

FLOOR STATEMENT
REMARKS -- PEDIATRIC RULE PASSAGE
SENATOR MIKE DEWINE
JULY 23, 2003

Mr. DeWINE. Mr. President, I rise this evening in support of the passage of this bill, the Pediatric Rule. Passage of this bill will be a very important step in protecting the health of our children. This bill will help keep the Pediatric Rule in place to help ensure the drugs we give our children when they are sick are actually tested for use by our children. The tragic reality is there are medicines on the market today that are being used by and prescribed for our Nation's children that are oftentimes not being tested for their use. It has been that way for years and years.

For many years, doctors have had to take a chance when prescribing medicines for our kids. Doctors have literally had to tell parents to cut the pill in half or in quarters to be given to a child. The doctors have used the best information they have to literally guess how much medicine to give a child. That is all they could do with the medicines; they have had to guess.

Quite frankly, these medicines have been over-prescribed, under-prescribed, or maybe not prescribed at all when they should have been prescribed. For example, recently the drug Paxil, which is an antidepressant, has been prescribed without being tested in children at all. Many people have heard of this drug. Many people have heard of the beneficial effects for adults with anxiety and panic disorders. What people did not know, what doctors did not know, was what we have recently found out.

Recently the British Government has warned doctors to stop prescribing this drug for children, warning that the medicine increased the risk of suicide or suicidal thinking among children with depression. This action, in turn, spurred the FDA to conduct its own investigation into the safety of this drug for younger patients, resulting in a similar warning to physicians here in the United States: Don't prescribe this drug for children.

That is just one example. We have page after page of examples of drugs that have been prescribed to children in the past and once we tested them -- once the protocols were done, the testing was done -- lo and behold, we found they were more effective for children than we thought. Sometimes they were not effective, sometimes the prescriptions, the amount, the dosage that had been used was too much, sometimes not enough.

The facts are these. As we all know, children are not just miniature adults. You can't just take the weight and just reduce the dosage. Kids react differently. That is why it is so important to have the testing done. Yet when Senator Dodd and I first started on this cause, five or six years ago, 80 percent of the drugs that came on the market had never been tested for children at all.

It has been over a year now since this Senate passed and the President signed into law the Best Pharmaceuticals for Children Act. The Best Act was a bill that followed the Better Pharmaceuticals for Children Act, which Senator Dodd and I introduced and helped pass and get

signed into law. While these laws are very important, they are just part of the solution to address the problem of getting medicines tested for use by children.

The Best Pharmaceuticals for Children Act provides, as its predecessor law did, a six-month patent extension to pharmaceutical companies in exchange for the testing of medicines in children. That was a voluntary law and it has worked pretty well. For as long as the bill has been law and its predecessor was law, the Food and Drug Administration reported success in ensuring that more medicines are tested for use in children. With the economic incentives of the Best Pharmaceutical and Better Pharmaceutical laws in place, companies are seeing the value of studying their drugs in children and are applying for the patent extensions, and children are benefiting.

But, the Best Pharmaceuticals incentive cannot work alone. It was never intended to work alone to ensure that medicines for children are properly tested for their use. In order to ensure that no medicines needed to treat children, including vaccines or other biologics, would go untested, the FDA, in 1997, proposed what is known as the Pediatric Rule, a companion rule. The Pediatric Rule allowed the FDA to require that drugs deemed important for children be tested for their safety, for their effectiveness, and that they be labeled properly for children.

Unfortunately -- and this is what brings us to the Senate Floor tonight to consider this bill -- the Pediatric Rule came under legal challenge and was, in fact, overturned in court in October 2002, last year, by a district court. That court ruled that the FDA lacked the statutory authority to require pediatric studies.

What the court said was it was incumbent upon Congress to fix it. That is why we are here tonight. This was a troubling step backward for children's health, considering that today 75 percent of the medicines on the market still -- even with the Better Pharmaceutical law and the Best Pharmaceutical law in place -- still 75 percent of the medicines on the market today are not tested or labeled for pediatric use.

Without the Pediatric Rule in place, without the necessary authority provided to the FDA, new medicines and biologics coming onto the market are not required to be tested for use by kids. Since that court decision on October 17, 2002, the FDA has indicated that over 300 medicines either have applications pending or incomplete studies pending, and that unless the Pediatric Rule stays in place, these studies will all be lost. Many more -- hundreds more -- will be lost in the future. Pediatricians will not know how to prescribe these drugs in the future or whether to prescribe them at all.

That is why Senator Clinton, Senator Dodd, and I introduced the bill that we hope to pass tonight. It is a bill that would codify a significant piece of the Pediatric Rule to assure that it stays in place and help ensure that children will remain on safe footing when it comes to the testing of the medications that they use.

Furthermore, we need to keep the Pediatric Rule in place right now because the Pediatric Rule and incentives work together to ensure that drugs are tested for use in children. The Best Pharmaceuticals for Children Act, as I said already, was never intended to be a substitute for the

Rule but, rather, to reinforce and work with the Rule. For example, the Pediatric Rule may be invoked in instances where pediatric information is essential, but the patent exclusivity incentive is no longer available.

The Pediatric Rule also applies to biologics, whereas the Best Pharmaceutical bill does not. A significant portion of therapeutics used in children, including many cancer treatments or biological products -- by that, of course, we mean products that include a live agent. Because the Best Pharmaceutical law does not apply to biologics, the Pediatric Rule is the only way to ensure proper and effective pediatric labeling for those products.

Finally, the Best Pharmaceutical Act is voluntary. For any number of reasons, including insufficient sales, a manufacturer simply may choose to conduct the necessary testing to receive additional exclusivity under the "Best" law, and when that happens and the drug is not tested for kids, children are the losers. But, just because a drug manufacturer chooses not to study the drug in children does not mean that the drug is not critical to the proper care of your children and my children or grandchildren. Without the Pediatric Rule that is in front of us today, there is no way to guarantee that a drug used in the pediatric population is tested for children's use.

With the establishment of the Pediatric Rule and the financial incentives of the Best Pharmaceutical law, which will go with this, there has been a dramatic increase in the number of studies that have been undertaken. Let me quote from the Government's Response to Plaintiff's Notice of Reauthorization of FDA Modernization Act. This is the document the Government filed to defend the lawsuit against the Rule.

"These two options -- Best Pharmaceuticals for Children Act and the Pediatric Rule -- have resulted in a number of drugs being labeled for use in pediatric applications. As of March 31, 2001, 94 applications containing complete or partial pediatric use and information have been submitted to the agency. Of these 94 applications, 45 are attributable to the statutory exclusivity provision. FDA attributes 48 of the 94 applications to the authority of the Pediatric Rule, alone."

You can see how the two must work together, and how important the Rule is. Our legislation is a step toward assuring that the progress we have made so far will not erode. Our bill, as amended, provides that the FDA may only impose the pediatric study requirement for already-marketed drugs when the pediatric exclusivity incentive provisions fail to yield necessary pediatric information. This means that for already-marketed drugs, drugs that the FDA has already approved and are already on the drugstore shelf, before FDA can require a company to study the drug for use in children, the incentive provisions of the Best Pharmaceuticals law have to be used first. So, the drug manufacturer has to choose to use the incentive provisions first, before FDA can invoke the pediatric study requirement.

Our bill also preserves the waiver and deferral process so that drug companies can get waivers or deferrals for a range of legitimate reasons. Waivers are a simple concept. Drugs, such as those used to treat Alzheimer's disease -- those drugs that would not be used in children at all -- obviously should not be tested for use in children. Those drug manufacturers would be allowed to waive the pediatric drug study requirement. Deferrals are similar. For drug manufacturers

who require additional time to complete the drug study or need to get additional information in the adult population before beginning to study the drug in children can, in consultation with the FDA, defer the pediatric drug studies until a later date.

Again, I am very pleased that my colleagues have agreed to pass our bill. It is a vital step toward ensuring that children are no longer a therapeutic afterthought. Our bill puts children on a level playing field with adults for the first time when it comes to the medications they take.

Before I yield the Floor, I would like to take this opportunity to thank the many people who have worked diligently to draft this bill and to help get it passed. I would like to thank Majority Leader Frist and Senators Clinton, Dodd, Gregg, Kennedy, and Murray for their leadership on this issue. Without their support, this bill would not be a reality.

I would also like to thank Abby Kral of my staff for her dedication and hard work on this issue -- she spent an unbelievable amount of time on it -- as well as Christina Ho from Senator Clinton's staff, Ben Berwick with Senator Dodd, Vince Ventimiglia with Senator Gregg's staff, and David Dorsey with Senator Kennedy. Finally, I would like to recognize two groups that provided my staff and the staff of the HELP Committee with invaluable comments and insights -- the American Academy of Pediatrics and the Elizabeth Glaser Pediatric AIDS Foundation.

Thank you all for your efforts and commitment to protecting our children's health and safety.