

I want to pay particular tribute to my staff and thank them. Eight members of my staff have been tested, as have hundreds of other members of other staffs. I also want to pay particular tribute to my State director, Barbara Schenk. Barbara has gone through a very difficult time in the last few weeks. Her brother, Doug Cherry, died in the World Trade Center. So our thoughts and prayers go to her and to her family and the Cherry family.

BEST PHARMACEUTICALS FOR CHILDREN ACT

Mr. DEWINE. One of the things that passed today was a bill that Senator DODD and I have been working on for some time. Senator DODD talked a little bit about it on the Senate floor earlier today. This bill is S. 838, the Best Pharmaceuticals for Children Act.

This is reauthorization legislation which Senator DODD and I wrote to ensure that more medicines are tested for children and that useful prescribing and dosing information appears on labels.

Let me take a moment on a personal note to congratulate my friend, Senator DODD, and his wife Jackie on the recent birth of their daughter Grace. I had the opportunity a couple of days ago when Senator DODD and his wife Jackie brought baby Grace into the Capitol to see baby Grace, a beautiful child—a great joy. So our congratulations go to both of them.

It is appropriate that the first piece of legislation that Senator DODD passed after the birth of his little girl was a bill that will help children, a bill that will make sure that good pharmaceuticals are available for children and that doctors, specifically pediatricians, and parents will know what the dosage for each medicine should be for their particular child, for the age of that child.

Four years ago, Senator DODD and I first learned that the vast majority of drugs in this country that came on the market every week—in fact over 80 percent—had never been formally tested or approved for pediatric use and therefore lacked even the most basic labeling information regarding dosing recommendations for children. When we found that out, we began writing what is now referred to as the pediatric exclusivity law. That bill passed. In the 3 years since that law went into effect, the FDA has issued about 200 written requests for pediatric studies.

Companies have undertaken over 400 pediatric studies, of which over 58 studies have been completed, for a wide range of critical diseases, including juvenile diabetes, the problem of pain, asthma, and hypertension.

Mr. President, 37 drugs have been granted pediatric exclusivity. Some studies generated by this incentive

have led to essential dosing information; for example, Luvox. Luvox is a drug prescribed to treat obsessive-compulsive disorder. Pediatric studies performed pursuant to our law have shown inadequate dosing for adolescents, which resulted in ineffective treatment. The studies also have shown that some girls between the ages of 8 and 11 were potentially overdosed, with levels up to 2 to 3 times that which was really needed.

Since our law has been in effect, the private sector has increased its investment in pediatric training and developing an infrastructure to support and expand pediatric research. The FDA stated in a January 2001 report:

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.

The bill this Senate and House passed 3 years ago has done a great deal of good. We are seeing more drugs for children on the market that have a label that tells how they can be used, and more basic information for pediatricians. So when they look at that little child and they know the age of that child and they know the weight of that child, they can look it up and see exactly what the prescription should be, what the dosage should be, what the indicators are. They can do that because we have given the pharmaceutical companies an incentive to do that research, research they were doing prior to passage of this bill in only 20 percent of the cases.

A great deal of progress has been made, but we have further to go. That is what we were about today with the passage of the bill that I am now describing. Senator DODD and I and the other cosponsors knew that the law we passed 3 years ago could be improved. We knew that it had some holes in it. We set out to improve that, to fill the gaps, and address the outstanding issues, such as the testing of off-patent drugs, which the original law was never designed to include. It is understandable why the original law wasn't designed to include off-patent drugs. The original law extended the patent by 6 months. They extend it for 6 months if and only if they tested these drugs for children.

If a drug is not on-patent, if it is off-patent, the patent has basically expired, obviously that incentive doesn't do any good. What we tried to do with this bill that we passed today was to change that and therefore expand it and expand the purpose of this bill to include off-patent drugs as well.

For some products and some age groups, the existing market incentives are simply inadequate to encourage new pediatric research. In the bill we passed several hours ago, we have built upon the existing law's basic incentive structure to further ensure that these

essential products, and young age groups, are included within the scope of the program.

To make perfectly clear the need for additional legislation, I would like to quote a significant passage from the FDA's January 2001 report, which stated the following:

A majority of marketed drugs are not labeled for use in pediatric patients, or are labeled for use only in specific pediatric age groups . . . And many of the drugs most widely used in pediatric patients carry disclaimers in their labeling stating that safety and effectiveness in pediatric patients have not been established. The absence of pediatric labeling information poses significant risks for children. Inadequate dosing information exposes pediatric patients to the risk of adverse reactions, usually age-specific adverse reactions that could be avoided if such information were provided 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 therapeutic advances because physicians choose to prescribe existing, less effective medications in the face of insufficient pediatric information about a new medication.

These facts are very disturbing. Through our bill, we have sought to find a way to improve the labeling process. Since our law has not been implemented for very long, many labels are still in the process of being requested and negotiated by the FDA. In this new bill, the new timeframes established in the bill for labeling negotiations, together with the enforcement authority under the existing misbranding statute, will help to ensure that essential pediatric information generated from studies implemented under this law, will result in necessary and timely labeling changes.

Our bill 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 refuses to relabel its drug. The government would then begin an enforcement action under its existing authority to seek a court order regarding the relabeling of the drug.

Through the bill that we are about to pass today, we will ensure that priority drugs which lack patent or other market exclusivity will be tested for children. For example, the Ritalin label states the following:

Precautions: Long-term effects of Ritalin in children have not been well established. Warning: Ritalin should not be used in children under six years since safety and [effectiveness] in this age group has not been established.

The point is that Ritalin is being prescribed off-label for children under six years of age, and yet we do not know the safety and effectiveness, since it has only been tested in children older than six, and we do not know long-term effects on children of any age.

Our bill creates a mechanism to "capture" the off-patent drugs for

which the Secretary determines additional studies are needed to assess the safety and effectiveness of the drug's use in the pediatric population.

In other words, our bill provides for the testing of some cases of these off-patent drugs.

By expanding the mission of the existing NIH Foundation to include collecting and awarding grants for conducting certain pediatric studies, we have provided a funding mechanism for ensuring studies that are completed for both off-patent drugs and those marketed on-patent drugs that a company declines to study—and for which the Secretary determines there is a continuing need for information relating to the use of the drug in the pediatric population.

That is the language in the bill. That is the correct area.

By first seeking funding through the Foundation, we provide a mechanism for drug companies to contribute to the funding of mainly off-patent drugs and also to a narrow group of on-patent drugs, including those for neonates, for which companies have declined to accept the written request to pursue the six month market exclusivity extension.

The Neonates, of course, are young children up to one-month of age.

If the Foundation lacks the funds to study that prioritized drug, the Secretary may then issue a request for proposal—"RFP"—for a third party to study the commercially available drug using money from a Research Fund that we create in this bill. The Secretary may then publish the name of the company that declined to study the drug, the name of the drug, and the indication or use that is being requested to be studied. This would ensure that more data is collected and reported, so that we can better understand which drugs are not being studied.

A condition of the RFP or contract with a third party is that all data and information generated from the pediatric study in the form of a report must be submitted to the NIH and the FDA. The FDA must then review the report and data and negotiate whatever labeling changes the FDA determines is appropriate.

I thank Senator BOND for his determined focus on helping to further ensure that neonates also benefit from this pediatric testing law. I congratulate and thank him. We have included neonates in the definition of "pediatric studies" to which this pediatric exclusivity applies. Throughout the bill we have also encouraged the inclusion of neonates in written requests, when appropriate.

To further ensure that the safety of children in clinical trials is protected, this bill requires that the Institute of Medicine—IOM—conduct a review of federal regulations, reports, and research involving children and provide

recommendations on best practices relating to research involving children. The IOM is to consider the results of the study by HHS that Senator DODD and I included as part of the Children's Health act last year. I look forward to working with Senators DODD, FRIST, and KENNEDY on the issue of human subject protections, especially in focusing on protections of children participating in clinical trials.

I want to thank my friend, Senator DODD for his relentless efforts in making this reauthorization a reality, and for his relentlessness in improving the bill. I look forward to working on many more pediatric initiatives with him in the future.

Let me also thank Senators KENNEDY and CLINTON for their strong support of this bill and of children's health overall. Let me also thank Senator COLLINS for her support and for her work in regard to this bill.

I want to acknowledge and thank Debra Barrett, Jeanne Ireland, Christie Onoda, David Dorsey, David Nexon, Paul Kim, Christina Ho, John Gilman, and Tim Trushel for their hard work in helping us reach agreement on such a well-crafted bill. I cannot think of a bill that took more hard work, more Members and staff than this bill.

I also extend my appreciation to Elaine Holland Vining with the American Academy of Pediatrics for the tenacious effort, technical assistance, and expertise she brought to this bill. She is expecting her first child shortly, and I wish her and her husband, Paul, my very best wishes as they begin their family.

I also appreciate the diligent work of Mark Isaac and Natasha Bilimoria with the Elizabeth Glaser Pediatric AIDS Foundation in helping us negotiate and pass this important reauthorization.

Finally, I must say a very special thanks to a former member of my staff, Helen Rhee, who is now working for Senator FRIST on the HELP Committee. She has been absolutely instrumental in seeing this legislation through from its inception to its passage. Without her tireless efforts, her dogged determination, and a work ethic that is just unsurpassed, we would not be at this point today, we would not have seen this bill pass. Literally, right up until the last moment, literally, before the bill passed, Helen was continuing her work. So I pay tribute to her. This bill is a real tribute to her dedication and to her efforts.

So I thank Helen and all the members of the different staffs who have worked so hard on this bill.

Let me also take a moment to thank Senator HATCH and his staff, Bruce Artim, for their work in drafting language to correct and clarify this bill, specifically to clarify that pediatric exclusivity law is not and was never intended to eliminate incentives granted to generic drug manufacturers that are

awarded 180 days of exclusivity under the 1984 Hatch-Waxman law for successfully challenging a patent.

Mr. President, I yield the floor.

The PRESIDING OFFICER (Mr. DAYTON). The Senator from Vermont.

COMPLETING THE WORK OF THE SENATE

Mr. LEAHY. Mr. President, I see my good friend, the deputy majority leader, the senior Senator from Nevada, in the Chamber. I first note my appreciation for the kind words he has said on several occasions about our efforts in the Judiciary Committee. The Senator and I have been friends from the day he came to the Senate. I value that friendship very much.

I also thank our leadership for having us in session today. Let me take a couple moments to say why.

This is a trying time for everybody—for our staffs, for the brave men and women of the Capitol Police, who protect us, for Dr. Eisold, and all those who work with him in the Capitol physician's office—for everybody, whether they are doorkeepers, or anybody else, including the young pages, both the Democratic and Republican pages who are here. The work is being done. It has been a difficult time.

What would have been more difficult for the Nation would have been if we had not been here today. I think it was essential we be here. We have actually accomplished a great deal by being here.

We have held hearings on judges, and voted a number out of committee, as well as a number of U.S. attorneys. We have completed action on an agreement on the counterterrorism bill. It is something that just a few days ago everybody said could not be done. We have done it. We are now at the point simply of drafting, which is not the easiest thing in the world with all the offices closed down. But the staffs of the various committees, including the Judiciary Committee, of course, have been working literally around the clock to get the paperwork done, to get the actual words on paper.

So I feel safe in predicting the House and the Senate will vote on a package on the counterterrorism bill that, interestingly enough, will be improved over what we passed in the Senate and improved over what they passed in the other body.

The sum is greater than the parts. And that shows what happens when we work together—both bodies; both parties—to get something done.

We have actually done the administration a favor by taking time to look at it. The piece of legislation originally proposed by the White House and Attorney General was deeply flawed. Had we accepted their proposal to immediately move forward and pass it, we would have given them a flawed bill