else might happen, with Iran expanding its influence.

I have to tell you that the substantial reduction in violence we have seen is not small. This is really large. If you told me when the surge started that we would see a 70-percent reduction in civilian deaths in Baghdad, I would not have believed it. I would have thought that would be more optimistic than I was prepared to be. So whether it will hold, I don't know. We have seen some improvement.

I know the Senator from Massachusetts would like to speak. I will just conclude by saying, OK, we have had these reports, we have seen this progress, and we know what the difficulties are. I have decided, based on General Petraeus's testimony, the Crocker testimony, the Jones Commission report, and other information we have, that things are moving in a better direction.

I personally believe it is the new tactics, not so much the number of soldiers. I am very happy General Petraeus has concluded he can draw down troops while maintaining this progress of reducing violence. In fact, he has recommended that within the next few weeks, a Marine unit not be replaced. So that represents an initial reduction in our forces within a few weeks. Then the next reduction will come before Christmas will be an Army brigade, and he would have 30,000 troops withdrawn by next summer and would report to us again in March on whether he could continue this rate of reduction or accelerate it.

There is not that much difference, I say to my colleagues, in what we want. Senator LEVIN wants to see troops withdrawn. He wants to see a stable Iraq. The question is, Do we do it with a mandated withdrawal rate dictated by Congress or do we do it in harmony with the situation on the ground that leaves us in the best possible position to allow a stable, peaceful Iraq, an ally to the United States, to exist?

I think we should accept the report. We should see this as good news, celebrate that some progress has been made and recognize that serious challenges are out there. I do believe Congress has every right to monitor this situation closely. We have every right to reject the President's recommendation, to reject General Petraeus's recommendation, to cut off funds and order our troops home if we so desire. I think that would not be a good decision. I think it would not be in the long-term interests of the United States of America. Therefore, I oppose the Levin amendment.

I yield the floor.

The PRESIDING OFFICER (Mr. SANDERS). The Senator from Michigan.

Mr. LEVIN. Mr. President, I believe Senator NELSON was scheduled to be the next speaker on this side of the aisle. He had to do that before 7 o'clock, so he will be unable to take that position. Senator KERRY is next in line on this side. However, I understand he is going to yield to Senator KENNEDY for a couple minutes for him to offer a unanimous consent agreement.

I thank Senator KERRY for his patience, as always. There is a lot of confusion and difficulty in scheduling speakers. He has been extremely patient. I appreciate it a great deal.

I wonder if Senator KENNEDY can be recognized for a couple of moments to propound a unanimous consent request, and then Senator KERRY can be recognized.

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

Mr. KENNEDY. Mr. President, I thank Senator LEVIN and my colleague and friend, Senator KERRY.

FOOD AND DRUG ADMINISTRATION AMENDMENTS ACT OF 2007

Mr. KENNEDY. Mr. President, I ask unanimous consent that the Senate proceed to the immediate consideration of H.R. 3580, received from the House and is at the desk.

The PRESIDING OFFICER. The clerk will report the bill by title.

The bill clerk read as follows:

A bill (H.R. 3580) to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and for medical devices, to enhance the postmarket authorities of the Food and Drug Administration with respect to the safety of drugs, and for other purposes.

There being no objection, the Senate proceeded to consider the bill.

Mr. KENNEDY. Mr. President, every day, families across America rely on the Food and Drug Administration in ways they barely realize. When they put dinner on the table, they are counting on FDA to see that it is free from contamination. When they care for a sick child, they are trusting FDA to make sure the drugs prescribed are safe and effective. From pacemakers to treatments for cancer to the foods we eat, FDA protects the health of millions of Americans, and oversees products that account for a quarter of the U.S. economy. The agency does all this on a budget that amounts to less than 2 cents a day for each citizen.

Yesterday, the House of Representatives approved legislation on FDA reform by a broad bipartisan majority of 405 to 7. Our House colleagues from all parts of the political spectrum united to send that bill to the Senate with a resounding bipartisan endorsement. We cannot wait another month, another week—or even another day. We must take action here and take action now to send that bill to the President.

The stakes could not be higher. Funding for the FDA's vital safety mission is reaching the breaking point. Unless we act, the FDA Commissioner will send a letter tomorrow to over 2,000 employees informing them that their jobs are slated for termination. This legislation provides nearly $500 million in new resources for FDA—including over $50 million for drug safety and $6 million for review of direct to consumer ads.

Americans are worried about the safety of the products they use—from food to toys to drugs—and they are right to be worried. Dangerous lapses in safety oversight have exposed American families to intolerable risks from lead paint in toys, to bacteria in foods, to drugs that cause unreported and lethal side effects. The right response is comprehensive, considered and bipartisan legislation—and that is what we have before us today.

At the heart of our proposal is a new way to oversee drug safety that is flexible enough to be tailored the characteristics of particular drugs, yet strong enough to allow decisive action when problems are discovered.

A second major element of our legislation is a public registry of clinical trials and their results. A complete central clearinghouse for this information will help patients, providers and researchers learn more and make better health care decisions. Now, the public will know about each trial underway, and will be able to review its results.

Our bill recognizes that innovation is the key to medical progress by establishing a new center, the Reagan-Udall Foundation, to develop new research methods to accelerate the search for medical breakthroughs.

The bill helps preserve the integrity of scientific review by improving FDA's safeguards against conflicts of interest on its scientific advisory committees, and it will end the abuse of citizens petitions that are too often used not for their intended purpose of brining important public health concerns to the attention of the FDA, but rather to delay the approval of generic drugs.

The proposal before the Senate today strikes the right balance on this issue. It rightly states that the mere filing of a citizen petition should not be cause for delay, but allows FDA to delay the approval of a generic application if it determines that doing so is necessary to protect public health. This is the right approach. It prevents abuse, but protects health.

The legislation also includes important reforms of direct-to-consumer, or DTC, advertising. I thank Senator ROBERTS and Senator HARKIN for working with Senator ENZI and me and with many members of the committee on this important provision.

Instead of the moratorium included in our original bill, the current proposal puts in place strong safety disclosures for DTC ads, coupled with effective enforcement. Under current law, safety disclosures can be an afterthought—a rushed disclaimer read by an announcer at the conclusion of a TV ad while distracting images help gloss over the important information provided. Our proposal requires safety announcements to be presented in a manner that is clear and conspicuous without distracting imagery. We also give FDA the authority to require safety disclosures in DTC ads if the risk profile of the drug requires them.

Our legislation also takes important first steps toward a safer food supply. These are only first steps—our committee will work on a comprehensive package of food safety legislation in the fall—but they are important steps. Consumers and FDA have too little information about contaminated food. Our bill creates a registry and a requirement to report food safety problems. Consumers will have information about recalls at their fingertips, and FDA's response will not be slowed by antiquated and inefficient reporting systems. Our bill also establishes strong, enforceable quality standards for the food we give our pets, to guard against the problems of tainted pet food that we have seen in recent months.

In this new era of the life sciences, medical advances will continue to bring immense benefits for our citizens. To fulfill the potential of that bright future, we need not only brilliant researchers to develop the drugs of tomorrow, but also strong and vigilant watchdogs for public health to guarantee that new drugs and medical devices are safe and beneficial, and that they actually reach the patients who urgently need them. Congress has ample power to restore the luster the FDA has lost in recent years, and this bipartisan consensus bill can do the job. I ask my colleagues to approve this needed legislation without delay.

H.R. 3580, the Food and Drug Administration Amendments of 2007, does a great deal to improve the regulatory process and to strengthen FDA's ability to enforce drug safety standards, particularly in the postmarket period. A recent study by the Institute of Medicine described FDA's post-market drug safety authority as ''aging and inadequate.'' Currently, FDA's ability to address potential health problems that become known after the drug has gone on the market is very limited. This is a serious weakness in the present system that must be corrected. This legislation will give FDA the authority, for the first time, to compel a drug company to add warnings of newly discovered risks on the drug label. As a result, in many cases the health risks involved in using potentially dangerous drugs will be disclosed to the public much sooner than they are today.

At the same time, this legislation makes clear that drug companies will continue to have the same independent responsibility to update the warning labels on their drugs in the future that they have under current law today. If a drug company learns of new dangers that its product potentially poses to the patients taking it, the company has a legal responsibility to immediately warn those patients of the risk of injury.

By enacting this legislation, we do not intend to alter existing state law duties imposed on a drug manufacturer to obtain and disclose information regarding drug safety hazards either before or after a drug receives FDA approval or labeling. We do not believe that the regulatory scheme embodied in this act is comprehensive enough to preempt the field or every aspect of state law. FDA's approved label has always been understood to be the minimum requirement necessary for approval. In providing the FDA with new tools and enhanced authority to determine drug safety, we do not intend to convert this minimum requirement into a maximum. The Institute of Medicine and others have found that FDA's past performance has been inadequate. While we fully expect substantial improvement as a result of the enactment of this bill, we cannot and do not expect the FDA or this new process to identify every drug specific safety concern before a drug manufacturer becomes aware or should have become aware of such concerns. Nor are the bill's requirements that companies disclose certain safety information to the government intended to substitute for the disclosure requirements that may be required under state law.

No one should be under the mistaken impression that the new authorities and resources provided under H.R. 3580 lessen in any way the obligation of a drug company to scrutinize vigilantly the safety signals for their drugs and proactively study such signals or change their labels when the evidence supports such a change. This new postmarket authority for FDA is not intended to alter the drug companies' independent obligation to promptly warn consumers of a drug's risks. Under current FDA regulations, a drug company is required to add new warnings to its labels as soon as it learns about new risks potentially posed by its drugs. The company must add the new warning even if FDA has not required a labeling change.

It is worth putting the situation in a little perspective. The legislation increases FDA's resources for post-market drug safety efforts significantly. FDA's current resources of about $25 million are increased by almost $55 million in the first year, to nearly $80 million. There will be increases in the next four years of $10 each year, so that FDA's post approval drug safety budget will be at about $120 million in 2012. This is the entire budget at the FDA to collect and analyze post-market safety information and respond with appropriate regulatory action. FDA must use these resources to police every prescription drug on the market—thousands of drugs.

By contrast, the drug industry had annual revenues in 2005 of over $200 billion. To be sure, significant portions of these revenues support research and development, profits, and marketing of drug products, but a mere 1 percent of these sales exceeds the entire budget of the FDA. It exceeds the agency's budget for postmarket drug safety by a factor of over one thousand. Many major brand drugs have annual revenues that exceed FDA's annual budget for post-approval drug safety. Consider the top 200 selling drugs in 2006: Merck's drug Fosamax Plus D came in 200th in 2006, with U.S. sales of $140 million. Sales from this one drug alone exceed the entire $120 million FDA budget for drug safety in the last year of this program. The 100th drug, Abbott's Kaletra, had 2006 sales of $350 million, nearly three times the FDA's annual drug safety budget for 2012. Thirtyeight drugs had U.S. sales exceeding $1 billion in 2006. The top selling drug, Pfizer's Lipitor had 2006 sales of nearly $6.6 billion, an amount more than 50 times FDA's annual drug safety budget in 2012 under this legislation.

Clearly, the resources of the drug industry to collect and analyze postmarket safety data vastly exceed the resources of the FDA, and no matter what we do, they will always have vastly greater resources to monitor the safety of their products than the FDA does. It is absurd to argue that the FDA, even with the enhanced resources and authorities provided by this legislation, commands the field when it comes to postmarket drug safety. The drug companies have the capacity to do a far more comprehensive job. If we are serious about quickly alerting the public to the health risks posed by drugs, the companies must be required to take the initiative in monitoring the safety of their products and immediately warning the public of newly discovered risks. Drug manufacturers cannot be allowed to ignore their responsibility and wait for the FDA to act.

To be sure, the legislation gives FDA the authority to command some of the resources of a drug company. FDA can order an epidemiological study or even a clinical trial, but this authority is not unlimited. Certain standards must be met before FDA can act to require a drug company to investigate a safety signal.

Importantly, a drug company has the ability and the responsibility to conduct these studies or clinical trials on its own initiative. Nothing in H.R. 3580 requires a company to wait and react to an order from the FDA for such a study or clinical trial, or to wait for FDA to order the company to change its label. The legislation retains the current, ongoing requirement, found in section 502(a) of the Federal Food, Drug, and Cosmetic Act, for a drug company to ensure that its label is not false and misleading. This statutory imperative is recognized in current FDA regulations. Section 901 of H.R. 3580 cites these regulations in the new section 505(o) of the Federal Food, Drug, and Cosmetic Act. These regulations obligate a company to propose a labeling change to enhance a warning or improve safety information without waiting to hear from FDA, and allow the company to implement the labeling change before the FDA has reviewed and approved the change.

In most cases, a drug company will learn about new risks from its product before the FDA does. Usually, it is the

manufacturer that possesses the information demonstrating a potential danger from the product. It is imperative that patients and health professionals learn about those new health risks as quickly as possible. For that reason, drug companies have, and must continue to have, an independent duty to warn drug users of the danger as soon as the company becomes aware of it. Otherwise, there will be long delays before consumers are alerted, and the number of injuries caused by the product will multiply.

What should motivate a drug company to investigate drug safety signals and take appropriate action to mitigate a safety risk? You can find the answer in several places: from the simple moral duty to do the right thing; from the duty to one's customers, who use one's products with the understanding, often promoted by direct-to-consumer advertising, that the company's highest interest is to bring safe and effective cures to the sick and ill of the Nation; and from a duty under State law to offer products that are free of defects, with adequate warnings about their risks. This legislation changes none of these duties, in any way, whether they arise from simple ethics, principles of contract law, or of tort law. Rather, the legislation provides FDA with additional resources and authority to be better able to step in when a company fails to live up to these responsibilities.

But some drug companies don't want to fully inform the public about these risks to patients' health, and they don't want to be held accountable when patients are injured or killed by their drugs. They would have liked this legislation to change the law to escape this responsibility. These drug companies wanted to convert FDA regulation from a safety floor into a ceiling, from a minimum safety standard designed to protect consumers into a liability shield designed to protect the drug companies. But Congress firmly rejected this approach.

If companies were allowed to conceal safety information until the FDA ordered them to disclose it, consumers would continue taking these dangerous drugs without knowing their risks for months or even years after the risks were discovered. Then, when the public finally learned of the risk, the drug company would be immune from suit for failing to warn its customers. Those who were seriously injured by the drug would have no legal recourse, even though the company had concealed the risk. The company would completely escape accountability for its failure to warn consumers. That would be totally unacceptable, and is not what we intend by this legislation.

Regulation by the Food and Drug Administration and product liability lawsuits against the manufacturers of harmful drugs work together to protect consumers. Both are needed to force drug companies to disclose health risks posed by their products as soon as those risks are discovered. Both are essential to identifying dangerous drugs and getting them off the market quickly. Effective regulation by the federal government and litigation by victims of dangerous drugs work hand-in-hand to keep patients safe and make drug companies more responsible. This legislation improves FDA oversight of postmarket drug safety, and does not undermine or preempt the efforts by injured patients to seek redress under State product liability law.

Congress has stated very clearly in the legislation that we do not intend the new authority being given to FDA to preempt common law liability for a drug company's failure to warn its customers of health risks. The legal duty of drug companies to warn consumers of the health risks of their products as soon as those risks are discovered is essential to effectively protecting the public from dangerous drugs. Legislation designed to protect consumers from dangerous drugs must not be distorted into a shield protecting drug companies from accountability.

Mr. ENZI. Mr. President, I rise today in support of HR 3580, the Food and Drug Administration Amendments of 2007. This comprehensive bill will enhance drug safety and provide key resources to the Food and Drug Administration. I am pleased that the House passed this bill yesterday, and that we have a chance to act on it today. It's been a long road for this bill, and I strongly urge my colleagues to vote yes and endorse the most comprehensive drug safety overt1aul in more than a decade.

This key FDA package includes four reauthorizations that must be done this year, along with essential new authorities for FDA to be able to react in a timely way to any safety problems that arise after a drug has been brought to market. With this new toolbox, FDA has the ability to identify side effects after the drug is marketed through active surveillance. FDA also has the authority to request labeling changes in response to new safety information, as well as a separate study or clinical trial to learn more about a particular, potential safety problem.

Not everyone got everything they wanted in this bill. That is as true of me as it is of anyone. I am deeply concerned about the provisions related to labeling changes and liability, given that we do not fully understand the implications of that language. This new rule of construction was part of the House-passed language and not something the Senate fully debated. If I would have drafted the bill, that language would not have been included. But this is a compromise bill, one that provides important new authorities, while preserving the quality we have come to expect of the agency. The changes made in the drug safety components of this legislation are critical to restoring peace of mind to Americans who want to be assured that the drugs they purchase to treat illnesses and chronic medical conditions can be relied upon and trusted. By acting today, we are ensuring that nearly 2000 dedicated public servants at FDA can continue to evaluate drugs and devices in a timely and thorough way, speeding these discoveries to patients while protecting the public health.

These new authorities will assist the agency in quickly and effectively responding to potential safety issues, including making labeling changes and requiring post-market studies to more fully examine potential risks. In addition, this bill expands access to clinical trials information for patients and providers and creates new methods to address potential conflicts of interest of advisory committee members to ensure greater accountability and preserve scientific integrity.

FDA currently has no mechanism for active, routine surveillance of potential safety problems. It cannot easily detect safety problems after a drug has been put on the market. This legislation fixes that challenge and ensures that FDA has the right tools to address drug safety after the drug is on the market. The legislation creates the capacity for routine, active, safety monitoring using large linked databases, what I like to call ''health IT for drug safety.'' I want to thank Senator GREGG for being the champion of this provision and ensuring that we crafted this provision appropriately.

This bill also includes renewal of two key provisions focused on children—the ''Best Pharmaceuticals for Children Act'' and the ''Pediatric Research Equity Act,'' which together ensure that drugs used in children are tested on children; as well as a proposal that will increase our ability to develop medical devices for children.

There has been a lot of attention paid to medical products in this debate. But we mustn't forget the ''F'' in FDA. This bill contains important food safety provisions to better protect our pet food supply, and track when food is adulterated.

I want to thank my colleagues Senators ROBERTS and HARKIN for their tireless efforts to provide an appropriate balance for direct-to-consumer advertising. I would also like to thank one of my colleagues on the other side of the Capitol, Representative SCHAKOWSKY of Illinois, for her constructive involvement in these issues. It was not an easy task to reconcile some very different opinions, and I am so pleased that we were able to reach a resolution to this issue that we could all support.

I would like to thank Senator ALEXANDER, Senator ALLARD, Senator BOND, Senator DODD, Senator CLINTON and others for their leadership on behalf of kids. Finally, I would like to thank Senator HATCH for his work on the antibiotics and other Hatch-Waxman issues.

On the other side of the Capitol, I would like to thank Chairman DINGELL, Ranking Member BARTON, and

Representatives PALLONE and DEAL for shepherding this legislation through the process.

I want to take a few minutes to thank the staff, who have spent countless hours over the past months negotiating and drafting this legislation. This dedication to public service often overlooked. They spent many evenings and weekends away from their homes and their families.

My health team worked overtime to get this bill to the floor and passed in the Senate. I would first like to thank my Health Policy Director, Shana Christrup. I also want to greatly thank Amy Muhlberg, for her work on drug safety, food safety and PDUFA. Her knowledge and drafting skills were central to this bill. I would also thank Keith Flanagan for his work on the children's statutes in this bill and Dave Schmickel, our resident drug patent expert for his work on citizens petitions and antibiotics issues. I would also like to thank Todd Spangler who provided the required backup that goes with moving a bill of this magnitude. Finally, I would like to thank my Staff Director, Katherine McGuire, whose steady hand and negotiating and communication skills provided the cement for the entire process.

I would also thank Ilyse Schuman, my chief counsel for her precision and attention to the details. Finally, I thank Amy Angelier Shank for her great work on the budget aspects of the bill and my press team Craig Orfield and Mike Mahaffey. My Chief of Staff Flip McConnaughey was great at putting out brush fires throughout the process.

Megan Hauck with Senator MCCONNELL's office, David Boyer with the White House, Craig Burton and Vince Ventimiglia at HHS and Stephen Mason of FDA were key to helping with both policy and process issues throughout the negotiations.

On Senator KENNEDY's staff, I would like to thank: Michael Myers, David Bowen, and David Dorsey. Senator KENNEDY's staffers were reasonable negotiators throughout the process and open and patient to hearing all sides of any issue.

On the other side of the Capitol, I would like to thank Chairman DINGELL, as well as John Ford, Virgil Miller and Pete Goodloe of his staff for their tireless work. Bobby Clark with Mr. PALLONE and John Little with Mr. DEAL were also instrumental in the negotiations. Ranking Member BARTON and his staff Ryan Long and Nandan Kenkeremath were outstanding. Yesterday, when this bill passed the House, Mr. BARTON reported that Ryan had been up all night working on the bill and was therefore wearing the same clothes as the day before. I would like to state for the record that all my staff showered today—I think.

Warren Burke with House Legislative Counsel and Stacy Kern-Sheerer of Senate Legislative Counsel were tremendous in handling a long and complex bill with lots of moving parts. There would be no bill without their efforts.

I would like to thank Senator HATCH and his staff Pattie DeLoatche, Trisha Knight, Remy Yucel and Matt Sandgren for their efforts on the bill overall, but particularly on the Citizen Petitions, antibiotics, and enantiomers provisions. Leigh-Anne Ross of Senator COCHRAN's staff and Landon Stropko of Representative CUBIN's office were also key on these antibiotic provisions.

With Senator GREGG's office, and for their assistance with ''health IT for drug safety,'' I thank Dave Fisher and Liz Wroe. Stephanie Carlton, from Senator COBURN's staff and Jenny Ware with Senator BURR were also integral to many parts of the bill.

I would also like to thank my colleague from Kansas, Senator ROBERTS, and his staff Jennifer Swenson, for their incredible work on direct-to-consumer advertising. I also thank my colleague Senator HARKIN and his staffer Janelle Krishnamoorthy for their hard work on this issue. Lindsay McAllister of Representative SCHAKOWSKY's office was also integral to the success of these negotiations.

I would like to thank Isaac Edwards and Amanda Makki of Senator MURKOWSKI's staff, Tyler Thompson with Senator ISAKSON, and Jennifer Claypool with Senator ALLARD for their hard work and dedication.

Ellie Dehoney of Senator BROWN's office was critical to reaching agreement on the Citizen Petitions and tropical disease provisions. Melanie Benning of Senator BROWNBACK's office was also instrumental on the tropical disease issue.

I would like to thank Mary-Sumpter Johnson with Senator ALEXANDER, Kelly Childress with Representative ROGERS, Jennifer Nieto with Representative ESHOO, Ann Gavaghan with Senator CLINTON, Tamar Magarik and Jeremy Sharp with Senator DODD for their exceptional work on the pediatric provisions.

And last, but not least, Cameron Bruett of Senator CHAMBLISS's Agriculture Committee staff, Adela Ramos of Chairman HARKIN's Agriculture Committee staff, and David Lazarus of Senator DURBIN's staff were extraordinarily helpful on the food safety provisions in the bill.

As you can see, this was a real team effort. I urge my colleagues to vote yes on this important bill. Patients are waiting. I yield the floor.

Mr. LEAHY. Mr. President, I am pleased that today the Senate is poised to pass H.R. 3580, a bill regarding the Food and Drug Administration. This legislation addresses many important health care issues and I commend the Senate leaders and relevant committee chairmen for coming to agreement on this complex bill. I have been monitoring the ongoing negotiations between the House and Senate on this legislation because a slight variation in language between the two relevant bills could have affected the claims of thousands of injured American consumers.

Last week, I chaired a Senate Judiciary Committee hearing on the emergence of regulatory agencies like the FDA asserting that its regulations preempt all State laws, even in the absence of congressional intent to do so. At this hearing we received extensive testimony that the Bush administration has been using this approach to shield corporations from civil liability. This regulatory preemption model has been especially troubling in the area of pharmaceutical drugs. Several times in the past several years we have learned from whistleblowers and smoking gun documents that certain corporations knew of dangers in their medical products yet failed to adequately warn consumers. Many consumers have been injured as a result of this corporate misconduct and it is certainly not congress' intent to shield such corporate decisionmaking.

The legislation we are set to pass today contains a rule of construction making clear that Congress has again decided that we are not preempting State law regarding the responsibility of drug manufacturers to immediately notify consumers of dangers without waiting for the FDA to act. Drug companies maintain the authority to correct their warning labels if they learn of any information that their products could harm consumers. These corporations can and must immediately correct any existing warning that has been issued and cannot hide behind the Byzantine regulatory structure of the FDA to shield them from liability for causing serious injury. To do otherwise would endanger all Americans who may be injured by their products and would remove the important incentive the corporations currently have to make their products safer and to adequately warn consumers of potential dangers.

Mr. HATCH. As the Senate completes its consideration of H.R. 3580, the Food and Drug Administration Amendments Act of 2007, I want to take this opportunity to commend publicly the Food and Drug Administration and especially to express support and appreciation to the dedicated FDA employees who work so hard to ensure the safety of our drug and food supply. They are led by a very capable and hard-working Commissioner, Dr. Andrew von Eschenbach.

In our race to legislate and regulate, we often forget the impact of our actions on agency employees and their ability to safeguard American consumers. And so I want to take this opportunity to thank them for their work.

While I will not belabor the point here, as the legislation makes clear, the agency is operating under severe funding constraints. That is a pressing public health issue of great priority and the Congress must work to address it in a meaningful way.

With passage of this legislation today, we will end the protracted game of ''chicken'' that threatened the jobs of hundreds of FDA employees, the stability of the agency, and indeed the integrity of Congress, an institution which has been under public criticism for not doing its job.

I am proud to support the passage of H.R. 3580. I want to applaud the efforts of HELP Chairman KENNEDY and Ranking Republican Member ENZI. They have worked tirelessly to ensure this bill would be completed before the expiration of the user fee programs at the end of this month. They have worked in a bipartisan way and they have worked very hard to embrace the views of each and every member of our committee.

Let me highlight some of the important components of the FDARA bill.

First, it is imperative that we continue the drug and device user fee programs. This is true for one simple fact—the agency relies greatly on the funding from these programs, and without it there would be unconscionable delays in drug and device reviews.

This is particularly important for Utah, a State with the hallmark of innovation, a State which is the home to countless drug and device manufacturers.

And while there are some problems with how these programs have worked—problems I have been pursuing, and will continue to pursue, with the FDA—all in all it must be recognized that there is no alternative to the user fee programs being continued.

The drug safety provisions that Chairman KENNEDY and Ranking Minority Member ENZI developed will be seen as an important hallmark in our Nation efforts to improve the safety of pharmaceuticals that Americans rely on.

The food safety legislation that our colleague Senator DURBIN developed—again, that is a vital component. I am supportive of that language, and especially appreciative to my colleagues for including the three pieces of language Senator HARKIN and I authored to make certain that the new food reporting system did not override the Dietary Supplement Health and Education Act's regulatory structure and that it did not supersede the serious adverse event reporting system for dietary supplements enacted last year—the Dietary Supplement and Nonprescription Drug Consumer Protection Act.

This legislation also includes many other laudable provisions. One particular provision in this legislation establishes a new and enhanced mechanism for the prompt consideration of new safety-related information and sets forth strict timelines for the evaluation of such new data. That provision is designed to ensure that all potential safety-related labeling changes are promptly raised and duly considered by the agency in carrying out its statutory duty to oversee the appropriate and accurate content of a drug's labeling.

This new procedure is designed to implement a more thorough and regularized methodology for the consideration and implementation of safety-related labeling changes and to ensure that FDA is the ultimate authority in making certain that drug labels convey safety information in a clear and consistent way.

This provision, which adds a new section 505(o) to the Federal Food, Drug and Cosmetic Act, is designed to ensure that both the agency and pharmaceutical companies are able to modify quickly with the agency's approval drug labels so that physicians are alerted promptly to new or increased risks associated with a drug. The provision does not affect the agency's general policy on labeling or its current labeling rules and policy.

Also, the legislation promotes pharmaceutical and medical device advancements in pediatric therapies. The bill reauthorizes the Best Pharmaceuticals for Children Act and the Pediatric Research and Equity Act which have been vital for important research used by doctors and parents. The final language on both these provisions is a good compromise between the House and Senate bills.

Finally, it is my profound regret that the bill we consider now does not contain the Biologics Price Competition and Innovation Act, legislation that Senators KENNEDY, ENZI, CLINTON, SCHUMER, and I have authored. This bill is intended to offer consumers access to lower cost biosimilar products, copies of such important medications as insulin or human growth hormone, while preserving the incentives for researchers, universities and manufacturers to develop and market the innovator biologics.

I am extremely disappointed that the bill could not be contained in H.R. 3580, but I recognize the importance of allowing the House to develop its version in regular order.

It remains my high priority, and I believe the priority of my colleagues as well, that this legislation be enacted in 2007.

Mr. DURBIN. Mr. President, today, the Senate will send a bipartisan bill to the President that will improve the FDA's ability to assure the safety of drugs in our medicine cabinets and the food in our kitchens.

The FDA is an essential guardian of the public's health and safety. In recent years, FDA's reputation has been marred by drug safety incidents and questions about its scientific independence.

In 2004, the public learned that taking Vioxx, a heavily marketed pain medication, increased your risk of a heart attack and stroke. The revelation raised serious questions about how the drug manufacturer responded to signs of a problem and how FDA handled disagreements among its staff.

The Vioxx episode and problems with other FDA-approved drugs in recent years exposed significant weaknesses in our Nation's drug-safety system.

This year, Congress decided to do something about it. In addition to reauthorizing user fee programs for prescription drugs and medical devices, we have engaged in a serious effort to improve drug safety.

The bill gives the FDA more tools to detect the safety problems of drugs after they are available to consumers. It also creates an active surveillance system that will help detect problems that were not apparent during the clinical trials conducted prior to a drug's approval and it promotes greater openness by requiring disclosure of clinical trials performed by drug companies. Lastly, the FDA is given greater authority to require drug companies to add warning labels and to conduct safety studies.

I note the provisions in the bill that give FDA the authority to compel a drug company to make changes to a drug's labeling. That authority should not be seen as an absolution of the companies' responsibility regarding drug labeling. Consumers should be made aware of a drug's risks at the earliest possible moment, and drug companies remain responsible for ensuring that consumers are provided with prompt and adequate warning of a drug's risks.

We have noticed a creeping trend in recent years towards implied and agency preemption of state laws. Last week, a Senate Judiciary Committee hearing looked at techniques that Federal agencies, including FDA, have recently used to assert that agency rulemakings preempt state liability laws. The drug labeling provisions in today's legislation include a rule of construction that makes clear that Congress does not intend to preempt state requirements regarding drug companies' responsibilities. Rather, this legislation recognizes that State liability laws, including liability laws for improper drug labeling, play an essential role in ensuring that drug products remain safe and effective for all Americans.

The bill addresses two other issues of particular interest to me, new restrictions on conflicts of interest for FDA advisory committees and important provisions related to food safety.

I have been troubled by the large number of waivers of conflicts-of-interest rules that FDA issues to members of its advisory committees. The public depends on these committees to make independent assessments about the safety and effectiveness of drugs. Including members with financial conflicts can erode the public's trust in the process.

When the Senate debated this bill in May, I offered an amendment with Senator BINGAMAN that would have limited the number of waivers to one per advisory committee meeting. While the amendment was defeated on a 47–47 vote, the House included the language in its FDA bill.

The final bill includes a 25-percent reduction in waivers over the next 5 years. I would have preferred more of a reduction, but this compromise moves us in the right direction and I commend the conferees for addressing concerns raised in both chambers around conflicts of interest.

On the issue of food safety, I am happy to report that the bill includes food safety language that I originally offered on the floor of the Senate. The language passed on the Senate floor by a 94–0 vote.

The language creates a new reporting requirement for food companies that determine there is a significant adulterated food product in their supply chain. Previously, companies consulted trade associations and attorneys to determine when to report significant adulterations to the FDA. Uncertainty about reporting requirements and an incentive to keep products on store shelves resulted in uneven, delayed reporting of significant incidents to FDA.

Under this new policy, companies will now be required to report these types of incidents to FDA within 24 hours of determining the presence of such an adulteration. These reports will trigger an FDA review and, depending on the findings of the review, FDA would then have the authority to require further action from the company, including an investigation, submission of additional information, and the sending of notifications to affected parties in the supply chain. Companies would be required to maintain records of reports and notifications for a period of 2 years. Failures to report incidents, falsify reports, or comply with follow-up FDA requirements would be subject to civil and criminal penalties.

The effect of this language will be to involve Federal regulators in the review process earlier, resulting in faster recalls, alerts, and notifications through the supply chain. Contaminated products will be tracked and removed from the supply chain earlier and faster. Recalls will be more targeted to specific lots and batches of contaminated products. We will minimize some of the uncertainty around the extent of contaminations once they are discovered.

This provision is an important step forward for food safety.

In addition to this provision, the language directs FDA to establish pet food ingredient, processing, and nutrition labeling standards. Previously, these standards were completely voluntary and did not carry the weight of law. This section also directs FDA to establish an early warning and surveillance system to identify pet food adulterations and outbreaks of disease. In addition, the language directs FDA to improve its outreach and coordination with professional associations, universities, and state and local authorities during recalls. The agency is also asked to enhance the display of recalls on its website.

The bill directs FDA to strengthen its coordination with states to ensure the safety of fresh and processed produce and requires the Department of Health and Human Services to submit more detailed reports to Congress on the number of inspections conducted each year and the number of violations and adulterants discovered through inspections.

Lastly, it includes sense-of-Congress language that commits this Congress to working on comprehensive food safety reform.

On that note, I want to emphasize one thing—the food safety provisions in this legislation are only the starting point for more comprehensive efforts to improve our Nation's food safety system.

For too long we have gone without updating the resources and authorities for our food safety efforts, and a broad coalition of stakeholders understands that our system is broken. We need to close the gaps in our current system.

Several months ago, Robert Brackett, Director of the FDA's food arm said this in response to the pet food recall, ''These outbreaks point to a need to completely overhaul the way the agency does business. We have 60,000 to 80,000 facilities that we're responsible for in any given year. We have to get out of the 1950s paradigm.''

Also in response to this recall, Dr. Stephen Sundlof, Director of the Center for Veterinary Medicine of FDA, implied the same when he said, ''We're going to have to look at this after the dust settles and determine if there is something from a regulatory standpoint that we could have done differently to prevent this incident from occurring.''

I agree with their sentiments and look forward to making more progress on the issue of food safety.

I would like to thank my colleagues, Chairman KENNEDY and Senator ENZI, for their cooperation and willingness to work on this language. I would also like to highlight the efforts of the following members of their staffs: David Noll; Amy Muhlberg; David Dorsey; and David Bowen. I look forward to working with the Senate HELP Committee on future food safety efforts. I would also like to thank Senators HARKIN, BROWN, HATCH, and CASEY for their assistance with this language.

In particular, I also would like to thank Chairman KENNEDY and Senator ENZI for their extraordinary leadership and hard work on this overall bill.

Mr. ALLARD. Mr. President, today I wish to speak on an issue that is weighing on the minds of many Members of this body, employees of the Federal Government, and patients in the United States.

Many people working for the FDA are faced with the possibility of receiving a reduction in force notice if new user fee legislation is not passed quickly. The FDA needs the necessary resources so that they may approve drug applications within a timely manner. Being able to access new drugs can allow patients to live fuller lives, and in some cases, save them from death.

I am frustrated by what I have seen as a desire to have a partisan debate on an issue of liability. We have been working for some time now on a bipartisan level to ensure that we have a bill passed by Friday. We should not be throwing partisan politics into the debate during the 11th hour. Because I am committed to working on a bipartisan level, I continue to hope that we will have legislation passed to ensure that patients can get the drugs that they desperately need.

Some believe that the Senate position on liability may have favored the pharmaceutical companies. However, I am of the opinion that the House position favored the trial lawyers. Should we make any changes we should also ensure that any labeling change authority would not provide for an opportunity for partiality by the courts. I strongly believe that every individual should be allowed to argue equally for their particular case in court.

Currently the FDA regulation allows for labeling changes by accepting submissions from companies, and the company may make a label change. This is referred to as ''changes being effected'' or CBEs. A company also has the opportunity to discuss the change with the FDA before making a label change, since the regulations have a particular bound on what sort of changes can and cannot be made under this regulation.

The current authority may not be adequate to deal with all cases in which a labeling change may be necessary. An example that is referenced frequently deals with a Vioxx label change in which FDA had been talking to the company for 18 months. This situation has led to many pending suits related to Merck's ''failure to warn'' people that the drug had some potential side effects.

In the user fee reauthorizations this year both the House and Senate decided to give FDA the authority to do an expedited labeling change provision. In addition to this new authority, the House and Senate language included provisions that made it clear that the ''changes being effected,'' CBE, regulations should still stand. However, the House and Senate took different stances as to how that additional information or regulatory option should play out in court.

The Senate-passed language, which was done on a bipartisan level, would have established a new labeling change process. This language would have also implied that if a company was already in discussions with the FDA about the labeling issue, and attempting to determine if the labeling change was necessary, then a future lawsuit would have to argue how the company was acting in an improper way. In this situation, the FDA regulation would have ''occupied the field'' with respect to liability for failure to warn.

The House-passed language would have the opposite effect. Essentially a

company would not be able to use the argument that they were in the midst of discussion with the FDA as a defense. In my mind, the House language is a huge boon to trial lawyers. It also makes it harder for companies that are working in the best interest of the patient to prove that they are doing so. I have long been a supporter of reducing the opportunity for frivolous lawsuits, and in my mind the House language increases this.

I would even be happy dropping both the House and Senate language regarding liability. This would leave a situation in which either side would be on an equal playing field to argue a case on failure to warn. This situation would allow suits to be determined on a case-by-case basis. Congress would not be weighing in one way or the other.

The legislation that is expected to pass uses the House language on liability. It provides a source for bias in the courts and opens the floodgates for frivolous lawsuits. This is a definite boon for trial lawyers.

As with many other instances in which Congress has addressed the demands of trial lawyers, I am not willing to risk the livelihood of the employees at the FDA or the health of my constituents who rely on the drug applications approved by the FDA. I will not hold up the legislation, but I wanted to take this opportunity to express my dismay at the partisan way that the liability issue was addressed.

Mr. DODD. Mr. President, I rise today to voice my support for H.R. 3580, the FDA Amendments Act of 2007. H.R. 3580 contains two bills which I authored, the Best Pharmaceuticals for Children Amendments of 2007 and the Pediatric Medical Device Safety and Improvement Act of 2007. I believe these bills will go a long way toward improving the health and safety our Nation's children. The bill will also make important changes to our Nation's drug safety system so that the FDA has clear authority backed up by new enforcement tools to ensure the safety of prescription drugs once they are on the market.

As the original author of BPCA in 1997 and its two subsequent reauthorizations, I am proud to say that no other program in history has done more to spur research and generate critical information about the use of prescription drugs in children than this one. In 10 years, nearly 800 studies involving more than 45,000 children in clinical trials have been completed due to BPCA. Useful new pediatric information is now part of product labeling for more than 119 drugs. In sum, there has been a twentyfold increase in the number of drugs studied in infants, children, and adolescents as a result of BPCA since its enactment.

Ten years ago when Senator Mike DeWine and I undertook this effort, only 11 drugs on the market that were being used in children had actually been tested and studied for their use. Prior to the enactment of BPCA 10 years ago, pediatricians were essentially flying blind because they lacked information regarding the safety and effectiveness of drugs they were prescribing for children. But it was children who suffered the most from taking drugs where so little was known about their effects.

With BPCA, we have changed the landscape both for drug companies and the FDA with respect to prescription drugs and children. However, we still have much further to go because even with the progress we have made so far, still less than half of all drugs being used in children have been studied for their use. H.R. 3580 makes several key improvements to BPCA that will better inform parents, pediatricians, and the public about the safety and effectiveness of drugs used in children. For instance, H.R. 3580 will improve transparency and accountability by making written requests for pediatric studies public and it will improve the accuracy and speed of labeling changes as a result of BPCA studies.

However, H.R. 3580 represents a real missed opportunity to inject a measure of rationality into this program to ensure that it will continue to thrive well into the future. H.R. 3580 dropped a Democratic compromise provision reducing the length of pediatric exclusivity from the current 6 months to 4.5 months only for blockbuster drugs, drugs with annual sales exceeding $1 billion. Five years ago and again recently, my colleagues on both sides of the Capitol dome have criticized this program over the 6-month length of the exclusivity that may be granted if the FDA believes a drug company successfully completed the pediatric studies it requested of them.

Most recently, data released by researchers at Duke University show that some companies receive as much as 73 times the amount they spent to conduct the pediatric trial under the 6 months of exclusivity. BPCA has always been about balancing the needs of children with the cost to consumers. That is why I strongly supported the provision I authored in the Senate bill, S. 1082, which reduced the length of exclusivity to 3 months for blockbuster drugs.

I was proud to have brokered a compromise between the House and Senate of 4.5 months for blockbuster drugs because this agreement was the right policy. But I am profoundly disappointed that the decision was made to drop this compromise. When my colleagues seek to make similar changes to the length of exclusivity in 5 years, I believe that the deal the House and Senate cut in H.R. 3580 will only make doing so more difficult.

I must also express my strong disappointment that the final bill inserts a 5-year sunset on the Pediatric Research Equity Act. As an original cosponsor of the reauthorization of PREA and a long-standing supporter of ensuring FDA has the authority to require pediatric studies of drugs in certain circumstances, there should be no expiration date on FDA's authority to ensure the safety of drugs in children.

The interplay between BPCA and PREA is changed slightly in H.R. 3580 from the Senate-passed bill. It is my understanding that H.R. 3580 will not delay the FDA's ability to utilize PREA's authority to require a pediatric assessment of new drugs that have not yet been approved should a company decline a written request under BPCA for such drug.

Similarly, an exhaustion provision was retained in BPCA that would allow the Secretary to take up to 30 days to certify in the affirmative that the Foundation for the National Institutes of Health has sufficient funding to initiate and fund all studies in a declined written request before determining whether an assessment under PREA can be required. Although the Secretary may take up to 30 days to make such a certification, the Secretary need not impose any delay before determining whether an assessment under PREA is warranted. As the Government Accountability Office found in its March 2007 report on BPCA, contributions to the Foundation for the National Institutes of Health by the drug industry totaled a mere $4 million since 2002. While I hope contributions to the foundation will improve significantly, there should be no unnecessary delays when it comes to important safety information about medications prescribed to our children.

Mr. President, BPCA has shown us that it is unsafe to simply treat children as small adults. Children face a similar inequity with respect to medical devices. Far too few medical devices are specifically designed for children's small and growing bodies. Experts say that the development of children's medical devices lags 5 to 10 years behind that of adults. That is largely due to the limited size of the market for pediatric devices.

When a medical device suitable for a child is needed to save that child's life but it does not exist, doctors are often forced to ''jury-rig'' adult versions of the device or, in some cases, perform a riskier surgery on the child. Ventilator masks, for instance, are far too large to fit over a baby's mouth. Often, the only alternative is to run an invasive tube down the baby's throat.

Because of what we witnessed over the past 10 years with the market incentives provided under BPCA, I introduced an initiative, the Pediatric Medical Device Safety and Improvement Act, to create similar incentives for device manufacturers. I am pleased that this legislation is contained within H.R. 3580 and I believe it will produce tremendous improvements in children's health.

This legislation streamlines the approval process for cutting-edge technology and establishes grants for matchmaking between inventors and manufacturers and the Federal Government. It is my hope that the FDA will

utilize its Office of Orphan Products Development to administer these matchmaking demonstration grants.

Balancing safety with reasonable incentives, this legislation closely mirrors recommendations made by the IOM in its 2005 report on pediatric medical device safety to improve the serious flaws in the current postmarket safety surveillance of these devices. Specifically, the IOM called for and the legislation allows the FDA to require postmarket studies as a condition of clearance or approval for certain categories of devices and it gives the FDA the ability to require studies longer than 3 years with respect to a device that is to have significant use in pediatric populations if such studies would be necessary to address longer-term pediatric questions, such as the impact on growth and development. This provision should not be seen to encourage or promote off-label pediatric use of devices that have been cleared or approved for adult use but for which there is no or limited safety and effectiveness data concerning uses in children.

H.R. 3580 will also go a long way toward restoring the public's confidence in the FDA to protect them against harmful prescription drugs and foods. For too long, the FDA has lacked the clear authority to require labeling changes when new safety information about a drug arises. H.R. 3580 will change that.

For too long, the pressure on FDA to approve drugs has outweighed the necessity to have a systemic, unbiased review of the post-market safety of drugs whereby the FDA can take swift action should new safety information arise. I am pleased that the drug safety provisions of H.R. 3580 will require contain requirements that the FDA's office responsible for post-market safety of drugs have equal footing with the office responsible for reviewing drugs.

As the author of S. 467, the Fair Access to Clinical Trials Act, I am pleased that H.R. 3580 contains many major improvements to the clinical trials provisions. Physicians, researchers, and the public will now have access to a clinical trials registry with information on results, making it tougher for companies to hide or skew undesirable clinical trial results data.

I would like to thank Chairman KENNEDY for his leadership on this bill and his willingness to work so closely with me to improve children's health. I would also like to recognize the many staff who put in long hours and weekends working on this legislation. In particular, I would like to commend Tamar Magarik and Jeremy Sharp, of my staff, who worked extensively on this bill.

Mr. President, the past several years have been marked with major drug controversies—Vioxx, Ketek, Avandia—with millions of families affected. The public deserves better. The mission of the FDA, to protect the public health by assuring the safety, efficacy, and security of human and veterinary drugs, must be restored. H.R. 3580 provides the necessary reforms to restore the FDA as the gold standard for assuring the safety of the public for many years to come.

Mr. BURR. Mr. President, I stand here with a heavy heart. Congress had the chance to reauthorize many important programs at the Food and Drug Administration and pass a targeted drug safety bill. Instead, we are passing a massive bill that triples FDA regulation and responsibility, puts clinical data out in the general domain that may be misleading to patients, and contains conflict of interest language that could harm participation on the FDA's advisory committees—a key part of the drug approval process.

I will start with a good part of the bill. This bill reauthorizes many important programs at the FDA, including the pediatric exclusivity program. The Best Pharmaceuticals for Children Act was originally enacted as part of the Food and Drug Administration Modernization Act in 1997, legislation I sponsored on the House side and was reauthorized in 2002. The goal of BPCA is to encourage the study of more drugs in the pediatric population. BPCA provides that incentive by giving drug companies an additional six months of market exclusivity to a product, or pediatric exclusivity, in exchange for conducting voluntary studies of prescription drugs on children.

Since its enactment, BPCA has been viewed as a highly successful program and has produced at least 132 completed studies, leading to approximately 120 pediatric label changes. According to the most recent General Accountability Office study on BPCA, issued March 22, 2007, prior to enactment of the Food and Drug Administration Modernization Act few drugs were studied for pediatric use. As a result, there was a lack of information on optimal dosage, possible side effects, and the effectiveness of drugs for pediatric use. Almost all the drugs—about 87 percent—that have been granted pediatric exclusivity under BPCA have had important labeling changes as a result of pediatric drug studies conducted under BPCA. Exclusivity is working.

Senator DODD tried to change the Best Pharmaceutical for Children Act by decreasing the exclusivity for some drugs. At a Health, Education, Labor, and Pension Committee hearing, witnesses expressed concern about Senator DODD's idea and speculated whether it would decrease the number of drugs studied for pediatric indications. I am pleased that the final bill does not include that misguided change to the pediatric program.

From the beginning of the HELP Committee's consideration of the drug safety issue I recognized the need to clarify existing authority or provide the FDA with a few new authorities in order to improve the interaction between the FDA and drug companies on safety issues. It was clear that labeling changes and clinical trials and studies were two key areas in which Congress should act.

To that end, I offered an amendment during the committee markup that provided the Secretary with additional authority and control over a drug or biological product's approved labeling, including the authority to require the holder of an approved application to make safety-related changes following an accelerated labeling review process. Under the new procedures added by my language, if either the Secretary or the holder of an approved application became aware of ''new safety information'' that the party believed should be included in the labeling, the other party should be notified promptly, and discussions should be initiated regarding whether a labeling change is needed and, if so, the content of any such labeling change.

That construct made sense to me and it made sense to Chairman KENNEDY who passed the amendment by unanimous consent. Given that current practice today is for a company to call the FDA when they become aware of new safety information, I thought it was a good idea to put current practice into statutory law. I want companies and the FDA to talk to each other about drug safety issues.

I support the safety labeling language in H.R. 3580, which reinforces the FDA's broad authority over prescription drug labels. These provisions allow the FDA to mandate changes to a drug's approved labeling whenever the FDA becomes aware of new safety information that it believes should be communicated in the labeling. Although the FDA already has broad authority over drug labeling and must approve all but the most minor labeling changes, this provision will enhance FDA's authority and help to ensure that labeling changes are made expeditiously using a process that facilitates dialogue between the drug company and the FDA. FDA has comprehensive authority over the regulation of drug products, particularly drug labeling, and this provision further accomplishes that goal.

As I said earlier, I have three main concerns with H.R. 3580. First, the bill is a complex web of regulation. It is going to take months, if not years, for drug companies and the FDA to understand all of the new regulations. I supported improving the FDA's authority in two areas: safety labeling changes, and clinical studies and trials. This bill goes far beyond those two areas and sets up a structure called REMS—Risk Evaluation and Mitigation Strategy. The REMS does not add any significant new authority. The FDA currently uses Risk Maps which do the same things as REMS. Now Risk Map regulations, which have never been studied for their effectiveness, are becoming law. It means more paperwork, deadlines, and checkpoints for drug companies, with

no guarantee that it will improve patient safety. I do not support regulation for the sake of regulation.

Second, H.R. 3580 expands the scope of the Government's current clinical trials website, www.clinicaltrials.gov, and adds clinical trial results. I understand the desire of some members to make clinical trials transparent and the desire of scientists to have as much access as possible to clinical trial data. But I am very concerned that average citizens will not understand all of the complex scientific information being presented to them and instead of talking to their physicians to understand the data about adverse events, primary and secondary outcomes, and baselines, they will instead avoid taking drugs that could make them feel better or save their lives. I hope that the National Institutes of Health and the Food and Drug Administration are very careful while implementing this title of H.R. 3580. If expanded improperly, clinicaltrials.gov will frighten people, not educate and assist them.

Third, this legislation changes the FDA process for granting waivers for participation on advisory committees. The FDA has 23 advisory committees that meet to discuss applications pending before the FDA and other issues. Currently, only four of those advisory committees have complete membership. Serving on an advisory committee is not a glamorous job, even though we rely on those committees to guide the FDA's approval and regulatory processes. Understandably, scientists that serve on the committees have more to gain from doing their research and making tenure, than working part-time for the Government. Given all of those issues, instead of creating incentives to work on the committees, this legislation makes it more burdensome and complex. People have expressed concern about biased committee members, but the facts demonstrate that the FDA is quite vigilant about screening individuals to serve on the committees. And the FDA has been working on new regulations to strengthen the screening process even more. I hope that we do not see a slowdown in the drug approval process due to an inability to fill the membership of advisory committees.

Senator BROWN and I also worked on language that would help bring new antibiotics and generic versions of old antibiotics to market. At the last minute, that language was stripped out of the House bill in order to pay for a half month of pediatric exclusivity. I hope that Representatives DINGELL and BARTON hold to their promise of moving that antibiotics legislation in the near future.

Overall, I am disappointed that necessary FDA reauthorizations became vehicles for legislation that need more work, are overly broad, and will weigh down the FDA at a time when we need to be helping, not hurting, the FDA.

Mr. COBURN. Mr. President, today the full Senate will probably agree to legislation—H.R. 3580, the Food and Drug Administration Amendments Act of 2007—that constitutes a massive overhaul and expansion of the Food and Drug Administration's authorities. Up until a couple days ago, determining the scope and details of the bill was an open and bipartisan process. Unfortunately, all of that changed at the eleventh hour and we were locked out of discussions to determine what a final product would look like. Now we are forced to either accept what we do not fully agree with or cause thousands of FDA employees to lose their jobs. This is not the way to ensure that we ''get it right'' with drug safety.

While this bill achieves the important and necessary objectives of reauthorizing the Pediatric Research Equity Act, the Best Pharmaceuticals for Children Act, the Pediatric Medical Device Safety and Improvement Act, the Prescription Drug User Fee Amendments, the Medical Device User Fee Amendments, and establishing a scientifically-based surveillance system for drug safety risks. There was still important work to be done to complete a bipartisan product. Because of unfair Democratic Majority tactics I and my colleagues have no opportunity to further amend and perfect this legislation.

Furthermore, I am frustrated that certain important provisions were removed from the final language of the bill at the last minute. We lost a provision to provide incentives for developing new antibiotics—a disastrous decision at a time when we are seeing a huge rise of antibiotic resistance in this country. Last minute negotiators also refused to recognize that patients desiring marijuana for medical purposes deserve to know critical information about whether or not marijuana can be safely used. Finally, the final bill did not contain an important Senate-passed resolution to protect American pharmaceutical companies' intellectual property rights around the globe.

This legislation is a very delicate balancing act. No drug is completely safe—otherwise a doctor's prescription wouldn't be needed—but we do have to ensure that lifesaving medicines are able to get to patients. New authorities in the area of Risk Evaluation and Mitigation Strategies, REMS, labeling, and postmarket commitments should not be taken lightly. These new authorities we are giving the FDA need to be used based on a measured assessment of risk vs. benefit in the intended patient population. For instance, labeling changes should only be undertaken when reliable data clearly shows safety problems that are not already reflected in the drug's label. If that data happens to come from a third party unknown to the application holder they should have the opportunity to review it along with the Agency so that appropriate labeling changes can be made based on sound science.

Another new authority granted to the FDA in a REMS is possible restrictions on distribution and use. If used, this restriction has the potential to impede patient access to important therapies and therefore should not be imposed where less burdensome approaches are available. This concept of a ''less burdensome approach'' is an important one and it is essential that product manufacturers have the opportunity to present alternative proposals to the Agency that would accomplish the goal of safety without imposing unduly restrictive actions to products and ultimately to patients. This legislation establishes that the FDA will not limit or restrict distribution or use unless a drug has been shown to actually cause an adverse event. We absolutely need FDA to have all the tools necessary to ensure the safety and efficacy of drugs, but doctors need tools as well, and one of those important tools is new drugs on the market. I appreciate the significant changes that were made in this language of the bill between Senate HELP Committee markup and full Senate consideration. These improvements remain in the final bill and are critical to ensure that physicians—not the FDA—can make risk/benefit decisions with their patients.

This bill ensures that the FDA has broad and exhaustive authorities to make sure that drug companies are doing the right and scientifically-justified thing when it comes to drug safety and the labeling of their drugs. This authority is placed rightly in the hands of highly-trained scientists at the FDA. It is clear that Congress relies on the scientists at the FDA to assess safety risks and drug labeling and this should be squarely and solely the FDA's role—that is why we have spent months and months trying to get this issue of drug safety right. The newly expanded role of the FDA does and should preempt State law when it comes to drug safety and labeling. In order to ensure scientific drug safety the last thing that we need is the regulatory nightmare of every State court being a mini-FDA.

Let me be clear, the FDA is the expert Federal agency charged by Congress with ensuring that drugs are safe and effective and that product labeling is truthful and not misleading. Appropriate preemption of State jurisdiction includes not only claims against manufacturers, but also against health care practitioners for claims related to dissemination of risk information to patients beyond what is included in the labeling.

Product liability lawsuits have directly threatened the FDA's ability to regulate manufacturer dissemination of risk information for prescription drugs. I note a recent case in California, Dowhal v. SmithKline Beecham, where trial lawyers tried to assert that a drug company had failed to warn consumers that nicotine-replacement products allegedly cause birth defects—even though there wasn't scientific evidence to back that up. In this case, the FDA had previously told

SmithKline Beecham that they should not include such an unscientific warning in its label because it would clutter up the label's warnings that actually were scientifically justified. A California court asserted that more warnings were always better. Subsequently, that assertion was overruled unanimously by the California Supreme Court as the FDA again asserted that its scientific judgment should prevail. The case was not properly before the court by operation of the doctrine of primary jurisdiction. Unless State law is preempted in this area, State law actions can conflict with the FDA's interpretations and frustrate the FDA's implementation of its statutory and scientific mandate.

Should the FDA's scientific judgment on drug safety and labeling be set aside, we would risk eroding and disrupting the truthful representation of benefits and risks that medical professionals need to make decisions about drug use. As a physician, I know that exaggeration of risk can discourage the important and right use of a clinically therapeutic drug. Superfluous liability concerns can create pressure on manufacturers to expand labeling warnings to include merely speculative risks and limit physician appreciation of potentially far more significant contraindications and side effects.

I note that the FDA has previously stated that ''labeling that includes theoretical hazards that are not well grounded in scientific evidence can cause meaningful risk information to 'lose its significance.' Overwarning, just like underwarning, can similarly have a negative effect on patient safety and public health.'' In this bill, we have created a clear labeling pathway between the FDA and a drug sponsor in this bill to ensure that consumers get scientifically accurate and appropriate warning of drug safety risks.

Furthermore, if not preempted in drug safety information and labeling, State law could conflict with achieving the full objectives of Federal law if it precludes a firm from including certain labeling information. If a manufacturer then complies with State law, the firm would be omitting a statement required under §201.100(c)(1) as a condition on the exemption from the requirement of adequate directions for use, and the omission would misbrand the drug under 21 U.S.C. 352(f)(1). The drug might also be misbranded on the ground that the omission is material within the meaning of 21 U.S.C. 321(n) and makes the labeling or advertising misleading under 21 U.S.C. 352(a) or (n).

While it is true that a manufacturer may, under FDA regulations, strengthen a labeling warning on its own, it is important to understand that in practice manufacturers typically consult with FDA before doing so. Otherwise they could risk enforcement action if the FDA ends up disagreeing.

Some misunderstand the FDA's labeling requirements to be a minimum safety standard and have used State law to force manufacturers to supplement safety regulation beyond that required by FDA. I want to be clear that the FDA's labeling requirements establish both a ''floor'' and a ''ceiling.'' Therefore, risk information beyond what is required by the FDA could be considered unsubstantiated or otherwise false or misleading. Given the comprehensiveness of FDA regulation of drug safety, effectiveness, and labeling additional requirements for the disclosure of risk information are not necessarily more protective of patients.

Finally, I want to specifically comment on language in H.R. 3580 that includes a new mechanism to further encourage the timely and accurate communication of new safety information on prescription drug labels. That mechanism reiterates the FDA's primacy in determining the content of prescription drug labeling, including through the new power to command a safety labeling change. New section 505(o)(4)(I) also makes clear that this enhanced safety labeling mechanism does not affect the obligation of a company to maintain a drug product's labeling in accordance with FDA's regulations, including 21 C.F.R. §314.70. This provision is meant to confirm the basic obligation of a drug's sponsor to propose—or, in some cases, make—changes to the approved labeling to reflect changes in the conditions established in the approved application and/or new information. Nothing in this rule of construction changes that obligation or FDA's ultimate authority over drug labeling; nor is it intended to change the legal landscape in this area. That is because there is an overriding Federal interest in ensuring that the FDA, as the public health body charged with making these complex and difficult scientific judgments, be the ultimate arbiter of how safety information is conveyed. In this manner, there can be confidence that uniform drug labeling conveys clear, consistent, and scientifically justified safety and medical information.

In fact, the courts have repeatedly upheld FDA's supremacy over prescription drug labeling in cases brought under State law. Nearly 20 years ago, the U.S. Court of Appeals for the Fifth Circuit emphasized that ''. . . manufacturers cannot change the language in the product insert without FDA approval,'' and accordingly ''[i]t would be patently inconsistent for a state then to hold the manufacturer liable for including that precise warning when the manufacturer would otherwise be liable for not including it.'' *Hurley v. Lederle Labs. Div. of Am. Cyanamid Co.*, 863 F.2d 1173, 1179 (5th Cir. 1989). As a more recent Court expressed this bedrock principle, allowing a State to decide what warnings are appropriate, and thus potentially subject companies to liability for otherwise FDA-approved labeling, would upset the careful benefit-risk balance that FDA has struck in approving a product for market, and doing so would ''undermine FDA's authority to protect the public health through enforcement of the prohibition against false and misleading labeling of drug products in the Federal Food, Drug and Cosmetic Act.'' *Sykes v. Glaxo-SmithKine*, 484 F. Supp. 2d. 289, 312 (E.D. Pa. 2007) (internal quotation omitted) .

CITIZENS' PETITIONS

Mr. HATCH. Mr. President, I wish to take this opportunity to clarify one issue related to the language on citizens' petitions and petitions for stay of agency action which is included in FDARA. As my colleagues are aware, I was a cosponsor of the citizens' petition amendment included in the Senate-passed bill, and I was pleased to work closely with my colleagues in the Senate—Senators KENNEDY, ENZI, BROWN, STABENOW, LOTT and THUNE to develop an acceptable compromise with the House. I understand the importance of making certain that generic drug approvals are not delayed unnecessarily, which is the intent of this amendment.

Mr. KENNEDY. Indeed, that was an important objective of the Food and Drug Administration Amendments Act, and I agree the citizens' petition language is an integral part of the final legislative effort.

Mr. HATCH. As my colleagues are aware, we had a number of discussions about this provision, and one issue we worked hard to balance was the need for the Food and Drug Administration to have adequate time to review any meritorious issues raised by a petitioner against the importance of not holding up the Abbreviated New Drug Applications—or ANDAs—or applications submitted under section 505(b)(2) of the Federal Food, Drug and Cosmetic Act. Our colleagues, Senators BROWN and STABENOW, were particularly forceful in their arguments that there should be a deadline for FDA action on a petition, but that the agency could have the ability to delay review of an application if it found that the petition raised a legitimate public health issue.

My concern, which I want to discuss with the chairman, goes to the discussions we had about the operation of that language. In particular, I want to discuss the ability of the agency to conserve its resources and not waste time acting on petitions that do not merit review. Indeed, the concept we discussed over the course of many days was that the agency would have the ability to deny a petition or a supplement if the petition were based on meritless or frivolous issues. We all recognized, however, that defining ''meritless'' and ''frivolous'' is imprecise at best. So, the final language contained in the bill we consider today says that the agency may deny a petition at any point if the Secretary determines that it was submitted ''with the primary purpose of delaying the approval of an application and the petition does not on its face raise valid scientific or regulatory issues . . .''

MR. KENNEDY. The Senator from Utah is correct.

Mr. HATCH. One concern that I raised, which we all agreed would have been included in the conference report language had we filed such a report was a clarification about the meaning of ''scientific or regulatory issues.'' It was our agreement during negotiations on FDARA about what is perhaps an obvious point: if the law requires a delay in approval of an ANDA or 505(b)(2) application, for example because of a patent or an exclusivity, this new provision will not change that required legal result. The law is the law, and its effect should not depend on whether or not it was brought up in a petition to FDA. I would appreciate the chairman clarifying if that was the agreement we had.

Mr. KENNEDY. I do agree. Let us be clear: The citizen petition provision is designed to address attempts to derail generic drug approvals. Those attempts, when successful, hurt consumers and the public health. The citizen petition provisions are not intended to alter laws not amended by the provision. I thank the Senator.

MEDICARE CLAIMS DATA

Mr. BAUCUS. Mr. President, today we have before us an important piece of legislation, the FDA Amendments Act of 2007. It has come to my attention that this bill includes a section that makes an effort to authorize the FDA to use and release Medicare claims data for use in postmarket surveillance of drugs approved by the FDA. I fully support the goal of making drugs safer for all Americans.

As chairman of the Finance Committee, however, I am obligated to point out that any use of Medicare data is exclusively governed by title XVIII of the Social Security Act, and that the Finance Committee has exclusive jurisdiction over title XVIII. I would ask the distinguished chairman of the Health, Education, Labor and Pensions Committee, Senator KENNEDY, to acknowledge that the Senate Finance Committee has sole jurisdiction over Medicare data and title XVIII of the Social Security Act and ask that he endeavor to consult us on matters before the HELP Committee that touch on the Senate Finance Committee's jurisdiction. I make the same commitment to him that he makes to me: I will commit to consult on matters before the Finance Committee that touch on the Senate HELP Committee's jurisdiction.

To avoid unnecessary confusion as to the jurisdiction of the Finance Committee or further delay in the consideration of this important conference agreement, I would agree to accommodate your request to withhold any objection to the Senate's consideration of it with the acknowledgement that the release and use of Medicare data are governed by title XVIII of the Social Security Act and are under the exclusive jurisdiction of the Finance Committee. This does not represent any waiver of jurisdiction on the part of the Finance Committee on this subject.

I would ask the chairman of the HELP Committee, Senator KENNEDY, whether he would agree to this request.

Mr. KENNEDY. It is a great pleasure to work with my distinguished colleagues from the Finance Committee on this reauthorization of important programs at the FDA. I know they have a deep interest in seeing that the medicines that Americans take are safe and effective.

Senator BAUCUS and Senator GRASSLEY have rightly raised a question regarding the interpretation of section 905 of this bill. Section 905 adds a new paragraph (3) to section 505(k) of the Federal Food, Drug and Cosmetic Act. This new paragraph establishes a system for FDA to query databases regarding information that may help detect adverse drug effects. It is essential to detect drug safety problems early, so that they may be corrected before people are hurt and an electronic drug safety system is one important tool for doing so.

The Medicare claims database is listed as one of several possible sources of data in section 505(k)(3)(C)(i)(III)(aa). I want to assure my friends from Montana and Iowa that our intent is that Medicare's participation will be determined by provisions of the Social Security Act, over which the Finance Committee has exclusive jurisdiction. Nothing in this section is intended to infringe on that jurisdiction or to in any way preempt the ability of the Finance committee to act to specify the participation or nonparticipation of the Medicare claims data base in the system established under section 905.

The matter before the Senate amends the Federal Food, Drug and Cosmetic Act. The section to which you have raised concerns authorizes use of Medicare data ''as available.'' I acknowledge that under current law, that is not possible.

Mr. BAUCUS. I thank the chairman. I intend to continue working with my good friend Senator GRASSLEY to address the release and use of Medicare data by Federal health agencies and private researchers soon through legislation written by the Finance Committee.

Mr. GRASSLEY. I agree with my colleague, Senator BAUCUS. I have been working a long time on legislation to permit the use of Medicare data to improve drug safety. After all this is some of the best and most complete data available. In fact, Senator BAUCUS and I joined together to introduce legislation to accomplish just that during the 109th Congress, S. 3987, the Medicare Data Access and Research Act, and this Congress, S. 1507, the Access to Medicare Data Act of 2007. Improving drug safety is a top priority of mine and the appropriate use of Medicare data will likely enhance drug safety. That will benefit all Americans. I look forward to completing our goals for Medicare data later this year and including this on legislation within the purview of the Finance Committee. We intend to clarify how Federal health agencies may use and release Medicare data and make the appropriate amendments in the Social Security Act. At that point, it will be important that the use of Medicare data be appropriately tied into the drug safety provisions of the FDA bill under consideration today. We would hope that our colleague, Senator KENNEDY, would agree to make conforming amendments to the Federal Food, Drug and Cosmetic Act as needed to make FDA law consistent with appropriate Medicare law.

Mr. KENNEDY. I appreciate that conforming amendments in the Federal Food, Drug and Cosmetic Act may be necessary as you point out. I agree to work with the Senator in the future on this issue.

Mr. KENNEDY. Mr. President, I ask unanimous consent that the bill be read a third time, passed, the motion to reconsider be laid upon the table, and that any statements relating to the bill be printed in the RECORD, without further intervening action or debate.

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

The bill (H.R. 3580) was ordered to a third reading, was read the third time, and passed.

Mr. KENNEDY. Mr. President, the New England Journal of Medicine, which is probably the most distinguished medical journal in not only this country, probably in the world, has made the comment that this legislation is the greatest progress, in terms of drug safety, in a century. This ought to be reassuring for every family as to the safety of their prescription drugs and also in terms of their food.

The PRESIDING OFFICER. The Senator from Massachusetts.

Mr. KERRY. Mr. President, I congratulate my colleague from Massachusetts on another landmark piece of legislation that he has been able to shepherd through this institution. It adds to a remarkable string of legislative accomplishments.

We are all pleased this important reform effort and advance is going to be made. It is a terrific step forward. I congratulate Senator KENNEDY, Senator ENZI, and others on the committee who worked so hard to make it happen.

NATIONAL DEFENSE AUTHORIZATION ACT FOR FISCAL YEAR 2008—Continued

Mr. KERRY. Mr. President, I have been listening to my colleagues on the other side of the aisle, and sometimes I think we are talking past each other and about different legislation.

The proposal in the Levin-Reed-Kerry and other Senators legislation says nothing about precipitous. I don't know how one interprets ''precipitous'' when we leave the President the discretion to decide how many troops he is going to have there for training, for prosecuting the war on terror against