

## Calendar No. 271

107<sup>TH</sup> CONGRESS  
1<sup>ST</sup> SESSION**S. 1789**

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 SENATE OF THE UNITED STATES

DECEMBER 8 (legislative day, DECEMBER 7), 2001

Mr. DODD (for himself and Mr. DEWINE) introduced the following bill; which was read the first time

DECEMBER 10, 2001

Read the second time and placed on the calendar

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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”.

1 **SEC. 2. PEDIATRIC STUDIES OF ALREADY-MARKETED**  
2 **DRUGS.**

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

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

6 (2) in subsection (c)—

7 (A) by inserting after “the Secretary” the  
8 following: “determines that information relating  
9 to the use of an approved drug in the pediatric  
10 population may produce health benefits in that  
11 population and”; and

12 (B) by striking “concerning a drug identi-  
13 fied in the list described in subsection (b)”.

14 **SEC. 3. RESEARCH FUND FOR THE STUDY OF DRUGS.**

15 Part B of title IV of the Public Health Service Act  
16 (42 U.S.C. 284 et seq.) is amended—

17 (1) by redesignating the second section 409C,  
18 relating to clinical research (42 U.S.C. 284k), as  
19 section 409G;

20 (2) by redesignating the second section 409D,  
21 relating to enhancement awards (42 U.S.C. 284l), as  
22 section 409H; and

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

24 **“SEC. 409I. PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.**

25 **“(a) LIST OF DRUGS FOR WHICH PEDIATRIC STUD-**  
26 **IES ARE NEEDED.—**

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

8                   “(A)(i) there is an approved application  
9                   under section 505(j) of the Federal Food,  
10                  Drug, and Cosmetic Act (21 U.S.C. 355(j));

11                  “(ii) there is a submitted application that  
12                  could be approved under the criteria of section  
13                  505(j) of the Federal Food, Drug, and Cos-  
14                  metic Act (21 U.S.C. 355(j));

15                  “(iii) there is no patent protection or mar-  
16                  ket exclusivity protection under the Federal  
17                  Food, Drug, and Cosmetic Act (21 U.S.C. 301  
18                  et seq.); or

19                  “(iv) there is a referral for inclusion on the  
20                  list under section 505A(d)(4)(C) of the Federal  
21                  Food, Drug, and Cosmetic Act (21 U.S.C.  
22                  355a(d)(4)(C)); and

23                  “(B) in the case of a drug referred to in  
24                  clause (i), (ii), or (iii) of subparagraph (A), ad-  
25                  ditional studies are needed to assess the safety

1           and effectiveness of the use of the drug in the  
2           pediatric population.

3           “(2) CONSIDERATION OF AVAILABLE INFORMA-  
4           TION.—In developing and prioritizing the list under  
5           paragraph (1), the Secretary shall consider, for each  
6           drug on the list—

7                   “(A) the availability of information con-  
8                   cerning the safe and effective use of the drug  
9                   in the pediatric population;

10                   “(B) whether additional information is  
11                   needed;

12                   “(C) whether new pediatric studies con-  
13                   cerning the drug may produce health benefits in  
14                   the pediatric population; and

15                   “(D) whether reformulation of the drug is  
16                   necessary.

17           “(b) CONTRACTS FOR PEDIATRIC STUDIES.—The  
18           Secretary shall award contracts to entities that have the  
19           expertise to conduct pediatric clinical trials (including  
20           qualified universities, hospitals, laboratories, contract re-  
21           search organizations, federally funded programs such as  
22           pediatric pharmacology research units, other public or pri-  
23           vate institutions, or individuals) to enable the entities to  
24           conduct pediatric studies concerning one or more drugs  
25           identified in the list described in subsection (a).

1       “(c) PROCESS FOR CONTRACTS AND LABELING  
2 CHANGES.—

3               “(1) WRITTEN REQUEST TO HOLDERS OF AP-  
4 PROVED APPLICATIONS FOR DRUGS LACKING EXCLU-  
5 SIVITY.—The Commissioner of Food and Drugs, in  
6 consultation with the Director of the National Insti-  
7 tutes of Health, may issue a written request (which  
8 shall include a timeframe for negotiations for an  
9 agreement) for pediatric studies concerning a drug  
10 identified in the list described in subsection  
11 (a)(1)(A) (except clause (iv)) to all holders of an ap-  
12 proved application for the drug under section 505 of  
13 the Federal Food, Drug, and Cosmetic Act. Such a  
14 written request shall be made in a manner equiva-  
15 lent to the manner in which a written request is  
16 made under subsection (a) or (b) of section 505A of  
17 the Federal Food, Drug, and Cosmetic Act, includ-  
18 ing with respect to information provided on the pedi-  
19 atric studies to be conducted pursuant to the re-  
20 quest.

21               “(2) REQUESTS FOR CONTRACT PROPOSALS.—  
22 If the Commissioner of Food and Drugs does not re-  
23 ceive a response to a written request issued under  
24 paragraph (1) within 30 days of the date on which  
25 a request was issued, or if a referral described in

1 subsection (a)(1)(A)(iv) is made, the Secretary, act-  
2 ing through the Director of the National Institutes  
3 of Health and in consultation with the Commissioner  
4 of Food and Drugs, shall publish a request for con-  
5 tract proposals to conduct the pediatric studies de-  
6 scribed in the written request.

7 “(3) DISQUALIFICATION.—A holder that re-  
8 ceives a first right of refusal shall not be entitled to  
9 respond to a request for contract proposals under  
10 paragraph (2).

11 “(4) GUIDANCE.—Not later than 270 days  
12 after the date of enactment of this section, the Com-  
13 missioner of Food and Drugs shall promulgate guid-  
14 ance to establish the process for the submission of  
15 responses to written requests under paragraph (1).

16 “(5) CONTRACTS.—A contract under this sec-  
17 tion may be awarded only if a proposal for the con-  
18 tract is submitted to the Secretary in such form and  
19 manner, and containing such agreements, assur-  
20 ances, and information as the Secretary determines  
21 to be necessary to carry out this section.

22 “(6) REPORTING OF STUDIES.—

23 “(A) IN GENERAL.—On completion of a  
24 pediatric study in accordance with a contract  
25 awarded under this section, a report concerning

1 the study shall be submitted to the Director of  
2 the National Institutes of Health and the Com-  
3 missioner of Food and Drugs. The report shall  
4 include all data generated in connection with  
5 the study.

6 “(B) AVAILABILITY OF REPORTS.—Each  
7 report submitted under subparagraph (A) shall  
8 be considered to be in the public domain (sub-  
9 ject to section 505A(d)(4)(D) of the Federal  
10 Food, Drug, and Cosmetic Act (21 U.S.C.  
11 355a(d)(4)(D)) and shall be assigned a docket  
12 number by the Commissioner of Food and  
13 Drugs. An interested person may submit writ-  
14 ten comments concerning such pediatric studies  
15 to the Commissioner of Food and Drugs, and  
16 the written comments shall become part of the  
17 docket file with respect to each of the drugs.

18 “(C) ACTION BY COMMISSIONER.—The  
19 Commissioner of Food and Drugs shall take ap-  
20 propriate action in response to the reports sub-  
21 mitted under subparagraph (A) in accordance  
22 with paragraph (7).

23 “(7) REQUESTS FOR LABELING CHANGE.—Dur-  
24 ing the 180-day period after the date on which a re-

1 port is submitted under paragraph (6)(A), the Com-  
2 missioner of Food and Drugs shall—

3 “(A) review the report and such other data  
4 as are available concerning the safe and effec-  
5 tive use in the pediatric population of the drug  
6 studied;

7 “(B) negotiate with the holders of ap-  
8 proved applications for the drug studied for any  
9 labeling changes that the Commissioner of Food  
10 and Drugs determines to be appropriate and re-  
11 quests the holders to make; and

12 “(C)(i) place in the public docket file a  
13 copy of the report and of any requested labeling  
14 changes; and

15 “(ii) publish in the Federal Register a  
16 summary of the report and a copy of any re-  
17 quested labeling changes.

18 “(8) DISPUTE RESOLUTION.—

19 “(A) REFERRAL TO PEDIATRIC ADVISORY  
20 SUBCOMMITTEE OF THE ANTI-INFECTIVE  
21 DRUGS ADVISORY COMMITTEE.—If, not later  
22 than the end of the 180-day period specified in  
23 paragraph (7), the holder of an approved appli-  
24 cation for the drug involved does not agree to  
25 any labeling change requested by the Commis-

1 sioner of Food and Drugs under that para-  
2 graph, the Commissioner of Food and Drugs  
3 shall refer the request to the Pediatric Advisory  
4 Subcommittee of the Anti-Infective Drugs Advi-  
5 sory Committee.

6 “(B) ACTION BY THE PEDIATRIC ADVISORY  
7 SUBCOMMITTEE OF THE ANTI-INFECTIVE  
8 DRUGS ADVISORY COMMITTEE.—Not later than  
9 90 days after receiving a referral under sub-  
10 paragraph (A), the Pediatric Advisory Sub-  
11 committee of the Anti-Infective Drugs Advisory  
12 Committee shall—

13 “(i) review the available information  
14 on the safe and effective use of the drug  
15 in 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 “(9) FDA DETERMINATION.—Not later than 30  
21 days after receiving a recommendation from the Pe-  
22 diatric Advisory Subcommittee of the Anti-Infective  
23 Drugs Advisory Committee under paragraph  
24 (8)(B)(ii) with respect to a drug, the Commissioner  
25 of Food and Drugs shall consider the recommenda-

1       tion and, if appropriate, make a request to the hold-  
2       ers of approved applications for the drug to make  
3       any labeling change that the Commissioner of Food  
4       and Drugs determines to be appropriate.

5           “(10) FAILURE TO AGREE.—If a holder of an  
6       approved application for a drug, within 30 days  
7       after receiving a request to make a labeling change  
8       under paragraph (9), does not agree to make a re-  
9       quested labeling change, the Commissioner may  
10      deem the drug to be misbranded under the Federal  
11      Food, Drug, and Cosmetic Act (21 U.S.C. 301 et  
12      seq.).

13          “(11) NO EFFECT ON AUTHORITY.—Nothing in  
14      this subsection limits the authority of the United  
15      States to bring an enforcement action under the  
16      Federal Food, Drug, and Cosmetic Act when a drug  
17      lacks appropriate pediatric labeling. Neither course  
18      of action (the Pediatric Advisory Subcommittee of  
19      the Anti-Infective Drugs Advisory Committee proc-  
20      ess or an enforcement action referred to in the pre-  
21      ceding sentence) shall preclude, delay, or serve as  
22      the basis to stay the other course of action.

23          “(12) RECOMMENDATION FOR FORMULATION  
24      CHANGES.—If a pediatric study completed under  
25      public contract indicates that a formulation change

1 is necessary and the Secretary agrees, the Secretary  
 2 shall send a nonbinding letter of recommendation re-  
 3 garding that change to each holder of an approved  
 4 application.

5 “(d) AUTHORIZATION OF APPROPRIATIONS.—

6 “(1) IN GENERAL.—There are authorized to be  
 7 appropriated to carry out this section—

8 “(A) \$200,000,000 for fiscal year 2002;  
 9 and

10 “(B) such sums as are necessary for each  
 11 of the 5 succeeding fiscal years.

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

15 **SEC. 4. WRITTEN REQUEST TO HOLDERS OF APPROVED AP-**  
 16 **PLICATIONS FOR DRUGS THAT HAVE MAR-**  
 17 **KET EXCLUSIVITY.**

18 Section 505A(d) of the Federal Food, Drug, and Cos-  
 19 metic Act (21 U.S.C. 355a(d)) is amended by adding at  
 20 the end the following:

21 “(4) WRITTEN REQUEST TO HOLDERS OF AP-  
 22 PROVED APPLICATIONS FOR DRUGS THAT HAVE  
 23 MARKET EXCLUSIVITY.—

24 “(A) REQUEST AND RESPONSE.—If the  
 25 Secretary makes a written request for pediatric

1 studies (including neonates, as appropriate)  
2 under subsection (c) to the holder of an applica-  
3 tion approved under section 505(b)(1), the  
4 holder, not later than 180 days after receiving  
5 the written request, shall respond to the Sec-  
6 retary as to the intention of the holder to act  
7 on the request by—

8 “(i) indicating when the pediatric  
9 studies will be initiated, if the holder  
10 agrees to the request; or

11 “(ii) indicating that the holder does  
12 not agree to the request.

13 “(B) NO AGREEMENT TO REQUEST.—

14 “(i) REFERRAL.—If the holder does  
15 not agree to a written request within the  
16 time period specified in subparagraph (A),  
17 and if the Secretary determines that there  
18 is a continuing need for information relat-  
19 ing to the use of the drug in the pediatric  
20 population (including neonates, as appro-  
21 priate), the Secretary shall refer the drug  
22 to the Foundation for the National Insti-  
23 tutes of Health established under section  
24 499 of the Public Health Service Act (42  
25 U.S.C. 290b) (referred to in this para-

graph as the ‘Foundation’) for the conduct of the pediatric studies described in the written request.

“(ii) PUBLIC NOTICE.—The Secretary shall give public notice of the name of the drug, the name of the manufacturer, and the indications to be studied made in a referral under clause (i).

“(C) LACK OF FUNDS.—On referral of a drug under subparagraph (B)(i), the Foundation shall issue a proposal to award a grant to conduct the requested studies unless the Foundation certifies to the Secretary, within a time-frame that the Secretary determines is appropriate through guidance, that the Foundation does not have funds available under section 499(j)(9)(B)(i) to conduct the requested studies. If the Foundation so certifies, the Secretary shall refer the drug for inclusion on the list established under section 409I of the Public Health Service Act for the conduct of the studies.

“(D) EFFECT OF SUBSECTION.—Nothing in this subsection (including with respect to referrals from the Secretary to the Foundation)

1           alters or amends section 301(j) of this Act or  
 2           section 552 of title 5 or section 1905 of title  
 3           18, United States Code.

4           “(E) NO REQUIREMENT TO REFER.—  
 5           Nothing in this subsection shall be construed to  
 6           require that every declined written request shall  
 7           be referred to the Foundation.

8           “(F) WRITTEN REQUESTS UNDER SUB-  
 9           SECTION (b).—For drugs under subsection (b)  
 10          for which written requests have not been ac-  
 11          cepted, if the Secretary determines that there is  
 12          a continuing need for information relating to  
 13          the use of the drug in the pediatric population  
 14          (including neonates, as appropriate), the Sec-  
 15          retary shall issue a written request under sub-  
 16          section (c) after the date of approval of the  
 17          drug.”.

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 Cos-  
6       metic Act (21 U.S.C. 321) is amended by adding at  
7       the end the following:

8           “(kk) PRIORITY SUPPLEMENT.—The term ‘pri-  
9       ority supplement’ means a drug application referred  
10      to in section 101(4) of the Food and Drug Adminis-  
11      tration Modernization Act of 1997 (111 Stat.  
12      2298).”.

13          (2) TREATMENT AS PRIORITY SUPPLEMENTS.—

14      Section 505A of the Federal Food, Drug, and Cos-  
15      metic Act (21 U.S.C. 355a) is amended by adding  
16      at the end the following:

17      “(l) LABELING SUPPLEMENTS.—

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

23          “(A) shall be considered to be a priority  
24      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.—

5           “(A) REQUEST FOR LABELING CHANGE  
6 AND FAILURE TO AGREE.—If the Commissioner  
7 determines that an application with respect to  
8 which a pediatric study is conducted under this  
9 section is approvable and that the only open  
10 issue for final action on the application is the  
11 reaching of an agreement between the sponsor  
12 of the application and the Commissioner on ap-  
13 propriate changes to the labeling for the drug  
14 that is the subject of the application, not later  
15 than 180 days after the date of submission of  
16 the application—

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

21           “(ii) if the sponsor of the application  
22 does not agree to make a labeling change  
23 requested by the Commissioner, the Com-  
24 missioner shall refer the matter to the Pe-

1           diatric Advisory Subcommittee of the Anti-  
2           Infective Drugs Advisory Committee.

3           “(B) ACTION BY THE PEDIATRIC ADVISORY  
4           SUBCOMMITTEE OF THE ANTI-INFECTIVE  
5           DRUGS ADVISORY COMMITTEE.—Not later than  
6           90 days after receiving a referral under sub-  
7           paragraph (A)(ii), the Pediatric Advisory Sub-  
8           committee of the Anti-Infective Drugs Advisory  
9           Committee shall—

10                   “(i) review the pediatric study reports;  
11                   and

12                   “(ii) make a recommendation to the  
13                   Commissioner concerning appropriate la-  
14                   beling changes, if any.

15           “(C) CONSIDERATION OF RECOMMENDA-  
16           TIONS.—The Commissioner shall consider the  
17           recommendations of the Pediatric Advisory  
18           Subcommittee of the Anti-Infective Drugs Advi-  
19           sory Committee and, if appropriate, not later  
20           than 30 days after receiving the recommenda-  
21           tion, make a request to the sponsor of the ap-  
22           plication to make any labeling change that the  
23           Commissioner determines to be appropriate.

24           “(D) MISBRANDING.—If the sponsor of the  
25           application, within 30 days after receiving a re-

1           quest under subparagraph (C), does not agree  
2           to make a labeling change requested by the  
3           Commissioner, the Commissioner may deem the  
4           drug that is the subject of the application to be  
5           misbranded.

6           “(E) NO EFFECT ON AUTHORITY.—Noth-  
7           ing in this subsection limits the authority of the  
8           United States to bring an enforcement action  
9           under this Act when a drug lacks appropriate  
10          pediatric labeling. Neither course of action (the  
11          Pediatric Advisory Subcommittee of the Anti-  
12          Infective Drugs Advisory Committee process or  
13          an enforcement action referred to in the pre-  
14          ceding sentence) shall preclude, delay, or serve  
15          as the basis to stay the other course of action.”.

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

17          (a) ESTABLISHMENT.—The Secretary of Health and  
18          Human Services shall establish an Office of Pediatric  
19          Therapeutics within the Food and Drug Administration.

20          (b) DUTIES.—The Office of Pediatric Therapeutics  
21          shall be responsible for coordination and facilitation of all  
22          activities of the Food and Drug Administration that may  
23          have any effect on a pediatric population or the practice  
24          of pediatrics or may in any other way involve pediatric  
25          issues.

1 (c) STAFF.—The staff of the Office of Pediatric  
 2 Therapeutics shall coordinate with employees of the De-  
 3 partment of Health and Human Services who exercise re-  
 4 sponsibilities relating to pediatric therapeutics and shall  
 5 include—

6 (1) 1 or more additional individuals with exper-  
 7 tise concerning ethical issues presented by the con-  
 8 duct of clinical research in the pediatric population;  
 9 and

10 (2) 1 or more additional individuals with exper-  
 11 tise in pediatrics as may be necessary to perform the  
 12 activities described in subsection (b).

13 **SEC. 7. NEONATES.**

14 Section 505A(g) of the Federal Food, Drug, and Cos-  
 15 metic Act (21 U.S.C. 355a(g)) is amended by inserting  
 16 “(including neonates in appropriate cases)” after “pedi-  
 17 atric age groups”.

18 **SEC. 8. SUNSET.**

19 Section 505A of the Federal Food, Drug, and Cos-  
 20 metic Act (21 U.S.C. 355a) is amended by striking sub-  
 21 section (j) and inserting the following:

22 “(j) SUNSET.—A drug may not receive any 6-month  
 23 period under subsection (a) or (c) unless—

1           “(1) on or before October 1, 2007, the Sec-  
 2       retary makes a written request for pediatric studies  
 3       of the drug;

4           “(2) on or before October 1, 2007, an applica-  
 5       tion for the drug is accepted for filing under section  
 6       505(b); and

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

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

9       Section 505A of the Federal Food, Drug, and Cos-  
 10      metic Act (21 U.S.C. 355a) (as amended by section  
 11      5(b)(2)) is amended by adding at the end the following:

12       “(m) DISSEMINATION OF PEDIATRIC INFORMA-  
 13      TION.—

14           “(1) IN GENERAL.—Not later than 180 days  
 15       after the date of submission of a report on a pedi-  
 16       atric study under this section, the Commissioner  
 17       shall make available to the public a summary of the  
 18       medical and clinical pharmacology reviews of pedi-  
 19       atric studies conducted for the supplement, including  
 20       by publication in the Federal Register.

21           “(2) EFFECT OF SUBSECTION.—Nothing in this  
 22       subsection alters or amends section 301(j) of this  
 23       Act or section 552 of title 5 or section 1905 of title  
 24       18, United States Code.”.

1 **SEC. 10. CLARIFICATION OF INTERACTION OF PEDIATRIC**  
 2 **EXCLUSIVITY UNDER SECTION 505A OF THE**  
 3 **FEDERAL FOOD, DRUG, AND COSMETIC ACT**  
 4 **AND 180-DAY EXCLUSIVITY AWARDED TO AN**  
 5 **APPLICANT FOR APPROVAL OF A DRUG**  
 6 **UNDER SECTION 505(j) OF THAT ACT.**

7 Section 505A of the Federal Food, Drug, and Cos-  
 8 metic Act (21 U.S.C. 355a) (as amended by section 9)  
 9 is amended by adding at the end the following:

10 “(n) CLARIFICATION OF INTERACTION OF MARKET  
 11 EXCLUSIVITY UNDER THIS SECTION AND MARKET EX-  
 12 CLUSIVITY AWARDED TO AN APPLICANT FOR APPROVAL  
 13 OF A DRUG UNDER SECTION 505(j).—If a 180-day period  
 14 under section 505(j)(5)(B)(iv) overlaps with a 6-month ex-  
 15 clusivity period under this section, so that the applicant  
 16 for approval of a drug under section 505(j) entitled to the  
 17 180-day period under that section loses a portion of the  
 18 180-day period to which the applicant is entitled for the  
 19 drug, the 180-day period shall be extended from—

20 “(1) the date on which the 180-day period  
 21 would have expired by the number of days of the  
 22 overlap, if the 180-day period would, but for the ap-  
 23 plication of this subsection, expire after the 6-month  
 24 exclusivity period; or

25 “(2) the date on which the 6-month exclusivity  
 26 period expires, by the number of days of the overlap

1 if the 180-day period would, but for the application  
 2 of this subsection, expire during the 6 month exclu-  
 3 sivity period.”.

4 **SEC. 11. PROMPT APPROVAL OF DRUGS UNDER SECTION**  
 5 **505(j) WHEN PEDIATRIC INFORMATION IS**  
 6 **ADDED TO LABELING.**

7 (a) IN GENERAL.—Section 505A of the Federal  
 8 Food, Drug, and Cosmetics Act (21 U.S.C. 355a) (as  
 9 amended by section 10) is amended by adding at the end  
 10 the following:

11 “(o) PROMPT APPROVAL OF DRUGS UNDER SECTION  
 12 505(j) WHEN PEDIATRIC INFORMATION IS ADDED TO LA-  
 13 BELING.—

14 “(1) GENERAL RULE.—A drug for which an ap-  
 15 plication has been submitted or approved under sec-  
 16 tion 505(j) shall not be considered ineligible for ap-  
 17 proval under that section or misbranded under sec-  
 18 tion 502 on the basis that the labeling of the drug  
 19 omits a pediatric indication or any other aspect of  
 20 labeling pertaining to pediatric use when the omitted  
 21 indication or other aspect is protected by patent or  
 22 by exclusivity under clause (iii) or (iv) of section  
 23 505(j)(5)(D).

24 “(2) LABELING.—Notwithstanding clauses (iii)  
 25 and (iv) of section 505(j)(5)(D), the Secretary may

1       require that the labeling of a drug approved under  
 2       section 505(j) that omits a pediatric indication or  
 3       other aspect of labeling as described in paragraph  
 4       (1) include—

5               “(A) a statement that, because of mar-  
 6       keting exclusivity for a manufacturer—

7                       “(i) the drug is not labeled for pedi-  
 8       atric use; or

9                       “(ii) in the case of a drug for which  
 10       there is an additional pediatric use not re-  
 11       ferred to in paragraph (1), the drug is not  
 12       labeled for the pediatric use under para-  
 13       graph (1); and

14               “(B) a statement of any appropriate pedi-  
 15       atric contraindications, warnings, or pre-  
 16       cautions that the Secretary considers necessary.

17       “(3) PRESERVATION OF PEDIATRIC EXCLU-  
 18       SIVITY AND OTHER PROVISIONS.—This subsection  
 19       does not affect—

20               “(A) the availability or scope of exclusivity  
 21       under this section;

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

24               “(C) the question of the eligibility for ap-  
 25       proval of any application under section 505(j)

1 that omits any other conditions of approval en-  
2 titled to exclusivity under clause (iii) or (iv) of  
3 section 505(j)(5)(D); or

4 “(D) except as expressly provided in para-  
5 graphs (1) and (2), the operation of section  
6 505.”.

7 (b) EFFECTIVE DATE.—The amendment made by  
8 subsection (a) takes effect on the date of enactment of  
9 this Act, including with respect to applications under sec-  
10 tion 505(j) of the Federal Food, Drug, and Cosmetic Act  
11 (21 U.S.C. 355(j)) that are approved or pending on that  
12 date.

13 **SEC. 12. STUDY CONCERNING RESEARCH INVOLVING CHIL-**  
14 **DREN.**

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

18 (1) the conduct, in accordance with subsection

19 (b), of a review of—

20 (A) Federal regulations in effect on the  
21 date of the enactment of this Act relating to re-  
22 search involving children;

23 (B) federally prepared or supported re-  
24 ports relating to research involving children;  
25 and

1 (C) federally supported evidence-based re-  
2 search involving children; and

3 (2) the submission to the Committee on Health,  
4 Education, Labor, and Pensions of the Senate and  
5 the Committee on Energy and Commerce of the  
6 House of Representatives, not later than 2 years  
7 after the date of enactment of this Act, of a report  
8 concerning the review conducted under paragraph  
9 (1) that includes recommendations on best practices  
10 relating to research involving children.

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

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

22 (2) The expectations and comprehension of  
23 child research participants and the parents, guard-  
24 ians, or legally authorized representatives of such  
25 children, for the direct benefits and risks of the

1 child's research involvement, particularly in terms of  
2 research versus therapeutic treatment.

3 (3) The definition of "minimal risk" with re-  
4 spect to a healthy child or a child with an illness.

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

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

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

18 (7) The unique roles and responsibilities of in-  
19 stitutional review boards in reviewing research in-  
20 volving children, including composition of member-  
21 ship on institutional review boards.

22 (c) REQUIREMENTS OF EXPERTISE.—The Institute  
23 of Medicine shall conduct the review under subsection  
24 (a)(1) and make recommendations under subsection (a)(2)  
25 in conjunction with experts in pediatric medicine, pediatric

1 research, and the ethical conduct of research involving  
2 children.

3 **SEC. 13. FOUNDATION FOR THE NATIONAL INSTITUTES OF**  
4 **HEALTH.**

5 Section 499 of the Public Health Service Act (42  
6 U.S.C. 290b) is amended—

7 (1) in subsection (b), by inserting “(including  
8 collection of funds for pediatric pharmacologic re-  
9 search)” after “mission”;

10 (2) in subsection (c)(1)—

11 (A) by redesignating subparagraph (C) as  
12 subparagraph (D); and

13 (B) by inserting after subparagraph (B)  
14 the following:

15 “(C) A program to collect funds for pedi-  
16 atric pharmacologic research and studies listed  
17 by the Secretary pursuant to section  
18 409I(a)(1)(A) of this Act and referred under  
19 section 505A(d)(4)(C) of the Federal Food,  
20 Drug, and Cosmetic Act (21 U.S.C.  
21 355a(d)(4)(C)).”;

22 (3) in subsection (d)—

23 (A) in paragraph (1)—

24 (i) in subparagraph (B)—

1 (I) in clause (ii), by striking  
2 “and” at the end;

3 (II) in clause (iii), by striking the  
4 period and inserting “; and”; and

5 (III) by adding at the end the  
6 following:

7 “(iv) the Commissioner of Food and  
8 Drugs.”; and

9 (ii) by striking subparagraph (C) and  
10 inserting the following:

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

17 “(i) representatives of the general bio-  
18 medical field;

19 “(ii) representatives of experts in pe-  
20 diatric medicine and research;

21 “(iii) representatives of the general  
22 biobehavioral field, which may include ex-  
23 perts in biomedical ethics; and

1 “(iv) representatives of the general  
2 public, which may include representatives  
3 of affected industries.”; and

4 (B) in paragraph (2), by realigning the  
5 margin of subparagraph (B) to align with sub-  
6 paragraph (A);

7 (4) in subsection (k)(9)—

8 (A) by striking “The Foundation” and in-  
9 serting the following:

10 “(A) IN GENERAL.—The Foundation”; and

11 (B) by adding at the end the following:

12 “(B) GIFTS, GRANTS, AND OTHER DONA-  
13 TIONS.—

14 “(i) IN GENERAL.—Gifts, grants, and  
15 other donations to the Foundation may be  
16 designated for pediatric research and stud-  
17 ies on drugs, and funds so designated shall  
18 be used solely for grants for research and  
19 studies under subsection (c)(1)(C).

20 “(ii) OTHER GIFTS.—Other gifts,  
21 grants, or donations received by the Foun-  
22 dation and not described in clause (i) may  
23 also be used to support such pediatric re-  
24 search and studies.

1           “(iii) REPORT.—The recipient of a  
2           grant for research and studies shall agree  
3           to provide the Director of the National In-  
4           stitutes of Health and the Commissioner of  
5           Food and Drugs, at the conclusion of the  
6           research and studies—

7                   “(I) a report describing the re-  
8                   sults of the research and studies; and

9                   “(II) all data generated in con-  
10                  nection with the research and studies.

11           “(iv) ACTION BY THE COMMISSIONER  
12           OF FOOD AND DRUGS.—The Commissioner  
13           of Food and Drugs shall take appropriate  
14           action in response to a report received  
15           under clause (iii) in accordance with para-  
16           graphs (7) through (12) of section 409I(c),  
17           including negotiating with the holders of  
18           approved applications for the drugs studied  
19           for any labeling changes that the Commis-  
20           sioner determines to be appropriate and re-  
21           quests the holders to make.

22           “(C) APPLICABILITY.—Subparagraph (A)  
23           does not apply to the program described in sub-  
24           section (c)(1)(C).”;

1           (5) by redesignating subsections (f) through  
 2           (m) as subsections (e) through (l), respectively;  
 3           (6) in subsection (h)(11) (as so redesignated),  
 4           by striking “solicit” and inserting “solicit,”; and  
 5           (7) in paragraphs (1) and (2) of subsection (j)  
 6           (as so redesignated), by striking “(including those  
 7           developed under subsection (d)(2)(B)(i)(II))” each  
 8           place it appears.

9 **SEC. 14. PEDIATRIC PHARMACOLOGY ADVISORY COM-**  
 10 **MITTEE.**

11           (a) IN GENERAL.—The Secretary of Health and  
 12 Human Services shall, under section 222 of the Public  
 13 Health Service Act (42 U.S.C. 217a), convene and consult  
 14 an advisory committee on pediatric pharmacology (re-  
 15 ferred to in this section as the “advisory committee”).

16           (b) PURPOSE.—

17           (1) IN GENERAL.—The advisory committee  
 18 shall advise and make recommendations to the Sec-  
 19 retary, through the Commissioner of Food and  
 20 Drugs and in consultation with the Director of the  
 21 National Institutes of Health, on matters relating to  
 22 pediatric pharmacology.

23           (2) MATTERS INCLUDED.—The matters re-  
 24 ferred to in paragraph (1) include—

1 (A) pediatric research conducted under  
 2 sections 351, 409I, and 499 of the Public  
 3 Health Service Act and sections 501, 502, 505,  
 4 and 505A of the Federal Food, Drug, and Cos-  
 5 metic Act;

6 (B) identification of research priorities re-  
 7 lated to pediatric pharmacology and the need  
 8 for additional treatments of specific pediatric  
 9 diseases or conditions; and

10 (C) the ethics, design, and analysis of clin-  
 11 ical trials related to pediatric pharmacology.

12 (c) COMPOSITION.—The advisory committee shall in-  
 13 clude representatives of pediatric health organizations, pe-  
 14 diatric researchers, relevant patient and patient-family or-  
 15 ganizations, and other experts selected by the Secretary.

16 **SEC. 15. PEDIATRIC SUBCOMMITTEE OF THE ONCOLOGIC**  
 17 **DRUGS ADVISORY COMMITTEE.**

18 (a) CLARIFICATION OF AUTHORITIES.—

19 (1) IN GENERAL.—The Pediatric Subcommittee  
 20 of the Oncologic Drugs Advisory Committee (re-  
 21 ferred to in this section as the “Subcommittee”), in  
 22 carrying out the mission of reviewing and evaluating  
 23 the data concerning the safety and effectiveness of  
 24 marketed and investigational human drug products  
 25 for use in the treatment of pediatric cancers, shall—

1 (A) evaluate and, to the extent practicable,  
 2 prioritize new and emerging therapeutic alter-  
 3 natives available to treat pediatric cancer;

4 (B) provide recommendations and guidance  
 5 to help ensure that children with cancer have  
 6 timely access to the most promising new cancer  
 7 therapies; and

8 (C) advise on ways to improve consistency  
 9 in the availability of new therapeutic agents.

10 (2) MEMBERSHIP.—

11 (A) IN GENERAL.—The Secretary shall ap-  
 12 point not more than 11 voting members to the  
 13 Pediatric Subcommittee from the membership  
 14 of the Pediatric Pharmacology Advisory Com-  
 15 mittee and the Oncologic Drugs Advisory Com-  
 16 mittee.

17 (B) REQUEST FOR PARTICIPATION.—The  
 18 Subcommittee shall request participation of the  
 19 following members in the scientific and ethical  
 20 consideration of topics of pediatric cancer, as  
 21 necessary:

22 (i) At least 2 pediatric oncology spe-  
 23 cialists from the National Cancer Institute.

24 (ii) At least 4 pediatric oncology spe-  
 25 cialists from—

1 (I) the Children’s Oncology  
2 Group;

3 (II) other pediatric experts with  
4 an established history of conducting  
5 clinical trials in children; or

6 (III) consortia sponsored by the  
7 National Cancer Institute, such as the  
8 Pediatric Brain Tumor Consortium,  
9 the New Approaches to Neuro-  
10 blastoma Therapy or other pediatric  
11 oncology consortia.

12 (iii) At least 2 representatives of the  
13 pediatric cancer patient and patient-family  
14 community.

15 (iv) 1 representative of the nursing  
16 community.

17 (v) At least 1 statistician.

18 (vi) At least 1 representative of the  
19 pharmaceutical industry.

20 (b) PRE-CLINICAL MODELS TO EVALUATE PROM-  
21 ISING PEDIATRIC CANCER THERAPIES.—Section 413 of  
22 the Public Health Service Act (42 U.S.C. 285a–2) is  
23 amended by adding at the end the following:

24 “(c) PRE-CLINICAL MODELS TO EVALUATE PROM-  
25 ISING PEDIATRIC CANCER THERAPIES.—

1           “(1) EXPANSION AND COORDINATION OF AC-  
 2           TIVITIES.—The Director of the National Cancer In-  
 3           stitute shall expand, intensify, and coordinate the  
 4           activities of the Institute with respect to research on  
 5           the development of preclinical models to evaluate  
 6           which therapies are likely to be effective for treating  
 7           pediatric cancer.

8           “(2) COORDINATION WITH OTHER INSTI-  
 9           TUTES.—The Director of the Institute shall coordi-  
 10          nate the activities under paragraph (1) with similar  
 11          activities conducted by other national research insti-  
 12          tutes and agencies of the National Institutes of  
 13          Health to the extent that those Institutes and agen-  
 14          cies have responsibilities that are related to pediatric  
 15          cancer.”.

16          (c) CLARIFICATION OF AVAILABILITY OF INVESTIGA-  
 17          TIONAL NEW DRUGS FOR PEDIATRIC STUDY AND USE.—

18               (1) AMENDMENT OF THE FEDERAL FOOD,  
 19               DRUG, AND COSMETIC ACT.—Section 505(i)(1) of  
 20               the Federal Food, Drug, and Cosmetic Act (21  
 21               U.S.C. 355(i)(1)) is amended—

22                       (A) in subparagraph (B), by striking  
 23                       “and” at the end;

24                       (B) in subparagraph (C), by striking the  
 25                       period at the end and inserting “; and”; and

1 (C) by adding at the end the following:

2 “(D) the submission to the Secretary by  
3 the manufacturer or the sponsor of the inves-  
4 tigation of a new drug of a statement of intent  
5 regarding whether the manufacturer or sponsor  
6 has plans for assessing pediatric safety and effi-  
7 cacy.”.

8 (2) AMENDMENT OF THE PUBLIC HEALTH  
9 SERVICE ACT.—Section 402(j)(3)(A) of the Public  
10 Health Service Act (42 U.S.C. 282(j)(3)(A)) is  
11 amended in the first sentence—

12 (A) by striking “trial sites, and” and in-  
13 serting “trial sites,”; and

14 (B) by striking “in the trial,” and insert-  
15 ing “in the trial, and a description of whether,  
16 and through what procedure, the manufacturer  
17 or sponsor of the investigation of a new drug  
18 will respond to requests for protocol exception,  
19 with appropriate safeguards, for single-patient  
20 and expanded protocol use of the new drug,  
21 particularly in children,”.

22 (d) REPORT.—Not later than January 31, 2003, the  
23 Secretary of Health and Human Services, acting through  
24 the Commissioner of Food and Drugs and in consultation  
25 with the Director of the National Institutes of Health,

1 shall submit to the Committee on Health, Education,  
2 Labor, and Pensions of the Senate and the Committee on  
3 Energy and Commerce of the House of Representatives  
4 a report on patient access to new therapeutic agents for  
5 pediatric cancer, including access to single patient use of  
6 new therapeutic agents.

7 **SEC. 16. REPORT ON PEDIATRIC EXCLUSIVITY PROGRAM.**

8 Not later than October 1, 2006, the Comptroller Gen-  
9 eral of the United States, in consultation with the Sec-  
10 retary of Health and Human Services, shall submit to  
11 Congress a report that addresses the following issues,  
12 using publicly available data or data otherwise available  
13 to the Government that may be used and disclosed under  
14 applicable law:

15 (1) The effectiveness of section 505A of the  
16 Federal Food, Drug, and Cosmetic Act and section  
17 409I of the Public Health Service Act (as added by  
18 this Act) in ensuring that medicines used by children  
19 are tested and properly labeled, including—

20 (A) the number and importance of drugs  
21 for children that are being tested as a result of  
22 this legislation and the importance for children,  
23 health care providers, parents, and others of la-  
24 beling changes made as a result of such testing;

1 (B) the number and importance of drugs  
2 for children that are not being tested for their  
3 use notwithstanding the provisions of this legis-  
4 lation, and possible reasons for the lack of test-  
5 ing; and

6 (C) the number of drugs for which testing  
7 is being done, exclusivity granted, and labeling  
8 changes required, including the date pediatric  
9 exclusivity is granted and the date labeling  
10 changes are made and which labeling changes  
11 required the use of the dispute resolution proc-  
12 ess established pursuant to the amendments  
13 made by this Act, together with a description of  
14 the outcomes of such process, including a de-  
15 scription of the disputes and the recommenda-  
16 tions of the Pediatric Advisory Subcommittee of  
17 the Anti-Infective Drugs Advisory Committee.

18 (2) The economic impact of section 505A of the  
19 Federal Food, Drug, and Cosmetic Act and section  
20 409I of the Public Health Service Act (as added by  
21 this Act), including an estimate of—

22 (A) the costs to taxpayers in the form of  
23 higher expenditures by medicaid and other Gov-  
24 ernment programs;

1 (B) sales for each drug during the 6-  
2 month period for which exclusivity is granted,  
3 as attributable to such exclusivity;

4 (C) costs to consumers and private insur-  
5 ers as a result of any delay in the availability  
6 of lower cost generic equivalents of drugs tested  
7 and granted exclusivity under the Federal  
8 Food, Drug, and Cosmetic Act (21 U.S.C. 301  
9 et seq.), and loss of revenue by the generic drug  
10 industry and retail pharmacies as a result of  
11 any such delay; and

12 (D) the benefits to the government, to pri-  
13 vate insurers, and to consumers resulting from  
14 decreased health care costs, including—

15 (i) decreased hospitalizations and  
16 fewer medical errors, due to more appro-  
17 priate and more effective use of medica-  
18 tions in children as a result of testing and  
19 re-labeling because of the amendments  
20 made by this Act;

21 (ii) direct and indirect benefits associ-  
22 ated with fewer physician visits not related  
23 to hospitalization;

24 (iii) benefits to children from missing  
25 less time at school and being less affected

1 by chronic illnesses, thereby allowing a bet-  
2 ter quality of life;

3 (iv) benefits to consumers from lower  
4 health insurance premiums due to lower  
5 treatment costs and hospitalization rates;  
6 and

7 (v) benefits to employers from reduced  
8 need for employees to care for family mem-  
9 bers.

10 (3) The nature and type of studies in children  
11 for each drug granted exclusivity under the Federal  
12 Food, Drug, and Cosmetic Act (21 U.S.C. 301 et  
13 seq.), including—

14 (A) a description of the complexity of the  
15 studies;

16 (B) the number of study sites necessary to  
17 obtain appropriate data;

18 (C) the numbers of children involved in  
19 any clinical studies; and

20 (D) the estimated cost of each of the stud-  
21 ies.

22 (4) Any recommendations for modifications to  
23 the programs established under section 505A of the  
24 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
25 355a) and section 409I of the Public Health Service

1 Act (as added by section 3) that the Secretary deter-  
2 mines to be appropriate, including a detailed ration-  
3 ale for each recommendation.

4 (5) The increased private and Government-  
5 funded pediatric research capability associated with  
6 this Act and the amendments made by this Act.

7 (6) The number of written requests and addi-  
8 tional letters of recommendation that the Secretary  
9 issues.

10 (7) The prioritized list of off-patent drugs for  
11 which the Secretary issues written requests.

12 (8)(A) The efforts made by Secretary to in-  
13 crease the number of studies conducted in the  
14 neonate population; and

15 (B) the results of those efforts, including efforts  
16 made to encourage the conduct of appropriate stud-  
17 ies in neonates by companies with products that  
18 have sufficient safety and other information to make  
19 the conduct of studies ethical and safe.

20 **SEC. 17. ADVERSE-EVENT REPORTING.**

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

1 of the Federal Food, Drug, and Cosmetic Act (regardless  
2 of the date on which approved) include the toll-free num-  
3 ber maintained by the Secretary for the purpose of receiv-  
4 ing reports of adverse events regarding drugs and a state-  
5 ment that such number is to be used for reporting pur-  
6 poses only, not to receive medical advice. With respect to  
7 the final rule:

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

12 (2) In promulgating the rule, the Secretary  
13 shall seek to minimize the cost of the rule on the  
14 pharmacy profession.

15 (3) The rule shall take effect not later than 60  
16 days after the date on which the rule is promul-  
17 gated.

18 (b) DRUGS WITH PEDIATRIC MARKET EXCLU-  
19 SIVITY.—

20 (1) IN GENERAL.—During the one-year begin-  
21 ning on the date on which a drug receives a period  
22 of market exclusivity under 505A of the Federal  
23 Food, Drug, and Cosmetic Act, any report of an ad-  
24 verse event regarding the drug that the Secretary of  
25 Health and Human Services receives shall be re-

1       ferred to the Office of Pediatric Therapeutics estab-  
 2       lished under section 6 of this Act. In considering the  
 3       report, the Director of such Office shall provide for  
 4       the review of the report by the Pediatric Advisory  
 5       Subcommittee of the Anti-Infective Drugs Advisory  
 6       Committee, including obtaining any recommenda-  
 7       tions of such Subcommittee regarding whether the  
 8       Secretary should take action under the Federal  
 9       Food, Drug, and Cosmetic Act in response to the re-  
 10      port.

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

18 **SEC. 18. MINORITY CHILDREN AND PEDIATRIC-EXCLU-**  
 19 **SIVITY PROGRAM.**

20           (a) PROTOCOLS FOR PEDIATRIC STUDIES.—Section  
 21 505A of the Federal Food, Drug, and Cosmetic Act (21  
 22 U.S.C. 355a) is amended in subsection (d)(2) by inserting  
 23 after the first sentence the following: “In reaching an  
 24 agreement regarding written protocols, the Secretary shall

1 take into account adequate representation of children of  
2 ethnic and racial minorities.”.

3 (b) STUDY BY GENERAL ACCOUNTING OFFICE.—

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

7 (A) The extent to which children of ethnic  
8 and racial minorities are adequately represented  
9 in studies under section 505A of the Federal  
10 Food, Drug, and Cosmetic Act; and to the ex-  
11 tent ethnic and racial minorities are not ade-  
12 quately represented, the reasons for such under  
13 representation and recommendations to increase  
14 such representation.

15 (B) Whether the Food and Drug Adminis-  
16 tration has appropriate management systems to  
17 monitor the representation of the children of  
18 ethnic and racial minorities in such studies.

19 (C) Whether drugs used to address dis-  
20 eases that disproportionately affect racial and  
21 ethnic minorities are being studied for their  
22 safety and effectiveness under section 505A of  
23 the Federal Food, Drug, and Cosmetic Act.

24 (2) DATE CERTAIN FOR COMPLETING STUDY.—

25 Not later than January 10, 2003, the Comptroller

1       General shall complete the study required in para-  
 2       graph (1) and submit to the Congress a report de-  
 3       scribing the findings of the study.

4   **SEC. 19. TECHNICAL AND CONFORMING AMENDMENTS.**

5       Section 505A of the Federal Food, Drug, and Cos-  
 6       metic Act (21 U.S.C. 355a) (as amended by sections 2(1),  
 7       5(b)(2), 9, 10, 11, and 17) is amended—

8               (1)(A) by striking “(j)(4)(D)(ii)” each place it  
 9       appears and inserting “(j)(5)(D)(ii)”;

10              (B) by striking “(j)(4)(D)” each place it ap-  
 11       pears and inserting “(j)(5)(D)”;

12              (C) by striking “505(j)(4)(D)” each place it ap-  
 13       pears and inserting “505(j)(5)(D)”;

14              (2) by redesignating subsections (a), (g), (h),  
 15       (i), (j), (k), (l), (m), (n), and (o) as subsections (b),  
 16       (a), (g), (h), (n), (m), (i), (j), (k), and (l) respec-  
 17       tively;

18              (3) by moving the subsections so as to appear  
 19       in alphabetical order;

20              (4) in paragraphs (1), (2), and (3) of sub-  
 21       section (d), subsection (e), and subsection (m) (as  
 22       redesignated by paragraph (2)), by striking “sub-  
 23       section (a) or (c)” and inserting “subsection (b) or  
 24       (c)”;

- 1 (5) in subsection (g) (as redesignated by para-
- 2 graph (2)), by striking “subsection (a) or (b)” and
- 3 inserting “subsection (b) or (c)”.



**Calendar No. 271**

107TH CONGRESS  
1ST SESSION

**S. 1789**

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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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DECEMBER 10, 2001

Read the second time and placed on the calendar