

breakpoints. This is important to assure that the antibiotics we and our children take are effective against bacterial infections and minimize the progression of resistance.

Antimicrobial resistance is a public health crisis. In many ways, it is even bigger than drug safety, a point our colleague, Dr. COBURN, made at the HELP mark up.

This is an issue that touches not just the old or the young, but all Americans throughout every walk of life. Antibiotics are as precious a natural resource as water is to a vibrant and healthy community and, guess what, the creek is drying up. The Hatch amendment only takes the first steps to address these issues.

If we cannot work together on these more minor provisions, how will we truly combat antimicrobial resistance? What will we say to the children, soldiers, athletes, elderly and so many others that contract these deadly diseases which only years before were successfully treated with antibiotics? Are we really willing to walk away and leave nothing in our arsenal to fight these bad bugs?

I would like to turn my attention now to a provision in the Hatch amendment which encourages innovation in another area. This provision provides for 5-year exclusivity for enantiomers of previously approved racemic drugs in different therapeutic areas based on new data.

Enantiomers are mirror images of the same drug. You can think of them as left-handed and right-handed molecules. We now understand that, in some cases, these enantiomers have very different activity and safety profiles.

In simplest terms, imagine the biological target is a glove that fits one hand better than the other. When Hatch-Waxman was passed originally, we didn't contemplate the isolation of one enantiomer from an approved drug made up of a mixture of enantiomers and its development for a new use based on all new data.

But today that is exactly what is happening. Sponsors are finding new important uses for enantiomers of drugs previously approved as a mixture of enantiomers.

Where FDA is requiring all new data for approval of these single enantiomers and will not allow a company to rely on any of the data submitted in the original application for the mixture of enantiomers, these single enantiomers are effectively new chemical entities and should be entitled to 5-year exclusivity.

In 1997, in a Federal Register notice, FDA laid out the issue, acknowledging the lack of clarity in the law regarding 5-year exclusivity for enantiomers and the need to incentivize this type of development. FDA requested comments but never finalized a policy.

The Hatch amendment makes it clear that development of an enantiomer for new use in a new therapeutic area

based on new data would qualify for 5-year exclusivity. However, in order to address the potential for abuse the revised provision limits 5-year exclusivity to approvals in a new therapeutic class.

As this chart states, innovation and development of enantiomers may provide treatments in cancer, Alzheimer's disease, type II diabetes. When it comes to FDA, we need to get it right.

I feel we have done a lot of good with this bill, and I voted for it in committee with the understanding the issues I raised on antibiotics and enantiomers would be addressed before we reached final passage. I am glad that, as of yesterday afternoon, we have worked out all remaining concerns and I believe the chairman's commitment at the markup has been honored.

I know that some were concerned about this amendment, specifically because its incentives provisions were fueled by exclusivity. With all due respect, I understand the importance of the generic drug industry. We spoke earlier about the need to get it right for follow-on biologics.

But we should listen to the public health associations, who understand the need to support innovation. Indeed, the Alliance for Aging Research, Infectious Diseases Society of America, National Organization of Rare Disorders, and Immune Deficiency Foundation are dedicated to advocating for patients and doctors and improving public health in this country, and they fully support this amendment in its entirety.

The Infectious Diseases Society of America represents doctors that see the threat of resistant bugs every day. They recognize the need for innovation in their therapeutic area.

This isn't different than 10 years ago when the American Academy of Pediatrics argued passionately for the need for innovation in pediatric research. Some may not remember that the generic drug industry opposed that provision saying that innovation was not necessary.

In contrast, I am pleased that we have achieved an agreement today that recognizes the need for this innovation in research involving antibiotics and enantiomers.

Ten years ago, Congress passed the last major piece of FDA legislation, the Food and Drug Administration Modernization Act, or FDAMA.

Those of us who were here then recall ever-so-vividly the infamous chart of the feet displayed with great effectiveness by our colleague Senator KENNEDY.

I hasten to say many have had recurring nightmares about the horror of these feet. The Senator and his very bright staff were ever-so-clever in their effective use of this chart. Today, I hope to have the same effect, although I do not wish to spawn a new generation of nightmares.

I submit to my colleagues, that if we had adequate antibiotics in develop-

ment, we never would have had to look at these diseased feet. With passage of my amendment today, perhaps this chart can be relegated to the Russell attic forever.

In closing, I thank my colleagues for recognizing that antimicrobial resistance is not a brand issue or a generic issue. Effective treatment for Alzheimer's, cancer, or type II diabetes is not a brand issue or a generic issue. These are public health issues.

I urge my colleagues to take these issues seriously and appreciate that we have joined together and not let these serious concerns fall subject to politics as usual. These are growing problems and require attention before it is too late.

We need to make sure that innovation is encouraged in these areas and high scientific standards are maintained and the Hatch amendment does just that.

The PRESIDING OFFICER (Mr. WEBB). The Senator from Ohio is recognized.

RULES GOVERNING THE FDA

Mr. BROWN. Today, we are likely to wrap up consideration of legislation that modifies the rules governing the FDA, an agency that oversees all of the medical products we use and most of the food we eat. FDA came into being about a century ago because Americans were being sold medicines that caused injury, that caused birth defects, that even caused death; and Americans were consuming food products that too often were not safe. Those kinds of medicines were being sold as cures, but they didn't cure anything.

FDA's first responsibility—first responsibility—is to safeguard the health of American consumers. But because the products under FDA's authority account for 25 cents out of every dollar U.S. consumers spend, there is a pull on the agency that has nothing to do with patient safety and everything to do with drugs, both brand name and generic, and medical device industry profits.

I remember a few years ago, when I served as ranking member of the Commerce Committee's Health Subcommittee in the House of Representatives, a representative from FDA started his testimony to us in front of that subcommittee by showing us a chart that tracked the U.S. drug industry's global market share.

As I told that representative, FDA is not the marketing arm of the drug industry. It is the patient safety arm of the Federal Government, to guarantee safe products for Americans who consume medicine, food, and the like.

But FDA's drug industry dog and pony show is emblematic of the key problem this bill is designed to address. FDA has strayed from its public health mission, and this legislation will help to get us back on track.

S. 1082 requires FDA and drugmakers to work together to assure the safety

of medicines before and after a new drug is approved for marketing. It gives FDA more authority to prevent misleading drug ads and limit patient exposure to drug risks that may still be emerging.

S. 1082 is intended to realign FDA's actions with its public safety mission. While there are aspects of the bill that I wish were stronger, I believe S. 1082 will improve patient safety and ultimately the bill will save lives.

Chairman KENNEDY and Ranking Member ENZI, their staff members, and Ellie Dehoney on my staff, literally worked night and day on this legislation. Other Senators have been there right along with them working to incorporate other key consumer health and safety provisions into this bill.

As a result, this legislation will not only help us prevent drug safety crises, it will help prevent the exploitation of the "citizen petition" process, which delays access to lower priced medicines.

Prescription drug affordability is a patient safety issue. What medicines cost determines who can afford them and who must forego them. That is a patient safety issue.

Thanks to the hard work of Senators HATCH and STABENOW, among others, this bill also responds to the problem of antibiotic resistance. It takes steps to spur innovation and reduce costs in that market.

Thanks to the hard work of Senators DODD, CLINTON, and others, this bill will help ensure children receive the right medicine at the right dosage and that they can benefit from medical devices tailored to their special needs.

S. 1082 is an important bill, and it will be a better bill if this body passes the Dorgan amendment to enable the safe importation of prescription drugs and rejects Senator COCHRAN's amendment to prevent safe reimportation.

Consumers are importing prescription drugs today. Seniors in Ohio are taking bus trips to Canada to buy their prescriptions in Windsor. It is happening in border States throughout our country because our country pays the highest prices in the world for prescription drugs.

Our Government isn't doing anything about that. Too many members of Congress—House and Senate—are, frankly, too involved and too influenced by big drug companies. So American consumers are now taking matters into their own hands. American consumers are importing prescription drugs today. We can help them do it safely or we can turn our backs and simply wish them well. This Senate, and the House, for too many years, along with this President, have turned our backs and wished them well.

It is time for something different. Let's help our citizens import prescription drugs safely. Vote for Senator DORGAN's drug safety initiative and vote against Senator COCHRAN's poison pill.

I yield the floor, and I suggest the absence of a quorum and ask unanimous

consent that the time be charged equally to both sides.

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

The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

Mr. GRASSLEY. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

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

Mr. GRASSLEY. We have 18 minutes remaining. I yield myself 9 minutes.

The PRESIDING OFFICER. The Senator is recognized.

AMENDMENTS TO THE FOOD AND DRUG ADMINISTRATION REVITALIZATION ACT

Mr. GRASSLEY. Mr. President, there are two amendments I am going to bring up on the bill that will be before the Senate. Amendment No. 1039, which Senators MIKULSKI and BROWN will also be cosponsoring, provides for joint postmarketing decisionmaking between two offices within the FDA—the Office of Surveillance and Epidemiology and the Office of New Drugs. These offices would address jointly postmarketing drug safety issues.

This postmarketing decisionmaking is intended to include labeling changes requiring additional postmarketing studies and restrictions on distribution and use of drugs. The joint decision-making would give the Office of Surveillance and Epidemiology signoff authority. This is different than its present role of being a mere consultant to the Office of New Drugs.

It is very important to understand that the core of this amendment was recommended by the Institute of Medicine last fall.

The other amendment is amendment No. 998, which Senator DODD will also be cosponsoring. It provides for the application of stronger civil penalties for noncompliance with approved risk evaluation.

Currently, S. 1082 contains penalties that are insignificant for large companies and amount to nothing more than the cost of doing business. This amendment is intended to give the FDA, the watchdog, some bite along with its bark.

Big PhRMA doesn't like my amendments because they shake up the status quo. The status quo includes FDA's debacle, such as Vioxx and the failure of FDA to notify doctors and parents of potentially tragic effects of antidepressants on children.

These amendments would make postmarketing safety concerns a forethought rather than an afterthought at the FDA. These amendments are intended to establish greater accountability, break the stronghold big PhRMA has on the FDA, and make postmarketing safety a meaningful effort at the agency.

Today, through my amendments, I hope to help Senator KENNEDY and Sen-

ator ENZI finish a very good job they started through the HELP Committee. S. 1082 is a first step in setting a new direction for the safety of prescription drugs. As I said the week before last, I am heartened by the fact that this bill attempts to address some of the many failures I have exposed over the last 3 years at the FDA, failures that negatively affect the core mission of the FDA. For the first time in almost a decade, we have an opportunity to reform, improve, and reestablish the FDA as what it should be: the gold standard of drug safety.

The bills Senator DODD and I have introduced in the past were intended to enhance drug and device safety and to bring transparency. Over the past two Congresses, I have worked with Senator DODD on these bills. One of these bills asks for the creation of a new center devoted solely to postmarketing drug safety, a center that would bow to no one but the American consumer, a center that would be an independent voice for consumers, a center that would reside in the FDA and decide what to do and when to do it when an unexpected safety risk arises from a drug.

There is strong opposition to such a center, I found. This is the case even though scientists and epidemiologists working in the FDA, as well as independent thought leaders, believe the Food and Drug Administration Safety Act of 2007 would prevent another Vioxx debacle.

The HELP Committee incorporated certain aspects of Grassley-Dodd and Dodd-Grassley bills in the bill before us, and I thank Senator KENNEDY and Senator ENZI for doing that.

During floor debates, I have seen agreements and long-term commitments fall through. It is clear to me S. 1082 will never include a separate center for postmarketing safety. The way the process works will not allow a new center to be created in the FDA. That is very unfortunate. It is particularly unfortunate for our consumers. Senator DODD and I concluded a new independent center was the best way to ensure postmarketing drug safety. But, again, there is strong opposition to such a center, despite the fact that it is the right thing to do.

The wheeling and dealing and lobbying on this bill have made it impossible for a new postmarketing center to become a reality. So instead, I am here to offer a lesser amendment. It is lesser because it is not the best we can do. I know we can do better. Amendment No. 1039 has its roots in the Institute of Medicine recommendations and should be embraced by every Member. Specifically, the Institute of Medicine stated in its report:

The committee recommends that CDER appoint an OSE staff member to each new drug application review team and assign joint authority to OND and OSE for the post-approval regulatory actions related to safety.

Two members of the Institute of Medicine committee which issued the