5           *avoid encumbrances that would result in a*  
6           *conflict of interest, including a financial*  
7           *conflict of interest or a divided allegiance.*  
8           *Such policies shall include requirements for*  
9           *the provision of information concerning any*  
10          *ownership or controlling interest in entities*  
11          *related to the activities of the Foundation*  
12          *by such officers, employees and agents and*  
13          *their spouses and relatives.*

14                 *“(iii) Policies for the conduct of the*  
15                 *general operations of the Foundation.*

16                 *“(B) In establishing bylaws under this sub-*  
17                 *section, the Board shall ensure that such bylaws*  
18                 *(and activities carried out under the bylaws) do*  
19                 *not—*

20                         *“(i) reflect unfavorably upon the abil-*  
21                         *ity of the Foundation to carry out its re-*  
22                         *sponsibilities or official duties in a fair and*  
23                         *objective manner; or*

24                         *“(ii) compromise, or appear to com-*  
25                         *promise, the integrity of any governmental*

1                   *agency or program, or any officer or em-*  
2                   *ployee involved in such program.*

3           “(e) *INCORPORATION.*—*The initial members of the*  
4 *Board shall serve as incorporators and shall take whatever*  
5 *actions necessary to incorporate the Foundation.*

6           “(f) *NONPROFIT STATUS.*—*The Foundation shall be*  
7 *considered to be a corporation under section 501(c) of the*  
8 *Internal Revenue Code of 1986, and shall be subject to the*  
9 *provisions of such section.*

10          “(g) *EXECUTIVE DIRECTOR.*—

11               “(1) *IN GENERAL.*—*The Foundation shall have*  
12 *an Executive Director who shall be appointed by the*  
13 *Board and shall serve at the pleasure of the Board.*  
14 *The Executive Director shall be responsible for the*  
15 *day-to-day operations of the Foundation and shall*  
16 *have such specific duties and responsibilities as the*  
17 *Board shall prescribe.*

18               “(2) *COMPENSATION.*—*The rate of compensation*  
19 *of the Executive Director shall be fixed by the Board.*

20          “(h) *POWERS.*—*In carrying out subsection (b), the*  
21 *Foundation shall operate under the direction of its Board,*  
22 *and may—*

23               “(1) *adopt, alter, and use a corporate seal, which*  
24 *shall be judicially noticed;*

1           “(2) provide for 1 or more officers, employees,  
2           and agents, as may be necessary, define their duties,  
3           and require surety bonds or make other provisions  
4           against losses occasioned by acts of such persons;

5           “(3) hire, promote, compensate, and discharge of-  
6           ficers and employees of the Foundation, and define  
7           the duties of the officers and employees;

8           “(4) with the consent of any executive depart-  
9           ment or independent agency, use the information,  
10          services, staff, and facilities of such in carrying out  
11          this section;

12          “(5) sue and be sued in its corporate name, and  
13          complain and defend in courts of competent jurisdic-  
14          tion;

15          “(6) modify or consent to the modification of  
16          any contract or agreement to which it is a party or  
17          in which it has an interest under this part;

18          “(7) establish a process for the selection of can-  
19          didates for positions under subsection (c);

20          “(8) solicit, accept, hold, administer, invest, and  
21          spend any gift, devise, or bequest of real or personal  
22          property made to the Foundation;

23          “(9) enter into such other contracts, leases, coop-  
24          erative agreements, and other transactions as the Ex-

1 *ecutive Director considers appropriate to conduct the*  
2 *activities of the Foundation; and*

3 *“(10) exercise other powers as set forth in this*  
4 *section, and such other incidental powers as are nec-*  
5 *essary to carry out its powers, duties, and functions*  
6 *in accordance with this part.*

7 *“(i) ADMINISTRATIVE CONTROL.—No participant in*  
8 *the program established under this part shall exercise any*  
9 *administrative control over any Federal employee, nor shall*  
10 *the Foundation attempt to influence an executive branch*  
11 *agency or employee.*

12 *“(j) GENERAL PROVISIONS.—*

13 *“(1) FOUNDATION INTEGRITY.—The members of*  
14 *the Board shall be accountable for the integrity of the*  
15 *operations of the Foundation and shall ensure such*  
16 *integrity through the development and enforcement of*  
17 *criteria and procedures relating to standards of con-*  
18 *duct (including those developed under subsection*  
19 *(d)(6)(A)(ii), financial disclosure statements, conflict*  
20 *of interest rules, recusal and waiver rules, audits and*  
21 *other matter determined appropriate by the Board.*

22 *“(2) FINANCIAL CONFLICTS OF INTEREST.—Any*  
23 *individual who is an officer, employee, or member of*  
24 *the Board of the Foundation may not (in accordance*  
25 *with policies and requirements developed under sub-*

1 *section (d)(6)(A)(ii) personally or substantially par-*  
2 *ticipate in the consideration or determination by the*  
3 *Foundation of any matter that would directly or pre-*  
4 *dictably affect any financial interest of the individual*  
5 *or a relative (as such term is defined in section*  
6 *109(16) of the Ethics in Government Act of 1978) of*  
7 *the individual, of any business organization or other*  
8 *entity, or of which the individual is an officer or em-*  
9 *ployee, or is negotiating for employment, or in which*  
10 *the individual has any other financial interest.*

11 *“(3) AUDITS; AVAILABILITY OF RECORDS.—The*  
12 *Foundation shall—*

13 *“(A) provide for annual audits of the finan-*  
14 *cial condition of the Foundation; and*

15 *“(B) make such audits, and all other*  
16 *records, documents, and other papers of the*  
17 *Foundation, available to the Secretary and the*  
18 *Comptroller General of the United States for ex-*  
19 *amination or audit.*

20 *“(4) REPORTS.—*

21 *“(A) Not later than 5 months following the*  
22 *end of each fiscal year, the Foundation shall*  
23 *publish a report describing the activities of the*  
24 *Foundation during the preceding fiscal year.*  
25 *Each such report shall include for the fiscal year*

1           *involved a comprehensive statement of the oper-*  
2           *ations, activities, financial condition, and ac-*  
3           *complishments of the Foundation.*

4           “(B) *With respect to the financial condition*  
5           *of the Foundation, each report under subpara-*  
6           *graph (A) shall include the source, and a de-*  
7           *scription of, all gifts or grants to the Foundation*  
8           *of real or personal property, and the source and*  
9           *amount of all gifts or grants to the Foundation*  
10          *of money. Each such report shall include a speci-*  
11          *fication of any restrictions on the purposes for*  
12          *which gifts or grants to the Foundation may be*  
13          *used.*

14          “(C) *The Foundation shall make copies of*  
15          *each report submitted under subparagraph (A)*  
16          *available for public inspection, and shall upon*  
17          *request provide a copy of the report to any indi-*  
18          *vidual for a charge not exceeding the cost of pro-*  
19          *viding the copy.*

20          “(D) *The Board shall annually hold a pub-*  
21          *lic meeting to summarize the activities of the*  
22          *Foundation and distribute written reports con-*  
23          *cerning such activities and the scientific results*  
24          *derived from such activities.*

1           “(5) *SERVICE OF FEDERAL EMPLOYEES.*—*Fed-*  
2           *eral employees may serve on committees advisory to*  
3           *the Foundation and otherwise cooperate with and as-*  
4           *sis*t the Foundation in carrying out its function, so  
5           long as the employees do not direct or control Foun-  
6           dation activities.

7           “(6) *RELATIONSHIP WITH EXISTING ENTITIES.*—  
8           *The Foundation may, pursuant to appropriate agree-*  
9           *ments, acquire the resources of existing nonprofit pri-*  
10          *vate corporations with missions similar to the pur-*  
11          *poses of the Foundation.*

12          “(7) *INTELLECTUAL PROPERTY RIGHTS.*—*The*  
13          *Board may adopt written standards with respect to*  
14          *the ownership of any intellectual property rights de-*  
15          *ri*ved from the collaborative efforts of the Foundation  
16          prior to the commencement of such efforts.

17          “(8) *NATIONAL INSTITUTES OF HEALTH AMEND-*  
18          *MENTS OF 1990.*—*The activities conducted in support*  
19          *of the National Institutes of Health Amendments of*  
20          *1990 (Public Law 101–613), and the amendments*  
21          *made by such Act, shall not be nullified by the enact-*  
22          *ment of this section.*

23          “(9) *LIMITATION OF ACTIVITIES.*—*The Founda-*  
24          *tion shall exist solely as an entity to collect funds and*

1       *award grants for research on drugs listed by the Sec-*  
2       *retary pursuant to section 409I(a)(1)(A).*

3               “(10) *TRANSFER OF FUNDS.—The Foundation*  
4       *may transfer funds to the National Institutes of*  
5       *Health. Any funds transferred under this paragraph*  
6       *shall be subject to all Federal limitations relating to*  
7       *federally-funded research.*

8               “(k) *DUTIES OF THE DIRECTOR.—*

9               “(1) *APPLICABILITY OF CERTAIN STANDARDS TO*  
10       *NON-FEDERAL EMPLOYEES.—In the case of any indi-*  
11       *vidual who is not an employee of the Federal Govern-*  
12       *ment and who serves in association with the National*  
13       *Institutes of Health, with respect to financial assist-*  
14       *ance received from the Foundation, the Foundation*  
15       *may not provide the assistance of, or otherwise permit*  
16       *the work at the National Institutes of Health to begin*  
17       *until a memorandum of understanding between the*  
18       *individual and the Director of NIH, or the designee*  
19       *of such Director, has been executed specifying that the*  
20       *individual shall be subject to such ethical and proce-*  
21       *dural standards of conduct relating to duties per-*  
22       *formed at the National Institutes of Health, as the*  
23       *Director of NIH determines is appropriate.*

1           “(2) *SUPPORT SERVICES.*—*The Director of NIH*  
2           *shall provide facilities, utilities and support services*  
3           *to the Foundation.*

4           “(1) *REPORTS OF STUDIES; LABELING CHANGES.*—

5           “(1) *IN GENERAL.*—*Upon completion of a pedi-*  
6           *atric study conducted pursuant to this section, a re-*  
7           *port concerning the study shall be submitted to the*  
8           *Director of National Institutes of Health and the*  
9           *Commissioner of Food and Drugs. The report shall*  
10          *include all data generated in connection with the*  
11          *study.*

12          “(2) *AVAILABILITY OF REPORTS; ACTION BY*  
13          *FOOD AND DRUG ADMINISTRATION; LABELING*  
14          *CHANGES.*—*With respect to a report submitted under*  
15          *paragraph (1), the provisions of paragraphs (3)(B)*  
16          *through (8) of section 409I(c) apply to such report to*  
17          *the same extent and in the same manner as such pro-*  
18          *vision apply to a report submitted under section*  
19          *409I(c)(3)(A).*

20          “(m) *FUNDING.*—

21          “(1) *AUTHORIZATION OF APPROPRIATIONS.*—*For*  
22          *the purpose of carrying out this part, there are au-*  
23          *thorized to be appropriated such sums as may be nec-*  
24          *essary for fiscal year 2002 and each subsequent fiscal*  
25          *year.*

1           “(2) *LIMITATION REGARDING OTHER FUNDS.—*  
2           *Amounts appropriated under any provision of law*  
3           *other than paragraph (1) may not be expended to es-*  
4           *tablish or operate the Foundation.”.*

5   **SEC. 14. STUDY CONCERNING RESEARCH INVOLVING CHIL-**  
6                                   **DREN.**

7           (a) *CONTRACT WITH INSTITUTE OF MEDICINE.—The*  
8           *Secretary of Health and Human Services shall enter into*  
9           *a contract with the Institute of Medicine for—*

10                   (1) *the conduct, in accordance with subsection*  
11                   *(b), of a review of—*

12                                   (A) *Federal regulations in effect on the date*  
13                                   *of the enactment of this Act relating to research*  
14                                   *involving children;*

15                                   (B) *federally-prepared or supported reports*  
16                                   *relating to research involving children; and*

17                                   (C) *federally-supported evidence-based re-*  
18                                   *search involving children; and*

19                   (2) *the submission to the appropriate committees*  
20                   *of Congress, by not later than 2 years after the date*  
21                   *of enactment of this Act, of a report concerning the*  
22                   *review conducted under paragraph (1) that includes*  
23                   *recommendations on best practices relating to re-*  
24                   *search involving children.*

1       (b) *AREAS OF REVIEW.*—*In conducting the review*  
2 *under subsection (a)(1), the Institute of Medicine shall con-*  
3 *sider the following:*

4           (1) *The written and oral process of obtaining*  
5 *and defining “assent”, “permission” and “informed*  
6 *consent” with respect to child clinical research par-*  
7 *ticipants and the parents, guardians, and the indi-*  
8 *viduals who may serve as the legally authorized rep-*  
9 *resentatives of such children (as defined in subpart A*  
10 *of part 46 of title 45, Code of Federal Regulations).*

11          (2) *The expectations and comprehension of child*  
12 *research participants and the parents, guardians, or*  
13 *legally authorized representatives of such children, for*  
14 *the direct benefits and risks of the child’s research in-*  
15 *volvement, particularly in terms of research versus*  
16 *therapeutic treatment.*

17          (3) *The definition of “minimal risk” with re-*  
18 *spect to a healthy child or a child with an illness.*

19          (4) *The appropriateness of the regulations appli-*  
20 *cable to children of differing ages and maturity levels,*  
21 *including regulations relating to legal status.*

22          (5) *Whether payment (financial or otherwise)*  
23 *may be provided to a child or his or her parent,*  
24 *guardian, or legally authorized representative for the*

1        *participation of the child in research, and if so, the*  
2        *amount and type of payment that may be made.*

3                *(6) Compliance with the regulations referred to*  
4        *in subsection (a)(1)(A), the monitoring of such com-*  
5        *pliance (including the role of institutional review*  
6        *boards), and the enforcement actions taken for viola-*  
7        *tions of such regulations.*

8                *(7) The unique roles and responsibilities of insti-*  
9        *tutional review boards in reviewing research involv-*  
10        *ing children, including composition of membership on*  
11        *institutional review boards.*

12        *(c) REQUIREMENTS OF EXPERTISE.—The Institute of*  
13        *Medicine shall conduct the review under subsection (a)(1)*  
14        *and make recommendations under subsection (a)(2) in con-*  
15        *junction with experts in pediatric medicine, pediatric re-*  
16        *search, and the ethical conduct of research involving chil-*  
17        *dren.*

18        **SEC. 15. STUDY ON EFFECTS OF THIS ACT.**

19        *Not later than October 1, 2006, the Comptroller Gen-*  
20        *eral of the United States shall submit to the Congress and*  
21        *the Secretary of Health and Human Services a report that*  
22        *describes the following:*

23                *(1) The effectiveness of the amendments made by*  
24        *this Act in ensuring that all drugs used by children*  
25        *are tested and properly labeled, including—*

1           (A) the number and importance for children  
2 of drugs that are being tested as a result of such  
3 amendments, and the importance for children,  
4 health care providers, parents, and others of la-  
5 beling changes made as a result of such testing;

6           (B) the number and importance for children  
7 of drugs that are not being tested for their use  
8 notwithstanding the amendments, and possible  
9 reason for this; and

10           (C) the number of drugs for which pediatric  
11 testing has been done, for which a period of mar-  
12 ket exclusivity has been granted, and for which  
13 labeling changes required the use of the dispute  
14 resolution process established pursuant to the  
15 amendments, together with a description of the  
16 outcomes of such process, including a description  
17 of the disputes and the recommendations of the  
18 advisory committee.

19           (2) The economic impact of the amendments  
20 made by this Act, including an estimate of—

21           (A) costs to taxpayers in the form of higher  
22 expenditures by Medicaid and other government  
23 programs;

24           (B) costs to consumers as a result of any  
25 delay in the availability of lower cost generic

1           *equivalents of drugs tested and granted exclu-*  
2           *sivity pursuant to such amendments, and loss of*  
3           *revenue by the generic drug industry and any*  
4           *other affected industry as a result of any such*  
5           *delay; and*

6                   *(C) benefits to the government, to private*  
7           *insurers, and to consumers resulting from de-*  
8           *creased health care costs, including—*

9                           *(i) decreased hospitalizations, due to*  
10           *more appropriate and more effective use of*  
11           *medications in children as a result of test-*  
12           *ing and re-labeling because of such amend-*  
13           *ments;*

14                           *(ii) direct and indirect benefits associ-*  
15           *ated with fewer physician visits not related*  
16           *to hospitalization;*

17                           *(iii) benefits to children from missing*  
18           *less time at school and being less affected by*  
19           *chronic illnesses, thereby allowing a better*  
20           *quality of life;*

21                           *(iv) benefits to consumers from lower*  
22           *health insurance premiums due to lower*  
23           *treatment costs and hospitalization rates;*  
24           *and*

1                   (v) benefits to employers from reduced  
2                   need for employees to care for family mem-  
3                   bers.

4                   (3) *The nature and types of studies in children*  
5                   *of drugs granted a period of market exclusivity pur-*  
6                   *suant to the amendments made by this Act, including*  
7                   *a description of the complexity of such studies, the*  
8                   *number of study sites necessary to obtain appropriate*  
9                   *data, and the numbers of children involved in any*  
10                   *clinical studies, and the cost of such studies for each*  
11                   *type of study identified.*

12                   (4) *The increased pediatric research capability,*  
13                   *both private and government-funded, associated with*  
14                   *the amendments made by this Act.*

15 **SEC. 16. MINORITY CHILDREN AND PEDIATRIC-EXCLU-**  
16 **SIVITY PROGRAM.**

17                   (a) *PROTOCOLS FOR PEDIATRIC STUDIES.*—Section  
18 *505A of the Federal Food, Drug, and Cosmetic Act (21*  
19 *U.S.C. 355a) is amended in subsection (c)(2) (as redesign-*  
20 *ated by section 2(a)(2) of this Act) by inserting after the*  
21 *first sentence the following: “In reaching an agreement re-*  
22 *garding written protocols, the Secretary shall take into ac-*  
23 *count adequate representation of children of ethnic and ra-*  
24 *cial minorities.”.*

25                   (b) *STUDY BY GENERAL ACCOUNTING OFFICE.*—

1           (1) *IN GENERAL.*—*The Comptroller General of*  
2 *the United States shall conduct a study for the pur-*  
3 *pose of determining the following:*

4                   (A) *The extent to which children of ethnic*  
5 *and racial minorities are adequately represented*  
6 *in studies under section 505A of the Federal*  
7 *Food, Drug, and Cosmetic Act; and to the extent*  
8 *ethnic and racial minorities are not adequately*  
9 *represented, the reasons for such under represen-*  
10 *tation and recommendations to increase such*  
11 *representation.*

12                   (B) *Whether the Food and Drug Adminis-*  
13 *tration has appropriate management systems to*  
14 *monitor the representation of the children of eth-*  
15 *nic and racial minorities in such studies.*

16                   (C) *Whether drugs used to address diseases*  
17 *that disproportionately affect racial and ethnic*  
18 *minorities are being studied for their safety and*  
19 *effectiveness under section 505A of the Federal*  
20 *Food, Drug, and Cosmetic Act.*

21           (2) *DATE CERTAIN FOR COMPLETING STUDY.*—  
22 *Not later than January 10, 2003, the Comptroller*  
23 *General shall complete the study required in para-*  
24 *graph (1) and submit to the Congress a report de-*  
25 *scribing the findings of the study.*

1 **SEC. 17. TECHNICAL AND CONFORMING AMENDMENTS.**

2 *Section 505A of the Federal Food, Drug, and Cosmetic*  
3 *Act (21 U.S.C. 355a) is amended—*

4 *(1)(A) by striking “(j)(4)(D)(ii)” each place such*  
5 *term appears and inserting “(j)(5)(D)(ii)”;* and

6 *(B) by striking “(j)(4)(D)” each place such term*  
7 *appears and inserting “(j)(5)(D)”;* and

8 *(2)(A) in subsection (c) (as redesignated by sec-*  
9 *tion 2(a)(2) of this Act), in each of paragraphs (1)*  
10 *through (3), by striking “subsection (a) or (c)” and*  
11 *inserting “subsection (a) or (b)”;* and

12 *(B) in subsection (d) (as so redesignated), in the*  
13 *last sentence, by striking “subsection (a) or (c)” and*  
14 *inserting “subsection (a) or (b)”.*



**Union Calendar No. 167**

107TH CONGRESS  
1ST SESSION

**H. R. 2887**

**[Report No. 107-277]**

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**A BILL**

To amend the Federal Food, Drug, and Cosmetic Act to improve the safety and efficacy of pharmaceuticals for children.

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NOVEMBER 9, 2001

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed