funds remaining for cleanups at the Ohio, Kentucky, and Tennessee facilities. The bill also increase the sizes of the Uranium Enrichment Decontamination and Decommissioning Fund in order to hold harmless the cleanups at the other facilities and mine sites, without raising the fees currently assessed on utility ratepayers. In addition the bill requires the General Accounting Office to audit the Fund to ensure it is, and will be, sufficient to cover the costs of all the activities authorized and to look at the current and likely costs of the cleanup activity at the various sites.

Last but not least, the bill contains language authored by the gentleman from Ohio, Representative STRICKLAND, that provides specific authorization for the Secretary of Energy to expend funds to keep the Portsmouth, Ohio, uranium enrichment facility in ''cold-standby'' mode. I believe this to be wise, for it allows the Secretary to use the facility again if needed to protect the continuity of domestic supply or to meet the contract demands of the Department.

I want to again thank my good friend, Chairman TAUZIN, and commend all the Members who worked with us to craft this compromise language, including Representatives STRICKLAND and WHITFIELD, Chairman BARTON and Ranking Member BOUCHER, of course the sponsor of the bill, representative SHIMKUS. I also want to thank Speaker HASTERT, with whom I have worked many times on legislation to ensure the cleanup of thorium wastes, for his assistance in moving this bill forward with bipartisan support.

H.R. 3343 is good legislation and deserves the support of all Members.

Mr. BOUCHER. Mr. Speaker, I have no further requests for time. I urge support for this measure, and I yield back the balance of my time.

Mr. SHIMKUS. Mr. Speaker, I have no further requests for time, and I yield back the balance of my time.

The SPEAKER pro tempore (Mr. SIMPSON). The question is on the motion offered by the gentleman from Illinois (Mr. SHIMKUS) that the House suspend the rules and pass the bill, H.R. 3343, as amended.

The question was taken; and (two-thirds having voted in favor thereof) the rules were suspended and the bill, as amended, was passed.

A motion to reconsider was laid on the table.

BEST PHARMACEUTICALS FOR CHILDREN ACT

Mr. TAUZIN. Mr. Speaker, I move to suspend the rules and pass the Senate bill (S. 1789) to amend the Federal Food, Drug, and Cosmetic Act to improve the safety and efficacy of pharmaceuticals for children.

The Clerk read as follows:

S. 1789

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Best Pharmaceuticals for Children Act''.

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

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

(1) by striking subsection (b); and

(2) in subsection (c)—

(A) by inserting after ''the Secretary'' the following: ''determines that information relating to the use of an approved drug in the pediatric population may produce health benefits in that population and''; and

(B) by striking ''concerning a drug identified in the list described in subsection (b)''.

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

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

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

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

(3) by adding at the end the following:

''SEC. 409I. PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.

''(a) LIST OF DRUGS FOR WHICH PEDIATRIC STUDIES ARE NEEDED.—

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

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

''(ii) there is a submitted application that could be approved under the criteria of section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j));

''(iii) there is no patent protection or market exclusivity protection under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.); or

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

''(B) in the case of a drug referred to in clause (i), (ii), or (iii) of subparagraph (A), additional studies are needed to assess the safety and effectiveness of the use of the drug in the pediatric population.

''(2) CONSIDERATION OF AVAILABLE INFORMATION.—In developing and prioritizing the list under paragraph (1), the Secretary shall consider, for each drug on the list—

''(A) the availability of information concerning the safe and effective use of the drug in the pediatric population;

''(B) whether additional information is needed;

''(C) whether new pediatric studies concerning the drug may produce health benefits in the pediatric population; and

''(D) whether reformulation of the drug is necessary.

''(b) CONTRACTS FOR PEDIATRIC STUDIES.—The Secretary shall award contracts to entities that have the expertise to conduct pediatric clinical trials (including qualified universities, hospitals, laboratories, contract research organizations, federally funded programs such as pediatric pharmacology research units, other public or private institutions, or individuals) to enable the entities to conduct pediatric studies concerning one or more drugs identified in the list described in subsection (a).

''(c) PROCESS FOR CONTRACTS AND LABELING CHANGES.—

''(1) WRITTEN REQUEST TO HOLDERS OF APPROVED APPLICATIONS FOR DRUGS LACKING EXCLUSIVITY.—The Commissioner of Food and Drugs, in consultation with the Director of the National Institutes of Health, may issue a written request (which shall include a timeframe for negotiations for an agreement) for pediatric studies concerning a drug identified in the list described in subsection (a)(1)(A) (except clause (iv)) to all holders of an approved application for the drug under section 505 of the Federal Food, Drug, and Cosmetic Act. Such a written request shall be made in a manner equivalent to the manner in which a written request is made under subsection (a) or (b) of section 505A of the Federal Food, Drug, and Cosmetic Act, including with respect to information provided on the pediatric studies to be conducted pursuant to the request.

''(2) REQUESTS FOR CONTRACT PROPOSALS.—If the Commissioner of Food and Drugs does not receive a response to a written request issued under paragraph (1) within 30 days of the date on which a request was issued, or if a referral described in subsection (a)(1)(A)(iv) is made, the Secretary, acting through the Director of the National Institutes of Health and in consultation with the Commissioner of Food and Drugs, shall publish a request for contract proposals to conduct the pediatric studies described in the written request.

''(3) DISQUALIFICATION.—A holder that receives a first right of refusal shall not be entitled to respond to a request for contract proposals under paragraph (2).

''(4) GUIDANCE.—Not later than 270 days after the date of enactment of this section, the Commissioner of Food and Drugs shall promulgate guidance to establish the process for the submission of responses to written requests under paragraph (1).

''(5) CONTRACTS.—A contract under this section may be awarded only if a proposal for the contract is submitted to the Secretary in such form and manner, and containing such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

''(6) REPORTING OF STUDIES.—

''(A) IN GENERAL.—On completion of a pediatric study in accordance with a contract awarded under this section, a report concerning the study shall be submitted to the Director of the National Institutes of Health and the Commissioner of Food and Drugs. The report shall include all data generated in connection with the study.

''(B) AVAILABILITY OF REPORTS.—Each report submitted under subparagraph (A) shall be considered to be in the public domain (subject to section 505A(d)(4)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(d)(4)(D)) and shall be assigned a docket number by the Commissioner of Food and Drugs. An interested person may submit written comments concerning such pediatric studies to the Commissioner of Food and Drugs, and the written comments shall become part of the docket file with respect to each of the drugs.

''(C) ACTION BY COMMISSIONER.—The Commissioner of Food and Drugs shall take appropriate action in response to the reports submitted under subparagraph (A) in accordance with paragraph (7).

''(7) REQUESTS FOR LABELING CHANGE.—During the 180-day period after the date on which a report is submitted under paragraph (6)(A), the Commissioner of Food and Drugs shall—

''(A) review the report and such other data as are available concerning the safe and effective use in the pediatric population of the drug studied;

''(B) negotiate with the holders of approved applications for the drug studied for any labeling changes that the Commissioner of Food and Drugs determines to be appropriate and requests the holders to make; and

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

''(ii) publish in the Federal Register a summary of the report and a copy of any requested labeling changes.

''(8) DISPUTE RESOLUTION.—

''(A) REFERRAL TO PEDIATRIC ADVISORY SUBCOMMITTEE OF THE ANTI-INFECTIVE DRUGS ADVISORY COMMITTEE.—If, not later than the end of the 180-day period specified in paragraph (7), the holder of an approved application for the drug involved does not agree to any labeling change requested by the Commissioner of Food and Drugs under that paragraph, the Commissioner of Food and Drugs shall refer the request to the Pediatric Advisory Subcommittee of the Anti-Infective Drugs Advisory Committee.

''(B) ACTION BY THE PEDIATRIC ADVISORY SUBCOMMITTEE OF THE ANTI-INFECTIVE DRUGS ADVISORY COMMITTEE.—Not later than 90 days after receiving a referral under subparagraph (A), the Pediatric Advisory Subcommittee of the Anti-Infective Drugs Advisory Committee shall—

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

''(ii) make a recommendation to the Commissioner of Food and Drugs as to appropriate labeling changes, if any.

''(9) FDA DETERMINATION.—Not later than 30 days after receiving a recommendation from the Pediatric Advisory Subcommittee of the Anti-Infective Drugs Advisory Committee under paragraph (8)(B)(ii) with respect to a drug, the Commissioner of Food and Drugs shall consider the recommendation and, if appropriate, make a request to the holders of approved applications for the drug to make any labeling change that the Commissioner of Food and Drugs determines to be appropriate.

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

''(11) NO EFFECT ON AUTHORITY.—Nothing in this subsection limits the authority of the United States to bring an enforcement action under the Federal Food, Drug, and Cosmetic Act when a drug lacks appropriate pediatric labeling. Neither course of action (the Pediatric Advisory Subcommittee of the Anti-Infective Drugs Advisory Committee process or an enforcement action referred to in the preceding sentence) shall preclude, delay, or serve as the basis to stay the other course of action.

''(12) RECOMMENDATION FOR FORMULATION CHANGES.—If a pediatric study completed under public contract indicates that a formulation change is necessary and the Secretary agrees, the Secretary shall send a nonbinding letter of recommendation regarding that change to each holder of an approved application.

''(d) AUTHORIZATION OF APPROPRIATIONS.—

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

''(A) $200,000,000 for fiscal year 2002; and

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

''(2) AVAILABILITY.—Any amount appropriated under paragraph (1) shall remain available to carry out this section until expended.''.

SEC. 4. WRITTEN REQUEST TO HOLDERS OF APPROVED APPLICATIONS FOR DRUGS THAT HAVE MARKET EXCLUSIVITY.

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

''(4) WRITTEN REQUEST TO HOLDERS OF APPROVED APPLICATIONS FOR DRUGS THAT HAVE MARKET EXCLUSIVITY.—

''(A) REQUEST AND RESPONSE.—If the Secretary makes a written request for pediatric studies (including neonates, as appropriate) under subsection (c) to the holder of an application approved under section 505(b)(1), the holder, not later than 180 days after receiving the written request, shall respond to the Secretary as to the intention of the holder to act on the request by—

''(i) indicating when the pediatric studies will be initiated, if the holder agrees to the request; or

''(ii) indicating that the holder does not agree to the request.

''(B) NO AGREEMENT TO REQUEST.—

''(i) REFERRAL.—If the holder does not agree to a written request within the time period specified in subparagraph (A), and if the Secretary determines that there is a continuing need for information relating to the use of the drug in the pediatric population (including neonates, as appropriate), the Secretary shall refer the drug to the Foundation for the National Institutes of Health established under section 499 of the Public Health Service Act (42 U.S.C. 290b) (referred to in this paragraph 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 timeframe 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) alters or amends section 301(j) of this Act or section 552 of title 5 or section 1905 of title 18, United States Code.

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

''(F) WRITTEN REQUESTS UNDER SUBSECTION (b).—For drugs under subsection (b) for which written requests have not been accepted, if the Secretary determines that there is a continuing need for information relating to the use of the drug in the pediatric population (including neonates, as appropriate), the Secretary shall issue a written request under subsection (c) after the date of approval of the drug.''.

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

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

(1) by striking subparagraph (F); and

(2) by redesignating subparagraph (G) as subparagraph (F).

(b) LABELING CHANGES.—

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

''(kk) PRIORITY SUPPLEMENT.—The term 'priority supplement' means a drug application referred to in section 101(4) of the Food and Drug Administration Modernization Act of 1997 (111 Stat. 2298).''.

(2) TREATMENT AS PRIORITY SUPPLEMENTS.—Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended by adding at the end the following:

''(l) LABELING SUPPLEMENTS.—

''(1) PRIORITY STATUS FOR PEDIATRIC SUPPLEMENTS.—Any supplement to an application under section 505 proposing a labeling change pursuant to a report on a pediatric study under this section—

''(A) shall be considered to be a priority supplement; and

''(B) shall be subject to the performance goals established by the Commissioner for priority drugs.

''(2) DISPUTE RESOLUTION.—

''(A) REQUEST FOR LABELING CHANGE AND FAILURE TO AGREE.—If the Commissioner determines that an application with respect to which a pediatric study is conducted under this section is approvable and that the only open issue for final action on the application is the reaching of an agreement between the sponsor of the application and the Commissioner on appropriate changes to the labeling for the drug that is the subject of the application, not later than 180 days after the date of submission of the application—

''(i) the Commissioner shall request that the sponsor of the application make any labeling change that the Commissioner determines to be appropriate; and

''(ii) if the sponsor of the application does not agree to make a labeling change requested by the Commissioner, the Commissioner shall refer the matter to the Pediatric Advisory Subcommittee of the Anti-Infective Drugs Advisory Committee.

''(B) ACTION BY THE PEDIATRIC ADVISORY SUBCOMMITTEE OF THE ANTI-INFECTIVE DRUGS ADVISORY COMMITTEE.—Not later than 90 days after receiving a referral under subparagraph (A)(ii), the Pediatric Advisory Subcommittee of the Anti-Infective Drugs Advisory Committee shall—

''(i) review the pediatric study reports; and

''(ii) make a recommendation to the Commissioner concerning appropriate labeling changes, if any.

''(C) CONSIDERATION OF RECOMMENDATIONS.—The Commissioner shall consider the recommendations of the Pediatric Advisory Subcommittee of the Anti-Infective Drugs Advisory Committee and, if appropriate, not later than 30 days after receiving the recommendation, make a request to the sponsor of the application to make any labeling change that the Commissioner determines to be appropriate.

''(D) MISBRANDING.—If the sponsor of the application, within 30 days after receiving a request under subparagraph (C), does not agree to make a labeling change requested by the Commissioner, the Commissioner may deem the drug that is the subject of the application to be misbranded.

''(E) NO EFFECT ON AUTHORITY.—Nothing in this subsection limits the authority of the United States to bring an enforcement action under this Act when a drug lacks appropriate pediatric labeling. Neither course of action (the Pediatric Advisory Subcommittee of the Anti-Infective Drugs Advisory Committee process or an enforcement action referred to in the preceding sentence) shall preclude, delay, or serve as the basis to stay the other course of action.''.

SEC. 6. OFFICE OF PEDIATRIC THERAPEUTICS.

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

(b) DUTIES.—The Office of Pediatric Therapeutics shall be responsible for coordination and facilitation of all activities of the Food

and Drug Administration that may have any effect on a pediatric population or the practice of pediatrics or may in any other way involve pediatric issues.

(c) STAFF.—The staff of the Office of Pediatric Therapeutics shall coordinate with employees of the Department of Health and Human Services who exercise responsibilities relating to pediatric therapeutics and shall include—

(1) 1 or more additional individuals with expertise concerning ethical issues presented by the conduct of clinical research in the pediatric population; and

(2) 1 or more additional individuals with expertise in pediatrics as may be necessary to perform the activities described in subsection (b).

SEC. 7. NEONATES.

Section 505A(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(g)) is amended by inserting ''(including neonates in appropriate cases)'' after ''pediatric age groups''.

SEC. 8. SUNSET.

Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended by striking subsection (j) and inserting the following:

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

''(1) on or before October 1, 2007, the Secretary makes a written request for pediatric studies of the drug;

''(2) on or before October 1, 2007, an application for the drug is accepted for filing under section 505(b); and

''(3) all requirements of this section are met.''.

SEC. 9. DISSEMINATION OF PEDIATRIC INFORMATION.

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

''(m) DISSEMINATION OF PEDIATRIC INFORMATION.—

''(1) IN GENERAL.—Not later than 180 days after the date of submission of a report on a pediatric study under this section, the Commissioner shall make available to the public a summary of the medical and clinical pharmacology reviews of pediatric studies conducted for the supplement, including by publication in the Federal Register.

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

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

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

''(n) CLARIFICATION OF INTERACTION OF MARKET EXCLUSIVITY UNDER THIS SECTION AND MARKET EXCLUSIVITY AWARDED TO AN APPLICANT FOR APPROVAL OF A DRUG UNDER SECTION 505(j).—If a 180-day period under section 505(j)(5)(B)(iv) overlaps with a 6-month exclusivity period under this section, so that the applicant for approval of a drug under section 505(j) entitled to the 180-day period under that section loses a portion of the 180-day period to which the applicant is entitled for the drug, the 180-day period shall be extended from—

''(1) the date on which the 180-day period would have expired by the number of days of the overlap, if the 180-day period would, but for the application of this subsection, expire after the 6-month exclusivity period; or

''(2) the date on which the 6-month exclusivity period expires, by the number of days of the overlap if the 180-day period would, but for the application of this subsection, expire during the 6 month exclusivity period.''.

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

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

''(o) PROMPT APPROVAL OF DRUGS UNDER SECTION 505(j) WHEN PEDIATRIC INFORMATION IS ADDED TO LABELING.—

''(1) GENERAL RULE.—A drug for which an application has been submitted or approved under section 505(j) shall not be considered ineligible for approval under that section or misbranded under section 502 on the basis that the labeling of the drug omits a pediatric indication or any other aspect of labeling pertaining to pediatric use when the omitted indication or other aspect is protected by patent or by exclusivity under clause (iii) or (iv) of section 505(j)(5)(D).

''(2) LABELING.—Notwithstanding clauses (iii) and (iv) of section 505(j)(5)(D), the Secretary may require that the labeling of a drug approved under section 505(j) that omits a pediatric indication or other aspect of labeling as described in paragraph (1) include—

''(A) a statement that, because of marketing exclusivity for a manufacturer—

''(i) the drug is not labeled for pediatric use; or

''(ii) in the case of a drug for which there is an additional pediatric use not referred to in paragraph (1), the drug is not labeled for the pediatric use under paragraph (1); and

''(B) a statement of any appropriate pediatric contraindications, warnings, or precautions that the Secretary considers necessary.

''(3) PRESERVATION OF PEDIATRIC EXCLUSIVITY AND OTHER PROVISIONS.—This subsection does not affect—

''(A) the availability or scope of exclusivity under this section;

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

''(C) the question of the eligibility for approval of any application under section 505(j) that omits any other conditions of approval entitled to exclusivity under clause (iii) or (iv) of section 505(j)(5)(D); or

''(D) except as expressly provided in paragraphs (1) and (2), the operation of section 505.''.

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

SEC. 12. STUDY CONCERNING RESEARCH INVOLVING CHILDREN.

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

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

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

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

(C) federally supported evidence-based research involving children; and

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

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

(1) The written and oral process of obtaining and defining ''assent'', ''permission'' and ''informed consent'' with respect to child clinical research participants and the parents, guardians, and the individuals who may serve as the legally authorized representatives of such children (as defined in subpart A of part 46 of title 45, Code of Federal Regulations).

(2) The expectations and comprehension of child research participants and the parents, guardians, or legally authorized representatives of such children, for the direct benefits and risks of the child's research involvement, particularly in terms of research versus therapeutic treatment.

(3) The definition of ''minimal risk'' with respect to a healthy child or a child with an illness.

(4) The appropriateness of the regulations applicable to children of differing ages and maturity levels, including regulations relating to legal status.

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

(6) Compliance with the regulations referred to in subsection (a)(1)(A), the monitoring of such compliance (including the role of institutional review boards), and the enforcement actions taken for violations of such regulations.

(7) The unique roles and responsibilities of institutional review boards in reviewing research involving children, including composition of membership on institutional review boards.

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

SEC. 13. FOUNDATION FOR THE NATIONAL INSTITUTES OF HEALTH.

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

(1) in subsection (b), by inserting ''(including collection of funds for pediatric pharmacologic research)'' after ''mission'';

(2) in subsection (c)(1)—

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

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

''(C) A program to collect funds for pediatric pharmacologic research and studies listed by the Secretary pursuant to section 409I(a)(1)(A) of this Act and referred under section 505A(d)(4)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(d)(4)(C)).'';

(3) in subsection (d)—

(A) in paragraph (1)—

(i) in subparagraph (B)—

(I) in clause (ii), by striking ''and'' at the end;

(II) in clause (iii), by striking the period and inserting ''; and''; and

(III) by adding at the end the following:

''(iv) the Commissioner of Food and Drugs.''; and

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

''(C) The ex officio members of the Board under subparagraph (B) shall appoint to the Board individuals from among a list of candidates to be provided by the National Academy of Science. Such appointed members shall include—

''(i) representatives of the general biomedical field;

''(ii) representatives of experts in pediatric medicine and research;

''(iii) representatives of the general biobehavioral field, which may include experts in biomedical ethics; and

''(iv) representatives of the general public, which may include representatives of affected industries.''; and

(B) in paragraph (2), by realigning the margin of subparagraph (B) to align with subparagraph (A);

(4) in subsection (k)(9)—

(A) by striking ''The Foundation'' and inserting the following:

''(A) IN GENERAL.—The Foundation''; and

(B) by adding at the end the following:

''(B) GIFTS, GRANTS, AND OTHER DONATIONS.—

''(i) IN GENERAL.—Gifts, grants, and other donations to the Foundation may be designated for pediatric research and studies on drugs, and funds so designated shall be used solely for grants for research and studies under subsection (c)(1)(C).

''(ii) OTHER GIFTS.—Other gifts, grants, or donations received by the Foundation and not described in clause (i) may also be used to support such pediatric research and studies.

''(iii) REPORT.—The recipient of a grant for research and studies shall agree to provide the Director of the National Institutes of Health and the Commissioner of Food and Drugs, at the conclusion of the research and studies—

''(I) a report describing the results of the research and studies; and

''(II) all data generated in connection with the research and studies.

''(iv) ACTION BY THE COMMISSIONER OF FOOD AND DRUGS.—The Commissioner of Food and Drugs shall take appropriate action in response to a report received under clause (iii) in accordance with paragraphs (7) through (12) of section 409I(c), including negotiating with the holders of approved applications for the drugs studied for any labeling changes that the Commissioner determines to be appropriate and requests the holders to make.

''(C) APPLICABILITY.—Subparagraph (A) does not apply to the program described in subsection (c)(1)(C).'';

(5) by redesignating subsections (f) through (m) as subsections (e) through (l), respectively;

(6) in subsection (h)(11) (as so redesignated), by striking ''solicit'' and inserting ''solicit,''; and

(7) in paragraphs (1) and (2) of subsection (j) (as so redesignated), by striking ''(including those developed under subsection (d)(2)(B)(i)(II))'' each place it appears.

SEC. 14. PEDIATRIC PHARMACOLOGY ADVISORY COMMITTEE.

(a) IN GENERAL.—The Secretary of Health and Human Services shall, under section 222 of the Public Health Service Act (42 U.S.C. 217a), convene and consult an advisory committee on pediatric pharmacology (referred to in this section as the ''advisory committee'').

(b) PURPOSE.—

(1) IN GENERAL.—The advisory committee shall advise and make recommendations to the Secretary, through the Commissioner of Food and Drugs and in consultation with the Director of the National Institutes of Health, on matters relating to pediatric pharmacology.

(2) MATTERS INCLUDED.—The matters referred to in paragraph (1) include—

(A) pediatric research conducted under sections 351, 409I, and 499 of the Public Health Service Act and sections 501, 502, 505, and 505A of the Federal Food, Drug, and Cosmetic Act;

(B) identification of research priorities related to pediatric pharmacology and the need for additional treatments of specific pediatric diseases or conditions; and

(C) the ethics, design, and analysis of clinical trials related to pediatric pharmacology.

(c) COMPOSITION.—The advisory committee shall include representatives of pediatric health organizations, pediatric researchers, relevant patient and patient-family organizations, and other experts selected by the Secretary.

SEC. 15. PEDIATRIC SUBCOMMITTEE OF THE ONCOLOGIC DRUGS ADVISORY COMMITTEE.

(a) CLARIFICATION OF AUTHORITIES.—

(1) IN GENERAL.—The Pediatric Subcommittee of the Oncologic Drugs Advisory Committee (referred to in this section as the ''Subcommittee''), in carrying out the mission of reviewing and evaluating the data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of pediatric cancers, shall—

(A) evaluate and, to the extent practicable, prioritize new and emerging therapeutic alternatives available to treat pediatric cancer;

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

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

(2) MEMBERSHIP.—

(A) IN GENERAL.—The Secretary shall appoint not more than 11 voting members to the Pediatric Subcommittee from the membership of the Pediatric Pharmacology Advisory Committee and the Oncologic Drugs Advisory Committee.

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

(i) At least 2 pediatric oncology specialists from the National Cancer Institute.

(ii) At least 4 pediatric oncology specialists from—

(I) the Children's Oncology Group;

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

(III) consortia sponsored by the National Cancer Institute, such as the Pediatric Brain Tumor Consortium, the New Approaches to Neuroblastoma Therapy or other pediatric oncology consortia.

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

(iv) 1 representative of the nursing community.

(v) At least 1 statistician.

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

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

''(c) PRE-CLINICAL MODELS TO EVALUATE PROMISING PEDIATRIC CANCER THERAPIES.—

''(1) EXPANSION AND COORDINATION OF ACTIVITIES.—The Director of the National Cancer Institute shall expand, intensify, and coordinate the activities of the Institute with respect to research on the development of preclinical models to evaluate which therapies are likely to be effective for treating pediatric cancer.

''(2) COORDINATION WITH OTHER INSTITUTES.—The Director of the Institute shall coordinate the activities under paragraph (1) with similar activities conducted by other national research institutes and agencies of the National Institutes of Health to the extent that those Institutes and agencies have responsibilities that are related to pediatric cancer.''.

(c) CLARIFICATION OF AVAILABILITY OF INVESTIGATIONAL NEW DRUGS FOR PEDIATRIC STUDY AND USE.—

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

(A) in subparagraph (B), by striking ''and'' at the end;

(B) in subparagraph (C), by striking the period at the end and inserting ''; and''; and

(C) by adding at the end the following:

''(D) the submission to the Secretary by the manufacturer or the sponsor of the investigation of a new drug of a statement of intent regarding whether the manufacturer or sponsor has plans for assessing pediatric safety and efficacy.''.

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

(A) by striking ''trial sites, and'' and inserting ''trial sites,''; and

(B) by striking ''in the trial,'' and inserting ''in the trial, and a description of whether, and through what procedure, the manufacturer or sponsor of the investigation of a new drug will respond to requests for protocol exception, with appropriate safeguards, for single-patient and expanded protocol use of the new drug, particularly in children,''.

(d) REPORT.—Not later than January 31, 2003, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs and in consultation with the Director of the National Institutes of Health, shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on patient access to new therapeutic agents for pediatric cancer, including access to single patient use of new therapeutic agents.

SEC. 16. REPORT ON PEDIATRIC EXCLUSIVITY PROGRAM.

Not later than October 1, 2006, the Comptroller General of the United States, in consultation with the Secretary of Health and Human Services, shall submit to Congress a report that addresses the following issues, using publicly available data or data otherwise available to the Government that may be used and disclosed under applicable law:

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

(A) the number and importance of drugs for children that are being tested as a result of this legislation and the importance for children, health care providers, parents, and others of labeling changes made as a result of such testing;

(B) the number and importance of drugs for children that are not being tested for their use notwithstanding the provisions of this legislation, and possible reasons for the lack of testing; and

(C) the number of drugs for which testing is being done, exclusivity granted, and labeling changes required, including the date pediatric exclusivity is granted and the date

labeling changes are made and which labeling changes required the use of the dispute resolution process established pursuant to the amendments made by this Act, together with a description of the outcomes of such process, including a description of the disputes and the recommendations of the Pediatric Advisory Subcommittee of the Anti-Infective Drugs Advisory Committee.

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

(A) the costs to taxpayers in the form of higher expenditures by medicaid and other Government programs;

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

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

(D) the benefits to the government, to private insurers, and to consumers resulting from decreased health care costs, including—

(i) decreased hospitalizations and fewer medical errors, due to more appropriate and more effective use of medications in children as a result of testing and re-labeling because of the amendments made by this Act;

(ii) direct and indirect benefits associated with fewer physician visits not related to hospitalization;

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

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

(v) benefits to employers from reduced need for employees to care for family members.

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

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

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

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

(D) the estimated cost of each of the studies.

(4) Any recommendations for modifications to the programs established under section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) and section 409I of the Public Health Service Act (as added by section 3) that the Secretary determines to be appropriate, including a detailed rationale for each recommendation.

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

(6) The number of written requests and additional letters of recommendation that the Secretary issues.

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

(8)(A) The efforts made by Secretary to increase the number of studies conducted in the neonate population; and

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

SEC. 17. ADVERSE-EVENT REPORTING.

(a) TOLL-FREE NUMBER IN LABELING.—Not later than one year after the date of the enactment of this Act, the Secretary of Health and Human Services shall promulgate a final rule requiring that the labeling of each drug for which an application is approved under section 505 of the Federal Food, Drug, and Cosmetic Act (regardless of the date on which approved) include the toll-free number maintained by the Secretary for the purpose of receiving reports of adverse events regarding drugs and a statement that such number is to be used for reporting purposes only, not to receive medical advice. With respect to the final rule:

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

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

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

(b) DRUGS WITH PEDIATRIC MARKET EXCLUSIVITY.—

(1) IN GENERAL.—During the one-year beginning on the date on which a drug receives a period of market exclusivity under 505A of the Federal Food, Drug, and Cosmetic Act, any report of an adverse event regarding the drug that the Secretary of Health and Human Services receives shall be referred to the Office of Pediatric Therapeutics established under section 6 of this Act. In considering the report, the Director of such Office shall provide for the review of the report by the Pediatric Advisory Subcommittee of the Anti-Infective Drugs Advisory Committee, including obtaining any recommendations of such Subcommittee regarding whether the Secretary should take action under the Federal Food, Drug, and Cosmetic Act in response to the report.

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

SEC. 18. MINORITY CHILDREN AND PEDIATRIC-EXCLUSIVITY PROGRAM.

(a) PROTOCOLS FOR PEDIATRIC STUDIES.—Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended in subsection (d)(2) by inserting after the first sentence the following: ''In reaching an agreement regarding written protocols, the Secretary shall take into account adequate representation of children of ethnic and racial minorities.''.

(b) STUDY BY GENERAL ACCOUNTING OFFICE.—

(1) IN GENERAL.—The Comptroller General of the United States shall conduct a study for the purpose of determining the following:

(A) The extent to which children of ethnic and racial minorities are adequately represented in studies under section 505A of the Federal Food, Drug, and Cosmetic Act; and to the extent ethnic and racial minorities are not adequately represented, the reasons for such under representation and recommendations to increase such representation.

(B) Whether the Food and Drug Administration has appropriate management systems to monitor the representation of the children of ethnic and racial minorities in such studies.

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

(2) DATE CERTAIN FOR COMPLETING STUDY.—Not later than January 10, 2003, the Comptroller General shall complete the study required in paragraph (1) and submit to the Congress a report describing the findings of the study.

SEC. 19. TECHNICAL AND CONFORMING AMENDMENTS.

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

(1)(A) by striking ''(j)(4)(D)(ii)'' each place it appears and inserting ''(j)(5)(D)(ii)'';

(B) by striking ''(j)(4)(D)'' each place it appears and inserting ''(j)(5)(D)''; and

(C) by striking ''505(j)(4)(D)'' each place it appears and inserting ''505(j)(5)(D)'';

(2) by redesignating subsections (a), (g), (h), (i), (j), (k), (l), (m), (n), and (o) as subsections (b), (a), (g), (h), (n), (m), (i), (j), (k), and (l) respectively;

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

(4) in paragraphs (1), (2), and (3) of subsection (d), subsection (e), and subsection (m) (as redesignated by paragraph (2)), by striking ''subsection (a) or (c)'' and inserting ''subsection (b) or (c)''; and

(5) in subsection (g) (as redesignated by paragraph (2)), by striking ''subsection (a) or (b)'' and inserting ''subsection (b) or (c)''.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Louisiana (Mr. TAUZIN) and the gentleman from Ohio (Mr. BROWN) each will control 20 minutes.

The Chair recognizes the gentleman from Louisiana (Mr. TAUZIN).

GENERAL LEAVE

Mr. TAUZIN. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days within which to revise and extend their remarks and include extraneous material on S. 1789.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Louisiana?

There was no objection.

Mr. TAUZIN. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I rise today in strong support of S. 1789, the Best Pharmaceuticals for Children Act. I wish to commend the hard work of the House sponsors of this legislation, the gentleman from Pennsylvania (Mr. GREENWOOD) and the gentlewoman from California (Ms. ESHOO), two extraordinarily valuable members of the Committee on Energy and Commerce, and urge swift passage of this bipartisan bill.

The bill before us today represents a product of bipartisan and bicameral negotiation. This is strikingly similar to the legislation that already passed this House on November 15 by a vote of 338 to 86. Because the bill passed by the other body differed slightly from the House-passed bills, the bills had to be reconciled. S. 1789 is a product of those negotiations. The Senate recently approved the bill without a single dissenting vote.

For years, drugs used in children were not tested for children. To address

this situation, the gentleman from Pennsylvania (Mr. GREENWOOD) and the gentleman from California (Mr. WAXMAN) worked together in 1997 to provide manufacturers with an incentive to test these drugs specifically for children. The incentive adopted then was an additional 6 months of exclusivity under the patents added to the existing exclusivity of patent protection for testing these drugs at the request of the FDA.

The incentive has worked extraordinarily well. According to the FDA: ''The pediatric exclusivity provision has done more to generate clinical studies and useful prescribing information for the pediatric population than any other regulatory or legislative process to date.'' According to the American Academy of Pediatrics, the incentive ''has advanced therapeutics for infants, children and adolescents, in a way that has not been possible in several decades prior to the passage of this law.''

Every children's group in America supports this reauthorization. This is why the Committee on Energy and Commerce reported the bill by a strong bipartisan vote of 41 to 6. The differences between the bill that passed the Committee on Energy and Commerce and the bill before us today are minimal. The main difference is that the Greenwood-Eshoo regulation created a new Foundation for Pediatric Research, while S. 1789 subsumes that foundation within the existing NIH Foundation.

A few Members may oppose the reauthorization by saying that pediatric exclusivity has provided a windfall to industry and increased costs to consumers. Well, truth be told, while some companies have indeed benefited financially for testing their drugs in children, the GAO notes that ''while there has been some concern that exclusivity may be sought and granted primarily for drugs that generate substantial revenue, most of the drugs studied are not top sellers.'' In fact, 20 of the 37 drugs which have been granted exclusivity fall outside the top 200 in terms of drug-sale revenues. Further, the FDA estimates that the cost of this provision adds about one-half of one percent to the Nation's pharmaceutical bill.

Importantly, because the FDA has failed to act, this legislation contains a provision which will result in generic drugs being approved when their labeling omits the pediatric indication or other aspect of labeling which is protected by the patent exclusivity.

While one drug has been prominently mentioned in this debate, the FDA has informed the committee that a number of drugs have received 3 years of additional exclusivity for pediatric use under Hatch-Waxman. It is my strong belief that in implementing this provision, the Secretary will apply it comprehensively and uniformly to all affected drugs; and to ensure that all interested parties have their voices heard, the Secretary should provide for public notice and comment in implementing this important provision.

Pediatric exclusivity has resulted in drugs which are used in children being tested on children and for children; and due to this law, drug labels are being changed to contain pediatric labeling. Now, because of the work of the gentleman from Pennsylvania (Mr. GREENWOOD) and the gentlewoman from California (Ms. ESHOO), the law will also ensure that generic drugs used in children will also have their labels changed.

The American Academy of Pediatrics, the Coalition for Children's Health, the National Association of Children's Hospitals, and the Elizabeth Glaser Pediatric AIDS Foundation are all telling us to pass the Greenwood-Eshoo legislation now. If this program is not reauthorized this year, it expires. Do not be in a position of having to explain to your children's hospitals or to the Academy of Pediatrics and the Pediatric AIDS Foundation why you killed their top priority.

My recommendation to this House is to vote yes on this worthy bill.

Mr. Speaker, I reserve the balance of my time.

Mr. BROWN of Ohio. Mr. Speaker, I yield myself 6 minutes.

Mr. Speaker, unfortunately, the legislation we are considering today, named the Best Pharmaceuticals for Children Act, is not about children; it is about money. It is about the most influential industry on Capitol Hill coopting an emotional issue to lock in another 5 years of unjustifiable, unearned revenues.

It is about reauthorizing a program that pays drug companies literally tens of billions of dollars, straight out of the pockets of consumers who will pay higher prices, for tests that cost relatively only a few million dollars to conduct. Again, it is about reauthorizing a program that pays drug companies tens of billions of dollars in higher prices for consumers for tests that cost a few million dollars to conduct.

No one disputes the need for pediatric drug testing. In a health care system as advanced as ours, it is unfathomable that our children are still being prescribed medicines on a hit-or-miss basis. But this bill does not ensure that medicines are first tested for use in children before they are sold for that purpose. It does not ensure that prescription drugs already on the market, already being used in children, are tested.

If we pass this legislation, we are guaranteeing one thing and one thing only: we are guaranteeing consumers an additional 6 months of grossly inflated prices for some of the most widely used prescription drugs on the market.

Five years ago, Mr. Speaker, Congress passed legislation offering 6 months of market exclusivity to drug companies if they conduct pediatric tests. Five years later, we know that the cost to consumers of this 6-month provision is astronomical, while the cost of testing is minimal. We could pay drug companies twice the cost of testing, three times the cost of testing, even four times the cost of testing. We would still save a fortune on behalf of consumers.

□ 1545

For drugs like Prilosec and Prozac and Zocor and Neurontin, the exclusivity provisions add $50 to $70 for every prescription that every American gets. Again, it is maybe 2 percent industry-wide, as the gentleman from Louisiana mentions, but these provisions, for those drugs, Prilosec, Prozac, Zocor, Neurontin, add $50 to $70 for each prescription. For those of us who have constituents that take Prilosec and Prozac and Zocor and Neurontin, a ''yes'' vote will mean they will pay, every time, $50 to $70 more for each prescription.

The manufacturer of these drugs will take home an additional $500 million to $1.6 billion for conducting tests that cost about $4 million each. Quite a return on their investment, Mr. Speaker.

I hoped committee deliberations on this legislation would have produced some legitimate arguments and reasonable justification for extending this 6-month exclusivity provision, but it did not happen. Proponents argue that we should sustain this program because, they say, 6 months exclusivity works. Giving the drug industry the keys to the Federal Treasury would also work. Does that mean it is a good idea? They say pediatric exclusivity is the most successful program ever when it comes to increasing the number of pediatric tests. It is also the only incentive program that Congress has ever tried. Previous attempts relied on subtle persuasion, not rewards, not mandates, not any kinds of big money incentives as this gets.

Proponents say pediatric exclusivity uses marketplace incentives. It is a ''free market'' solution, they tell us. Pediatric exclusivity is not a free market solution, and it does not use marketplace incentives. In free markets, competition and demand drive behavior. When it comes to pediatric exclusivity, the prospect that the Federal Government will step in and block generic competition is what drives behavior. Monopolies are anathema to free markets.

Proponents say that when we factor in lower children's health care costs, pediatric exclusivity actually saves money. I wonder if the authors of this research factored in the health care costs that accrue when seniors who cannot afford this $50 or $70 increase, as this bill allows, who cannot afford these prescriptions, I wonder what happens when they remain ill, when children whose parents cannot afford inflated drug prices remain ill.

Why do I oppose this legislation? Simply because Congress did not give serious consideration to less costly alternatives. Because this bill, frankly,

Mr. Speaker, uses children as bait to capture another windfall for the drug industry. It uses children as bait to capture another windfall for the drug industry. I oppose this bill because it promotes bad policy and consumers throughout the country will pay for it.

Before closing, Mr. Speaker, I want to speak for a moment about a provision in this legislation that is in the public's best interests. It is the clarification amendments set forth in section 10, which is intended to make absolutely sure that an important incentive for generic competition is, in fact, preserved. This section clarifies that the grant of pediatric exclusivity does not diminish the generic exclusivity period awarded to the first genetic firm to file a paragraph IV certification. Obviously, this clarifying amendment applies to pediatric exclusivity periods that have already been granted as well as those that will be granted in the future. That good language in section 10 of the bill notwithstanding, Mr. Speaker, this is bad legislation. We should vote ''no.''

Mr. Speaker, I reserve the balance of my time.

Mr. TAUZIN. Mr. Speaker, I am pleased to yield 3½ minutes to the distinguished gentleman from Indiana (Mr. BURTON), the distinguished chairman of the Committee on Government Reform.

Mr. BURTON of Indiana. Mr. Speaker, I thank the gentleman for yielding me this time.

I think this is probably a very good bill and I support it. However, there are a few things I would like to say to the members of the Committee on Energy and Commerce, because I think it is very important, and I have not had an opportunity to do it before.

One of the things that is not widely known is many of the children's vaccinations contain a substance called thimerosal, and thimerosal is a substance that is put in there as a preservative when they put many vaccinations in one vial. Thimerosal contains Mercury. Mercury is a toxic substance that should not be put in anybody's body, let alone children. Children get as many as 25 to 30 vaccinations by the time they go to school. Children get sometimes as much as 45 to 50 times the amount of Mercury in their systems that is tolerable in an adult and, as a result, many children suffer mental disorders because of this, according to some leading scientists.

The number of children in America that are autistic has gone from 1 in 10,000 to 1 in 500. We have an absolute epidemic of autism in this country. Many scientists around the world believe one of the major contributing factors is these toxic substances that are being used as preservatives in these vaccinations; in particular, mercury.

Now, we have taken mercury out of all topical dressings. One cannot get a topical dressing now that has mercury in it, and yet there are a lot of substances such as eye drops, vaccinations and a whole host of things that contain mercury. I have talked to the FDA. We have had them before my committee many times. Two years ago we talked to them about the DPT shot. We asked them about mercury and we asked them about the other shots that have mercury in them, and they said they were going to try to get that substance out. They have not done so. I think it is, in large part, because many of the pharmaceutical companies want to use this because it does help enhance profits. But mercury should not be injected into any child.

I would like to say to my colleagues who are maybe here in the Chamber or back in their offices, and I hope the chairman will listen to this, because we have been told that we should all get a flu shot because of the anthrax scare. Do Members know that the flu shots that we are getting at the doctor's office here in the Capitol contain mercury? Many scientists believe that mercury is a contributing factor to Alzheimer's as well as other children's diseases like autism.

So I would just like to say to the chairman, I hope he will consider holding hearings as we have in our committee, because his committee is the committee of jurisdiction, to force the FDA to get toxic substances like mercury out of those vaccinations for children and adults, because it is not necessary. If they go to single shot vials, they do not need that in there. But they put 10 shots in one vial, and because they put the needle continually in there, they say they need to have mercury in there as a preservative.

For the sake of our children, 1 in 500, in some parts of the country it is 1 in 180 are autistic now, it is an absolute epidemic, I suggest that anything that might be a contributing factor ought to be extricated from these vaccinations, and I hope the gentleman from Louisiana (Mr. TAUZIN) and the gentleman from Pennsylvania (Mr. GREENWOOD) will take a look at this problem.

Mr. TAUZIN. Mr. Speaker, will the gentleman yield?

Mr. BURTON of Indiana. I yield to the gentleman from Louisiana.

Mr. TAUZIN. Mr. Speaker, I certainly want to thank the chairman and ensure him that our committee is anxious to work with his Committee on Government Reform. If he will be kind enough to share the documentation and the results of his hearings with our committee, we will be more than happy to work with him.

Mr. BURTON of Indiana. Mr. Speaker, I thank the gentleman, and we will have it to him right away.

Mr. BROWN of Ohio. Mr. Speaker, I yield myself such time as I may consume to comment on the comments of the gentleman from Indiana (Mr. BURTON) about mercury and to thank him for raising the call about mercury. It is a substance banned in almost every country in the world and I appreciate the work that he has done in raising the public knowledge of that toxic substance.

Mr. Speaker, I yield 2½ minutes to the gentlewoman from California (Ms. HARMAN), a member of the Committee on Commerce.

Ms. HARMAN. Mr. Speaker, I thank the gentleman for yielding me this time, and also say that though I support this legislation, I very much respect his views and his leadership on competition issues.

Mr. Speaker, I want to alert this body that one of the principal sponsors of this legislation, the gentlewoman from California (Ms. ESHOO), is on her way in from the airport. Sadly, she may miss this debate. I stand here to salute her leadership on this issue, along with the gentleman from Pennsylvania (Mr. GREENWOOD), and to say that even if she does miss this debate, she will not miss the fact that through her contribution, we today will overwhelmingly, I predict, pass this legislation.

Notwithstanding the importance of competition, Mr. Speaker, this legislation is about harnessing the promise of the most advanced pharmaceuticals for the most vulnerable members of our society, our children. Dr. Jay Lieberman, a pediatric disease specialist from my district, has told me that literally every day he sees children with serious, sometimes life-threatening infections on whom he must use the antibiotics and other drugs that have not been tested to determine how safe they are for kids.

We must do all we can to end this lack of knowledge, and the extension of patent exclusivity for companies that test their pharmaceuticals for children is the proven way to help kids. Over the past 4 years, pharmaceutical companies have dramatically increased the number of pediatric trials for new prescription drugs. More products are being labeled with proper dosage for children and potentially harmful interactions, and more companies are conducting research into special drug formulations for children.

What we are doing today, Mr. Speaker, is not enacting a new law; we are renewing good law that has brought about better treatments for children. We also clarify that drug companies cannot draw more than 6 months exclusivity for conducting pediatric trials. We must do all we can to improve the safety of pharmaceuticals for kids. This bill is the narrowest way to do this, consistent with protecting competition and consistent with assuring that drug companies already doing this work will continue to do it.

I want to salute the bipartisan sponsorship of the bill, our chairman, the gentleman from Louisiana (Mr. TAUZIN) who is standing here and the gentleman from Pennsylvania (Mr. GREENWOOD), and to say that the gentlewoman from California (Ms. ESHOO), were she here, would be saying the same things. I thank the chairman for his leadership. I urge passage of this bill.

Mr. TAUZIN. Mr. Speaker, I yield myself 30 seconds, first of all, to thank

the gentlewoman from California (Ms. HARMAN) and particularly the gentlewoman from California (Ms. ESHOO) who could not be here today for her handling of the bill and for her excellent work with the gentleman from Pennsylvania (Mr. GREENWOOD) on this legislation.

Finally, I would mention that while there are some costs to this exclusivity, Tufts University has estimated that while it costs Americans about $700 million for this 6 months of extra exclusivity, that we gain $7 billion of savings each year in medical costs for children. It is a 10 to 1 savings. That is worth doing.

Mr. Speaker, I am pleased to yield 3 minutes to the gentleman from Pennsylvania (Mr. GREENWOOD), the chairman of the Subcommittee on Oversight and Investigations of the Committee on Commerce and the author of the legislation.

Mr. GREENWOOD. Mr. Speaker, I thank the gentleman from Louisiana (Mr. TAUZIN), the chairman of the full committee for yielding me this time and I also thank him for his support throughout this progress on this important piece of legislation.

Mr. Speaker, this bill, as has been mentioned by the chairman, passed just about a month ago by the overwhelming margin of 338 to 86 in this House and, in fact, it passed in the Senate unanimously. So today we pass the Senate version of this bill so we can get it to the President so we can continue to provide these health benefits for children. It passed by that overwhelming majority because there is wide agreement on just about every facet of this issue. There is universal agreement, no one debates the question, that for decades; in fact, for all of the health history of this country, we have had a serious problem in trying to get pharmaceutical companies to test their products on children so that pediatricians and other doctors and specialists can prescribe these medications in ways that benefit children particularly and take into consideration of the different physiology and the different size and weight of children. Everyone agrees to that.

Everyone agrees that since 1997 when we enacted this Better Pharmaceuticals for Children bill, there has been a dramatic and unanticipated flurry of these studies, about 400 of them, which the pediatric community and all of these organizations, the American Academy of Pediatrics, the National Association of Children's Hospitals, the Elizabeth Glazier Pediatric AIDS Foundation, the March of Dimes, the American Academy of Child and Adolescent Psychiatry, and on and on, all of these groups universally acknowledge and agree that this has been a saviour in providing good medical information to physicians.

There has been one area of dispute, and that area of dispute is what is the proper incentive to give the pharmaceutical companies in order to get them to provide these studies. What we say in the bill is if the Food and Drug Administration, the FDA, asks a pharmaceutical company, please provide clinical trials for children for your product, and the company does that study, and we have that information available, we have a clean, simple, neat incentive, and that is, you will gain 6 months of additional exclusivity; when the 6 months is over, in comes generic competition and the prices go down.

Now the opponents of this bill have suggested a series of rather Rube Goldberg complicated, unworkable and unfair alternatives to this plan.

□ 1600

We have looked at them; and overwhelmingly, the Food and Drug Administration has said to us, we do not want to get involved in those kinds of complicated schemes that are unworkable and unmanageable for us.

What we have is working; it is working well. Let us not fix something that is not broken. Let us not quarrel with success. Let us provide another overwhelming vote in support of this legislation for children.

Today, Mr. Speaker, I am happy that the House is considering S. 1789, the Best Pharmaceuticals for Children Act.

This bill is the essence of bipartisan policy. It originally passed the House by a vote of 338–86 on November 15, and the Senate passed it by unanimous consent yesterday.

Chairman TAUZIN, and Chairman BILIRAKIS, thank you for your leadership and hard work in moving this bill from committee to the floor and for achieving a unified bill with the Senate.

Mr. Speaker, I am also pleased to have worked with Ms. ESHOO and the 16 other members of the minority who have cosponsored this legislation.

Mr. Speaker, this is public policy at its best. Over 400 studies are currently underway to fulfill 200 study requests from FDA. Contrast this with the change that from the prior 6 years, when only 11 studies had been done.

As the Food and Drug Administration itself said in its report to Congress, the Better Pharmaceuticals for Children Act has had ''unprecedented success,'' and ''the pediatric exclusivity provision has done more to generate clinical studies and useful prescribing information than any other regulatory or legislative process to date.''

This Act has helped get drugs to kids who need them, let us better understand how drugs work in kids, and also know when we should and should not be giving kids certain drugs. Or as Linda Suydam, the FDA representative who testified in front of the Health subcommittee earlier this year pointed out, ''The results speak for themselves.''

Let me give you an example of how this has worked.

Take Lodine, which treats Juvenile rheumatoid arthritis. This drug did not have safety and effectiveness in children prior to this program. With the studies, we have determined a new indication for children 6–16 years in age and recommended a higher dosage in younger children.

Contrast this with the traditional mindset of just ''taking the pill and breaking it in half'' to determine the dosage for children.

This has been a fantastic law. And we can do better.

Six of the 10 most used drugs by children have not been studies because they are off-patent. This bill provide the funds for the studies to be completed on those off-patent drugs that are used so often to treat our children. Furthermore, we have developed a foundation to provide resources for the completion of these studies that will have so much value.

Some will argue that this is a Republican bill, helping drug companies. Nothing could be further from the truth. This bill, which I am proud to work on with Ms. ESHOO, is the very essence of bipartisanship. It passed out of the Energy and Commerce Committee by a vote of 41–6. And this bill has had more Democrat cosponsors than Republican, including several members of the committee.

Some of my colleagues on the opposite side of the aisle will try to suggest that this bill is both costly and helps blockbuster drugs stay-off competition. This provision is not about blockbuster drugs. Over half of the 38 drugs that have been granted exclusivity do not even make the list of top 200 selling drugs.

Simply put, this bill is good policy. It is sound, it is tested. It is tried. It works.

We need to reauthorize pediatric exclusivity. We need to send the bill to the President for his signature. America's kid's are counting on it.

I urge my colleagues to vote ''yes'' on S. 1789

I would like to clarify a point regarding a provision in this legislation. It is my understanding regarding section 15 that the eleven voting members of the pediatric subcommittee of the Oncologic Drugs Advisory Committee, cited in section 15(2)(A) shall be drawn from the pediatric oncology specialists listed in (2)(B) of the bill.

Mr. BROWN of Ohio. Mr. Speaker, I yield myself 2 minutes.

Mr. Speaker, I hear the gentleman from Pennsylvania (Mr. GREENWOOD), who does outstanding work on the Subcommittee on Health on a variety of issues, say that opponents to this bill offered a Rube Goldberg collection of responses or fixes, if you will, to this problem that we believe exists, this problem of paying the drug companies in many cases tens, sometimes hundreds of millions, of dollars, and in one case over $1 billion to do a study that costs simply $4 million.

Our proposals to fix this are not at all Rube Goldberg. One was to reduce the 6-month exclusivity to 3 months so a drug company, by investing $4 million, would then only make tens of millions of dollars, or $100 million instead of $200 million. That was a very simple, straightforward solution.

Another was simply to reimburse the drug company for the study they did. If they paid $4 million for the study, then reimburse them $4 million; or we were generous enough to say reimburse them $8 million or $12 million. We said, give them 100 percent or 200 percent return on investment, but do not raise the price, as this legislation does, do not raise the price of Prilosec, Prozac, Zocor, and Neurontin $50 to $70 per prescription.

Remember, Mr. Speaker, everyone that votes for this legislation is saying

to her constituents or his constituents, yes, I am signing off on increasing for at least 6 months the price of Prilosec and Prozac and Zocor and Neurontin $50 to $70 per prescription. It is not the 2 percent that the gentleman from Louisiana (Mr. TAUZIN) talks about industry-wide. That may be true; I do not dispute his numbers. But for those four drugs and for some others, the cost of Prilosec will go up $50 to $70 for that 6-months for consumers, for our constituents. So will the cost of Prozac, Zocor, and Neurontin.

In times of recession, when people are losing their jobs, when the economy seems to be going downward, is that what we want to do is say to our constituents it is okay, pay $50 or $60 or $70 per prescription, it is for the good of some other cause?

Mr. Speaker, I reserve the balance of my time.

Mr. TAUZIN. Mr. Speaker, I am pleased to yield 2 minutes to the gentlewoman from Maryland (Mrs. MORELLA).

Mrs. MORELLA. Mr. Speaker, I thank the chairman of the Committee on Commerce for yielding time to me, and for his leadership in bringing this bill, which I think is an important one, to the floor.

Mr. Speaker, I am in strong support of S. 1789, the Best Pharmaceuticals for Children Act; and I want to congratulate the sponsor of the bill, the gentleman from Pennsylvania (Mr. GREENWOOD), and the gentlewoman from California (Ms. ESHOO) for working on crafting this legislation, which is important. It is a much-needed piece of legislation. It creates an incentive for pharmaceutical companies to conduct pediatric studies to increase pediatric information.

Children are subject to many of the same diseases as adults and, by necessity, are often treated with the same drugs. According to the American Academy of Pediatrics, only a small fraction of all drugs marketed in the United States has been studied in pediatric patients; and a majority of marketed drugs are not labeled or are insufficiently labeled for use in pediatric patients.

Safety and effectiveness information for the youngest pediatric age groups is particularly difficult to find in product labeling. The absence of pediatric testing and labeling may also expose pediatric patients to ineffective treatment through underdosing, or may deny pediatric patients the ability to benefit from therapeutic advances because physicians choose to prescribe existing, less-effective medications in the face of insufficient pediatric information about a new medication.

In addition, pharmaceutical companies have little incentive to perform pediatric studies on drugs marketed primarily for adults; and FDA efforts to increase pediatric testing and labeling of certain drugs have failed. As a result, the FDA issued a report in January of this year, 2001, that the pediatric exclusivity provision was ''highly effective in generating pediatric studies on many drugs, and in providing useful new information in product labeling.''

I urge my colleagues to support this bill, as there is no greater job that Congress can undertake than to improve and enhance the health of children.

Mr. BROWN of Ohio. Mr. Speaker, I yield myself 3 minutes.

Mr. Speaker, a study from the Department of Health and Human Services in a January, 2001, ''Status Report to Congress,'' the Food and Drug Administration, within Health and Human Services, wrote that ''the impact of the lack of lower-cost generic drugs on some patients, especially those without health insurance and the elderly, may be significant.''

This government report from the Food and Drug Administration concluded that ''the greatest burden of this increase will fall on consumers with no private or public insurance support, which may disproportionately affect lower-income purchasers, and the pediatric exclusivity provision imposes substantial costs on consumers and on taxpayers.''

Mr. Speaker, I sit here amazed that this Congress today is about to pass legislation to increase the cost of drugs, of prescription drugs, to America's elderly and to consumers of these prescription drugs, when this Congress has done nothing for unemployed workers, has done nothing for health insurance for people that are unemployed, has done nothing in terms of an economic stimulus package.

We will not pass a stimulus package, we will not do anything for 125,000 laid-off airline workers, we will not do anything for the millions of newly laid-off workers in this country, we will not do anything about 45 million uninsured Americans, one-fourth of whom are children. Yet in the name of a children's bill, which is very misnamed, in the name of that legislation, of that group, we are going to raise prescription drug prices.

I repeat, Mr. Speaker, that for certain drugs, like Prilosec and Prozac and Zocor and Neurontin, a vote for this bill is saying yes to the drug companies adding $50 to $70 per cost of prescriptions.

So people watching this should understand, as we all go home and talk to our constituents, we just might get asked, Why did you vote for this pediatric exclusivity provision, which adds to the cost of my Prozac, Zocor, Neurontin, or Prilosec?

Mr. Speaker, in the midst of a recession, this makes no sense to add to the cost of prescription drugs for America's elderly and for the consumers of these drugs.

Mr. Speaker, I reserve the balance of my time.

Mr. TAUZIN. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, this bill is not about the stimulus package, it is not about the airlines, it is not about drilling in ANWR. It is about children. It is about whether or not we are going to continue a law that is working; not pass a new law, but simply continue a law that is working, and that everyone who has looked at it says it is working not just well, but exceptionally well.

Let me point out a couple of things:

One, the bill does not raise drug costs to anybody. It simply extends pediatric exclusivity, exclusivity of patents, for 6 months. It does not do it because the drug company wants that. It does it because the FDA decides that a certain drug that is being given to adults may have serious consequences if given to children without a special study done on the effects of the drug on the young mind and body of a young child to make sure in fact that a drug that is very potent and helpful for adults may not have the same effect on children.

The FDA decides to ask the drug company to do special testing for children, and then if they find out that this drug has special effects on children, to make sure that the label on the drug indicates that to the doctor before he prescribes it to a child.

Now, I ask Members, does this extra 6 months of patent protection help the drug company? Of course it does. They get 6 more months of protection under their patent if they agree to do this testing that the FDA requests, and if in fact they do it and the tests are run and children, we find out, should not be getting a half-dose or quarter-dose but maybe an eighth of a dose, and under special kinds of treatments and circumstances, then we end up protecting children in a very special way.

How much so? We are told that this extra 6 months of exclusivity may add about one-half of 1 percent to the drug costs in America during that 6 months of extra exclusivity under the patent. What do we get back for it? According to the study, we save $7 billion a year in health care costs for our children, and so we are not crippling them and hurting them with drugs that could hurt and cripple them instead of helping them.

Seven billion dollars, ten-to-one benefits for the most vulnerable, the most sacred of all the charges that God has ever presented us with on this Earth, the protection of our own children and their health. That is what we are talking about.

It is not about the stimulus plan or drilling in Alaska or airline workers. It is about whether or not we are going to continue a law that is about to expire; that protects children in this country; that works exceptionally well; that was designed by a Democrat, the gentleman from California (Mr. WAXMAN), together with the gentleman from Pennsylvania (Mr. GREENWOOD) in 1997 and has proven itself out.

So today we cast a vote along with the Senate, which did not cast a dissenting vote against this bill. We cast a vote today to continue this good law in effect. Is that worth doing? Yes. And

I hope this House joins me in passing this bill.

Ms. JACKSON-LEE of Texas. Mr. Speaker, I stand in support of the Best Pharmaceuticals for Children Act (S. 1789). Until 1997, American children were at substantial risk due to the lack of instructions in most prescription drug labels on how to use those drugs in children. Since the pediatric exclusivity incentive was enacted in 1997, there have been numerous studies of drugs in children, and drug labels are finally starting to carry this critical pediatric dosing information. It would be shameful for Congress to shut down the investment in pediatric studies by failing to reauthorize the pediatric exclusivity incentive. The Congress should pass the Best Pharmaceuticals for Children Act so that all drugs, present and future, contain the dosing information so critical to proper pediatric care.

The only flaw in the bill is Section 11, which would actually permit the FDA to approve drugs that omit critical pediatric dosing information. Such omissions could cripple the very purpose—complete, accurate pediatric labeling—of the Best Pharmaceuticals for Children Act. Consequently, FDA cannot implement Section 11 without engaging in notice-and-comment rulemaking under the Administrative Procedure Act. This will ensure that if FDA does assert the discretion it is granted under Section 11, it will not do so in a way that would allow approval of any drug without complete, accurate and up-to-date pediatric labeling.

MEMORANDUM TO THE UNTIED STATES CONGRESS RE: PROPOSED AMENDMENT TO THE HATCH-WAXMAN ACT (H.R. 2887)

Section 11 of H.R. 2887 has the effect of amending the Hatch-Waxman Act to abolish retroactively an existing exclusive marketing period for Glucophage, a pioneer drug manufactured and marketed by Bristol-Myers Squibb (''BMS'') for treatment of Type 2 diabetes. An exclusive marketing period, whether derived from a government grant of a patent or other similar governmental action, is a valuable property. Any legislative effort to terminate such an existing right without compensation raises obvious constitutional problems.

In the case of Glucophage, the proposed legislative action is particularly egregious since the marketing exclusivity came as a result of extensive studies welcomed by the government and successfully performed by BMS with respect to pediatric use of Glucophage. The FDA authorized and agreed to the studies pursuant to legislation and regulations designed to encourage pediatric testing to maximize health benefits to children. BMS agreed to do the extensive—and expensive—testing of this pioneer drug. The results were positive, and accordingly, BMS in the spring of 2000 submitted a supplemental new drug application (''sNDA'') to add pediatric use information to its Glucophage label.

The FDA approved such labeling and granted BMS three years of pediatric labeling exclusivity as provided under the law. Under existing law and regulations, the grant of labeling exclusivity amounted to a grant of marketing exclusivity for Glucophage for all users, not simply children, because all prescription drugs (including generics) were required by FDA regulations promulgated in 1994 to include pediatric information in their labels. That this broader exclusivity would result from the pediatric labeling was relied upon by BMS when it undertook to conduct the testing. It is this broader exclusivity that Section II of the proposed legislation seeks to eliminate retroactively.

There is, of course, no question of Congress' constitutional power to change legislative standards for the exercise of regulations prospectively; to do so may raise questions of legislative policy but no legal or constitutional questions. The constitutional problem arises only when the power is exercised to make such changes retroactively—to take away an existing valuable right already vested with respect to an existing product. The Congressional power is broad; the constitutional limitation on that power, narrow. In legislative encouragement of the arts and sciences, Congress is free to expand or contract the period of marketing exclusivity with respect to future creations and inventions. But it is not free to take away grants of existing exclusivity without compensation.

The fact that the marketing exclusivity is achieved indirectly through labeling exclusivity rather than through a direct marketing grant is of no moment from either a policy or a constitutional perspective. There is no question that the FDA had the authority to do what it did both in granting labeling exclusivity and in regulating the requirements with respect to labeling. That since 1994 labeling exclusivity amounted to marketing exclusivity was well known and served as a means to promote research and testing for pediatric use as well as promoting safety and efficiency.

Section 355a (Pediatric studies of drugs) was enacted in 1997, three years after the FDA regulation requiring pediatric use information be included in all labeling. It provides for a six month extension of marketing exclusivity for a drug where its manufacturer agrees to a request by the FDA for pediatric research and testing and performs the required tests in a timely fashion. This extension is granted whether or not the drug is approved for pediatric use. But if an application for pediatric use is made and a sNDA granted, the use becomes subject to the FDA's labeling requirements.

Without some period of exclusivity there would be little or not incentive to apply for the sNDA. If labeling exclusivity did not include marketing exclusivity it would have little value. Generic manufacturers producing bio-equivalent drug could not include pediatric use on the labels, but the medical profession (especially HMO's) would be aware of the use and would prescribe the generic rather than the labeled drug.

As a policy matter one can agree or disagree with the FDA's 1994 regulation that pediatric information must, for reasons of safety and effective use, be included in every prescription drug. The proposed legislation disagrees with any such requirement. Whatever the impact of this change on future pediatric research and testing, Congress is obviously free to make such a policy choice. But with respect to products already marketed under an exclusive pediatric label, the effect of such a change is to destroy a valuable property right. The government should not engage in such an act, and the constitution requires that such a taking be compensated.

The attached memo discusses the constitutional question. As a policy matter, there is little to be gained by engaging in almost certain litigation where there is no important principle to be established. Glucophage may be the only drug involved (or at least one of a small number), and it is easy to make the legislation prospective only. Even in the unlikely event that the government would prevail, that victory would almost certainly be hedged with a variety of technical requirements which would create future legislative problems. A loss could be costly in monetary terms. And either a victory or a loss almost certainly would involve language problematic in terms of governmental fairness.

CONSTITUTIONALITY OF PROPOSED AMENDMENT TO THE HATCH-WAXMAN ACT (H.R. 2887)

This memorandum respectfully addresses the constitutional infirmity of H.R. 2887 sec. 11.

The underlying statute regarding new drug approvals, the Hatch-Waxman Act, provides an initial period of marketing exclusivity for a pioneer drug manufacturer that holds an approved new drug application (''NDA''). See 21 U.S.C. §355(j)(5)(D)(ii). It also provides an additional period of labeling exclusivity for a pioneer that holds an approved supplemental new drug application (''sNDA'') based on a new use indication developed after the basic drug had been approved. See id, at §355(j)(5)(D)(iv).

Once the initial exclusivity expires, a generic drug maker is entitled to seek approval for an abbreviated new drug application (''ANDA'') based on a demonstration of bioequivalence with the pioneer drug. See id at §355(j)(2)(A)(iv). The FDA may not approve an ANDA unless the labeling is the ''same as the labeling approved for the listed drug''. See 21 U.S.C. §355(j)(2)(A)(v). although pursuant to 1992 FDA regulations, a generic drug label may differ from the label of the pioneer drug by ''omission of an indication or other aspect of labeling protected by patent or accorded exclusivity under [Hatch-Waxman]'' (see 21 C.F.R. §314.94(a)(8)(iv)), omissions may be approved only if they ''do not render the proposed drug product less safe or effective than the listed drug for all remaining, nonprotected conditions of use''. 21 C.F.R. §314.127(a)(7)(emphasis added).

In 1994, the FDA created an exception to the above regulation, concerning acceptable label omissions, affording pioneer drug manufacturers extended total marketing exclusivity based on the development of new pediatric use indications. In particular, the FDA adopted regulations requiring that pediatric information be included in the labeling of every prescription drug. See 21 C.F.R. §201.57(f)(9)(ii). The FDA based the new regulations on its finding that ''[t]his action promotes safer and more effective use of prescription drugs in the pediatric population''. 59 Fed. Reg. 64,240 (Dec. 13, 1994). With this regulation, the FDA noted that ''a drug product that is not in compliance with revised §201.57(f)(9) would be considered to be misbranded and an unapproved new drug under the act''. 57 Fed. Reg 47,423, 47,425 (Oct. 16, 1992).

Further, in 1997, Congress enacted legislation providing pioneer drug manufactures a six-month period of marketing exclusivity in return for performing pediatric studies on already approved drugs, even if the studies do not yield results permitting pediatric labeling. See 21 U.S.C. §355a.

These statutes and regulations collectively were designed to encourage drug manufacturers to invest in pediatric testing in an effort to maximize the health benefits to children. A review of the record plainly reveals this intent as well as the benefits achieved. For example:

The FDA described its 1992 proposed pediatric labeling regulation as an initiative to ''stimulate development of sufficient information for labeling to allow the safe and effective use of drugs in children''. 57 Fed. Reg. 47,423, 47,424 (Oct. 16, 1992).

In its 1994 Unified Agenda, the FDA explained that its then forthcoming final regulation was created in response to a concern that prescription labeling did not contain adequate information about pediatric drug use. 59 Fed. Reg. 57,572 57,577 (Nov. 14, 1994).

In its mandated 2001 status report to Congress, the FDA reported that pediatric exclusivity has ''done more to generate clinical studies and useful prescribing information for the pediatric population that any other regulatory or legislative process to date'' S. Rep. No. 107–79 (2001).

Linda Suydam, Senior Associate FDA Commissioner, testified at a House hearing that the ''purpose of encouraging pediatric studies is to provide needed pediatric efficacy, safety and dosing information to physicians in product labeling''. Food and Drug Administration Modernization: Hearing Before the House Comm. on Energy and Commerce, 107th Cong. (May 3, 2001) (statement of Linda A. Suydam).

At a May 2001 Senate hearing, Senator Chris Dodd wanted that the absence of pediatric labeling poses significant risks to children describing it as ''playing Russian roulette with their health''. Pediatric Drug Testing: Hearing Before the Senate Comm. on Health, Educ., Labor and Pensions, 107th Cong. (May 8, 2001) (statement of Senator Dodd).

In the context, the FDA, in 1998 and 1999, issued ''Written Requests'' to Briston-Myers Squibb (''BMS'') for the performance of extensive pediatric studes on Glucophage, a pioneer drug initially approved in 1995 for the treatment of type 2 diabetes. At that time, no oral type 2 diabetes treatment had been approved for pediatric use. BMS completed the studies as agreed. IN the spring of 2000, BMS submitted an sNDA seeking approval to add pediatric use informaiton to the Glucophage label based on the findings of its studies. As expected, the FDA approved the sNDA, authorized BMS to add pediatric use informaiton to the Glucophage label, and granted three years of Hatch-Waxman labeling exclusivity pursuant to 21 U.S.C. §355(j)(5)(D)(iv). Under existing law, that grant resulted in total marketing exclusivity with respect to Glucophage for the applicable period because BMS has acquired exclusive rights to the only pediatric use indication that applied under the pediatric labeling requirements. See 21 C.F.R. §201.57(f)(9)(iv).

H.R. 2887 sec. 11, which is apparently widely referred to as the ''Anti-Glucophage Bill'', proposes to revise the Hatch-Waxman Act to override the current requirement that generic versions of pioneer drugs bear labeling for pediatric indications. Accordingly, the proposed legislation would eliminate the marketing exclusivity that BMS currently enjoys as a result of its exclusive right to the pediatric use labeling for Glucophage.

The retroactive impact of such a government action offends notions of basic fairness and has long been frowned upon by our courts. ''[R]etro-spective laws are, indeed, generally unjust; and as has been forcibly said, neither accord with sound legislation nor with the fundamental principles of the social compact''. Eastern Enters v. Apfel, 524 U.S. 498, 533 (1998) (quoting 2 J. Story, Commentaries on the Constitution §1398 (5th ed. 1891)). If H.R. 2887 is signed into law, it would effect an unconstitutional taking. See U.S. Const. amend. V (''private property [shall not] be taken for public use without just compensation'').

BMS, pursuant to Written Requests from the FDA, went to great lengths to perform pediatric studies on Glucophage. The fruits of BMS's research and development effort—including data relating to, among other things, the drug's indication and use, clinical pharmacology, adverse reactions, and dosage and administration—constitute intellectual property and qualify as trade secrets under state law. See Restatement (First) of Torts §757 cmt. b (1939) (trade secret may consist of ''any formula, pattern, device or compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it.'') (cited with approval in Ashland Mgmt. Inc. v. Janien, 624 N.E.2d 1007, 1012–13 (N.Y. 1993)). Such intangible property is subject to the protections of the Takings Clause of the Constitution. See e.g., Ruckelshaus v. Monsanto Co., 467 U.S. 986, 1003–04 (1984) (trade secrets in pesticide testing data); Patlex Corp. v. Mossinghoff, 758 F.2d 594, 599–600 (Fed. Cir. 1985), modified on reh'g on other grounds, 771 F.2d 480 (Fed. Cir. 1985) (laster technology patents); Tri-Bio Labs., Inc. v. United States, 836 F.2d 135, 142 (3d Cir. 1987) (trade secrets in animal drug testing data).

Moreover, similar to a patent, the marketing exclusivity that BMS was granted in exchange for the dedication of its intellectual property constitutes a valid property interest. See Patlex Corp., 758 F.2d at 599 (''The encouragement of investment-based risk is the fundamental purpose of the patent grant, and is based directly on the right to exclude.''). Our legal system makes plain that the right to exclude is ''essential'' to the concept of private property. See Kaiser Aetna v. United States, 444 U.S. 164, 176 (1979).

In determining whether a taking of property has occurred, courts will consider the following factors: (1) the government action's interference with reasonable investment backed expectations; (2) the character of the action; and (3) the economic impact of the action. See Ruckelshaus, 467 U.S. at 1005.

With respect to Glucophage, there can be little question that H.R. 2887 sec. 11 would turn BMS's reasonable investment-backed expectation on its head. The Supreme Court's opinion in Ruckelshaus is instructive. Monsanto, a pioneer manufacturer of pesticides, successfully challenged legislation that would have permitted the Environmental Protection Agency to disclose and/or use trade secret data from Monsanto's pesticide approval applications filed after a 1972 amendment guaranteeing that no such use or disclosure would occur and prior to a 1978 amendment repealing that protection. The Court found the interference with reasonable investment backed expectations ''so overwhelming . . . that it dispose[d] of the taking question''. Ruckelshaus, 467 U.S. at 1005 (emphasis added).

Similarly, BMS has developed intellectual property necessary to support its Glucophage sNDA for pediatric use. BMS submitted that intellectual property to the FDA in exchange for what BMS understood to be a promise of marketing exclusivity. Although the proposed legislation here nominally would preserve BMS's use of pediatric data by making that portion of the label exclusive, the taking would be effected through off-label sales, i.e., the lack of any given indication in a generic's label will not prevent a generic drug from being prescribed or substituted for the branded drug for that indication. In 1994, well before the Written Requests issued for pediatric testing of Glucophage, the FDA adopted regulations precluding such off-label sales from undermining the exclusivity granted with regard to pediatric use indications. BMS invested accordingly. Now that Congress has secured the desired benefits from BMS, it is refusing to follow through on its promise. Such action plainly interferes with reasonable investment-backed expectations.

Although the character of the government action here is not the same as that of the traditional physical invasion of property, the effect is the same. The proposed legislation would nullify, not just diminish the value of BMS's property interest. See Ruckelshaus, 467 U.S. at 1012 (change in regulation ''destroy[ed]'' value of trade secrets). The ''Anti-Glucophage Bill'', as designed, completely would deprive BMS of its intellectual property and its corresponding entitlement to market the drug on an exclusive basis for the remainder of the applicable period.

With respect to the economic impact of the proposed legislation, there is little question that it would be severe. See Eastern Enters., 524 U.S. at 534 (plurality) (finding a taking based on retroactive liability that was ''substantial and particularly far reaching''); United States Fid. & Guar. Co. v. McKeithen, 226 F.3d 412, 416 (5th Cir. 2000) (finding a taking based on ''considerable, novel financial burden''). Indeed, the action would deprive BMS of Glucophage's market value to the extent of billions of dollars. If the proposed legislation were enacted, and assuming the courts did not block its implementation, the appropriate measure of BMS's injury would be extremely high. See United States v. W.G. Reynolds, 397 U.S. 14, 16 (1970) (''just compensation' means the full monetary equivalent of the property taken . . . the owner is entitled to the fair market value of the property''). BMS would have to be put in ''as good position pecuniarily as [it] would have occupied if [its] property had not been taken''. See United States v. Miller, 317 U.S. 369, 373 (1943).

For these reasons, the enactment of H.R. 2887 sec. 11 would constitute an unconstitutional taking of BMS's property for which it would be entitled to just compensation. I respectfully urge Congress to reconsider the constitutional implications of this provision of the proposed legislation.

Ms. ESHOO. Mr. Speaker, I rise in support of the Best Pharmaceuticals for Children Act, which I'm proud to sponsor with Mr. GREENWOOD of Pennsylvania.

This bill is the conferenced version of legislation that passed the House a month ago on the suspension calendar 338–86.

Importantly the bill we will vote on today and send to the President closes the ''Glucophage loophole'' which allowed one company to get an additional 3 years of marketing exclusivity. This bill ensures that no company will be able to take advantage of the exclusivity granted by this very important legislation.

This legislation extends the pediatric exclusivity provision, one of the most successful programs created by Congress to inspire medical therapeutic advances for children.

Prior to its enactment, 80 percent of all medications had never been tested for use by children, even though most are widely used by pediatricians to treat them.

Many of these drugs carried disclaimers stating that they were not approved for children. Pediatricians cut pills in half or even in fourths for children.

Throughout this period, we were basically experimenting on children, forcing doctors to rely on anecdotal information or guesswork. This was not acceptable for our nation's children.

In 1997 the Congress passed the pediatric exclusivity provision as part of the FDA Modernization Act, which Congressman BARTON and I sponsored.

This provision has made a dramatic change in the way pediatricians are practicing and administering medicine to children. Now, pediatricians have the necessary dosage guidance on drug labels to administer drugs safely to children.

But there are many more drugs that can and should be used in the pediatric population. This bill ensures that those drugs will

also be studied and information on safe use will be provided to pediatricians.

Because previous attempts to address drug studies for children had failed, this provision was given a four-year lifespan. It expires January 1, 2002, which is why we're here today.

The pediatric exclusivity provision provides pharmaceutical companies with an incentive to study drugs for children . . . six months of additional market exclusivity.

This incentive has made a dramatic difference.

Since the law has been in place, the FDA has received close to 250 proposed pediatric study requests from pharmaceutical companies and has issued nearly 200 requests to conduct over 400 pediatric studies.

By comparison, in the seven years prior to enactment of this provision, only 11 studies were completed.

The FDA has granted market exclusivity extensions for 33 products. 20 products include new labeling information for pediatricians and parents.

What this means is that doctors are now making better-informed decisions when administering medicine to children.

During our Committee deliberations a number of proposals by my colleagues Representatives PALLONE and DEGETTE were adopted and are part of the underlying bill we will vote on today.

The bill before us also makes some significant improvements to the original pediatric exclusivity provisions by creating an off-patent drug fund within NIH and setting up a public-private foundation to support the research necessary for these important drugs.

The bill also addresses some concerns that were raised by both the FDA and GAO with regard to labeling. Our bill enhances the labeling process and provides the FDA Commissioner the authority to misbrand a drug if companies drag their heels.

28 National Children's health advocacy groups support this bill's passage . . . among them are the American Academy of Pediatrics, the March of Dimes, and the National Association of Children's Hospitals. They're requesting that Congress not delay in passing this legislation.

Our colleagues in the Senate have acted . . . last week, the Senate unanimously passed the same bill sponsored by Senators DODD and DEWINE.

As I said during the initial House consideration of this bill, many of my colleagues have concerns, valid concerns with the cost of drugs.

I continue to share these concerns, and I shall continue to work for a legislative solution to provide prescription drug coverage for our seniors.

This bill should not have to bear the burden of what Congress has failed to address. The FDA, the GAO, and one of the largest groups of children's health advocacy groups say this is the best way to provide safe and effective drugs for children.

The benefits of this program are clear and bear repeating—in the seven years prior to enactment of this provision only 11 studies on drugs for children were completed; since its enactment four years ago the FDA has received close to 250 proposed pediatric studies.

Since September 11th the entire Congress has legitimately been addressing national security concerns. Today, we can ensure the health security of our children by passing this bill overwhelming and sending it to the President for his signature.

Mr. TOWNS. Mr. Speaker, I am very pleased that the Congress will act today to preserve the gains that we have made in the development of pediatric drugs. I want to congratulate my colleagues, the gentleman from Pennsylvania, Mr. GREENWOOD, and the gentlelady from California, Ms. ESHOO, on their hard work in promoting the reauthorization of pediatric exclusivity. Before the passage of ''The Better Pharmaceuticals for Children's Act in 1997'', many children were denied access to medicines because drugs were not produced in dosable forms that could be used by pediatric patients. It was not very encouraging to be a pediatrician prescribing medicine to children. It was mostly guesswork.

This legislation provided an incentive for research-based pharmaceutical companies to conduct studies on pediatric indications for medicines. The Act included additional market exclusivity for pediatric studies on new and existing pharmaceuticals. The January 2001 Status Report to Congress from the Food and Drug Administration stated that, ''the pediatric exclusivity provision has done more to generate clinical studies and useful prescribing information for the pediatric population than any other regulatory or legislative process to date.''

We should not return to pediatric medicine as it was practiced before 1997. By renewing this law, which will now include a fund to conduct studies on off-patent drugs and reduce the time by which the labeling information reaches consumers, we will ensure that we can continue innovations in the practice of pediatrics and the development of new drug therapies for our children. I know our doctors and their young patients and their parents are pleased that we are moving forward rather than backward in terms of pediatric medications. The March of Dimes, The National Association of Children's Hospitals and the American Academy of Pediatrics all support this legislation and I would urge my colleagues to join them by voting for S. 1789.

Mr. BURTON of Indiana. Mr. Speaker, today we are voting on the passage of the Best Pharmaceuticals for Children Act. Everyone in Congress wants to see better and safer pharmaceuticals for children.

As Chairman of the Committee on Government Reform, I have made oversight of health care issues a priority. In particular, I have been greatly concerned with the safety and efficacy of children's vaccines and drugs given to children with cancer. I am greatly concerned that we continue to inject babies and young children with vaccines that contain mercury—a known neurotoxin. I hope that through the passage of this bill that the Food and Drug Administration (FDA) takes seriously the concerns of the public and Congress that all products given to children need to be adequately and appropriately tested in children to take the guess work out of safety and efficacy issues as well as dosing.

I hope that the Department will make a priority of reviewing products that contain hazardous ingredients such as mercury. All products, including vaccines need to be safe and effective. Ingredients that have been banned in other forms of medication the way that thimerosal has, should certainly be high on the list for review and consideration of removal from the marketplace. Thimerosal, which has been used since the 1930's, is not routinely tested for safety and efficacy in new products. It was grandfathered in and the FDA and manufacturers presume it to be safe. We know a lot more about the neurotoxic affects of mercury today than we did in 1930. This mercury derivative may be a contributing factor in the dramatic rise in rates of autism, pervasive developmental disorders, and speech and language delays. While the FDA continues to state there is no proof of harm, they are making that presumption in the absence of scientific evidence. I continue to feel that these products pose an unacceptable risk to our nation's children and should be recalled. Every time the Institute of Medicine conducts a review of vaccine research, they have recommended research to look at the long-term effects of vaccines. To date the research funding in this area has been woefully inadequate. There is a paucity of data in the safety of children's vaccines. I hope that the Director of the National Institutes of Health will review the numerous research recommendations offered in several Institute of Medicine reports published in the last ten years and quickly move to develop a Request Agenda, including funding, and a Request for Proposal to be issued and funded next year. I will remain vigilant on this issue.

I am also concerned that many of the drugs used in pediatric oncology are being used ''off-label''. While I support the option of using a drug off-label, I have been concerned that chemotherapy agents that are routinely given to children have not been evaluated by the Food and Drug Administration and found to be safe and effective for children and their specific type of cancer. We need to do a better job in pediatric cancers. We need safer, less toxic cancer treatments that do cure cancer and do not adversely affect a child's IQ, their hearing, speech, sight, their gait, and that do not generate secondary cancers.

In this Bill there are provisions, which call for referral to the Advisory Committees disputes on labeling changes. As part of a Committee on Government Reform oversight investigation, we learned that many individuals who sit on FDA advisory committees have been granted waivers for their conflict of interests—financial ties to the companies or organizations affected by Committee on which they are serving. Stock ownership in affected or competing companies, research grants from affected or competing companies, or research grants or personal/financial interests in affected and competing products needs to be very carefully scrutinized. The FDA needs to be more cautious in the granting of waivers to financial conflicts of interest to its advisory committee members, especially those reviewing products that affect children. We must not have even the appearance of a conflict of interest in the review of safety and efficacy of products that will be given to our nation's children.

I remain committed to improving our health care system. We as a government need to embrace the role of nutrition, lifestyle and behavior, traditional healing systems from other cultures, complementary and alternative medicine and work to gather the existing science in these and conventional medicines. We need to identify areas were there is a gap in the scientific evidence, and work aggressively to fill this research gap. We also need to provide

accurate and balanced information to the public and allow Americans to make their own medical decisions. Additionally, we need to work to extend assess to therapies that are both safe and effective in government-funded programs where feasible.

Mr. FORBES. Mr. Speaker, I rise in support of the Best Pharmaceuticals for Children Act, to ensure that our children get the medicines that are best suited to their growing bodies.

Four years ago, Congress authorized incentives for pharmaceutical manufacturers to do pediatric research for their products and to provide pediatric labeling information. That legislation has been an extraordinary success for our children. In the six years prior to enactment of that change in law, only 11 pediatric studies were conducted by the pharmaceutical industry. But, in the four years since its enactment, the industry has agreed to more than 400 such studies.

Mr. Speaker, children are not simply small adults. They have special needs for nutrition and medical care, and the pharmaceutical products we develop should reflect these needs. The pediatric exclusivity provision Congress passed in 1997 ensures that they do. Today's legislation simply reauthorizes that expiring provision through Fiscal Year 2007.

I appreciate the bipartisan effort of the Energy and Commerce Committee to move this bill so swiftly through the legislative process, and I encourage my colleagues to support it.

Mr. DINGELL. Mr. Speaker, I rise to oppose passage of S. 1789, a bill that would continue a program that grants drug companies an additional six month period of market exclusivity, if they conduct tests on the use of their drugs for children. This bill is a slight improvement on H.R. 2887 that passed this House last month. We all agree that improved testing and labeling of prescription drugs for use in children is a good thing. The only question for debate is how to accomplish that important public health objective.

The bill does close a potential loophole by instructing the FDA to approve generic drugs without proprietary pediatric labeling awarded to product sponsors under the Hatch-Waxman Act. But I continue to oppose the bill because its central feature, exclusivity, is about further increasing the profits of an already bloated industry—an industry that does not seem to be able to moderate its pricing practices even as it increasingly burdens its customers, American consumers, and taxpayers.

The impact of pediatric exclusivity falls directly on those who consume the drugs that get the exclusivity. Who are these people? They include seniors, many that cannot afford the prescription drugs they need. And, ironically, pediatric exclusivity can hurt the very people it is intended to help because many unemployed, uninsured, and working poor cannot afford the expensive drugs needed by their children.

What benefit have consumers and taxpayers received for this multi-billion dollar extension of monopoly prices? Of the 38 drugs that have been granted pediatric exclusivity, less than 20 of them now have pediatric labeling. The Committee and the Senate rejected, unwisely in my view, an amendment by Representative STUPAK that would have closed this dangerous loophole in the law by conditioning the grant of exclusivity to actual pediatric labeling.

This bill forces our citizens to overpay drug companies for pediatric testing that should simply be required by law. I oppose it.

Mr. BILIRAKIS. Mr. Speaker I rise today in support of S. 1789, The Best Pharmaceuticals for Children Act. If it's not broken—don't fix it. By all accounts Mr. Speaker, this program is a resounding success. According to the Food and Drug Administration, ''the pediatric exclusivity provision has been highly effective in generating pediatric studies on many drugs and in providing useful new information in product labeling.'' The American Academy of Pediatrics states that they ''can not overstate how important this legislation has been in advancing children's therapeutics.''

The legislation before us today is virtually identical to H.R. 2887, which passed the House on November 15, 2001 by a 338–86 vote. Moreover, this legislation has recently passed the Senate unanimously.

The legislation reauthorizes the pediatric exclusivity program for an additional six years. It keeps the present incentive in place, and makes important improvements. The legislation ensures that off-patent generic drugs are studied, and tightens the timeline for making labeling changes.

The bill retains the improvements that were in both the Senate and House versions to ensure timely labeling changes occur. First, we make pediatric supplements ''priority supplements,'' which will dramatically speed up the process for getting new labels. Second, by giving the Secretary authority to deem drugs misbranded we guarantee that label changes will be made. We believe, and children's groups agree, that the changes we make are the right compromises to maintain the incentives and get labels changed.

I would also like to acknowledge the hard work of my colleagues Representatives JIM GREENWOOD and ANNA ESHOO. These two Members have worked tirelessly to bring this process to a conclusion, and it has been a pleasure working with them. I again would also like to thank the staff that worked so long and hard on this legislation, including John Ford, David Nelson, Eric Olson, Brent Del Monte, Alan Eisenberg, and Steve Tilton. And, yet again a special thanks to Pete Goodloe our legislative counsel. We are so thankful for all of this help.

Mr. Speaker, this is great legislation that the Subcommittee and Full Committee put a lot of thought and effort into. It does wonders for children's health and is widely supported. I urge all Members to support its swift passage.

Mr. BROWN of Ohio. Mr. Speaker, I have no further requests for time, and I yield back the balance of my time.

Mr. TAUZIN. Mr. Speaker, I yield back the balance of my time.

The SPEAKER pro tempore (Mr. SIMPSON). The question is on the motion offered by the gentleman from Louisiana (Mr. TAUZIN) that the House suspend the rules and pass the Senate bill, S. 1789.

The question was taken; and (two-thirds having voted in favor thereof) the rules were suspended and the Senate bill was passed.

A motion to reconsider was laid on the table.

RECESS

The SPEAKER pro tempore. Pursuant to clause 12 of rule I, the Chair declares the House in recess subject to the call of the Chair.

Accordingly (at 4 o'clock and 10 minutes p.m.), the House stood in recess subject to the call of the Chair.

□ 1837

AFTER RECESS

The recess having expired, the House was called to order by the Speaker pro tempore (Mr. LATOURETTE) at 6 o'clock and 37 minutes p.m.

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX, the Chair will now put the question on motions to suspend the rules on which further proceedings were postponed earlier today.

Votes will be taken in the following order:

H.R. 3379, by the yeas and nays;

H.R. 3054, de novo.

The Chair will reduce to 5 minutes the time for any electronic vote after the first such vote in this series.

RAYMOND M. DOWNEY POST OFFICE BUILDING

The SPEAKER pro tempore. The pending business is the question of suspending the rules and passing the bill, H.R. 3379.

The Clerk read the title of the bill.

The SPEAKER pro tempore. The question is on the motion offered by the gentlewoman from Virginia (Mrs. JO ANN DAVIS) that the House suspend the rules and pass the bill, H.R. 3379, on which the yeas and nays are ordered.

The vote was taken by electronic device, and there were—yeas 393, nays 0, not voting 40, as follows:

[Roll No. 499]

YEAS—393

Abercrombie	Borski	Costello
Ackerman	Boswell	Coyne
Aderholt	Boucher	Cramer
Akin	Boyd	Crane
Allen	Brady (PA)	Crenshaw
Andrews	Brady (TX)	Crowley
Armey	Brown (FL)	Culberson
Baca	Brown (OH)	Cunningham
Bachus	Brown (SC)	Davis (CA)
Baird	Bryant	Davis (FL)
Baldacci	Burr	Davis (IL)
Baldwin	Burton	Davis, Jo Ann
Ballenger	Buyer	Davis, Tom
Barcia	Calvert	Deal
Barrett	Camp	DeFazio
Bartlett	Cannon	DeGette
Barton	Capito	DeLauro
Bass	Capps	DeLay
Bentsen	Capuano	DeMint
Bereuter	Cardin	Deutsch
Berkley	Carson (IN)	Diaz-Balart
Berman	Carson (OK)	Dicks
Berry	Castle	Dingell
Biggert	Chabot	Doggett
Bilirakis	Chambliss	Dooley
Bishop	Clayton	Doolittle
Blagojevich	Clement	Doyle
Blumenauer	Clyburn	Dreier
Boehlert	Coble	Duncan
Boehner	Collins	Dunn
Bonilla	Combest	Edwards
Bonior	Condit	Ehlers
Bono	Conyers	Emerson