

Mr. WARNER. Will the Senator yield for a moment?

Mr. ALLEN. I am pleased to yield.

The PRESIDING OFFICER. The senior Senator from Virginia.

Mr. WARNER. Madam President, I associate myself with my colleague's remarks. I say to Senator ALLEN, indeed, you knew her very well. I had come to know her in later years.

The Presiding Officer might be interested in this little story. I had a chance to be with her about 6 or 8 months ago, it seems to me, when she won an award in Northern Virginia and I was sort of the toastmaster of that evening. We had a very friendly conversation—as we often do.

I talked to her about my father, who had likewise died from cancer. He was a medical doctor who devoted his life to others. We engaged briefly in a conversation.

I said: It took great courage for you not to seek the Lieutenant Governor's post.

She acknowledged that, and then, with a twinkle in her eye—she was a very attractive woman, by the way—she said: Yes. I thought about the Lieutenant Governor post because that was going to be a way stop to come and have a campaign against you, Senator WARNER.

And she could have waged a campaign against this old Senator that would give him a wakeup call, for sure.

Our State has lost one of its shining stars, but that is God's will, and we must accept it. I share with the Senator our prayers for her family and her friends.

Mr. ALLEN. Thank you, Madam President.

The PRESIDING OFFICER. The Senator from Connecticut.

Mr. DODD. Madam President, I add my voice to that of the two Senators from Virginia. I did not know Emily Couric, but having listened to the distinguished junior Senator from Virginia speak about her, and the senior Senator, not only did Virginia lose someone of great value but the country did as well. I am sure her family and friends appreciate immensely the words spoken in this Chamber this afternoon. I am sure all of us would like to associate ourselves with them. We express our sympathies to them.

BEST PHARMACEUTICALS FOR CHILDREN ACT

Mr. DODD. Madam President, I ask unanimous consent that the Senate now proceed to the consideration of Calendar No. 184, S. 838; that the only amendment in order other than the committee-reported substitute be a Dodd-DeWine amendment; that the amendment be agreed to, the committee substitute, as amended, be agreed to, the bill, as amended, be read three times, passed, and the motion to

reconsider be laid upon the table, with the above occurring with no intervening action or debate.

The PRESIDING OFFICER. Without objection, it is so ordered.

The Senate proceeded to consider the bill (S. 838) to amend the Federal Food, Drug, and Cosmetic Act to improve the safety and efficacy of pharmaceuticals for children, which had been reported from the Committee on Health, Education, Labor, and Pensions, with an amendment to strike all after the enacting clause and inserting in lieu thereof the following:

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 LACKING EXCLUSIVITY.

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 LACKING EXCLUSIVITY.

"(a) LIST OF DRUGS LACKING EXCLUSIVITY 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)); or

"(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.); and

"(B) 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 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.—

"(A) IN GENERAL.—The Commissioner of Food and Drugs, in consultation with the Director of 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) to all holders of an approved application for the drug under section 505 of the Federal Food, Drug, and Cosmetic Act. Such a request shall be made in accordance with section 505A of the Federal Food, Drug, and Cosmetic Act.

"(B) PUBLICATION OF REQUEST.—If the Commissioner of Food and Drugs does not receive a response to a written request issued under subparagraph (A) within 30 days of the date on which a request was issued, the Secretary, acting through the Director of 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.

"(C) DISQUALIFICATION.—A holder that receives a first right of refusal shall not be entitled to respond to a request for contract proposals under subparagraph (B).

"(D) 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 subparagraph (A).

"(2) 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.

"(3) REPORTING OF STUDIES.—

"(A) Upon 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 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, 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 (4).

"(4) REQUEST FOR LABELING CHANGES.—During the 180-day period after the date on which a report is submitted under paragraph (3)(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; and

“(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.

“(5) DISPUTE RESOLUTION.—If, not later than the end of the 180-day period specified in paragraph (4), 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—

“(A) the Commissioner of Food and Drugs shall immediately refer the request to the Pediatric Advisory Subcommittee of the Anti-Infective Drugs Advisory Committee; and

“(B) not later than 90 days after receiving the referral, the Subcommittee 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.

“(6) FDA DETERMINATION.—Not later than 30 days after receiving a recommendation from the Subcommittee under paragraph (5)(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.

“(7) 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 (6), 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.

“(8) 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. 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:

“(1) 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.—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—

“(A) 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 by that date, the Commissioner shall immediately refer the matter to the Pediatric Advisory Subcommittee of the Anti-Infective Drugs Advisory Committee;

“(B) not later than 90 days after receiving the referral, 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) 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; and

“(D) 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.”

SEC. 5. OFFICE OF PEDIATRIC THERAPEUTICS.

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

(b) DUTIES.—The Office of Pediatric Therapeutics shall be responsible for oversight and coordination 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 include—

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

(2) 1 or more additional individuals with expertise concerning ethical issues presented by the conduct of clinical research in the pediatric population; and

(3) 1 or more additional individuals with expertise in pediatrics who shall consult and collaborate with all components of the Food and Drug Administration concerning activities described in subsection (b).

SEC. 6. 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. 7. 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 approvable application for the drug is submitted under section 505(b)(1); and

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

SEC. 8. DISSEMINATION OF PEDIATRIC INFORMATION.

Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) (as amended by section 4(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 in any way section 552 of title 5 or section 1905 of title 18, United States Code.”

SEC. 9. CLARIFICATION OF INTERACTION OF MARKET EXCLUSIVITY UNDER SECTION 505A OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT AND MARKET 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 8) 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).—

“(1) IN GENERAL.—If a 180-day period under section 505(j)(5)(B)(iv) overlaps with a 6-month extension 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—

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

“(B) if the 180-day period would, but for this subsection, expire during the 6-month extension, by 6 months.

“(2) EFFECT OF SUBSECTION.—Under no circumstances shall application of this section result in an applicant for approval of a drug under section 505(j) being enabled to commercially market the drug to the exclusion of a subsequent applicant for approval of a drug under section 505(j) for more than 180 days.”

SEC. 10. 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 appropriate committees of Congress, by 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. 11. 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), 4(b)(2), 8, and 9) 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)”;

(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), and (n) as subsections (b), (a), (g), (h), (m), (l), (i), (j), and (k), 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 (1)), by striking “subsection (a) or (c)” and inserting “subsection (b) or (c)”;

(5) in subsection (g) (as redesignated by paragraph (1)), by striking “subsection (a) or (b)” and inserting “subsection (b) or (c)”.

Mr. HATCH. Mr. President, I rise to commend my colleagues Senators DEWINE and DODD for their efforts to reauthorize an important piece of legislation—the pediatric exclusivity rules. The DeWine-Dodd pediatric exclusivity law was passed as part of the Food and Drug Administration Modernization Act of 2001. This bill has helped spur a great deal of research into pediatric indications for many pharmaceutical products. It is a good law.

I also want to recognize the efforts of Chairman KENNEDY and Ranking Member GREGG and Senator FRIST for their work in moving this through the HELP Committee.

I am offering a technical amendment that I believe will be acceptable to all, that clarifies how the pediatric exclusivity provisions work in conjunction with certain provisions of the Drug Price Competition and Patent Term Restoration Act. Representative WAXMAN and I were instrumental in developing this important 1984 law.

I have worked with my colleagues, the administration, and interested parties to make certain that the 1997 pediatric exclusivity law does not act to curtail the incentives of those generic drug manufacturers awarded 180 days of exclusivity under the 1984 law because they have successfully challenged a patent or have shown that a pioneer drug product is not infringed.

The amendment I offer today helps make clear that a generic firm that qualifies for the 180-day patent non-infringement/patent invalidity incentives gains just that—180 days, no more, no less.

I also thank Senator DODD for agreeing to continue to work to iron out some issues as this bill is conferenced with the House. For example, we want to work together to make certain the overlap language applies to generic drug applications already in the pipeline at FDA. I also understand that some may have concerns that certain aspects of this language may raise questions with respect to the takings clause. It is my hope that the conferees will work to perfect the language.

I commend Helen Rhee, who has worked on this bill for both her old boss, Senator DEWINE and her new boss Senator FRIST and Deborah Barrett of Senator DODD’s office for their work on this bill.

I also commend the expert staff of the Food and Drug Administration, including Melinda Plaisier, Jarilyn Dupont, Liz Dickinson, and Kim Dettelbach for their hard work on this legislation.

I urge my colleagues to work together to reauthorize the DeWine-Dodd pediatric bill.

Mr. FRIST. Mr. President, I rise today to support S. 838, the Best Pharmaceuticals for Children Act. In the January 2001 report to Congress, the

FDA stated that the law that we are reauthorizing today, “has done more to generate clinical studies and useful prescribing information for the pediatric population than other regulatory or legislative process to date.”

In just the 3 years since the law was implemented, it has made a positive difference in the lives of thousands of children. I am pleased to be a cosponsor and strong supporter of this highly successful program. In the short time that this program has been in existence, FDA has issued about 200 written requests for pediatric studies. Companies have undertaken over 400 pediatric studies, of which 58 studies have been completed, in a wide range of critical therapeutic areas, including gastroesophageal reflux disease, diabetes mellitus, pain, asthma, and hypertension. Thirty-seven drugs have been granted pediatric exclusivity, and important label changes have either been made, or are underway, as a result of pediatric studies.

For instance, new pediatric dosing information for a new oral formulation of midazolam, a medication used to sedate children in surgery, now offers an alternative to the injectable form of the drug that needs to be directly injected into a child’s vein. The studies submitted under this pediatric exclusivity law not only resulted in this new oral syrup formulation and correct dosing information, but also identified a subpopulation of pediatric patients with heart disease and pulmonary hypertension who are at higher risk for adverse events unless they are given lower doses than other children. A pediatric nephrologist from Memphis, TN, prescribed Randitidine, using new dosing and labeling information that resulted from this law, to neonates who were experiencing health problems due to acid reflux.

Despite the successes of this law, we did not settle for a straight reauthorization. We instead sought to improve this already highly successful law. This law provides a funding mechanism to ensure that off-patent drugs and certain declined written requests for the study of on-patent drugs, for which the Secretary believes there is a continuing need for pediatric testing, are studied. It establishes timeframes for responding to written requests, timeframes and processes for negotiating label changes, and authorizes the Federal Government to deem a drug misbranded if the company ultimately disagrees with FDA’s proposed new drug label. The government could then begin an enforcement action under existing authority to seek a court order regarding relabeling of the drug.

We also lift the current restrictions on user fees established under the Prescription Drug User Fee Act to include this pediatric testing program. By including pediatric testing in the user fee program, the FDA will be given additional resources needed to give priority

review to pediatric testing applications.

We provide for the public dissemination of summaries of the pediatric studies that are submitted so that certain unprotected information will be disseminated to pediatricians even before labeling information has been finalized.

I would like to thank Senator HATCH and his staff, Bruce Artim and Trish Knight, for their work in drafting language to clarify that this pediatric incentive program does not, and is not intended to, preclude other incentives, for example, one that provides for a 180-day exclusivity period for the first generic drug company that challenges a patent. Another important clarification we made in this bill is that the pediatric exclusivity program is not intended to prevent generics from entering the market solely based on the fact that some or all of the pediatric use information may be protected under the pediatric exclusivity law. Allowing generic drug companies to market a drug to adults, while requiring that any precautions, warnings, or contraindication for pediatric use that the Secretary determines to be necessary ensures that the safety of children is protected and that the intent of two different laws are both met.

To further ensure that the safety of children in clinical trials is protected, this bill requires that the Institute of Medicine conduct a review of federal regulations, reports, and research involving children and provide recommendations on best practices relating to research involving children. This builds on an important review and report from the Department of Health and Human Services that Senator KENNEDY and I worked with Senator DEWINE and DODD to include in the Children's Health Act last year.

While we ensure that the Secretary convenes and consults with the Pediatric Advisory Committee, we also ensure that pediatric oncology remains a research priority. Twenty written requests have been issued so far for oncology drugs, and this bill authorizes the Pediatric Oncology Subcommittee to evaluate therapeutic alternatives to treat pediatric cancer and provide recommendations and guidance to ensure children with cancer having timely access to the most promising new cancer therapies.

I would like to thank my colleagues, Senators DODD, DEWINE, AND KENNEDY for their relentless effort to create such a strong bill. We have worked hard to make major improvements to an already highly successful law. I would like to thank Senators COLLINS and BOND for their early support and for helping to draft language to ensure that drugs used in the neonate population are studied, when safely and ethically appropriate. I also appreciate the support of Senators GREGG, MIKUL-

SKI, JEFFORDS, MURRAY, CLINTON, BINGAMAN, and WELLSTONE for this bill and for their help in improving this already highly successful pediatric testing law.

I would also like to thank Helen Rhee on my staff and Debra Barrett from Senator DODD's staff for their tireless dedication and effort to help us bring so many Members from across the aisle and off the Hill together to pass this legislation. Finally, I would like to thank Elaine Holland Vining with the American Academy of Pediatrics, Mark Isaac and Natasha Bilimoria with the Elizabeth Glaser Pediatric AIDS Foundation, and Jeanne Ireland, Christie Onoda, and Stephanie Sikora from Senator DODD's office for their expertise and guidance in drafting this bill. Vince Ventimiglia from Senator GREGG's staff, Christina Ho from Senator CLINTON's staff, and David Dorsey, David Nexon, and Paul Kim from Senator KENNEDY's office also deserve much credit for negotiating and bringing this bill to final passage today.

AMENDMENT NO. 1905

The amendment (No. 1905) was agreed to.

(The text of the amendment is printed in today's RECORD under "Amendments Submitted.")

The committee amendment in the nature of a substitute, as amended was agreed to.

The bill (S. 838), as amended, was read the third time and passed.

ORDER OF PROCEDURE

Mr. DODD. Madam President, we are about to go into recess.

I ask unanimous consent that when the Senate reconvenes and after the remarks of Senator BYRD and Senator VOINOVICH, Senator DEWINE and I be recognized for a half hour with the time equally divided.

The PRESIDING OFFICER. Without objection, it is so ordered.

RECESS

The PRESIDING OFFICER. Under the previous order, the Senate stands in recess until 2 p.m.

Thereupon, the Senate, at 12:45 p.m., recessed until 2 p.m. and reassembled when called to order by the Presiding Officer (Mr. REED).

The PRESIDING OFFICER. Under the previous order, the Senator from West Virginia is recognized for up to 35 minutes.

CONTINUING THE WORK OF THE SENATE

Mr. BYRD. Mr. President, in the early days of the Great Depression, I lived in the coal mining camps of southern West Virginia. I remember those days when we only had an old

Philco radio up on the wall of the house. But the voice of President Franklin Roosevelt was a golden voice. When his voice came over the airways, the coal miners and their families gathered around and listened intently and always with hope.

Roosevelt, in his first inaugural address, stated quite clearly:

[T]he only thing we have to fear is fear itself—nameless, unreasoning, unjustified terror which paralyzes needed efforts to convert retreat into advance.

Mr. President, the U.S. Senate must not be paralyzed. At a time when the Senate must lead by example, we must show the Nation that work can continue and that our Government will not close down.

Congress is supposed to approve 13 appropriations bills—these are the regular appropriations bills—by the start of the fiscal year on October 1. But that fiscal year started several days ago. Yet we have only sent the Interior and the military construction appropriations conference reports to the President for his signature. At the same time, we have now approved a third continuing resolution—this one to last until October 31. That is Halloween. The Appropriations Committees in the House and Senate have been doing their work. The legislation is being written and reported to the Senate for consideration. But instead of debating and voting on these bills, instead of expeditiously doing the work of the people, the Senate is moving all too slowly—moving at a snail's pace, as a matter of fact—on these essential funding bills.

The American people are looking for leadership in their elected representatives, and they have a right to demand it. We need to act; we need to show them, we need to show the world that the Senate is undaunted, that we can accomplish our goals notwithstanding those who would seek to have the American people cower in fear.

One of the bills, for example, delayed on the floor is the fiscal year 2002 foreign operations appropriations bill includes \$450 million to combat HIV-AIDS, the worst global health crisis in half a millennium. The bill includes money for medicines to treat malaria and tuberculosis. Hundreds of millions of dollars for efforts to reduce poverty, improve basic health care, and build basic housing and sanitation systems are also being delayed. Even funds to combat terrorism and to reduce threats from biological, chemical, and nuclear weapons are currently in that bill, the bill being held up by one side of the aisle on this Senate floor.

I appreciate the efforts of the majority leader to bring these appropriations bills to the floor. Unfortunately, his efforts to date have been blocked to a considerable extent.

Now is the time for the Members of the Senate to exercise the leadership