the Members who helped make this happen? It didn't happen just with Senator DEWINE and I. A lot of people were involved, and I am grateful to them all.

The bill would have gone out of existence; it expires at the end of December. The period of exclusivity would be over and the question of whether or not we would be able to see the continued development of children's products in the area of pharmaceuticals would become less attractive.

Look at some of the comments. This is from the Food and Drug Administration status report to Congress in January of this year:

> The pediatric exclusivity provision has done more to generate clinical studies and is more useful in prescribing information for the pediatric population than any other regulatory or legislative process to date.

That is a pretty remarkable statement. I am grateful for that. Further down here, this is from the National Association of Children's Hospitals:

> This is a remarkable achievement for children's health. We know from talking with pediatric researchers at children's hospitals across the country that the effect of the pediatric exclusivity provision has been very positive for children and their families and their providers of care.

Further down is a letter from the American Academy of Pediatrics. These are the pediatricians across the country:

> We cannot overstate how important this legislation has been in advancing children's therapeutics. It is allowing children to have the same kind of drug safety and efficacy information that was only available previously to adults.

There is also a letter from the Elizabeth Glaser Pediatric AIDS Foundation:

> Regarding costs, the FDA estimates that consumer prices of drugs have increased by one-half of one percent annually as a result of the initiatives of pediatric testing. As individuals who have fought for decades for better health care for children, we firmly believe this is a legitimate price to pay to ensure our children's well-being.

I don't know of anybody who will argue with that when you consider the difference we can make in children's lives. If I can, let me share with my colleagues more specifically what has happened. In light of the extraordinary times we find ourselves in today, the national debate on how to prepare and protect all Americans from bioterrorism further highlights the importance of drug safety and the efficacy of information when it comes to treating children. Children are especially vulnerable to the release of chemical or biological toxins. As we identify antibiotics or vaccines to prevent or treat illnesses related to bioterrorism, we are going to need to know the proper dosing information, possible side effects or risks of this kind of medicine, and the effectiveness of the various agents children would be ingesting. Any antidotes used for children will be affecting them at critical periods of childhood growth and development. We need to have proper medications to prevent or reduce those risks.

This bill could help ensure that essential treatments for exposure to hazardous materials are studied. I will work with the FDA and my colleagues, Senators CLINTON of New York, KENNEDY, and FRIST. In fact, I thank Senator FRIST and Senator CLINTON for their contribution to this effort today. Our hope is that we will get it done in conference and strengthen some language to require that the industry start developing children's vaccines and antibiotics in the area of bioterrorism.

So this bill is a timely piece of legislation. I am confident the House will act. I urge them to do so quickly, to incorporate some of the changes that we think can make a difference in terms of children's health.

I will say what was going on before we passed this bill. In the 3 years, 36 months, since we passed this legislation—prior to the passage of this bill, there had been a total in the previous 7 years of 11 clinical trials for products designed for children. I think there may have been 2 or 3 products that had come on the market designed specifically for children in 6 or 7 years. In the 36 months, since the bill that Senator DEWINE and I wrote, there have been 400 clinical trials. In 36 months, there have been 400 clinical trials as opposed to 11 in the previous 7 years in children's pharmaceutical products. Today, there are 40 new products in 36 months being prescribed for children. They did not exist 36 months ago.

It occurs specifically because of the legislation we adopted—this body and the other body—in 1997. That bill was about to go out of existence. The bill we passed today—and every Member ought to take pride in it because every Member allowed this bill to go forward. Many, such as my friend from North Dakota, Senator CONRAD, are cosponsors. I will leave the record open for others who would like to be associated with it.

In the midst of all of these terrible events going on—this body is working today, by the way, and we did excellent work today, this body passed a bill that will make a difference in people's lives. So we are not just meeting for the sake of meeting to have a good show, but actually we adopted this legislation by unanimous consent. It would not have occurred without the cooperation of Democrats and Republicans—the 100 Members in this body who allowed this legislation to go forward.

In 36 months, there have been 400 clinical trials and almost 40 new products on the shelves. That is the record of this little bill attached to the FDA Modernization Act.

Let me talk about one product and make this case more clearly. I am talking about a product that, as a result of pediatric studies, would make any parent's heart skip a beat; it is called Versed. Versed is one of the most commonly used sedatives for children undergoing surgery or other hospital procedures.

As a result of these pediatric studies, the label has been changed to indicate a higher risk of serious life-threatening situations in children with congenital heart disease and pulmonary hypertension who need lower doses than predicted to prevent respiratory compromise.

Can you imagine doctors using Versed without knowing that information? Until we got these studies underway, it was unknown. But as a result of 36 months of effort, this product today is being used in a way that is saving lives and making a difference. Maybe it does not get banner headlines and it will not lead the news tonight, but it is something that will make a difference in the lives of children and their parents who care about their health.

I heard from a doctor from Children's Mercy Hospital about a 6-year-old boy, Darryl, who required metal pins to be inserted in his leg after his femur was broken in a bicycling accident. Darryl was prescribed Versed to relieve his anxiety and discomfort when the doctors and nurses each day cleaned the wounds resulting from his injury. This new information on Versed allowed health care providers to treat this young man safely and effectively with this drug.

The second chart is before and after effects of our legislation. It is in small print. I will try to describe it.

We get the products, indications, what labeling was prior to the adoption of this bill 36 months ago, and what has occurred afterwards. I will run down from everything dealing with diabetes, hepatitis, hypertension, juvenile arthritis, seizures, and the like. This is just a partial list to give my colleagues some idea of the drugs to treat hepatitis B, hypertension, diabetes, juvenile rheumatoid arthritis, and epilepsy, just to name a few. They previously had labels that simply read:

> Safety and effectiveness in children not established.

That was the guideline a doctor or parent had in these areas.

Now we have dosing information, safety information, and the information on adverse side effects. In fact, in one drug study for epilepsy, Neurontin was found to be most effective in higher doses for children under 5 years of age. I heard from Dr. Philip Walson at Children's Hospital Medical Center in Ohio who told me:

> Some children with previously uncontrolled seizures now are controlled with higher doses of this drug than [what] would have been used [prior to pediatric testing] if adult doses were just ''scaled down.''

In this case, instead of breaking off the aspirin and getting a smaller dose, as a result of the studies, we learned Neurontin, which is a seizure controlling medication—people who have had strokes know about Neurontin—for children makes a difference. Increasing the dosage actually made a difference.

Far more significant than the number of studies and drugs tested are the stories of kids who can be helped by