

107TH CONGRESS  
1ST SESSION

**H. R. 2887**

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**AN ACT**

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



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## AN ACT

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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Best Pharmaceuticals  
3 for Children Act”.

4 **SEC. 2. PEDIATRIC STUDIES OF ALREADY-MARKETED**  
5 **DRUGS.**

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

9 (1) by striking subsection (b); and

10 (2) by redesignating subsections (c) through  
11 through (k) as subsections (b) through (j), respec-  
12 tively.

13 (b) CONFORMING AMENDMENTS.—Section 505A of  
14 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
15 355a) is amended in subsection (b) (as redesignated by  
16 subsection (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  
21 and”; 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  
6 (relating to clinical research) as section 409G;

7 (2) by redesignating the second section 409D  
8 (relating to enhancement awards) as section 409H;

9 and

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

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

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

15 “(1) IN GENERAL.—Not later than 1 year after  
16 the date of enactment of this section, the Secretary,  
17 acting through the Director of the National Insti-  
18 tutes of Health and in consultation with the Com-  
19 missioner of Food and Drugs and experts in pedi-  
20 atric research, shall develop, prioritize, and publish  
21 an annual list of approved drugs for which—

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

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

1 505(j) of the Federal Food, Drug, and Cos-  
2 metic 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,  
8 a referral for inclusion on such list; and

9 “(B) additional studies are needed to as-  
10 sess the safety and effectiveness of the use of  
11 the drug 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  
18 in 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  
2 Secretary shall award contracts to entities that have the  
3 expertise to conduct pediatric clinical trials (including  
4 qualified universities, hospitals, laboratories, contract re-  
5 search organizations, federally funded programs such as  
6 pediatric pharmacology research units, other public or pri-  
7 vate institutions, or individuals) to enable the entities to  
8 conduct pediatric studies concerning one or more drugs  
9 identified in 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 Di-  
17       rector of National Institutes of Health, may  
18       issue a written request (which shall include a  
19       timeframe for negotiations for an agreement)  
20       for pediatric studies concerning a drug identi-  
21       fied in the list described in subsection (a) to all  
22       holders of an approved application for the drug  
23       under section 505 of the Federal Food, Drug,  
24       and Cosmetic Act. Such a written request shall  
25       be made in a manner equivalent to the manner

1 in which a written request is made under sub-  
2 section (a) or (b) of section 505A of the Fed-  
3 eral Food, Drug, and Cosmetic Act, including  
4 with respect to information provided on the pe-  
5 diatric studies to be conducted pursuant to the  
6 request.

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

18 “(C) DISQUALIFICATION.—A holder that  
19 receives a first right of refusal shall not be enti-  
20 tled to respond to a request for contract pro-  
21 posals under subparagraph (B).

22 “(D) GUIDANCE.—Not later than 270 days  
23 after the date of enactment of this section, the  
24 Commissioner of Food and Drugs shall promul-  
25 gate guidance to establish the process for the

1            submission of responses to written requests  
2            under subparagraph (A).

3            “(2) CONTRACTS.—A contract under this sec-  
4            tion may be awarded only if a proposal for the con-  
5            tract is submitted to the Secretary in such form and  
6            manner, and containing such agreements, assur-  
7            ances, and information as the Secretary determines  
8            to be necessary to carry out this section.

9            “(3) REPORTING OF STUDIES.—

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

17            “(B) AVAILABILITY OF REPORTS.—Each  
18            report submitted under subparagraph (A) shall  
19            be considered to be in the public domain, and  
20            shall be assigned a docket number by the Com-  
21            missioner of Food and Drugs. An interested  
22            person may submit written comments con-  
23            cerning such pediatric studies to the Commis-  
24            sioner of Food and Drugs, and the written com-

1           ments shall become part of the docket file with  
2           respect to each of the drugs.

3           “(C) ACTION BY COMMISSIONER.—The  
4           Commissioner of Food and Drugs shall take ap-  
5           propriate action in response to the reports sub-  
6           mitted under subparagraph (A) in accordance  
7           with paragraph (4).

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

12           “(A) review the report and such other data  
13           as are available concerning the safe and effec-  
14           tive use in the pediatric population of the drug  
15           studied; and

16           “(B) negotiate with the holders of ap-  
17           proved applications for the drug studied for any  
18           labeling changes that the Commissioner of Food  
19           and Drugs determines to be appropriate and re-  
20           quests the holders to make; and

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

1           “(ii) publish in the Federal Register a  
2           summary of the report and a copy of any re-  
3           quested labeling changes.

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

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

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

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

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

23           “(6) FDA DETERMINATION.—Not later than 30  
24           days after receiving a recommendation from the  
25           Subcommittee under paragraph (5)(B)(ii) with re-

1 spect to a drug, the Commissioner of Food and  
2 Drugs shall consider the recommendation and, if ap-  
3 propriate, make a request to the holders of approved  
4 applications for the drug to make any labeling  
5 change that the Commissioner of Food and Drugs  
6 determines to be appropriate.

7 “(7) FAILURE TO AGREE.—If a holder of an  
8 approved application for a drug, within 30 days  
9 after receiving a request to make a labeling change  
10 under paragraph (6), does not agree to make a re-  
11 quested labeling change, the Commissioner may  
12 deem the drug to be misbranded under the Federal  
13 Food, Drug, and Cosmetic Act.

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

21 “(d) CONFIDENTIAL COMMERCIAL INFORMATION;  
22 TRADE SECRETS.—Nothing in this section requires or au-  
23 thorizes the use or disclosure of confidential commercial  
24 information or trade secrets.

25 “(e) AUTHORIZATION OF APPROPRIATIONS.—

1           “(1) IN GENERAL.—For the purpose of car-  
2           rying out this section, there are authorized to be ap-  
3           propriated \$200,000,000 for fiscal year 2002, and  
4           such sums as may be necessary for each of the fiscal  
5           years 2003 through 2007.

6           “(2) AVAILABILITY.—Any amount appropriated  
7           under paragraph (1) shall remain available to carry  
8           out this section until expended.”.

9   **SEC. 4. WRITTEN REQUEST TO HOLDERS OF APPROVED AP-**  
10                           **PLICATIONS FOR DRUGS THAT HAVE MAR-**  
11                           **KET EXCLUSIVITY.**

12           Section 505A of the Federal Food, Drug, and Cos-  
13           metic Act (21 U.S.C. 355a) is amended in subsection (c)  
14           (as redesignated by section 2(a)(2) of this Act) by adding  
15           at the end the following:

16           “(4) WRITTEN REQUEST TO HOLDERS OF AP-  
17           PROVED APPLICATIONS FOR DRUGS THAT HAVE  
18           MARKET EXCLUSIVITY.—

19                           “(A) REQUEST AND RESPONSE.—If the  
20           Secretary makes a written request for pediatric  
21           studies under subsection (b) to the holder of an  
22           application approved under section 505(b)(1),  
23           the holder, not later than 180 days after receiv-  
24           ing the written request, shall respond to the

1 Secretary as to the intention of the holder to  
2 act on the request by—

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

6 “(ii) indicating that the holder does  
7 not agree to the request.

8 “(B) NO AGREEMENT TO REQUEST.—

9 “(i) REFERRAL.—If the holder does  
10 not agree to a written request within the  
11 time period specified in subparagraph (A),  
12 and if the Secretary determines that there  
13 is a continuing need for information relat-  
14 ing to the use of the drug in the pediatric  
15 population (including neonates as appro-  
16 priate), the Secretary shall refer the drug  
17 to the Foundation for Pediatric Research  
18 established under section 499A of the Pub-  
19 lic Health Service Act (referred to in this  
20 paragraph as the ‘Foundation’) for consid-  
21 eration for the conduct of the pediatric  
22 studies described in the written request.

23 “(ii) PUBLIC NOTICE.—The Secretary  
24 shall give public notice of a referral under  
25 clause (i), including notice of the name of

1           the drug, the name of the manufacturer,  
2           and the indication to be studied.

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

11          “(D) CONFIDENTIAL COMMERCIAL INFOR-  
12          MATION; TRADE SECRETS.—Nothing in this  
13          paragraph requires or authorizes the use or dis-  
14          closure of confidential commercial information  
15          or trade secrets.

16          “(E) NO REQUIREMENT TO REFER.—  
17          Nothing in this subsection shall be construed to  
18          require that every declined written request shall  
19          be referred to the Foundation.”.

20   **SEC. 5. TIMELY LABELING CHANGES FOR DRUGS GRANTED**  
21                   **EXCLUSIVITY; DRUG FEES.**

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

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

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

4 (b) LABELING CHANGES.—

5 (1) DEFINITION OF PRIORITY SUPPLEMENT.—

6 Section 201 of the Federal Food Drug, and Cos-  
7 metic Act (21 U.S.C. 321) is amended by adding at  
8 the end the following:

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

13 (2) TREATMENT AS PRIORITY SUPPLE-

14 MENTS.—Section 505A of the Federal Food, Drug,  
15 and Cosmetic Act (21 U.S.C. 355a), as amended by  
16 section 2(a)(2) of this Act, is amended by adding at  
17 the end the following:

18 “(k) LABELING SUPPLEMENTS.—

19 “(1) PRIORITY STATUS FOR PEDIATRIC SUP-  
20 PLEMENTS.—Any supplement to an application  
21 under section 505 proposing a labeling change pur-  
22 suant to a report on a pediatric study under this  
23 section—

24 “(A) shall be considered to be a priority  
25 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  
10          and the Commissioner on appropriate changes to the  
11          labeling 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  
21                         requested by the Commissioner by that  
22                         date, the Commissioner shall immediately  
23                         refer the matter to the Pediatric Advisory  
24                         Subcommittee of the Anti-Infective Drugs  
25                         Advisory 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 la-  
9 beling changes, if any;

10           “(C) the Commissioner shall consider the  
11 recommendations of the Pediatric Advisory  
12 Subcommittee of the Anti-Infective Drugs Advi-  
13 sory Committee and, if appropriate, not later  
14 than 30 days after receiving the recommenda-  
15 tion, make a request to the sponsor of the ap-  
16 plication to make any labeling change that the  
17 Commissioner determines to be appropriate;  
18 and

19           “(D) if the sponsor of the application,  
20 within 30 days after receiving a request under  
21 subparagraph (C), does not agree to make a la-  
22 beling change requested by the Commissioner,  
23 the Commissioner may deem the drug that is  
24 the subject of the application to be mis-  
25 branded.”.

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  
5 Food and Drugs.

6 (b) DUTIES.—The Office of Pediatric Therapeutics  
7 shall be responsible for oversight and coordination of all  
8 activities 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  
13 Therapeutics 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 con-  
20 duct of clinical research in the pediatric population;  
21 and

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

26 (b).

1 **SEC. 7. NEONATES.**

2 Section 505A of the Federal Food, Drug, and Cos-  
3 metic Act (21 U.S.C. 355a) is amended in subsection (f)  
4 (as redesignated by section 2(a)(2) of this Act) by insert-  
5 ing “(including neonates in appropriate cases)” after “pe-  
6 diatric age groups”.

7 **SEC. 8. SUNSET.**

8 Section 505A of the Federal Food, Drug, and Cos-  
9 metic Act (21 U.S.C. 355a) is amended by striking sub-  
10 section (i) (as redesignated by section 2(a)(2) of this Act)  
11 and inserting 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 Sec-  
15 retary makes a written request for pediatric studies  
16 of the drug;

17 “(2) on or before October 1, 2007, an approv-  
18 able application for the drug is submitted under sec-  
19 tion 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 Cos-  
23 metic Act, as amended by section 5(b)(2) of this Act, is  
24 amended 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 pedi-  
3 atric study under this section, the Commissioner  
4 shall make available to the public a summary of the  
5 medical and clinical pharmacology reviews of pedi-  
6 atric studies conducted for the supplement, including  
7 by publication 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 Cos-  
19 metic Act, as amended by section 9 of this Act, is amended  
20 by adding at the end the following:

21           “(m) CLARIFICATION OF INTERACTION OF MARKET  
22 EXCLUSIVITY UNDER THIS SECTION AND MARKET EX-  
23 CLUSIVITY AWARDED TO AN APPLICANT FOR APPROVAL  
24 OF A 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  
5 the 180-day period under that section loses a portion  
6 of the 180-day period to which the applicant is enti-  
7 tled for the drug, the 180-day period shall be  
8 extended—

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

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

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

1 **SEC. 11. PROMPT APPROVAL OF GENERIC DRUGS WHEN**  
2 **PEDIATRIC INFORMATION ADDED TO LABEL-**  
3 **ING.**

4 (a) IN GENERAL.—Section 505A of the Federal  
5 Food, Drug, and Cosmetic Act, as amended by section 10  
6 of this Act, is amended by adding at the end the following  
7 subsection:

8 “(n) PROMPT APPROVAL OF GENERIC DRUGS WHEN  
9 PEDIATRIC INFORMATION ADDED TO LABELING.—

10 “(1) IN GENERAL.—A drug for which an appli-  
11 cation has been submitted or approved under section  
12 505(j) and which otherwise meets all other applica-  
13 ble requirements under that section shall be consid-  
14 ered eligible for approval and shall not be considered  
15 misbranded under section 502 even when its labeling  
16 omits a pediatric indication or other aspect of label-  
17 ing pertaining to pediatric use that is protected by  
18 patent or by market exclusivity pursuant to clause  
19 (iii) or (iv) of section 505(j)(5)(D).

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

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

3           “(B) any warnings against unsafe pediatric  
4           use that the Secretary considers necessary.

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

7           “(A) the availability or scope of exclusivity  
8           under this section;

9           “(B) the availability or scope of exclusivity  
10          under section 505 for pediatric formulations; or

11          “(C) except as expressly provided in para-  
12          graph (1) and (2), the operation of section  
13          505.”.

14          (b) EFFECTIVE DATE.—The amendments made by  
15          subsection (a) take effect on the date of the enactment  
16          of this Act, including with respect to applications under  
17          section 505(j) of the Federal Food, Drug, and Cosmetic  
18          Act that are approved or pending on that date.

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

20          (a) TOLL-FREE NUMBER IN LABELING.—Not later  
21          than one year after the date of the enactment of this Act,  
22          the Secretary of Health and Human Services shall promul-  
23          gate a final rule requiring that the labeling of each drug  
24          for which an application is approved under section 505  
25          of the Federal Food, Drug, and Cosmetic Act (regardless

1 of the date on which approved) include the toll-free num-  
2 ber maintained by the Secretary for the purpose of receiv-  
3 ing reports of adverse events regarding drugs. With re-  
4 spect to the final rule:

5 (1) The rule shall provide for the implementa-  
6 tion of such labeling requirement in a manner that  
7 the Secretary considers to be most likely to reach  
8 the broadest consumer audience.

9 (2) In promulgating the rule, the Secretary  
10 shall seek to minimize the cost of the rule on the  
11 pharmacy profession.

12 (3) The rule shall take effect not later than 60  
13 days after the date on which the rule is promul-  
14 gated.

15 (b) DRUGS WITH PEDIATRIC MARKET EXCLU-  
16 SIVITY.—

17 (1) IN GENERAL.—During the one-year begin-  
18 ning on the date on which a drug receives a period  
19 of market exclusivity under 505A of the Federal  
20 Food, Drug, and Cosmetic Act, any report of an ad-  
21 verse event regarding the drug that the Secretary of  
22 Health and Human Services receives shall be re-  
23 ferred to the Office of Pediatric Therapeutics estab-  
24 lished under section 6 of this Act. In considering the  
25 report, the Director of such Office shall provide for

1 the review of the report by the Pediatric Advisory  
2 Subcommittee of the Anti-Infective Drugs Advisory  
3 Committee, including obtaining any recommenda-  
4 tions of such Subcommittee regarding whether the  
5 Secretary should take action under the Federal  
6 Food, Drug, and Cosmetic Act in response to the re-  
7 port.

8 (2) RULE OF CONSTRUCTION.—Paragraph (1)  
9 may not be construed as restricting the authority of  
10 the Secretary of Health and Human Services to con-  
11 tinue carrying out the activities described in such  
12 paragraph regarding a drug after the one-year pe-  
13 riod described in such paragraph regarding the drug  
14 has expired.

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

16 Title IV of the Public Health Service Act (42 U.S.C.  
17 281 et seq.) is amended by adding at the end the following  
18 part:

19 **“PART J—FOUNDATION FOR PEDIATRIC**  
20 **RESEARCH**

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

22 “(a) IN GENERAL.—The Secretary, acting through  
23 the Director of NIH and in consultation with the Commis-  
24 sioner of Food and Drugs, shall establish a nonprofit cor-  
25 poration to be known as the Foundation for Pediatric Re-

1 search (hereafter in this section referred to as the ‘Foun-  
2 dation’). The Foundation shall not be an agency or instru-  
3 mentality of the United States Government.

4 “(b) PURPOSE OF FOUNDATION.—The purpose of  
5 the Foundation shall be to collect funds and award grants  
6 for research on drugs listed by the Secretary pursuant to  
7 section 409I(a)(1)(A).

8 “(c) CERTAIN ACTIVITIES OF FOUNDATION.—

9 “(1) IN GENERAL.—In carrying out subsection  
10 (b), the Foundation may solicit and accept gifts,  
11 grants, and other donations, establish accounts, and  
12 invest and expend funds in support of a program to  
13 encourage donations for the conduct of studies of  
14 drugs referred to in subsection (b).

15 “(2) FEES.—The Foundation may assess fees  
16 for the provision of professional, administrative and  
17 management services by the Foundation in amounts  
18 determined reasonable and appropriate by the Exec-  
19 utive Director.

20 “(3) AUTHORITY OF FOUNDATION.—The Foun-  
21 dation shall be the sole entity responsible for car-  
22 rying out the activities described in this subsection.

23 “(d) BOARD OF DIRECTORS.—

24 “(1) COMPOSITION.—

1           “(A) The Foundation shall have a Board  
2 of Directors (hereafter referred to in this sec-  
3 tion as the ‘Board’), which shall be composed of  
4 ex officio and appointed members in accordance  
5 with this subsection. Appointed members of the  
6 Board shall be the voting members.

7           “(B) The ex officio members of the Board  
8 shall be—

9                   “(i) the Chairman and ranking minor-  
10 ity member of the Subcommittee on Health  
11 (Committee on Energy and Commerce) or  
12 their designees, in the case of the House of  
13 Representatives;

14                   “(ii) the Chairman and ranking mi-  
15 nority member of the Committee on  
16 Health, Education, Labor and Pensions or  
17 their designees, in the case of the Senate;

18                   “(iii) the Director of NIH; and

19                   “(iv) the Commissioner of Food and  
20 Drugs.

21           “(C) The ex officio members of the Board  
22 under subparagraph (B) shall appoint to the  
23 Board 11 individuals from among a list of can-  
24 didates to be provided by the National Academy  
25 of Science. Of such appointed members—

1                   “(i) 5 shall be representative of the  
2                   experts in pediatric medicine and research  
3                   field;

4                   “(ii) 1 shall be a biomedical ethicist;  
5                   and

6                   “(iii) 5 shall be representatives of the  
7                   general public, which may include rep-  
8                   resentatives of affected industries.

9                   “(D)(i) Not later than 30 days after the  
10                  date of the enactment of the Best Pharma-  
11                  ceuticals for Children Act, the Director of NIH  
12                  shall convene a meeting of the ex officio mem-  
13                  bers of the Board to—

14                  “(I) incorporate the Foundation and  
15                  establish the general policies of the Foun-  
16                  dation for carrying out the purposes of  
17                  subsection (b), including the establishment  
18                  of the bylaws of the Foundation; and

19                  “(II) appoint the members of the  
20                  Board in accordance with subparagraph  
21                  (C).

22                  “(ii) Upon the appointment of the mem-  
23                  bers of the Board under clause (i)(II), the  
24                  terms of service of the ex officio members of the

1 Board as members of the Board shall termi-  
2 nate.

3 “(E) The agreement of not less than three-  
4 fifths of the members of the ex officio members  
5 of the Board shall be required for the appoint-  
6 ment of each member to the initial Board.

7 “(F) No employee of the National Insti-  
8 tutes of Health shall be appointed as a member  
9 of the Board.

10 “(2) CHAIR.—

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

14 “(B) Upon the termination of the term of  
15 service of the initial Chair of the Board, the ap-  
16 pointed members of the Board shall elect a  
17 member of the Board to serve as the Chair of  
18 the Board.

19 “(3) TERMS AND VACANCIES.—

20 “(A) The term of office of each member of  
21 the Board appointed under paragraph (1)(C)  
22 shall be 5 years, except that the terms of offices  
23 for the initial appointed members of the Board  
24 shall expire as determined by the ex officio  
25 members and the Chair.

1           “(B) Any vacancy in the membership of  
2           the Board shall be filled in the manner in which  
3           the original position was made and shall not af-  
4           fect the power of the remaining members to  
5           execute the duties of the Board.

6           “(C) If a member of the Board does not  
7           serve the full term applicable under subpara-  
8           graph (A), the individual appointed to fill the  
9           resulting vacancy shall be appointed for the re-  
10          mainder of the term of the predecessor of the  
11          individual.

12          “(D) A member of the Board may continue  
13          to serve after the expiration of the term of the  
14          member until a successor is appointed.

15          “(4) COMPENSATION.—Members of the Board  
16          may not receive compensation for service on the  
17          Board. Such members may be reimbursed for travel,  
18          subsistence, and other necessary expenses incurred  
19          in carrying out the duties of the Board, as set forth  
20          in the bylaws issued by the Board.

21          “(5) MEETINGS AND QUORUM.—A majority of  
22          the members of the Board shall constitute a quorum  
23          for purposes of conducting the business of the  
24          Board.

25          “(6) CERTAIN BYLAWS.—

1           “(A) In establishing bylaws under this sub-  
2 section, the Board shall ensure that the fol-  
3 lowing are provided for:

4                   “(i) Policies for the selection of the  
5 officers, employees, and agents of the  
6 Foundation.

7                   “(ii) Policies, including ethical stand-  
8 ards, for the acceptance, solicitation, and  
9 disposition of donations and grants to the  
10 Foundation and for the disposition of the  
11 assets of the Foundation. Policies with re-  
12 spect to ethical standards shall ensure that  
13 officers, employees and agents of the  
14 Foundation (including members of the  
15 Board) avoid encumbrances that would re-  
16 sult in a conflict of interest, including a fi-  
17 nancial conflict of interest or a divided al-  
18 legiance. Such policies shall include re-  
19 quirements for the provision of information  
20 concerning any ownership or controlling in-  
21 terest in entities related to the activities of  
22 the Foundation by such officers, employees  
23 and agents and their spouses and relatives.

24                   “(iii) Policies for the conduct of the  
25 general operations of the Foundation.

1           “(B) In establishing bylaws under this sub-  
2           section, the Board shall ensure that such by-  
3           laws (and activities carried out under the by-  
4           laws) do not—

5                   “(i) reflect unfavorably upon the abil-  
6                   ity of the Foundation to carry out its re-  
7                   sponsibilities or official duties in a fair and  
8                   objective manner; or

9                   “(ii) compromise, or appear to com-  
10                  promise, the integrity of any governmental  
11                  agency or program, or any officer or em-  
12                  ployee involved in such program.

13           “(e) INCORPORATION.—The initial members of the  
14           Board shall serve as incorporators and shall take whatever  
15           actions necessary to incorporate the Foundation.

16           “(f) NONPROFIT STATUS.—The Foundation shall be  
17           considered to be a corporation under section 501(c) of the  
18           Internal Revenue Code of 1986, and shall be subject to  
19           the provisions of such section.

20           “(g) EXECUTIVE DIRECTOR.—

21                   “(1) IN GENERAL.—The Foundation shall have  
22                   an Executive Director who shall be appointed by the  
23                   Board and shall serve at the pleasure of the Board.  
24                   The Executive Director shall be responsible for the  
25                   day-to-day operations of the Foundation and shall

1 have such specific duties and responsibilities as the  
2 Board shall prescribe.

3 “(2) COMPENSATION.—The rate of compensa-  
4 tion of the Executive Director shall be fixed by the  
5 Board.

6 “(h) POWERS.—In carrying out subsection (b), the  
7 Foundation shall operate under the direction of its Board,  
8 and may—

9 “(1) adopt, alter, and use a corporate seal,  
10 which shall be judicially noticed;

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

15 “(3) hire, promote, compensate, and discharge  
16 officers and employees of the Foundation, and define  
17 the duties of the officers and employees;

18 “(4) with the consent of any executive depart-  
19 ment or independent agency, use the information,  
20 services, staff, and facilities of such in carrying out  
21 this section;

22 “(5) sue and be sued in its corporate name, and  
23 complain and defend in courts of competent jurisdic-  
24 tion;

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

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

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

9           “(9) enter into such other contracts, leases, co-  
10          operative agreements, and other transactions as the  
11          Executive Director considers appropriate to conduct  
12          the activities of the Foundation; and

13          “(10) exercise other powers as set forth in this  
14          section, and such other incidental powers as are nec-  
15          essary to carry out its powers, duties, and functions  
16          in accordance with this part.

17          “(i) ADMINISTRATIVE CONTROL.—No participant in  
18          the program established under this part shall exercise any  
19          administrative control over any Federal employee, nor  
20          shall the Foundation attempt to influence an executive  
21          branch agency or employee.

22          “(j) GENERAL PROVISIONS.—

23                 “(1) FOUNDATION INTEGRITY.—The members  
24                 of the Board shall be accountable for the integrity  
25                 of the operations of the Foundation and shall ensure

1 such integrity through the development and enforce-  
2 ment of criteria and procedures relating to stand-  
3 ards of conduct (including those developed under  
4 subsection (d)(6)(A)(ii), financial disclosure state-  
5 ments, conflict of interest rules, recusal and waiver  
6 rules, audits and other matter determined appro-  
7 priate by the Board.

8 “(2) FINANCIAL CONFLICTS OF INTEREST.—

9 Any individual who is an officer, employee, or mem-  
10 ber of the Board of the Foundation may not (in ac-  
11 cordance with policies and requirements developed  
12 under subsection (d)(6)(A)(ii) personally or substan-  
13 tially participate in the consideration or determina-  
14 tion by the Foundation of any matter that would di-  
15 rectly or predictably affect any financial interest of  
16 the individual or a relative (as such term is defined  
17 in section 109(16) of the Ethics in Government Act  
18 of 1978) of the individual, of any business organiza-  
19 tion or other entity, or of which the individual is an  
20 officer or employee, or is negotiating for employ-  
21 ment, or in which the individual has any other finan-  
22 cial interest.

23 “(3) AUDITS; AVAILABILITY OF RECORDS.—The

24 Foundation shall—

1           “(A) provide for annual audits of the fi-  
2 nancial condition of the Foundation; and

3           “(B) make such audits, and all other  
4 records, documents, and other papers of the  
5 Foundation, available to the Secretary and the  
6 Comptroller General of the United States for  
7 examination or audit.

8           “(4) REPORTS.—

9           “(A) Not later than 5 months following the  
10 end of each fiscal year, the Foundation shall  
11 publish a report describing the activities of the  
12 Foundation during the preceding fiscal year.  
13 Each such report shall include for the fiscal  
14 year involved a comprehensive statement of the  
15 operations, activities, financial condition, and  
16 accomplishments of the Foundation.

17           “(B) With respect to the financial condi-  
18 tion of the Foundation, each report under sub-  
19 paragraph (A) shall include the source, and a  
20 description of, all gifts or grants to the Founda-  
21 tion of real or personal property, and the source  
22 and amount of all gifts or grants to the Foun-  
23 dation of money. Each such report shall include  
24 a specification of any restrictions on the pur-

1           poses for which gifts or grants to the Founda-  
2           tion may be used.

3           “(C) The Foundation shall make copies of  
4           each report submitted under subparagraph (A)  
5           available for public inspection, and shall upon  
6           request provide a copy of the report to any indi-  
7           vidual for a charge not exceeding the cost of  
8           providing the copy.

9           “(D) The Board shall annually hold a pub-  
10          lic meeting to summarize the activities of the  
11          Foundation and distribute written reports con-  
12          cerning such activities and the scientific results  
13          derived from such activities.

14          “(5) SERVICE OF FEDERAL EMPLOYEES.—Fed-  
15          eral employees may serve on committees advisory to  
16          the Foundation and otherwise cooperate with and  
17          assist the Foundation in carrying out its function, so  
18          long as the employees do not direct or control Foun-  
19          dation activities.

20          “(6) RELATIONSHIP WITH EXISTING ENTI-  
21          TIES.—The Foundation may, pursuant to appro-  
22          priate agreements, acquire the resources of existing  
23          nonprofit private corporations with missions similar  
24          to the purposes of the Foundation.

1           “(7) INTELLECTUAL PROPERTY RIGHTS.—The  
2 Board may adopt written standards with respect to  
3 the ownership of any intellectual property rights de-  
4 rived from the collaborative efforts of the Founda-  
5 tion prior to the commencement of such efforts.

6           “(8) NATIONAL INSTITUTES OF HEALTH  
7 AMENDMENTS OF 1990.—The activities conducted in  
8 support of the National Institutes of Health Amend-  
9 ments of 1990 (Public Law 101–613), and the  
10 amendments made by such Act, shall not be nullified  
11 by the enactment of this section.

12           “(9) LIMITATION OF ACTIVITIES.—The Foun-  
13 dation shall exist solely as an entity to collect funds  
14 and award grants for research on drugs listed by the  
15 Secretary pursuant to section 409I(a)(1)(A).

16           “(10) TRANSFER OF FUNDS.—The Foundation  
17 may transfer funds to the National Institutes of  
18 Health. Any funds transferred under this paragraph  
19 shall be subject to all Federal limitations relating to  
20 federally-funded research.

21           “(k) DUTIES OF THE DIRECTOR.—

22           “(1) APPLICABILITY OF CERTAIN STANDARDS  
23 TO NON-FEDERAL EMPLOYEES.—In the case of any  
24 individual who is not an employee of the Federal  
25 Government and who serves in association with the

1 National Institutes of Health, with respect to finan-  
2 cial assistance received from the Foundation, the  
3 Foundation may not provide the assistance of, or  
4 otherwise permit the work at the National Institutes  
5 of Health to begin until a memorandum of under-  
6 standing between the individual and the Director of  
7 NIH, or the designee of such Director, has been exe-  
8 cuted specifying that the individual shall be subject  
9 to such ethical and procedural standards of conduct  
10 relating to duties performed at the National Insti-  
11 tutes of Health, as the Director of NIH determines  
12 is appropriate.

13 “(2) SUPPORT SERVICES.—The Director of  
14 NIH shall provide facilities, utilities and support  
15 services to the Foundation.

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

17 “(1) IN GENERAL.—Upon completion of a pedi-  
18 atric study conducted pursuant to this section, a re-  
19 port concerning the study shall be submitted to the  
20 Director of National Institutes of Health and the  
21 Commissioner of Food and Drugs. The report shall  
22 include all data generated in connection with the  
23 study.

24 “(2) AVAILABILITY OF REPORTS; ACTION BY  
25 FOOD AND DRUG ADMINISTRATION; LABELING

1 CHANGES.—With respect to a report submitted  
2 under paragraph (1), the provisions of paragraphs  
3 (3)(B) through (8) of section 409I(c) apply to such  
4 report to the same extent and in the same manner  
5 as such provision apply to a report submitted under  
6 section 409I(c)(3)(A).

7 “(m) FUNDING.—

8 “(1) AUTHORIZATION OF APPROPRIATIONS.—  
9 For the purpose of carrying out this part, there are  
10 authorized to be appropriated such sums as may be  
11 necessary for fiscal year 2002 and each subsequent  
12 fiscal year.

13 “(2) LIMITATION REGARDING OTHER FUNDS.—  
14 Amounts appropriated under any provision of law  
15 other than paragraph (1) may not be expended to  
16 establish or operate the Foundation.”.

17 **SEC. 14. STUDY CONCERNING RESEARCH INVOLVING CHIL-**  
18 **DREN.**

19 (a) CONTRACT WITH INSTITUTE OF MEDICINE.—The  
20 Secretary of Health and Human Services shall enter into  
21 a contract with the Institute of Medicine for—

22 (1) the conduct, in accordance with subsection  
23 (b), of a review of—

1 (A) Federal regulations in effect on the  
2 date of the enactment of this Act relating to re-  
3 search involving children;

4 (B) federally-prepared or supported reports  
5 relating to research involving children; and

6 (C) federally-supported evidence-based re-  
7 search involving children; and

8 (2) the submission to the appropriate commit-  
9 tees of Congress, by not later than 2 years after the  
10 date of enactment of this Act, of a report concerning  
11 the review conducted under paragraph (1) that in-  
12 cludes recommendations on best practices relating to  
13 research involving children.

14 (b) AREAS OF REVIEW.—In conducting the review  
15 under subsection (a)(1), the Institute of Medicine shall  
16 consider the following:

17 (1) The written and oral process of obtaining  
18 and defining “assent”, “permission” and “informed  
19 consent” with respect to child clinical research par-  
20 ticipants and the parents, guardians, and the indi-  
21 viduals who may serve as the legally authorized rep-  
22 resentatives of such children (as defined in subpart  
23 A of part 46 of title 45, Code of Federal Regula-  
24 tions).

1           (2) The expectations and comprehension of  
2 child research participants and the parents, guard-  
3 ians, or legally authorized representatives of such  
4 children, for the direct benefits and risks of the  
5 child’s research involvement, particularly in terms of  
6 research versus therapeutic treatment.

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

9           (4) The appropriateness of the regulations ap-  
10 plicable to children of differing ages and maturity  
11 levels, including regulations relating to legal status.

12           (5) Whether payment (financial or otherwise)  
13 may be provided to a child or his or her parent,  
14 guardian, or legally authorized representative for the  
15 participation of the child in research, and if so, the  
16 amount and type of payment that may be made.

17           (6) Compliance with the regulations referred to  
18 in subsection (a)(1)(A), the monitoring of such com-  
19 pliance (including the role of institutional review  
20 boards), and the enforcement actions taken for viola-  
21 tions of such regulations.

22           (7) The unique roles and responsibilities of in-  
23 stitutional review boards in reviewing research in-  
24 volving children, including composition of member-  
25 ship on institutional review boards.

1 (c) REQUIREMENTS OF EXPERTISE.—The Institute  
2 of Medicine shall conduct the review under subsection  
3 (a)(1) and make recommendations under subsection (a)(2)  
4 in conjunction with experts in pediatric medicine, pediatric  
5 research, and the ethical conduct of research involving  
6 children.

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

8 Not later than October 1, 2006, the Comptroller Gen-  
9 eral of the United States shall submit to the Congress and  
10 the Secretary of Health and Human Services a report that  
11 describes the following:

12 (1) The effectiveness of the amendments made  
13 by this Act in ensuring that all drugs used by chil-  
14 dren are tested and properly labeled, including—

15 (A) the number and importance for chil-  
16 dren of drugs that are being tested as a result  
17 of such amendments, and the importance for  
18 children, health care providers, parents, and  
19 others of labeling changes made as a result of  
20 such testing;

21 (B) the number and importance for chil-  
22 dren of drugs that are not being tested for their  
23 use notwithstanding the amendments, and pos-  
24 sible reason for this; and

1 (C) the number of drugs for which pedi-  
2 atric testing has been done, for which a period  
3 of market exclusivity has been granted, and for  
4 which labeling changes required the use of the  
5 dispute resolution process established pursuant  
6 to the amendments, together with a description  
7 of the outcomes of such process, including a de-  
8 scription of the disputes and the recommenda-  
9 tions of the advisory committee.

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

12 (A) costs to taxpayers in the form of high-  
13 er expenditures by Medicaid and other govern-  
14 ment programs;

15 (B) costs to consumers as a result of any  
16 delay in the availability of lower cost generic  
17 equivalents of drugs tested and granted exclu-  
18 sivity pursuant to such amendments, and loss  
19 of revenue by the generic drug industry and any  
20 other affected industry as a result of any such  
21 delay; and

22 (C) benefits to the government, to private  
23 insurers, and to consumers resulting from de-  
24 creased health care costs, including—

1 (i) decreased hospitalizations, due to  
2 more appropriate and more effective use of  
3 medications in children as a result of test-  
4 ing and re-labeling because of such amend-  
5 ments;

6 (ii) direct and indirect benefits associ-  
7 ated with fewer physician visits not related  
8 to hospitalization;

9 (iii) benefits to children from missing  
10 less time at school and being less affected  
11 by chronic illnesses, thereby allowing a bet-  
12 ter quality of life;

13 (iv) benefits to consumers from lower  
14 health insurance premiums due to lower  
15 treatment costs and hospitalization rates;  
16 and

17 (v) benefits to employers from reduced  
18 need for employees to care for family mem-  
19 bers.

20 (3) The nature and types of studies in children  
21 of drugs granted a period of market exclusivity pur-  
22 suant to the amendments made by this Act, includ-  
23 ing a description of the complexity of such studies,  
24 the number of study sites necessary to obtain appro-  
25 priate data, and the numbers of children involved in

1 any clinical studies, and the cost of such studies for  
2 each type of study identified.

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

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

8 (a) **PROTOCOLS FOR PEDIATRIC STUDIES.**—Section  
9 505A of the Federal Food, Drug, and Cosmetic Act (21  
10 U.S.C. 355a) is amended in subsection (c)(2) (as redesign-  
11 nated by section 2(a)(2) of this Act) by inserting after  
12 the first sentence the following: “In reaching an agree-  
13 ment regarding written protocols, the Secretary shall take  
14 into account adequate representation of children of ethnic  
15 and racial minorities.”.

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

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

20 (A) The extent to which children of ethnic  
21 and racial minorities are adequately represented  
22 in studies under section 505A of the Federal  
23 Food, Drug, and Cosmetic Act; and to the ex-  
24 tent ethnic and racial minorities are not ade-  
25 quately represented, the reasons for such under

1 representation and recommendations to increase  
2 such representation.

3 (B) Whether the Food and Drug Adminis-  
4 tration has appropriate management systems to  
5 monitor the representation of the children of  
6 ethnic and racial minorities in such studies.

7 (C) Whether drugs used to address dis-  
8 eases that disproportionately affect racial and  
9 ethnic minorities are being studied for their  
10 safety and effectiveness under section 505A of  
11 the Federal Food, Drug, and Cosmetic Act.

12 (2) DATE CERTAIN FOR COMPLETING STUDY.—  
13 Not later than January 10, 2003, the Comptroller  
14 General shall complete the study required in para-  
15 graph (1) and submit to the Congress a report de-  
16 scribing the findings of the study.

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

18 Section 505A of the Federal Food, Drug, and Cos-  
19 metic Act (21 U.S.C. 355a) is amended—

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

22 (B) by striking “(j)(4)(D)” each place such  
23 term appears and inserting “(j)(5)(D)”;

24 (2)(A) in subsection (c) (as redesignated by sec-  
25 tion 2(a)(2) of this Act), in each of paragraphs (1)

1 through (3), by striking “subsection (a) or (c)” and  
2 inserting “subsection (a) or (b)”; and

3 (B) in subsection (d) (as so redesignated), in  
4 the last sentence, by striking “subsection (a) or (c)”  
5 and inserting “subsection (a) or (b)”.

Passed the House of Representatives November 15,  
2001.

Attest:

*Clerk.*