

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