good progress. And we could consider eight or even fewer relevant amendments per side on a long-term bill.

And thus I believe that the Senate can consider a long-term bill in the next work period. And I am committed to turning to a long-term bill in June.

The PRESIDING OFFICER. The Senator from Louisiana.

Mr. VITTER. Mr. President, I thank the distinguished majority leader very much for this important announcement and this plan. It certainly meets two—

Mr. REID. Mr. President, it is my understanding he was going to ask me a question, because I do not want to lose the floor.

The PRESIDING OFFICER. The majority leader has the floor.

Mr. VITTER. Yes. I have no intention of his losing the floor. I just want to thank him for the announcement. From my perspective, it meets the two main goals we have been in search of: first of all, making sure in the short term there is not a lapse of the program; that would be disastrous; that would cancel, as the majority leader suggested, thousands of good closings, really put a hiccup in the economy for no good reason—and, in addition, getting to a permanent bill in the next work period. So I appreciate the leader's announcement.

I would also note, as he did, that there has been great work and great progress in narrowing the field of relevant amendments. I certainly hope that leads to a limited and reasonable number of amendment votes, as he does, on the floor. I understand what he said about, if that becomes unwieldy, we will just proceed with the bill as is. But that certainly it is my expectation. I will continue to work on that amendment list so we can have a reasonable opportunity for relevant amendments.

The PRESIDING OFFICER. The majority leader.

Mr. REID. Mr. President, I am glad the Republican leader is on the floor. We have worked very hard to arrive at this point where I am going to ask for this consent agreement. I appreciate everyone's help, and it takes everyone's help to get to where we are. That is why we call them unanimous consent agreements.

I ask unanimous consent that the only first-degree amendments in order to the bill that is now pending before the Senate be the following: Bingaman No. 2111; McCain No. 2107——

The PRESIDING OFFICER. Will the majority leader suspend for one moment.

FOOD AND DRUG ADMINISTRATION SAFETY AND INNOVATION ACT

The PRESIDING OFFICER. Under the previous order, the motion to proceed to S. 3187 is agreed to and the clerk will report the bill by title.

The bill clerk read as follows:

A bill (S. 3187) to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes.

AMENDMENT NO. 2122

(Purpose: In the nature of a substitute)

The PRESIDING OFFICER. Under the previous order, amendment No. 2122 is agreed to.

(The amendment is printed in the RECORD of Monday, May 21, 2012, under ''Text of Amendments.'')

The PRESIDING OFFICER. The majority leader.

Mr. REID. Thank you very much, Mr. President. I am sorry I got ahead of the Chair a little bit.

I ask unanimous consent that the only first-degree amendments in order to the bill be the following: Bingaman No. 2111; McCain No. 2107; Sanders No. 2109; Murkowski No. 2108; Cardin No. 2125; Cardin No. 2141; Grassley No. 2121; Grassley No. 2129; Manchin No. 2151, as modified; Portman No. 2146, as modified; Portman No. 2145, as modified; Reed No. 2126; Coburn No. 2132; Coburn No. 2131; Durbin No. 2127; Paul No. 2143; and Burr No. 2130; that there be no second-degree amendments in order prior to the votes in relation thereto; that there be no motions or points of order to the amendments or the bill other than budget points of order and the applicable motions to waive or motions to table; that there be up to 30 minutes of debate on each of the amendments, with the exception of the McCain amendment, which will have 2 hours of debate, and 60 minutes on the bill, with all time equally divided in the usual form; that at 2 p.m. on Thursday, May 24, all debate time be considered expired and the Senate proceed to votes in relation to the amendments in the order listed above; that there be 2 minutes of debate equally divided in the usual form prior to each vote; that all after the first vote be 10-minute votes; that the following amendments be subject to a 60 affirmative vote threshold: Bingaman No. 2111, McCain No. 2107, Sanders No. 2109, and Murkowski No. 2108; that upon disposition of the amendments, the bill be read a third time and the Senate proceed to vote on passage of the bill, as amended.

That upon disposition of S. 3187, the Senate proceed to the consideration of Calendar No. 365, S. 2343; that the only amendment in order to the bill be an amendment from the Republican leader or his designee, the text of which is identical to S. 2366; that there be 10 total minutes of debate on the amendment and the bill equally divided between the two leaders or their designees prior to a vote on the McConnell or designee amendment; that no amendment be in order to the McConnell or designee amendment; that no motions or points of order be in order to the amendment or the bill other than budget points of order and the applicable motions to waive; that upon disposition of the amendment, the Senate proceed to vote on passage of the bill, as amended, if amended; that the amendment and the bill be subject to a 60 affirmative vote threshold; that if the bill does not achieve 60 affirmative votes, S. 2343 be returned to the calendar; and finally, that the motion to reconsider with respect to the cloture vote on the motion to proceed to S. 2343 be withdrawn.

The PRESIDING OFFICER. Is there objection?

Without objection, it is so ordered.

Mr. REID. So, Mr. President, we are going to have votes on these amendments. It is my understanding that there is time, 30 minutes per amendment. We need to get as much of that done today as possible. We have an event for spouses tonight, so we are not going to be working late into the night. We have tomorrow to finish this. We should be able to do that. I hope we can. I hope it does not spill and there is no reason it should spill over until the next day. We are going to also have votes on the Republican student loan legislation and ours. That is what we are doing in the next 36 hours.

The PRESIDING OFFICER. The Republican leader.

Mr. MCCONNELL. Mr. President, let me just add that I think this is a good agreement that allows us to go forward on the FDA bill with appropriate amendments and also allows an opportunity for the Senate to express itself on the issue of the student loans.

I would join the majority leader in encouraging people to do their debate today or in the morning because once we get into the votes tomorrow afternoon, they will be dealt with in rapid succession.

I yield the floor.

The PRESIDING OFFICER. The Senator from Utah.

Mr. HATCH. Mr. President, I rise to discuss my amendment that would repeal the costly and counterproductive medical device tax in President Obama's health care law. In the mad scramble to find money to pay for his $2.6 trillion health spending law, the President and his Democratic allies created a number of new taxes that serve no purpose other than to fuel this new spending. Economically, these taxes are a disaster. They will undercut job creation, and they will increase costs for patients.

The new 2.3-percent tax on medical device manufacturers, which kicks in at the beginning of next year, is particularly onerous. For that reason, last year I introduced legislation to repeal it. That bill, the Medical Device Access and Innovation Protection Act, S. 17, has been cosponsored by 25 of my colleagues.

They understand that all of ObamaCare needs to go. The President's health care law is now over 2 years old. It is not aging well. Even before ObamaCare became law, the American people made themselves absolutely clear they wanted nothing to do with this Washington takeover of the Nation's health care system. The President and his advisers refused to face reality, telling reluctant Democrats all

was well in spite of the tea party townhalls.

According to the President and his congressional Democratic leadership, as soon as the legislation became law, Americans would come to embrace the wonderful benefits bestowed on them by the Department of Health and Human Services. It has not quite turned out that way.

Poll after poll shows that substantial majorities of Americans continue to oppose the law and favor its full repeal. A majority of Democrats think the law is unconstitutional. In a matter of weeks, the Supreme Court might issue a coup de grace to President Obama's misguided adventure in big government.

Whatever the Supreme Court does, I want to be clear about something. All of ObamaCare needs to go. It needs to be pulled out root and branch. The entire thing needs to be repealed. That said, some part of the law stand out for their wrongheadedness. The individual mandate and Medicaid expansions are flat out unconstitutional.

The IPAB, the CLASS Act, the Medicare cuts, and the employer mandate all deserve honorable mention for being bad public policy. Among the most counterproductive parts of the law are its over $500 billion in new taxes and penalties.

The medical device tax sits at the top of the list of foolish new ObamaCare taxes, and my colleagues who have supported S. 17 and this amendment understand the critical importance of eliminating it. I thank in particular my colleagues, Senator BROWN from Massachusetts, and Senator TOOMEY from Pennsylvania, who have spoken on this issue and understand completely the devastation this tax will create for patients and for employers who provide good jobs for communities in their States.

Thanks to ObamaCare, medical devices will get hit with a $28 billion tax. So we are clear about what these medical devices are, they include surgical tools, bed pans, wheelchairs, stethoscopes, and countless other products that patients and doctors rely on every day. Surgical masks, gloves, blood pressure monitors, scissors, needles, cribs, trays, lights, stents, pacemakers, scales, scalpels, inhalers, and ankle, knee, and hip braces, and a lot more.

The cost of all of those products is going up thanks to this tax. Somebody is going to have to pay for it, and that someone is the already overburdened American taxpayer and middle-class breadwinner.

The President and his supporters seem to think we can simply tax corporations and individuals with impunity and face no adverse economic consequences. Yet economists understand when we tax these companies, employees will pay for it in lower wages, the unemployed will pay for it with a job that was never created, and patients will pay for it with higher health care costs.

Whatever our economic circumstances, this tax is bad news. But it is particularly foolish given the precarious state of our economic recovery. The President once liked to tout all of the jobs created or saved by his over $800 billion stimulus bill. Yet by supporting the medical device tax, the President and his allies have shown a real disregard for good high-paying American jobs.

Medical device companies employ nearly half a million people. They pay a salary that is nearly 40 percent higher than the national average. These manufacturers are small businesses we must be cultivating if our economy is going to recover and we are going to be successful in bringing down unemployment.

Roughly 80 percent of medical device companies have fewer than 50 employees; 98 percent have fewer than 500 employees. ObamaCare's $28 billion tax hike on these manufacturers will do nothing to improve health care, but it will do plenty to undercut the viability of these companies that provide good wages and good opportunities for American families.

According to one recent analysis, the medical device industry provided jobs to 409,000 employees in 2009. Yet this tax could result in job losses in excess of 43,000. It will hit certain States harder than others: California, Florida, Illinois, Massachusetts, Minnesota, New Jersey, New York, Ohio, Pennsylvania, Wisconsin, and my State of Utah. The presence of medical device manufacturers is significant in all of these States.

This new tax will roughly double the device industry's total tax bill and raise the average effective corporate income tax to one of the highest effective tax rates faced by any industry in the world. The President and his allies frequently attack industries that choose to move their operations overseas. But they do not seem to grasp that their policies are driving these industries to do just that. With the onset of this new tax, U.S. device manufacturers are increasingly likely to close plants in the United States and replace them with plants in foreign countries.

According to another report by the Lewin Group, the medical technology industry contributes nearly $382 billion in economic output to the U.S. economy every year. President Obama, in the middle of a weak economy, facing high rates of joblessness, has decided to attack that industry. It is bewildering to me. An industry that pays workers on average $84,156 has become a victim of the President's desire to pay for his new health spending law or, better put, those workers and the families they support become the victims of the President's health spending law.

In my own State of Utah, the device tax is an issue of great importance. There are over 120 medical device companies in Utah. As the Utah Technology Council wrote in a letter to me, these companies ''are a vibrant part of the Utah economy providing high-paying, high-tech jobs for citizens of our great state.''

They certainly are all of that, and they are under assault as a result of this tax, targeted for nothing other than their success and the fact that they were a so-called stakeholder that could pay a so-called fair share to subsidize the President's health spending bonanza.

I ask unanimous consent that letter be printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

JANUARY 25, 2011.

Hon. ORRIN G. HATCH,
U.S. Senate,
Hart Office Building,
Washington DC.

DEAR SENATOR HATCH: As you are aware, the Utah Technology Council represents the life science community in Utah. There are over 120 medical device companies in Utah that are part of that community. They are a vibrant part of the Utah economy providing high-paying, high tech jobs for citizens of our great state. Many of these companies you would recognize immediately including Merit Medical, Dynatronics, WorldHeart, Aribex, Utah Medical, Edwards Life Science, Becton Dickinson, Watson Laboratories and Fresenius Medical Care.

The Governor of the State of Utah as part of his long-range economic plan has identified the life sciences, including medical device companies, as a targeted area of growth for the state of Utah. The state's economic growth initiatives recognize the importance of these industries to our future and the rich resources our state offers to companies operating in this market. The industry-specific taxes imposed by the 2010 Patient Protection and Affordable Care Act are of great concern to us as an industry association because of the impact these taxes could have in slowing economic growth in this targeted area.

Therefore, we strongly support the Medical Device Access and Innovation Protection Act that you are introducing. The removal of this unfair and onerous tax will assure the continued growth of jobs and innovation in this important market sector. We appreciate the fact that you have recognized the need for this statutory change. The imposition of an excise tax is particularly burdensome for our small companies here in Utah that operate on less than average profit margins. To take 2.3 percent of sales as an excise tax would render some companies unprofitable and significantly reduce the profitability of most—not to mention the catastrophic effect this tax would have on companies that are already not profitable. If a medical device company is operating on a 5 percent net profit margin, the excise tax represents the equivalent of a 50 percent income tax. Such a tax takes money that would otherwise be deployed in new jobs, R&D, capital equipment and reinvestment in product lines and redirects it to an entitlement program. It may seem a small percentage of sales, but as a percentage of pre-tax profits, this could range from 25 percent to well over 100 percent. That is simply unacceptable and unwise tax policy—especially in the current environment that is already struggling to produce jobs and economic vitality.

Just as important as the effect on current companies is the impact on investment capital. This new tax will have a chilling effect on investors who will likely redirect their capital to other industries not so burdened with industry-specific taxes. Few investors

will appreciate the fact that the government gets paid tax dollars from sales before investors can be paid from profits. It is a paradigm that creates significant disincentives for investment. Without capital investment, job creation and innovation suffer.

We not only support this legislation to repeal the medical device tax imposed by the 2010 Patient Protection and Affordable Care Act, we feel it is essential to protecting an industry vital to Utah's present and future economic growth. We lend our full support to your efforts.

Sincerely,

RICHARD R. NELSON,
Founder & CEO,
Utah Technology Council.

Mr. HATCH. Just yesterday, the Governor of Utah, the Honorable Gary Herbert, sent a letter to Congress addressing the negative impact this tax will have on our State. He wrote:

As a Governor of a state with a significant concentration of medical technology manufacturers, I believe this tax could harm U.S. global competitiveness, stunt medical innovation and result in the loss of tens of thousands of good paying jobs.

Now, there is little doubt the President's medical device tax, one that unfortunately received the vote of every Democrat in the Senate, will do just that—kill jobs and undercut our economy.

I ask unanimous consent that Governor Herbert's letter be printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

STATE OF UTAH,
OFFICE OF THE GOVERNOR,
Salt Lake City, UT, May 22, 2012.

Speaker JOHN BOEHNER,
U.S. Capitol,
Washington, DC.
Minority Leader NANCY PELOSI,
U.S. Capitol,
Washington, DC.
Majority Leader REID,
Hart Senate Office Building,
Washington, DC.
Minority Leader MCCONNELL,
Russell Senate Office Building,
Washington, DC.

DEAR SPEAKER BOEHNER, LEADER REID, LEADER PELOSI, AND LEADER MCCONNELL: On behalf of the State of Utah, I am writing to express my concern over the impact of the 2.3% excise tax on medical devices set to begin in 2013. As a Governor of a state with a significant concentration of medical technology manufacturers, I believe this tax could harm U.S. global competitiveness, stunt medical innovation and result in the loss of tens of thousands of good paying jobs.

As you know, America is the global leader in medical technology, one of our only manufacturing sectors in which the U.S. is a net exporter. The United States annually exports $5.4 billion more medical technology than we import, and accounts for 40 percent of the global medical technology market. However, our lead has shrunk dramatically in the last decade, and we stand to lose further ground.

One of my priorities as Governor is creating an economic environment in which business can grow and thrive. As part of this effort, I supported a comprehensive tax reform strategy that reduced sales, income, and corporate taxes in the State of Utah by nearly $400 million. In order for our nation to remain economically competitive, it is time to also reform our country's tax system.

The United States has not undertaken major business tax reform since 1986. While the world's economy has changed, our tax system has not. The medical device tax is an example of a policy that runs counter to efforts to make American manufacturing industries more competitive. In fact, the medical device tax will make our tax system even less competitive. Worse still, it is already causing layoffs as companies prepare to absorb its impact.

At a critical time for both the U.S. economy and state economies, the new tax will undoubtedly stifle economic growth and job creation. We must have a national tax strategy that encourages growth, investment, and export industries, to help create jobs and expand the economy. Therefore, I strongly urge you to consider legislation that would repeal the medical device excise tax before it takes effect.

Sincerely,

GARY R. HERBERT,
Governor.

Mr. HATCH. The President's health care law is a travesty. The American people know it. They think it is fundamentally illegitimate, unconstitutional to its core, and enacted over the deep and loud objections of citizens and taxpayers.

All 2,700 pages of that law must be stricken from the U.S. Code one way or another. Eliminating its medical device tax is absolutely essential. It is critical for our States, for our economy, and for America's families and workers. I ask my colleagues join the repeal effort, and I thank my colleagues who have already joined as cosponsors.

I would like to briefly touch on one other issue that is of great importance to me and to the people of Utah and others all over the country. Over 150 million Americans regularly consume dietary supplements as a means of improving and maintaining their health.

The passage of the Dietary Supplement Health and Education Act, or DSHEA, in 1994 brought clarity, predictability, and a better understanding of what the FDA expected from industry and vice-versa. DSHEA provides an appropriate structure that balances the risks and benefits to consumers, with continued access and affordability.

Unfortunately, my colleague from Illinois, Senator DURBIN, has filed an amendment to the current bill that would undo that well-balanced approach. As the author of DSHEA, along with my dear friend and colleague, Senator HARKIN in the Senate, I strongly oppose his amendment. It would require facilities engaged in the manufacturing, processing, packing, or holding of dietary supplements to register with the FDA, provide a description with a list of all ingredients, as well as a copy of the labeling for each dietary supplement product. Additionally, the facilities must also register with respect to new, reformulated, and discontinued dietary supplement products.

While I appreciate my colleague's commitment, his amendment is based on the misguided presumption that the current regulatory framework for dietary supplements is flawed and that the FDA lacks authority to regulate these products. This is simply not the case. Previously FDA Commissioners, including Drs. Jane Henney, Mark McClellan, Les Crawford, and Andy von Eschenbach, as well as the former Deputy Commissioner, Dr. Josh Sharfstein, have all agreed DSHEA provides an appropriate and sufficient level of oversight of this industry.

Under DSHEA, Congress set out a legal definition of what could be marketed as a dietary supplement and safety standards that products have to meet. It allowed the FDA to develop good manufacturing practice standards and clarified what types of claims could be made. It provided the Secretary of Health and Human Services with the authority to impose an immediate ban on any dietary supplement that poses an imminent risk to public health.

DSHEA already provides the Secretary with enforcement tools of seizure, injunction, or criminal prosecution for ingredients that pose an unreasonable risk of illness or injury, are poisonous or deleterious, contain unapproved drugs or food additives, or fail to meet good manufacturing practice standards.

Furthermore, under the Dietary Supplement and Nonprescription Drug Consumer Protection Act, a manufacturer, packer, or distributor whose name appears on the label is required to report a serious adverse event related to the use of a supplement within 15 business days to HHS; submit any related medical information received within 1 year of the initial report within 15 business days; maintain records related to each report for 6 years; and permit inspection of such records.

To me, that sounds like a whole lot of regulation. The FDA already has a tremendous amount of regulatory oversight and enforcement tools when it comes to dietary supplements. Yet instead of urging FDA to use its current enforcement authority to find and punish those companies that are not following the law, Senator DURBIN's amendment serves to punish all responsible companies with its overreaching mandates.

Finally, I would be remiss if I did not mention another obvious point. Senator DURBIN's amendment would have the devastating effect of piling on more work for an underfunded agency already struggling to keep above water with its current core responsibilities.

Now, let me just say this: Before we passed DSHEA, there basically was no regulation over this industry. We brought together, Senator HARKIN and I, the whole dietary supplement industry to get behind DSHEA. They are behind it. It took over 10 years to get the good manufacturing practices completed by FDA—more than 10 years, as a matter of fact. But we provided for them in that agreement. We provided all the tools that are necessary to supervise and regulate dietary supplements. To now add other obligations

onto this industry is just plain not right, and I hope my colleagues in the Senate and the House of Representatives will recognize this is an overreach and not put up with it. We are not going to put up with it. I will be voting against Senator DURBIN's amendment, and I urge all of our colleagues to do the same.

At this point, I pay tribute to my colleague, Senator HARKIN from Iowa. Senator HARKIN worked tirelessly on this bill along with me. We worked all the way through the Senate on a number of occasions on various things. We have improved the bill from time to time. We have gone along with the improvements. We have done everything we can to protect the American citizens with everything that should be done. Nothing further needs to be done.

This is an industry that deserves support, not condemnation. Senator HARKIN has been there every step of the way. He is a champion for the dietary supplement industry, as am I, and a lot of others in this body. I think it is time to quit trying to overregulate everything to death and cause costs to go up by leaps and bounds. Dietary supplements are not inexpensive today, although they are a lot less expensive than they would be if we keep piling on these regulations.

Frankly, we believe we have all of the necessary language in the law today to protect the American public regarding dietary supplements. We have given the Food and Drug Administration all the authority they need, and every FDA Commissioner has met with me, as I recall, since DSHEA was passed in 1994, and has said they have enough tools to be able to supervise this industry properly and they don't need anything more.

To make a long story short, again, this is an overreach by a colleague, sincere though he may be, and as important as he believes it to be. I hope he will withdraw his amendment so we don't have to go through this again. If he won't, I hope our colleagues on both sides of the aisle—and this is a bipartisan effort—will rise and say we have had enough of this and let's vote these kinds of amendments down.

I yield the floor.

The PRESIDING OFFICER. The Senator from Iowa.

Mr. HARKIN. Mr. President, I thank the Senator from Utah for his concluding remarks regarding the amendment that I assume will be offered by the Senator from Illinois, as it is cleared to be offered.

I thank Senator HATCH for his great leadership on the issue of making sure the American people can have access to healthy, life-supporting vitamins, minerals and supplements, without having it go through untold processes and reviews and approvals by the FDA, and all that kind of regulation.

Senator HATCH was the leader on the DSHEA bill when we passed it in 1994. I was happy to work in tandem with him on that. It has proven, through the years, to be a great success for the American people. The American people all over this country take vitamins and other supplements, and they are living healthier because of this.

I say to my friend that I heard the Senator from Illinois on the floor yesterday give an impassioned speech about a very sad case about a young woman who evidently consumed some energy drinks with a lot of caffeine in them and had heart arrest and died. It is a very sad story. But as sad as that is, you can't keep people from abusing things. People also die every year from aspirin poisoning, where they took too many aspirin.

Reasonableness has to enter into this. We have worked together to make sure the labels are good on all of these things, so that people know what is in them. The FDA has the authority—as the Senator said, every Commissioner has said they have the authority to keep dangerous products off the shelf and to remove them from the shelf. They have all that authority. These cases, as I said, that Senator DURBIN brought up are very sad, and you wish it were not so. I don't think it lends itself, though, to overturning what has been working now for 17, going on 18, years and working well for the American people.

I join the Senator from Utah, and I hope the amendment might not come up. But if it does, it does. I am sure there will be some debate on it. I join with the Senator from Utah in urging all Members of the Senate to vote that amendment down. If it comes up, I will move to table that amendment. Hopefully, we can approach this in a much more judicious, responsible, thinking manner.

I say to my friend from Utah—and I know he agrees—we are not taking the position that nothing has ever been changed. We have changed DSHEA in the past to make it work better. We did it after due deliberation, committee hearings, and going through the process to see what it means in terms of access to these products by the American people, to make sure we keep the intent of DSHEA there.

Again, I am more than willing, as chairman of the committee—and the Senator used to be chairman of the committee at one time, and then ranking member—we are always willing to look at these things and have a hearing on them and get more information. Again, I thank the Senator from Utah, who has been a great leader on this issue.

Mr. HATCH. I thank the Senator from Iowa. I know Senator DURBIN is sincere, but, my gosh, there is enough regulation and regulatory authority in this bill, including the amendments we have added voluntarily, to resolve any problem that exists. Frankly, I hope everybody will vote against the Durbin amendment.

Mr. HARKIN. Mr. President, how much time does this side have on the bill?

The PRESIDING OFFICER. For general debate, 24½ minutes.

Mr. HARKIN. I reserve the remainder of my time on the bill. If the Senator from Illinois wishes to bring up his amendment, we can bring it up.

Mr. President, again, I understand I have 24 minutes left.

The PRESIDING OFFICER. That is correct.

Mr. HARKIN. I will make a short general statement about the bill. I talked about it in the past. I want every Senator to know that we are now on the FDA reauthorization bill. This is reauthorizing the prescription drug user fee, the medical device user fees, and then we are authorizing a new program, the generic drug user fee, biosimilar user fee, and so we are on the bill now. There is 30 minutes for debate on each amendment that has been listed. Senators know who they are and what the amendments are.

I want to make it clear that the unanimous consent we just adopted says that all debate time will expire at 2 p.m. tomorrow. So I say to Senators, if you want to take your 30 minutes and debate your amendment, now is the time to do it. If you wait too long, 2 o'clock will come tomorrow, you won't have the time, and you will be limited to 1 minute. There will be 2 minutes on each amendment after that. Those who have amendments and wish to discuss them, you are guaranteed at least 30 minutes, but all time runs out at 2 p.m. tomorrow. If you want to talk on your amendment and make your point, now is the time to do it this afternoon.

I yield the floor.

The PRESIDING OFFICER. The Senator from Illinois.

AMENDMENT NO. 2127

Mr. DURBIN. Mr. President, I call up amendment No. 2127.

The PRESIDING OFFICER. The clerk will report.

The legislative clerk read as follows:

The Senator from Illinois [Mr. DURBIN], for himself and Mr. BLUMENTHAL, proposes an amendment numbered 2127.

The amendment is as follows:

(Purpose: To require manufacturers of dietary supplements to register dietary supplement products with the Food and Drug Administration)

At the end of title XI, add the following:

SEC. 11___. REGISTRATION OF FACILITIES WITH RESPECT TO DIETARY SUPPLEMENTS.

(a) IN GENERAL.—Section 415(a) (21 U.S.C. 350d(a)) is amended by adding at the end the following:

''(6) REQUIREMENTS WITH RESPECT TO DIETARY SUPPLEMENTS.—

''(A) IN GENERAL.—A facility engaged in the manufacturing processing, packing, or holding of dietary supplements that is required to register under this section shall comply with the requirements of this paragraph, in addition to the other requirements of this section.

''(B) ADDITIONAL INFORMATION.—A facility described in subparagraph (A) shall submit a registration under paragraph (1) that includes, in addition to the information required under paragraph (2)—

''(i) a description of each dietary supplement product manufactured by such facility;

''(ii) a list of all ingredients in each such dietary supplement product; and

''(iii) a copy of the label and labeling for each such product.

''(C) REGISTRATION WITH RESPECT TO NEW, REFORMULATED, AND DISCONTINUED DIETARY SUPPLEMENT PRODUCTS.—

''(i) IN GENERAL.—Not later than the date described in clause (ii), if a facility described in subparagraph (A)—

''(I) manufactures a dietary supplement product that the facility previously did not manufacture and for which the facility did not submit the information required under clauses (i) through (iii) of subparagraph (B);

''(II) reformulates a dietary supplement product for which the facility previously submitted the information required under clauses (i) through (iii) of subparagraph (B); or

''(III) no longer manufactures a dietary supplement for which the facility previously submitted the information required under clauses (i) through (iii) of subparagraph (B),

such facility shall submit to the Secretary an updated registration describing the change described in subclause (I), (II), or (III) and, in the case of a facility described in subclause (I) or (II), containing the information required under clauses (i) through (iii) of subparagraph (B).

''(ii) DATE DESCRIBED.—The date described in this clause is—

''(I) in the case of a facility described in subclause (I) of clause (i), 30 days after the date on which such facility first markets the dietary supplement product described in such subclause;

''(II) in the case of a facility described in subclause (II) of clause (i), 30 days after the date on which such facility first markets the reformulated dietary supplement product described in such subclause; or

''(III) in the case of a facility described in subclause (III) of clause (i), 30 days after the date on which such facility removes the dietary supplement product described in such subclause from the market.''.

(b) ENFORCEMENT.—Section 403 (21 U.S.C. 343) is amended by adding at the end the following:

''(z) If it is a dietary supplement for which a facility is required to submit the registration information required under section 415(a)(6) and such facility has not complied with the requirements of such section 415(a)(6) with respect to such dietary supplement.''.

Mr. DURBIN. Mr. President, this amendment is very straightforward. I will not ask for a show of hands among Senators, staff, or those who are following this debate, about how many of them got up this morning and took a vitamin pill. I did, and I didn't have a prescription. I bought it voluntarily. I don't know if it does any good, but it was my decision, right? I voluntarily made that decision. I think that is a good thing.

The FDA is an agency that looks at what we buy and consume. It has an important responsibility. When it comes to certain things, such as prescription drugs, they test them—maybe the pharmaceutical companies do the testing, but the FDA monitors it to make sure what is given to you by your doctor is safe, won't kill you, and is effective. The same thing is true for over-the-counter drugs. The FDA has that responsibility.

When it comes to the ingredients and the dosage, those things are established through the FDA based on disclosures by the companies, testing, experience—it is all there. But there is another world out there, a completely different world called dietary supplements, which includes the vitamin I took this morning. That is a much different world, a world with less disclosure, less transparency, and far less regulation. In fact, there is no requirement in the law today—none—that the people who sell us dietary supplements have to register with the FDA the name of their product, the ingredients it contains, and a copy of the label.

That is what my amendment says. We don't require any testing by a dietary supplement company. We don't require any assertions of safety. It would require simply that they register with the FDA that they are selling it in America. That, to me, seems pretty basic. It is not my original idea. It comes from a report of the General Accountability Office in 2009. They recommended this after they made a review of the safety issues with the FDA:

To improve the information available to FDA for identifying safety concerns and better enable FDA to meet its responsibility to protect the public health, we [the GAO] recommend that the Secretary of the Department of Health and Human Services direct the Commissioner of FDA to request authority to require dietary supplement companies to identify themselves as a dietary supplement company as part of the existing registration requirements and update this information annually; provide a list of all dietary supplement products they sell and a copy of the labels and update this information annually, and report all adverse events related to dietary supplements.

In other words, did you take the pill and get sick? Does that seem like an onerous, heavyhanded, big government overregulation of an industry? Remember, the dietary supplement companies are not all based in the United States. Products are sitting on the shelf which you may not know come from other countries, including China. Do we want to know that? Would you want to know the company that is selling you whatever it is is at least registered in the United States? Is that too much to ask if you are going to sell the product in the United States, that they have to register with the FDA and tell us what the ingredients are? That seems pretty basic to me. I bet that 99 percent of the American people thought they already had to do that. No. Let me tell you that dietary supplements go beyond vitamin pills.

Yesterday I told the story on the floor about a 16-year-old girl in Hagerstown, MD, who drank two Monster Energy Drinks. When you go to the store, you see Coke and other things there. There are all kinds of them out there. She drank two of those Monster Energy Drinks and died of cardiac arrest. I met with her mom yesterday. She stopped breathing while watching TV. She was dead on the floor. They took her to the hospital and barely got her back to life for a little while, and then she died a few days later.

Is it too much to ask of a dietary supplement company that is making that to tell us what ingredients are in that drink? Is that the heavy hand of government? I don't think so.

Here is what we have found. Sometimes ingredients that may appear to be benign and OK today turn out to be dangerous when you look at them more closely, and maybe more dangerous for people who are younger, pregnant, or in a compromised immune situation.

This amendment basically says that American consumers have the right to know the dietary supplements sitting on the shelf have at least been registered with the FDA. I heard Senators HATCH and HARKIN say this goes too far, it is too much to ask. I think they are wrong.

Manufacturers, some say, voluntarily provide product labels to the National Institutes of Health. That is true, and it is a voluntary system. Good actors share their labels with the FDA, but the bad actors don't do that. The NIH is in the process of developing a label database that currently has 7,500 dietary supplement labels. Do you know how many products are on the market? They have 7,500 labels, with 75,000 products—75,000. So 10 percent are volunteering this information. So to say the NIH already has the information is 90 percent wrong.

Requiring registration, they say, of these labels is just too much work for the FDA. No, as a matter of fact, the FDA responded to the GAO recommendation and said: We agree the agency's ability to ensure the safety of dietary supplements used by consumers would be improved if FDA had more information on the identity of firms marketing dietary supplements as well as the identity and compositions of the products they market. The FDA responded by saying: We want this information to keep Americans safe.

So to argue this is a burden we shouldn't put on the FDA, well, they asked for it. The other thing is about how many supplements are being sold in the United States. I said 75,000. That was the estimate in 2008. The number, I am afraid, is much larger. In terms of how many come on the market each year, it is just a wild guess because it is the Wild West. It is an open market. Any country that wants to export their dietary supplement to the United States—whether it is from China or India or Africa or Europe or Mexico—be my guest. They don't even have to show up and register with the FDA.

This is a simple amendment. It just says any company wishing to do business in the United States, to sell their dietary supplement, must tell us who they are and what they are selling and what their label looks like. That is not too much to ask to protect families from some harmful consequences.

I reserve the remainder of my time.

Mr. President, I ask unanimous consent that the time Senator HATCH used

be counted retroactively against the time in opposition to my amendment, No. 2127.

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

The Senator from Wyoming.

Mr. ENZI. On this amendment, I appreciate the concern, the interest, and the effort the Senator from Illinois has gone to on this bill. But in looking at it, there is still a couple of steps missing if this were to become law. Yes, it would provide a lot of information to the FDA. It would, in fact, flood them with information, and I think we would flood them with more information than they could possibly process.

But that part doesn't even bother me. What bothers me is how we get that information to the consumer. It is the consumer that needs to know what they are drinking, eating, and everything else. That is why we provide labeling on a lot of things. But even the things we already provide labeling on, the consumer doesn't necessarily pay attention to it. Probably the people who need to pay the most attention to it don't pay any attention to it. So just making this information available to the FDA doesn't get it to the point where the consumer can know. Of course, anytime we start talking in this area, people get worried about the amount of regulation we put on things they consider to be very important to them and can do no harm.

The right way to address this important issue is for the HELP Committee to have hearings and work together, as we have done on this bill, to find common ground on the policy. When we find common ground, as we have on this FDA bill, then we can get something done. But I think this is a little premature. So I hope people will not support this amendment at this time.

I yield the floor, and I reserve the remainder of my time.

Mr. HARKIN. Mr. President, how much time remains on this amendment?

The PRESIDING OFFICER. Seven minutes in favor of the amendment.

Mr. HARKIN. Mr. President, I just want to say, first of all, that I have the greatest respect, as he knows, for the Senator from Illinois. He is one of the true consumer champions in the entire Congress and has been for all of his time here. So it is kind of hard to argue against the Senator when he is such a champion of consumers. But on this issue I think we part a little company.

I want to make it very clear that under DSHEA, supplement labels must already disclose their ingredients—must disclose their ingredients. Even when a product is reformulated, if the supplement contains new ingredients, then the label must reflect that change. These were all added to the bill. We added that for consumer protection.

Now, again, it is not as though FDA doesn't know what is out there. Under current law, supplement manufacturers have to biannually register their products. There is a biannual registration requirement right now. So the concern is that FDA just doesn't have the resources to do anything. I have tried—and the Senator knows because he is on the Appropriations Committee—to get more funds for the FDA to do this, but we haven't been able to get the funds necessary for the FDA to even do what jobs they are supposed to do now.

I repeat for emphasis sake that every FDA Commissioner—those appointed both by Democratic or Republican Presidents—have said the DSHEA gives them adequate authority to keep dangerous products off the shelves. So the authority is already there. What the FDA needs is the resources. That is money. That means appropriations. Quite frankly, I don't see that happening this year—that we are going to give them any more. We are just going to give them more of a burden, and I think it will give a false sense of security to people because FDA simply won't be able to do that.

Lastly, as the Senator did say, we do have a voluntary program for ingredients and things with the dietary supplements with the National Institutes of Health that is already in place. That is coupled with the biannual reporting requirements plus the fact every dietary supplement has to have the ingredients listed on the label. So there is plenty of consumer protections out there. It is just that we can't protect a consumer who doesn't want to follow directions, who doesn't want to follow the guidelines listed on the labels themselves. I don't know how to protect people from that. Sometimes we just have to continually tell people to follow the directions. If they follow the directions, they will be fine.

That is why I think this amendment is ill-timed. I said to the Senator, and I mean this, that the Senator from Utah and our committee would be more than happy to have hearings again to flesh it out a little more and to see just what might be possible. But I come down to this as the bottom line: The FDA needs more money and they need more personnel to do this job.

I yield the floor.

Mr. DURBIN. Mr. President, how much time remains on my amendment?

The PRESIDING OFFICER. Seven minutes.

Mr. DURBIN. On my side?

The PRESIDING OFFICER. On the Senator's side.

Mr. DURBIN. Any time remaining on the opposite side?

The PRESIDING OFFICER. One minute.

Mr. DURBIN. Mr. President, I respect the Senator from Iowa and the Senator from Wyoming as well. They are two excellent colleagues, good people, and this is a tough bill. The underlying bill is a masterpiece of bipartisan accomplishment they can both be proud of.

What I am saying about dietary supplements is no reflection on Senators HARKIN or ENZI. This is an industry I have been watching for a long time for a variety of reasons.

I would say the argument Senator ENZI made—that merely disclosing the label ingredients and name of the product to the FDA doesn't get to the consumer—argues for a bigger amendment than I am offering. It argues for a Web site and access and so forth. I understood that going in, and I agree with Senator HARKIN that is an overreach in this time of budgetary problems. I wish we could do it. I think we should. I think we have an obligation to. But I didn't put it in here because I knew the first thing that would be said is we can't afford it.

So we went to the FDA and said: Do you want this information?

They said: Not only do we want it, we have already publicly stated we want it in reply to the GAO report.

We said: Can you handle it if we send you the basic information of the products presently being sold?

They said: Yes.

I could go further and say more can be done, but that calls for a bigger role of government than even this amendment suggests. But when the Institute of Medicine tells us that each year there are 1,000 new products—dietary supplements—being placed on shelves all across America in stores and drugstores, where families and children are walking in and buying them, how does anyone argue we shouldn't know they are here; that we don't want that Chinese product that just made it to the shelf in Springfield, IL, to register with the FDA before they do business here? How do you make that argument?

Shouldn't we assume, as a consumer, a family member, that when we walk in the store that somebody somewhere knows this company exists, that this product exists? Right now, they do not. The only disclosure to the government is voluntary. As I said, about 1 out of 10 companies volunteers the information. That, to me, is not the way to protect consumers.

Why do we need this information? Simply put, when an ingredient turns out to be dangerous, we want to know if that ingredient is in more than one product and then go after it to protect American consumers. If we don't know the product is in the United States, and we don't know what the ingredients are, how are we going to find that out? Wouldn't we want that basic information?

God forbid something happens with one of these products and someone loses their life, like this poor young girl in Hagerstown, MD, who drank that Monster Energy Drink. She had two of them, and it killed her, put her in cardiac arrest. God forbid that happens again and we say: You know, we didn't even know that product was in America because they don't have to tell anybody anything.

The argument made by Senator HARKIN is they have to put a label on the product. That is a good thing. We also

found out that sometimes the ingredients listed aren't the actual ingredients. I will not get into that because that is another whole issue the FDA is working on. But that isn't enough. My colleagues should see some of the claims being made on the labels of these dietary supplements. They are preposterous. Not for all of them, some are basic and good, but some go way overboard.

Don't we owe it to consumers across America to give them the basic information, to at least let them know we know the name of the company and the ingredients in the product sold? Some people say they ought to be able to sell whatever they want in America and never tell a soul. I don't believe that. I think we have a responsibility in Congress to protect these families.

I reserve the remainder of my time.

The PRESIDING OFFICER. The Senator from Iowa.

Mr. HARKIN. Just one minor correction I would make, and that is under the DSHEA law, the FDA must approve any health claims made by any dietary supplement or vitamin. The only health claims they can make are structure function claims, but they have to be approved by the FDA. I just wanted to clear up that point.

I would also say further that I honestly don't know of any vitamin or supplement that is out there in the market that is dangerous if taken as directed—if taken as directed. As I said, anybody can abuse things. But if taken as directed, I, quite frankly, don't know of any supplement out there that is dangerous. Quite frankly, if taken as directed, they help maintain people's health and keep them healthy rather than being injurious to their health.

I yield the floor.

Mr. DURBIN. Mr. President, how much time remains?

The PRESIDING OFFICER. Three minutes.

Mr. DURBIN. I will just close.

I thank the Senator from Iowa. He will acknowledge, I hope, that no one tests dietary supplements. No one tests them. Companies that make these products may test them if they wish, but there is no requirement under the law that they test them. There is certainly no agency of government that tests the dietary supplements. So to say they are perfectly safe as they instruct people to take them on the label, how would we know that? How could we possibly know that? There is no testing involved.

When it comes to prescription drugs and over-the-counter drugs, there is testing involved. At least we can point to the test to say whether it is safe and effective. Dietary supplements is a whole different world. I will just say that we are conscientious enough on behalf of consumers to limit the amount of caffeine that can be put in a cola, but then a company such as this Monster drink company decides to call theirs a dietary supplement rather than a beverage or a food, and it is no holds barred. They can put in as much as they want. That is why that poor girl died. Two Monster Energy Drinks—480 milligrams, I believe, of caffeine—and she died from cardiac arrest. Is it too much to ask that we know the ingredients and know the company?

The next time there is another tragedy, I would like to be sure we can say we at least took this modest, tiny, small step forward to say to the industry: If you are a good actor, don't be threatened. But when it comes to bad actors and things coming in from overseas, we are going to make you show up and identify who you are and what you are selling, period. That is it.

So at this point, I yield the floor and yield back the remainder of my time.

I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

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

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

Mr. HARKIN. Again, Mr. President, I have to ask, how much time remains on the bill for both sides?

The PRESIDING OFFICER. The majority has 19 minutes and the minority has 29 minutes.

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

AMENDMENT NO. 2109

Mr. SANDERS. Mr. President, I thank the chairman for his hard work on this legislation and for the opportunity to talk about what I consider to be a very important amendment.

I ask unanimous consent to call up my amendment No. 2109.

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

The clerk will report.

The assistant legislative clerk read as follows:

The Senator from Vermont [Mr. SANDERS] proposes an amendment numbered 2109.

Mr. SANDERS. I ask unanimous consent that reading of the amendment be dispensed with.

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

The amendment is as follows:

(Purpose: To revoke the exclusivity of certain entities that are responsible for violations of the Federal Food, Drug, and Cosmetic Act, the False Claims Act, and other certain laws)

At the end of title XI, add the following:

SEC. 11___. CONDITIONS ON AWARD OF DRUG EXCLUSIVITY.

Subchapter E of chapter V (21 U.S.C. 360bbb et seq.) is amended by inserting after section 569C, as added by this Act, the following:

"SEC. 569D. CONDITIONS ON AWARD OF DRUG EXCLUSIVITY.

''(a) TERMINATION OF EXCLUSIVITY.—Notwithstanding any other provision of this Act, any period of exclusivity described in subsection (b) granted to a person or assigned to a person on or after the date of enactment of this section with respect to a drug shall be terminated if the person to which such exclusivity was granted or any person to which such exclusivity is assigned—

''(1) commits a violation described in subsection (c)(1) with respect to such drug; or

''(2) fails to report such a violation as required by subsection (e).

''(b) EXCLUSIVITIES AFFECTED.—The periods of exclusivity described in this subsection are those periods of exclusivity granted under any of the following sections:

''(1) Clause (ii), (iii), or (iv) of section 505(c)(3)(E).

''(2) Clause (iv) of section 505(j)(5)(B).

''(3) Clause (ii), (iii), or (iv) of section 505(j)(5)(F).

''(4) Section 505A.

''(5) Section 505E.

''(6) Section 527.

''(7) Section 351(k)(7) of the Public Health Service Act.

''(8) Any other provision of this Act that provides for market exclusivity (or extension of market exclusivity) with respect to a drug.

''(c) VIOLATIONS.—

''(1) IN GENERAL.—A violation described in this subsection is a violation of a law described in paragraph (2) that results in—

''(A) a criminal conviction of a person described in subsection (a);

''(B) a civil judgment against a person described in subsection (a); or

''(C) a settlement agreement in which a person described in subsection (a) admits to fault.

''(2) LAWS DESCRIBED.—The laws described in this paragraph are the following:

''(A) The provisions of this Act that prohibit—

''(i) the adulteration or misbranding of a drug;

''(ii) the making of false statements to the Secretary or committing fraud; or

''(iii) the illegal marketing of a drug.

''(B) The provisions of subchapter III of chapter 37 of title 31, United States Code (commonly known as the 'False Claims Act').

''(C) Section 287 of title 18, United States Code.

''(D) The Medicare and Medicaid Patient Protection and Program Act of 1987 (commonly known as the 'Antikickback Statute').

''(E) Section 1927 of the Social Security Act.

''(F) A State law against fraud comparable to a law described in subparagraphs (A) through (E).

''(d) DATE OF EXCLUSIVITY TERMINATION.—The date on which the exclusivity shall be terminated as described in subsection (a) is the date on which, as applicable—

''(1) a final judgment is entered relating to a violation described in subparagraph (A) or (B) of subsection (c)(1); or

''(2)(A) a settlement agreement described in subsection (c)(1)(C) is approved by a court order that is or becomes final and nonappealable; or

''(B) if there is no court order approving a settlement agreement described in subsection (c)(1)(C), a court order dismissing the applicable case, issued after the settlement agreement, is or becomes final and nonappealable.

''(e) REPORTING OF INFORMATION.—A person described in subsection (a) that commits a violation described in subsection (c)(1) shall report such violation to the Secretary no later than 30 days after the date that—

''(1) a final judgment is entered relating to a violation described in subparagraph (A) or (B) of subsection (c)(1); or

''(2)(A) a settlement agreement described in subsection (c)(1)(C) is approved by a court order that is or becomes final and nonappealable; or

''(B) if there is no court order approving a settlement agreement described in subsection (c)(1)(C), a court order dismissing the applicable case, issued after the settlement agreement, is or becomes final and nonappealable.''.

Mr. SANDERS. Mr. President, this amendment, to my mind, is an extremely important amendment and it has the support of some of the major consumer organizations in our country, including Public Citizen, U.S. PIRG, the Consumer Federation of America, Consumers Union, the National Committee to Preserve Social Security and Medicare, and the National Women's Health Network. These are some of the large consumer organizations in America representing tens of millions of our people.

When we talk about prescription drugs, it is important to understand that in our country we pay by far the highest prices in the world for prescription drugs. That is simply the reality. That causes enormous problems because millions of our people go to the doctor, the doctor writes a prescription, and then the person can't afford to fill that prescription. That is pretty crazy, because doctors are doing the diagnosis, telling the patients what they need; patients can't afford to pay for the drugs because they are the highest prices in the world in this country. This is an issue we have to deal with.

There are a number of reasons why prices in this country are higher than in Canada, Europe, and Scandinavia. Certainly one of them is that we are the only major country on Earth that doesn't have a national health care program so that the government can negotiate prices with the drug companies. So what happens in this country is the drug companies simply charge us what the market will bear—any price they can come up with by which they can make money. The end result is that in 2009, prices in this country were 85 percent higher than Canada, 150 percent higher than France, Italy, Sweden, Switzerland, and so forth and so on.

But the reason drug prices are high in this country is not just that we don't have a national health care program, it is because of the enormous amount of fraud that takes place within the pharmaceutical industry. In fact, every single year the major drug companies are ripping off the American people to the tune of billions of dollars a year because of fraudulent practices.

While I do not have enough time here today to recite every example of fraud that has been caught and prosecuted in the last 10 years. But here is the bottom line—and I am going to list some of the cases of fraud. Virtually every major pharmaceutical company in this country has either been convicted of fraud—i.e., ripping off the Federal Government, State government, or individuals—or else has reached a settlement. We have got to get a handle on this crisis. I am going to bore some people because it is a long list. Sadly, it is a long list. But it is a list that has to get out, and it is an issue we have got to deal with.

Abbott Labs is one of the top 10 pharmaceutical companies in the world. It had $38.8 billion in revenues and $4.7 billion in profits in 2011. Last month, Abbott reached an agreement with the U.S. Department of Justice to pay $1.6 billion for illegally marketing the antiseizure drug Depakote. According to the New York Times:

As part of the agreement, Abbott said that it would pay $800 million to resolve civil cases brought by federal and state authorities, $700 million in criminal penalties and $100 million to states in connection with consumer protection matters.

That was just last month, they are going to pay $1.6 billion.

In 2010, 2 years ago, Abbott and two smaller companies collectively agreed to pay $429 million to settle charges that they deliberately misreported drug pricing in order to hike reimbursements from Medicare and Medicaid. That is Abbott in recent years.

Pfizer is the largest pharmaceutical company in the world, $67.9 billion in revenues and $10 billion in profits in 2011. Pfizer in 2012, this year, allegedly avoided paying hundreds of millions in rebates due to State Medicaid Programs for Prontonix. Pfizer holds four different exclusives for Prontonix. Talks are under way with the U.S. Department of Justice to settle the charges for up to $2 billion for ripping off Medicaid.

In 2009, Pfizer agreed to plead guilty to a felony of ''misbranding Bextra with the intent to defraud or mislead'' and to pay $1 billion to resolve allegations under the civil False Claims Act.

In 2004, a division of Pfizer pled guilty to two felonies and agreed to pay $430 million to settle charges that it fraudulently promoted the drug Neurontin for a string of unapproved uses.

Johnson & Johnson is the second largest pharmaceutical company in the world, which had $65 billion in revenues and almost $10 billion in profits in 2011.

In 2012, this year, Johnson & Johnson illegally marketed Risperdal, an antipsychotic medication, to nursing home patients, and paid over $2 billion in fines, which constituted a mere 6.3 percent of sales revenue from the drugs.

In 2010, two subsidiaries of Johnson & Johnson illegally marketed the epilepsy drug Topamax for off-label psychiatric uses.

Now we go to Merck. Merck is the third largest pharmaceutical company in the world. In 2011, last year, Merck pleaded guilty to a criminal misdemeanor charge for violation of the Food, Drug, and Cosmetic Act, and paid a $950 million settlement for illegally promoting Vioxx for rheumatoid arthritis before that use was approved.

In 2011, Merck will pay the State of Massachusetts $24 million to settle claims that former subsidiary Warrick Pharmaceuticals reported inflated and false prices for asthma medications, causing the State's Medicaid Program to overpay.

In 2008, Merck reached a $670 million settlement for fraud on patients and Medicare/Medicaid, involving a conspiracy with hospitals to give the elderly cheaper drugs but charging them for the more expensive product.

Now we go to GlaxoSmithKline. GlaxoSmithKline is, again, one of the largest pharmaceutical companies in the world. It made profits of almost $44 billion in 2011.

GlaxoSmithKline in 2011 announced that it had reached an ''agreement in principle'' with the U.S. government to pay $3 billion to conclude the company's most significant ongoing Federal Government investigations, specifically illegal sales and marketing practices in Colorado and Massachusetts; overcharging the Medicaid rebate program; and illegal development and marketing of Avandia, a diabetes drug.

In 2006, GlaxoSmithKline agreed to pay $14 million to settle allegations that it engaged in patient fraud.

In 2005, GlaxoSmithKline paid $150 million to settle claims it overcharged the government for two antinausea drugs.

In 2003, GlaxoSmithKline signed a corporate integrity agreement and paid $88 million in a civil fine for overcharging Medicaid.

And on and on and on it goes.

When we talk about the high cost of health care, when we talk about the fact that the United States has the highest prices in the world for prescription drugs, it is important for us to address the crisis in terms of fraud within the pharmaceutical industry and the fact that virtually every major drug company has been found guilty of fraud or reached a settlement in terms of fraud charges.

In 2010, the pharmaceutical industry achieved a dubious distinction. It surpassed the notoriously corrupt defense contracting industry in defrauding the government. The pharmaceutical industry accounted for nearly half—$1.8 billion of a total of $4.1 billion—of the penalties collected in 2011 by the Department of Justice/Health and Human Services Health Care Fraud and Abuse Control Program.

In 2012—and this is quite amazing—the pharmaceutical industry is expected to pay out up to four times the amount of last year's penalty, between $8 billion to $9 billion in penalties due to pending fraud settlements with the Department of Justice. And those are the penalties for fraud that has been discovered. Who knows what type of fraud is taking place on behalf of the drug companies that has not been discovered.

Let me recapitulate. Virtually every major drug company has either been found guilty of, or settled charges of, significant fraud over the last 10 years.

The question arises—and this is an important question—is fraud within

the pharmaceutical industry the exception or, is it, simply put, their business model? Is fraud the business model of the pharmaceutical industry, which thinks that in most cases they can get away with the fraud, make huge profits and, in some cases when they get caught, they will in fact pay a penalty but the penalty will in no way match the kinds of huge profits they are making from their fraudulent activity?

The question the Senate has got to address is, Do we look away from this issue, do we ignore this issue, or do we finally address the very important issue of fraud within the pharmaceutical industry, fraud being practiced by virtually every drug company in our country?

It is obvious to anyone paying attention to the prevalence of pharmaceutical industry fraud that our punishments are not enough to address this problem, because apparently the drug companies are not too intimidated by the laws on the books. They think it makes business sense for them to continue going forward on their fraudulent activities.

The amendment I am offering would send a strong and clear message to the drug industry: Illegal behavior will not be rewarded with continued government-granted monopolies. There are some things—patients' safety, the devotion of scarce public resources to provide health care to needy patients—that are more important than drug company profits.

This amendment is designed to effectively deter pharmaceutical fraud by making government-granted monopolies contingent on good corporate behavior. I think that is the least we can do.

This amendment would penalize any instance of pharmaceutical fraud resulting in a civil or criminal judgment or a settlement with an acknowledgement of fault by revoking any applicable data or marketing exclusivity for the particular drug or product involved in the fraud. giving pharmaceutical companies another factor to consider, when weighing whether to violate the law in their sales or billing practices.

If a company violated Federal or State law by inflating the price of a drug in Medicare or Medicaid billing or illegally marketing a medication, under my amendment that company would lose the remainder of any exclusivity period for that medication. Companies would be required to self-report qualifying violations to the FDA within 30 days.

Let me conclude by saying this: Our people are paying the highest prices——

The PRESIDING OFFICER. The time of the Senator has expired.

Mr. SANDERS. I ask unanimous consent for 1 additional minute.

The PRESIDING OFFICER (Mr. DURBIN). Without objection, it is so ordered.

Mr. SANDERS. Our people are paying the highest prices in the world for prescription drugs. One of the reasons is widespread fraudulent activity on the part of virtually every major drug company in our country. It is no longer acceptable to turn a blind eye to that crisis. The time to act is now. This amendment would go a long way forward to ending that outrageous fraud. I ask the support of my colleagues for this amendment.

I yield the floor.

The PRESIDING OFFICER (Mr. MERKLEY). The Senator from Wyoming.

Mr. ENZI. Mr. President, I appreciate the concern by the Senator from Vermont, but I have to oppose the amendment, No. 2109, because of some of the unintended consequences it will have.

This amendment would require drug companies to forfeit exclusivity for certain violations of the Federal Food, Drug, and Cosmetic Act and other laws.

''Exclusivity'' means exclusive market rights granted by the Food and Drug Administration upon approval of a drug. It may or may not run concurrently with a patent. Exclusivity is a very important type of intellectual property protection. Without it, innovators cannot predictably obtain returns on their drug development investments.

The stated purpose of the amendment is to combat healthcare related fraud. The premise is, if companies know their profits are at risk, they will be strongly discouraged from engaging in fraudulent activity. But this amendment is counterproductive: It will make it more costly for law enforcement to fight fraud and could hurt patients.

Congress is also thinking of ways to improve healthcare antifraud programs. For example, in a recent open letter to the health care community, six members of the Senate Finance Committee, led by Chairman BAUCUS and Ranking Member HATCH, announced a bipartisan effort to solicit ideas from the healthcare community on ways to reduce healthcare waste, fraud and abuse.

Estimates of the amount of fraud and misspending in Medicare and Medicaid vary widely, from $20 billion to as much as $100 billion. To address this problem, the six Senators solicited ideas on program integrity and fraud and abuse enforcement reforms.

This sort of constructive search for real solutions is long overdue. Healthcare fraud is a serious problem, and I strongly agree that the Congress should develop substantive solutions to it.

The problem here is, the pending amendment does not really tackle the problem of fraud.

Instead, the amendment uses a blunt instrument—revocation of exclusivity—to punish an incredibly broad range of legal violations.

This amendment would discourage settlements in fraud cases. A settlement agreement concerning a listed violation would trigger forfeiture.

If a company knows that settlement would trigger a result that could cost it hundreds of millions of dollars, it will be less likely to settle. This will make it harder for the government to settle cases, and increase the backlog of cases waiting for trial. It also creates the risk that a fraudster could prevail or appeal, and prevent the prosecutor from pursuing other cases.

Settlement is an important tool in a prosecutor's toolkit. It enables them to pursue a higher volume of cases, while still obtaining sizable judgments to deter future fraud.

In fiscal year 2011, the Departments of Justice and Health and Human Services together recovered nearly $4.1 billion in taxpayer dollars through healthcare anti-fraud prevention and enforcement efforts. The ability to settle claims contributed substantially to this achievement by allowing the government to pursue a higher volume of cases.

Within the Federal Food, Drug, and Cosmetic Act itself, there are already robust standards and enforcement tools concerning industry marketing and communications, and interactions with healthcare providers and professionals.

The False Claims Act and strong anti-kickback laws are also on the books already.

This amendment will also discourage manufacturers from developing new cures. It creates tremendous uncertainty about whether investors can obtain returns on their drug development investments. If a trivial violation of FDA's detailed, elaborate regulations could put the entire investment in a drug at risk, it will discourage investment in new treatments.

This would severely threaten biomedical investment and jobs. More importantly, it would lead to fewer lifesaving therapies for patients.

This amendment could produce absurd results. For example, the amendment would revoke exclusivity for a civil judgment concerning adulteration of a drug. A drug is considered adulterated if a manufacturer violates FDA's current Good Manufacturing Practices, known as cGMPs. There is no intent requirement, and no minimum number of inspection requirements to trigger liability. Some examples of cGMP violations include: Washing and toilet facilities are not easily accessible to working areas; adequate lighting is not provided in all areas; laboratory records do not include complete records of the periodic calibration of laboratory instruments.

It obviously does not make sense to strip drug companies of exclusivity for violations like this, which do not reflect fraudulent intent. It is disproportionate and counterproductive.

Again, I strongly agree that healthcare fraud is a significant problem. The best way to solve it is through robust enforcement of the many current laws on point, and continuing to work with the health care community to find effective solutions.

That would be going through committee hearings as well. The pending amendment would not reduce fraud. On the contrary, it would frustrate the government's current anti-fraud efforts, and ultimately harm patients and taxpayers alike.

I encourage a ''no'' vote on this amendment.

I yield the floor and reserve the remainder of our time.

Mr. COBURN. I ask unanimous consent that the pending amendment be set aside and that Coburn amendment No. 2131 be called up.

Mr. HARKIN. Mr. President, I object. How much time is left on the Sanders amendment?

The PRESIDING OFFICER. The Senator from Vermont has no time left. The Senator from Wyoming controls 10 minutes.

Mr. HARKIN. Will the Senator from Oklahoma withhold? We have some people who want to speak. Once the time has run, then we automatically move on to another amendment and could bring up the Senator's amendment at that point.

Mr. COBURN. It is my understanding that the time is under our control. At present, there is 10 minutes left.

Mr. HARKIN. There is 10 minutes in opposition to the amendment.

Mr. COBURN. I will be happy to yield to the ranking member. If he has people who wish to speak in opposition, that is fine.

Mr. HARKIN. Senator MIKULSKI was here earlier. She wants to speak on this amendment. If we just wait 5 minutes?

The PRESIDING OFFICER. The Senator from Maryland.

Ms. MIKULSKI. Mr. President, first I thank my colleague from Oklahoma. I just want to take a few minutes, if I could, to talk about an important issue.

Mr. HARKIN. I am sorry, I was wrong. I thought the Senator wanted to speak on the Sanders amendment. She wanted to speak on the underlying bill itself?

Ms. MIKULSKI. Yes.

Mr. HARKIN. The Senator just seeks 5 minutes?

Ms. MIKULSKI. Or less.

Mr. HARKIN. Since it is my time, I yield the Senator from Maryland 5 minutes on the underlying bill.

Ms. MIKULSKI. I will be very brief.

The PRESIDING OFFICER. The Senator from Maryland.

Ms. MIKULSKI. Mr. President, I say to our colleague from Oklahoma, himself a physician, that he will be very keenly interested in this issue of prescription drug shortages. This is a problem that has been brought to my attention by Marylanders, leaders of great institutions such as the University of Maryland and Hopkins, as well as family members who care for someone and find that, although there has been the right diagnosis and there is even the right drug to care for that problem—like the dread ''cancer'' word—the drug is not available. So you can imagine the last thing you want to hear is that your child has cancer, and then the worst thing you want to hear is that there is a shortage of that drug to take care of that child. That is not because it has not been developed, not because there has not been a scientific breakthrough, but because there has been a manufacturing problem or because the company stopped making the drug when it was no longer profitable. That is inexcusable. The bill before us does something about it.

In 2011 we had more than 250 drug shortages. That is not incidents, that is 250 drugs that were in shortage. Half of the drugs that experience a shortage go into shortage multiple times.

This drug shortage threatens public health by preventing patients and physicians from accessing needed medications. It forces doctors to often delay medical procedures, use alternative products that may carry unwanted side effects or to rely on foreign versions of drugs that might not have been reviewed by FDA or it sends their very able pharmacists in their institutions to spend endless hours on the phone to be able to come up with the needed drug.

As I said, this was brought to my attention by letters from some famous constituents—meaning well-known in our community—with great health insurance who had a child who had leukemia and then found the drug was in short supply. We heard from doctors who were forced to delay or turn to alternative treatments, hospitals scrambling to manage these shortages, and pharmacists trying to track down needed treatments. Even then, we heard about gouging and we heard about a gray market. The gouging was pumping up the price when there was a shortage, and then there is a gray market where you can go to buy these drugs, but they might not be the drug you wanted or they might have been on somebody's shelf a long time and were flawed and even dangerous or they had not been refrigerated.

I could go through one horror story after another. I wanted to bring this to the attention of the full Senate because as we work on this excellent, bipartisan bill on user fees, what we also have is a very commonsense way of dealing with the drug shortage issue.

It has the support of the private sector and certainly those who care for patients, as well as patients themselves. I hope we pass this underlying bill, and I hope we do not tie up this legislation with amendments that could either derail or deter it.

I yield the floor.

Mr. HARKIN. Mr. President, how much time is remaining on the Sanders amendment?

The PRESIDING OFFICER. There is 7 minutes in opposition that remains on the Sanders amendment.

Mr. HARKIN. I will yield myself a couple of minutes.

I join with my colleague Senator ENZI in opposition to the Sanders amendment. We are all disturbed by a lot of what we are reading and these big settlements. I know the recent one a couple of weeks ago on Abbott Labs where part of the prosecution case was actually that this was part of their business model. Then they had to settle it. So this is all very disturbing.

However, that cries out more for, perhaps, looking at the criminal charges and perhaps strengthening some of those things but not taking away exclusivity. If you do that, a lot of times you could take away exclusivity from someone who just committed a misdemeanor. A lot of these settlements were misdemeanor charges where no intent was shown.

A lot of times, if you did this, you might penalize someone who maybe had done something wrong in the past, and now maybe they have new leadership, a new company, and reformed themselves, and now they have to lose their exclusivity? You would not want to do that.

Third, if you do this—I think Senator ENZI pointed this out correctly—if there is no reason to settle, then people are going to go to the wall in terms of defending themselves, and DOJ doesn't have all that kind of personnel and the time to do that. I think we would then have an even worse situation of people committing fraud because then they would know they would not have any reason to settle it whatsoever. Settlement is a good tool to be used by prosecutors to get cases to justice, to make sure consumers are made whole, and to let people know they are being watched. That is what they do.

I think the Sanders amendment, while maybe well-intentioned—I know it is well-intentioned. I know the Senator has all good intentions of what he wants to do. But I think it goes too far and is not the right solution to that problem. So I would oppose Senator SANDERS amendment also.

I yield the floor.

The PRESIDING OFFICER. The Senator from Oklahoma.

AMENDMENT NO. 2131

Mr. COBURN. I ask unanimous consent that the pending amendment be set aside, and I call up amendment No. 2131, which is at the desk, and ask that it be reported.

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

The assistant legislative clerk read as follows:

The Senator from Oklahoma [Mr. COBURN], for himself, and Mr. BURR, proposes an amendment numbered 2131.

Mr. COBURN. Mr. President, I ask unanimous consent that the reading of the amendment be dispensed with.

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

The amendment is as follows:

(Purpose: To require an independent assessment of the Food and Drug Administration's review of drug applications)

At the end of title VII, add the following:

SEC. 7___. INDEPENDENT ASSESSMENT.

(a) IN GENERAL.—The Secretary shall contract with a private, independent consulting

firm capable of performing the technical analysis, management assessment, and program evaluation tasks required to conduct a comprehensive assessment of the process for the review of drug applications under subsections (b) and (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b), (j)) and subsections (a) and (k) of section 351 of the Public Health Service Act (42 U.S.C. 262(a), (k)). The assessment shall address the premarket review process of drugs by the Food and Drug Administration, using an assessment framework that draws from appropriate quality system standards, including management responsibility, documents controls and records management, and corrective and preventive action.

(b) PARTICIPATION.—Representatives of the Food and Drug Administration and manufacturers of drugs subject to user fees under part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g et seq.) shall participate in a comprehensive assessment of the process for the review of drug applications under section 505 of the Federal Food, Drug, and Cosmetic Act and section 351 of the Public Health Service Act. The assessment shall be conducted in phases.

(c) FIRST CONTRACT.—The Secretary shall award the contract for the first assessment under this section not later than March 31, 2013. Such contractor shall evaluate the implementation of recommendations and publish a written assessment not later than February 1, 2016.

(d) FINDINGS AND RECOMMENDATIONS.—

(1) IN GENERAL.—The Secretary shall publish the findings and recommendations under this section that are likely to have a significant impact on review times not later than 6 months after the contract is awarded. Final comprehensive findings and recommendations shall be published not later than 1 year after the contract is awarded.

(2) IMPLEMENTATION PLAN.—The Food and Drug Administration shall publish an implementation plan not later than 6 months after the date of receipt of each set of recommendation.

(e) SCOPE OF ASSESSMENT.—The assessment under this section shall include the following:

(1) Identification of process improvements and best practices for conducting predictable, efficient, and consistent premarket reviews that meet regulatory review standards.

(2) Analysis of elements of the review process that consume or save time to facilitate a more efficient process. Such analysis shall include—

(A) consideration of root causes for inefficiencies that may affect review performance and total time to decision;

(B) recommended actions to correct any failures to meet user fee program goals; and

(C) consideration of the impact of combination products on the review process.

(3) Assessment of methods and controls of the Food and Drug Administration for collecting and reporting information on premarket review process resource use and performance.

(4) Assessment of effectiveness of the reviewer training program of the Food and Drug Administration.

(5) Recommendations for ongoing periodic assessments and any additional, more detailed or focused assessments.

(f) REQUIREMENTS.—The Secretary shall—

(1) analyze the recommendations for improvement opportunities identified in the assessment, develop and implement a corrective action plan, and ensure it effectiveness;

(2) incorporate the findings and recommendations of the contractors, as appropriate, into the management of the premarket review program of the Food and Drug Administration; and

(3) incorporate the results of the assessment in a Good Review Management Practices guidance document, which shall include initial and ongoing training of Food and Drug Administration staff, and periodic audits of compliance with the guidance.

Mr. COBURN. Mr. President, let me say how proud I am of all of the members of the HELP Committee on this difficult and complicated issue they are bringing before us. Having been in business and under the control of the FDA as a medical device manufacturer, this is a very complicated area of law that, if done right, will have tremendous positive effects, and I think the Senators have put out a very good bill. I congratulate my colleagues and all the members on doing that.

I have two amendments, and I am going to speak for a very short period of time on both of them. I will work with the ranking member and the chairman to see if we can't get to where we don't have to vote on them.

I would like to give just a little history on PDUFA and MDUFA. The reason they were set up in the first place was to help fund the FDA, and the reason the manufacturers agreed to do that was to get more timeliness in terms of response to their applications. That was the whole basis for it. And what we have before us today is some improvement in terms of the FDA's response but really not everything we should have gotten.

I, along with Senator BURR, asked for a GAO study to the FDA in terms of meeting stated performance goals, and we found out a whole lot about that, and that is my next amendment, but I say that to preface why I have this amendment.

In this bill is a wonderful requirement that causes the FDA to contract with an independent management company to assess the management of the missions and resources of the device regulation component of the FDA. What is missing is that same independent review in terms of drugs. It is one of those situations where we invest in something that would pay us additional big dividends. I know it will pay big dividends in the device area. It will also pay big dividends in the drug area. I don't know what the workings of the committee are and why they decided not to put this in as far as the drug review process, but having a second look at a very complicated regulatory and approval structure could be very beneficial in terms of improving both the quality of the outcome as well as the timeliness.

So this amendment simply says that what we are going to do for the device, which is in the bill already, we are also going to do for the drug side of the FDA. It is about gathering knowledge for both the FDA and for us as we help this agency perform very needed things.

As a physician, I read a lot about new science on new drugs. The things that are coming in this country are going to be phenomenal in terms of new treatments and new drugs and new capabilities. In terms of our competitiveness worldwide but also in terms of how we address these diseases, we need to have the most efficient regulatory agency we can.

All I am asking is that we treat all of the FDA the same in terms of taking a look at how well they are doing, what could they do better, and how they could do it better. That report comes to us and the FDA, and so we can see the weaknesses. We have not been through every area of the FDA as Members of the Senate, and to have an independent assessment of the drug side as well as the device side will pay huge benefits to the FDA, but mostly it will pay huge benefits to people of this country in terms of the timeliness of drug presentation.

I won't speak any more to that. It is a commonsense, good-government amendment. Part of it is in the bill, and part of it is not in the bill. It is something that will pay us big dividends not only in terms of health care and improving the operation of the FDA but also in terms of improving our competitiveness worldwide.

AMENDMENT NO. 2132

Mr. COBURN. Mr. President, I ask that that amendment be set aside, and I call up amendment No. 2132, which is at the desk, and ask that it be reported.

The PRESIDING OFFICER. The clerk will report.

The assistant legislative clerk read as follows:

The Senator from Oklahoma [Mr. COBURN], for himself, and Mr. BURR, proposes an amendment numbered 2132.

Mr. COBURN. Mr. President, I ask unanimous consent that the reading of the amendment be waived.

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

The amendment is as follows:

(Purpose: To provide that a portion of the performance awards of each employee of the Center for Drug Evaluation and Research, the Center for Devices and Radiological Health, and the Center for Biologics Evaluation and Research be connected to an evaluation of the employee's contribution to goals under the user fee agreements)

At the end of title XI, add the following:

SEC. 11___. PERFORMANCE AWARDS.

(a) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall establish a system by which a portion of the performance awards of each employee described in subsection (b) shall be connected to the evaluation of the employee's contribution, in the discretion of the Secretary, to the goals under the user fee agreements described in section 101(b), 201(b), 301(b), or 401(b), as appropriate.

(b) EMPLOYEES DESCRIBED.—

(1) IN GENERAL.—Subsection (a) shall apply only to employees who—

(A) are employed by the Center for Drug Evaluation and Research, the Center for Devices and Radiological Health, or the Center for Biologics Evaluation and Research; and

(B) are involved in the review of drugs, devices, or biological products.

(2) COMMISSIONED CORPS.—For purposes of this section, the term ''employee'' includes members of the Public Health Service Commissioned Corps.

(c) EFFECT ON AWARD.—The degree to which the performance award of an employee is affected by the evaluation of the employee's contribution to the goals under the user fee agreements, as described in subsection (a), shall be proportional to the extent to which the employee is involved in the review of drugs, devices, or biological products.

(d) REPORT.—The Secretary shall issue an annual report detailing how many employees were involved in meeting the goals under the user fee agreements described in section 101(b), 201(b), 301(b), and 401(b), and the manner of the involvement of such employees.

Mr. COBURN. Mr. President, this is an amendment that comes out of a study of GAO's findings, and GAO did a wonderful job looking at the FDA. What we found out—part of it will be covered if, in fact, we do this other study on the management, but what GAO is telling us is that there is an irregular pattern of performance review at the FDA. Part of the evaluation of about 40 percent of the people who are involved in the drug and device approval process, in terms of their performance review, has to do with the timeliness of their work product. And it is only a small component, but it is still a component of it.

What this amendment does is it says: FDA, make this part of your component on the people who are actually reviewed in the review process—not to try to push them to do it better but to have a management tool with which to evaluate individual employees doing this.

The fact that they are already doing this on some—and what GAO really said is that it is just a lack of management effectiveness that they have not installed it everywhere else. All this amendment says is that this should be one component as they evaluate their employees on their performance reviews and ask: How did you do on timeliness? Was your work product timely?

The idea behind this is not to push drugs out that should not be approved. It is not to push out devices that should not be approved. But remember that the purpose for PDUFA and MDUFA in the first place was to fund FDA with additional money so they would be more timely.

The opposition I hear to this amendment that we are afraid that if this is a component of review, they might review a product and let it go when they shouldn't does not make sense since already 40 percent of the employees doing this are being evaluated on this performance standard anyway. So I would raise the question: If we are in opposition to this amendment, why in the world haven't we eliminated this as a part of all the review process already if, in fact, there is a concern? There is not a concern with it. It is a good management tool. It is used in all sorts of government agencies. And I commend to the attention of my colleagues the GAO report that backs up exactly what I am saying and their recommendation. These are not TOM COBURN's recommendations, these are the GAO recommendations for FDA. They address the concerns of inappropriate pressure for early approval or inappropriate approval for drugs or devices.

Again, it is good government and common sense. It is how one would manage a private organization. You would put every component that the employee is involved with as a component as part of the review process.

My hope is that we do not have to vote on this. When my colleagues actually thoroughly study the GAO report, they will embrace what they are saying. It is common sense with sound judgment that deals with the FDA.

I yield the floor.

Mr. HARKIN. Would the Senator yield for a question?

Mr. COBURN. I would be happy to.

Mr. HARKIN. I think the Senator is making a lot of common sense. The only question I would ask is—and I don't know a lot about this. I haven't read the GAO report. But if, in fact, every employee says, I know they are going to get me on this timeliness. So it is the balance of safety and quickness, safety and expediency. In other words, we try to get a balance. We want devices and drugs approved as quickly as possible, but we don't want to jeopardize safety. Those are the two things we always try to balance here, safety being the foremost. We want things to be safe.

My question is, by enshrining this into law rather than in the administration, would this somehow put more undue pressure on reviewers and others to do something quickly and jeopardize the safety aspect?

Mr. COBURN. My answer to the chairman through the Chair is that the FDA does nothing quickly now, and he knows that because he has been sitting in oversight over them for years. That is No. 1. The answer to No. 2 is, if the Senator reads the GAO report, they have no explanation on why they do it on some employees and not others. The fact is, if this is a bad thing, why are they doing it on 40 percent of the employees now? The No. 1 and No. 2 things the FDA is charged with are safety and efficacy. Safety comes first. They get graded on how well they do on that. So we have this counterbalance.

Well, what we have is a lack of responsiveness even though billions of dollars are going to the FDA from the device companies and the drug companies. Part of the deal was to make them more timely. That means in no way do you ignore safety and in no way do you ignore efficacy. The fact is they do deserve answers, and what is happening a lot of times is they are not.

I fully support the bureaucracy of the FDA in terms of them doing their job. I think they do an awfully good job. They are just awfully slow at it, and when you ask why, there is not a good answer.

The point is, if there are a large number of employees who are already reviewed as a small component, it doesn't have to be a major one, but it ought to be something you think about. Do I push this off my desk because I am bored with it? Does the timeframe mean anything?

We are not going after eliminating safety and efficacy, we are going after smart management, and those two things, safety and efficacy, reign supreme at the FDA. That is why we spend so much in this country. That is why most of the drugs are approved outside of this country way ahead of when they get approved here, because our drugs and devices are safer and we are slow to approve, and rightly so, but we should not be like frozen ice slowly slipping down a hill. All this says is, let's make it one component of many in terms of review. Again, I tell the chairman, this is not my recommendation, this is the GAO's recommendation.

So I would appreciate consideration by the chairman and ranking member for these amendments. I think they are common sense. We could look at them again. If the Senator thinks there is a problem, we can put in a caveat. Let's look at it in a year and say: Have there been problems because we have done this? But it is good management, it does make sense, and they are already doing it on 40 percent of their employees who are involved in the approval of both drugs and devices.

I thank the chair for his question.

I yield the floor, and I will be back.

The PRESIDING OFFICER. The Senator from Iowa.

AMENDMENT NO. 2129

Mr. GRASSLEY. Mr. President, I rise for the purpose of calling up amendment No. 2129.

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

The assistant legislative clerk read as follows:

The Senator from Iowa [Mr. GRASSLEY], proposes an amendment numbered 2129.

Mr. GRASSLEY. Mr. President, I ask unanimous consent that the reading of the amendment be dispensed with.

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

The amendment is as follows:

(Purpose: To provide deadlines for the issuance of certain regulations and to require a GAO report on the implementation of the clinical trial registration and reporting requirements under the Public Health Service Act)

At the end of title XI, add the following:

SEC. 11___. REGULATIONS ON CLINICAL TRIAL REGISTRATION; GAO STUDY OF CLINICAL TRIAL REGISTRATION AND REPORTING REQUIREMENTS.

(a) DEFINITIONS.—In this section—

(1) the term ''applicable clinical trial'' has the meaning given such term under section 402(j) of the Public Health Service Act (42 U.S.C. 282(j));

(2) the term ''Director'' means the Director of the National Institutes of Health;

(3) the term ''responsible party'' has the meaning given such term under such section 402(j); and

(4) the term ''Secretary'' means the Secretary of Health and Human Services.

(b) REQUIRED REGULATIONS.—

(1) PROPOSED RULEMAKING.—Not later than 180 days after the date of enactment of this Act, the Secretary, acting through the Director, shall issue a notice of proposed rulemaking for a proposed rule on the registration of applicable clinical trials by responsible parties under section 402(j) of the Public Health Service Act (42 U.S.C. 282(j)) (as amended by section 801 of the Food and Drug Administration Amendments Act of 2007).

(2) FINAL RULE.—Not later than 180 days after the issuance of the notice of proposed rulemaking under paragraph (1), the Secretary, acting through the Director, shall issue the final rule on the registration of applicable clinical trials by responsible parties under such section 402(j).

(3) LETTER TO CONGRESS.—If the final rule described in paragraph (2) is not issued by the date required under such paragraph, the Secretary shall submit to Congress a letter that describes the reasons why such final rule has not been issued.

(c) REPORT BY GAO.—

(1) IN GENERAL.—Not later than 2 years after the issuance of the final rule under subsection (b), the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the implementation of the registration and reporting requirements for applicable drug and device clinical trials under section 402(j) the Public Health Service Act (42 U.S.C. 282(j)) (as amended by section 801 of the Food and Drug Administration Amendments Act of 2007).

(2) CONTENT.—The report under paragraph (1) shall include—

(A) information on the rate of compliance and non-compliance (by category of sponsor, category of trial (phase II, III, or IV), whether the applicable clinical trial is conducted domestically, in foreign sites, or a combination of sites, and such other categories as the Comptroller General determines useful) with the requirements of—

(i) registering applicable clinical trials under such section 402(j);

(ii) reporting the results of such trials under such section; and

(iii) the completeness of the reporting of the required data under such section; and

(B) information on the promulgation of regulations for the registration of applicable clinical trials by the responsible parties under such section 402(j).

(3) RECOMMENDATIONS.—If the Comptroller General finds problems with timely compliance or completeness of the data being reported under such section 402(j), or finds that the implementation of registration and reporting requirements under such section 402(j) for applicable drug and device clinical trials could be improved, the Comptroller General shall, after consulting with the Commissioner of Food and Drugs, applicable stakeholders, and experts in the conduct of clinical trials, make recommendations for administrative or legislative actions to increase the compliance with the requirements of such section 402(j).

Mr. GRASSLEY. Mr. President, first of all, I congratulate my colleague from Iowa and my colleague from Wyoming for the bipartisanship of this legislation.

The FDA amendments of 2007 mandated basic public results reporting for all clinical trials supporting FDA-approved drugs and devices. Clinical trials results help both patients and doctors understand the benefits and efficacy of a particular medical product.

Moreover, a July 2011 FDA report stated:

Understanding variable characteristics in clinical trial sites is becoming increasingly important because of the international nature of current clinical trials. The sources of differences in efficacy results between the U.S. and foreign clinical trials sites have yet to be determined, but differences rooted in the conduct of the clinical trial should be evaluated.

It has been 5 years since the passage of the FDA Amendments Act, and the National Institutes of Health is still in the process of writing proposed regulations. The clinicaltrials.gov program and title VIII of the FDA Amendments Act were considered major reforms and helped science information advances. If they are not being implemented well or adequately enforced, society will fail to reap the full benefits of the billions of dollars in good medical science research.

This amendment before the Senate will impose a deadline by which the NIH will finalize both the proposed and final regulations. Further, 2 years after the regulation has been in place, the Government Accountability Office will conduct a study on compliance with regulations and will look at, among other things, whether the applicable clinical trial is conducted domestically, in foreign sites, or in a combination of sites. The rapid increase in trials being run overseas makes it imperative that the Government Accountability Office investigate this matter.

Currently, ''80 percent of approved marketing applications for drugs and biologics contained data from foreign clinical trials.'' The ''FDA inspected 1.9 percent of domestic clinical trial sites and 0.7 percent of foreign clinical trial sites.'' We need stronger reporting requirements to ensure we understand what the implications are of this move to having so many trials conducted overseas. I encourage my colleagues to support this important amendment.

Before I move on, I wish to talk about another amendment I am a cosponsor of, which is an amendment offered by Senator PORTMAN that will make dangerous synthetic drugs such as K2 and bath salts schedule I narcotics. I have worked for over a year now to get this legislation passed through the Senate after a constituent of mine named David Rozga committed suicide shortly after smoking K2 with some friends nearly 2 years ago.

I introduced the David Mitchell Rozga Act in March of 2011, and the Senate Judiciary Committee unanimously passed it out of committee along with two other related bills sponsored by Senator SCHUMER and Senator KLOBUCHAR last July. Since that time, the use of synthetic drugs has grown very rapidly, with the number of calls into poison control centers going from as few as 19 in the year 2009 to over 6,000 in the year 2011.

The House passed their version of this bill last December on a strong bipartisan vote, but one Senator has blocked consideration of this legislation in this Chamber up to now.

So I am grateful we are finally able to have a vote on this issue, and I urge passage of the Portman amendment as well.

Madam President, I wish to go to another amendment, if that would be appropriate at this time.

The PRESIDING OFFICER (Ms. KLOBUCHAR). Without objection, it is so ordered.

AMENDMENT NO. 2121

Mr. GRASSLEY. I call up amendment No. 2121.

The PRESIDING OFFICER. The clerk will report.

The bill clerk read as follows:

The Senator from Iowa [Mr. GRASSLEY] proposes an amendment numbered 2121.

Mr. GRASSLEY. I ask unanimous consent that the reading of the amendment be dispensed with.

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

The amendment is as follows:

(Purpose: To provide employee protections for the Commissioned Corps of the Public Health Service Act)

At the end of title XI, add the following:

SEC. 11___. PROTECTIONS FOR THE COMMISSIONED CORPS OF THE PUBLIC HEALTH SERVICE ACT.

(a) IN GENERAL.—Section 221(a) of the Public Health Service Act (42 U.S.C. 213a(a)) is amended by adding at the end the following:

''(18) Section 1034, Protected Communications; Prohibition of Retaliatory Personnel Actions.''.

(b) CONFORMING AMENDMENT.—Section 221(b) of the Public Health Service Act (42 U.S.C. 213a(b)) is amended by adding at the end the following: ''For purposes of paragraph (18) of subsection (a), the term 'Inspector General' in section 1034 of such title 10 shall mean the Inspector General of the Department of Health and Human Services.''.

Mr. GRASSLEY. Madam President, the bill before us, S. 3187, did not address a top priority of mine, and that is ensuring whistleblowers have adequate protections.

Four months ago my office learned of a very abusive treatment by the FDA on certain whistleblowers due to those whistleblowers' protected communications with Congress and, more specifically, with this Senator's office. Once the agency learned of the communication, even though they were on personal e-mail, it began actively monitoring and observing employees' personal e-mail, as one might expect, and they observed those e-mail accounts for 2 years—for a whole 2 years—until the agency was able to have the employee fired.

Whistleblowers shouldn't be fired for doing what is patriotic; that is, reporting wrongdoing to Congress. Regrettably, I was not shocked to learn that the FDA was mistreating whistleblowers within its agency, as it has done on more than one occasion, and as I have pointed out to my colleagues. I have been reporting those things ever since the Vioxx situation of 2004, I believe.

What makes this example different, though—and even worse—is the FDA intentionally went after an employee because it knew this employee was not covered by the Whistleblower Protection Act. Now, it might surprise some of my colleagues that all employees aren't covered by the Whistleblower Protection Act. This employee in question was a member of the Public Health Service Commissioned Corps, and because of a decision from the Court of Federal Claims these employees—meaning the Public Health Service along with other members of the uniformed services—are not covered by the Federal employee whistleblower protections.

I think the court case was wrong, but anyway, that is the way the Court of Federal Claims ruled. That ruling came as a result of the Verbeck v. United States case, and the Court of Federal Claims held that an officer in the Public Health Service Commissioned Corps is a member of the uniformed service and as such is not covered by the civilian Whistleblower Protection Act, nor even the Military Whistleblower Protection Act. This same logic extends to the commissioned corps of the National Oceanic and Atmospheric Administration as well. So under the precedent of this Verbeck case, the officers of both the Public Health Service and NOAA currently have no whistleblower protection under Federal law.

This is particularly problematic when we consider that the Public Health Service and NOAA officers can be detailed to agencies such as the FDC or the Centers for Disease Control. There, these officers, working in another agency, happen to work side-by-side with civilian employees of that agency doing very critical work to review and approve drugs, oversee medical devices, and even work on infectious diseases. However, unlike their civilian colleagues who are employees of that agency and who are sitting right next to them, if these employees uncover wrongdoing, waste, fraud, and abuse, they can be retaliated against by the agency and have no recourse for it. That is exactly what happened to this Public Health Service employee working in the Food and Drug Administration when they reported wrongdoing at that agency to Congress. They did it by personal e-mail, and the FDA got on to it and then fired the one employee who was reporting to Congress but did not fire the employees who were protected by the Whistleblower Protection Act. So that is why I say this is wrong, and it needs to be fixed. This amendment will fix it.

Whistleblowers point out fraud, waste, and abuse when no one else will, and they do so while risking their professional careers. Whistleblowers have played a critical role in exposing government failures, and retaliation against whistleblowers should never be tolerated.

For this reason, I offered an amendment that expands whistleblower protection for uniformed employees of the Public Health Service. It corrects the anomaly pointed out by the Court of Federal Claims and ensures that officers in the Public Health Service have some baseline whistleblower protection. It expressly includes the commissioned corps of the Public Health Service within the protections of the Military Whistleblower Protection Act. This is consistent with the structure of the commissioned corps functioning like a military organization and matches the fact that these officers receive military-like benefits in retirement.

Unfortunately, this amendment, which I was able to get into this legislation, only covers employees of the Public Health Service. It does not address the commissioned corps of NOAA because of other Senators' concern that is not related to the underlying bill. So I hope to be able to address that remaining gap in whistleblower protections in the near future so that all employees of the Federal Government are covered.

All Federal employees should feel comfortable expressing their opinions both inside the agency they work for as well as to Congress. The inclusion of this language will ensure those opinions receive appropriate protections.

I wish to take this opportunity, as I did in my opening comments on these two amendments, to express my appreciation to Senators HARKIN and ENZI and their commitment and efforts over the years to reform and improve the FDA.

I yield the floor.

The PRESIDING OFFICER. The Senator from North Carolina.

Mr. BURR. What is the pending business on the Senate floor?

The PRESIDING OFFICER. The pending business is Grassley amendment No. 2121.

AMENDMENT NO. 2130

Mr. BURR. I ask unanimous consent to set aside the pending amendment and to call up amendment No. 2130.

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

The clerk will report.

The bill clerk read as follows:

The Senator from North Carolina [Mr. BURR], for himself and Mr. COBURN, proposes an amendment numbered 2130.

The PRESIDING OFFICER. I ask unanimous consent that the reading of the amendment be dispensed with.

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

The amendment is as follows:

(Purpose: To ensure transparency in Food and Drug Administration user fee agreement negotiations)

At the end of title XI, add the following:

SEC. 11___. TRANSPARENCY IN FDA USER FEE AGREEMENT NEGOTIATIONS.

(a) PDUFA.—Section 736B(d) (21 U.S.C. 379h–2(d)), as amended by section 104, is further amended by adding at the end the following:

''(7) INCLUSION OF CONGRESSIONAL REPRESENTATIVES.—Notwithstanding any other provision of this section, Members of Congress or their designated staff may be present at any negotiation meeting conducted under this subsection between the Food and Drug Administration and the regulated industry, if a Member of Congress decides to attend, or have his or her designated staff attend on his or her behalf. Any staff designated under the preceding sentence may be required to comply with applicable confidentiality agreements.''.

(b) MDUFA.—Section 738A(b) (21 U.S.C. 379j–1(b)), as amended by section 204, is further amended by adding at the end the following:

''(7) INCLUSION OF CONGRESSIONAL REPRESENTATIVES.—Notwithstanding any other provision of this section, Members of Congress or their designated staff may be present at any negotiation meeting conducted under this subsection between the Food and Drug Administration and the regulated industry, if a Member of Congress decides to attend, or have his or her designated staff attend on his or her behalf. Any staff designated under the preceding sentence may be required to comply with applicable confidentiality agreements.''.

(c) GDUFA.—Section 744C(d), as added by section 303 of this Act, is amended by adding at the end the following:

''(7) INCLUSION OF CONGRESSIONAL REPRESENTATIVES.—Notwithstanding any other provision of this section, Members of Congress or their designated staff may be present at any negotiation meeting conducted under this subsection between the Food and Drug Administration and the regulated industry, if a Member of Congress decides to attend, or have his or her designated staff attend on his or her behalf. Any staff designated under the preceding sentence may be required to comply with applicable confidentiality agreements.''.

(d) BSUFA.—Section 744I(e), as added by section 403 of this Act, is amended by adding at the end the following:

''(4) INCLUSION OF CONGRESSIONAL REPRESENTATIVES.—Notwithstanding any other provision of this section, Members of Congress or their designated staff may be present at any negotiation meeting conducted under this subsection between the Food and Drug Administration and the regulated industry, if a Member of Congress decides to attend, or have his or her designated staff attend on his or her behalf. Any staff designated under the preceding sentence may be required to comply with applicable confidentiality agreements.''.

Mr. BURR. Madam President, let me reiterate what my colleague just said, which is that Chairman HARKIN and Ranking Member ENZI have done a wonderful job with a very complicated bill in navigating what was a negotiation that Members of Congress never played a part in—negotiations that happened between the Food and Drug Administration and the pharmaceutical industry for one piece, the device industry for another piece, and the generic drug industry for a third piece; and, I might say, the third piece is the first time Congress will consider this.

I think it is important that Members of the Senate, Members of Congress, and the American people understand that, typically, all legislation is crafted in the Congress of the United States. It is not negotiated in the back room of the Food and Drug Administration or in the back rooms of the device, pharmaceutical, and generic drug

manufacturers—except for this. In fact, my amendment gets at the heart of that issue. It is called the amendment ''to ensure transparency in the Food and Drug Administration user fee agreement negotiations.''

The amendment is straightforward. It would ensure transparency in FDA's drug and device user agreement negotiations by allowing Members of Congress or their designated staff to attend the negotiations between the FDA and the industry. What a novel thing to say, that those who are responsible to actually implement the policy could sit in the room and listen. I am not talking about playing a role in negotiating.

Why is this amendment necessary? The bottom line is while the FDA may consult with many of the stakeholders at various points in the process, the drug and device user fee agreements are not negotiated so Members of Congress and the general public know exactly what is in them. Congress is effectively shut out of the process until the negotiated deal behind closed doors is announced. In other words, we are presented with what they have negotiated, and we are basically told: Here is what we want you to pass. At no other point in the legislative process does it happen like this in the Congress of the United States.

The drug and device user fee agreements have significant implications for the American people as well as Congress's ability to do oversight. The No. 1 role of the Congress of the United States is to serve on behalf of the American people as an oversight tool over Federal agencies. Congress should not have to read between the lines of the minutes of a negotiation to try to figure out, in fact, the spirit of those negotiations. The ability for Congress and the American people to fully understand and weigh the negotiated agreements and the implications they present for patients, taxpayers, the FDA, and for Congress would greatly be improved by ensuring that Congress might attend the negotiations.

Some of my colleagues will probably come down and suggest this amendment would put Congress at the negotiating table and potentially would jeopardize negotiations. It is not true. It is not what I am attempting to do with this amendment. The amendment merely states if a Member of Congress wants to attend or if they want to have their designated to attend in their place, they may. This amendment does not call for Members of Congress to participate in the negotiation, or certainly staff. The negotiations would still be between the FDA and the industry, but it does ensure that Members of Congress or their staff may be in the room and be informed of the negotiations in real time. Congressional staff may be required to comply with all applicable confidentiality agreements. The FDA's negotiations with the industry would not be jeopardized. Let me say that again to my colleagues: would not be jeopardized because the Members of Congress or the staff would be there just for observation purposes.

Let me suggest that if our being in the room jeopardizes the outcome, then we would not be allowed to attend the Supreme Court when some of the most important cases are tried across the street. But Members of Congress and their staff regularly sit in and listen to the arguments that are made.

The fact is, Congress should not have to wait to be informed of how FDA's public health mission could be strengthened and improved on behalf of patients. By having the option to attend the negotiations, Congress and its staff would gain invaluable insight into how Congress can work with the FDA to ensure the agency is fulfilling its public health mission on behalf of patients.

Congress has a critical role to play in the process. When the negotiated user fee agreements arrive on our doorstep, we are expected to take them up, and we are expected to pass them quickly without change. Let me say that again. We are expected to take them up, we are expected to take them up quickly because we do not want to break the continuity of the user fee agreements, and we are expected to do it without change, because to change those agreements would be to break what was negotiated.

Let me suggest to my colleagues: This is the only time in the legislative process where Congress is asked to take somebody else's negotiated product and not to provide the input of two Senators from every State or every Member of the House of Representatives. It completely goes around the structure, the legislative structure, of the Congress of the United States—something that has been tested and tested for hundreds of years.

So Congress is told to tiptoe around the agreements, and we focus our efforts on belt-and-suspender policies to complement the agreements. This does not make for the most deliberative process in considering how Congress can work with the FDA and industry to strengthen and improve FDA's drug and device work.

As a matter of fact, I would say to my colleagues, as we talk about health care policy in this institution, where our goal today is how we reduce the overall cost of health care, remember, as we sign off on this user fee agreement, every dime that is transferred from the industry to an agency means industry is going to have to raise the price of its products to accommodate what they are paying.

What are we here doing? We are raising the cost of pharmaceutical products, devices, and for the first time we are raising the cost of generics because an industry has negotiated something outside of the walls of the Congress of the United States.

FDA faces unprecedented challenges today—challenges we could not have envisioned a generation ago. The agreements and many of the provisions in the Senate bill are intended to help address these real challenges the agency is facing.

But I ask my colleagues this, in closing: What if they do not? What if they do not address the challenges? What if now generic drugs become more expensive than some people can pay because of this agreement? That is why it is absolutely crucial that Congress play a part in this role to balance this policy.

Where will we be in 5 years when it is time to renegotiate this agreement? Well, I hope we are in a much better situation than we are today, that we actually have the right matrix in place through this legislation—not something that was negotiated between the FDA and the industry but something that the Senate of the United States put into this language that gives people on both sides of the aisle the ability to have a yardstick of measurement of success. Did the agency live up to what they promised the industry and, more importantly, does that compute to a beneficial product for patients across this country? I hope that is what we will find 5 years from now. It is what we have tried to construct in a very difficult and challenging piece of legislation.

I will tell my colleagues, this is not an amendment I will ask for a vote on. At the end of the day, the reality is this probably upsets the apple cart a little too much. But I think it is absolutely crucial that somebody ask the questions of how can Congress legitimately stand here and allow something this complex and this important to be negotiated without the input, the full input of the Congress of the United States.

Again, I conclude the same way I started: I think Chairman HARKIN and Ranking Member ENZI have done a magnificent job of navigating a very difficult issue, and they deserve a tremendous amount of credit for taking a negotiated product and incorporating what I think are some very positive changes that make this a better product than was negotiated by the private sector and the agency.

My only wish is that the next time we do this, we will not have to try to figure out why certain things happened in the negotiations, we will be privy to those negotiations, and we will better understand collectively how we can take an agency and an industry and public policy and move it in a situation where the American patients are the beneficiaries of it in a much more effective way than I think we have today.

I yield the floor.

The PRESIDING OFFICER. The Senator from Wyoming is recognized.

Mr. ENZI. Madam President, I thank the Senator for his comments and his insight and his idea. I appreciate that we are not going to be voting on this one right away because I think this needs a little time to germinate. I

think it is something that, as people look at it and think about it, they will recognize the value there would be if we had more insight into what the negotiations were—not just on this but perhaps on regulations that are being done as well.

I want to thank the Senator, though, for the way he has dug into the entire user fee bill and made some very substantial changes in a number of other places. I do not know of anybody who works as hard on the medical issues as does Senator BURR, and understands it, and gets into some of the details. And, of course, he worked all of these when he was in the House and now works them in the Senate, and is our foremost expert on any of the pandemic issues and was very successful earlier in the year in getting that bill through the Senate. He has been very cooperative on the other amendments which are now a part of the bill that we will not be voting on because they are already in there. I appreciate this one more suggestion and suggest that is something we should take a look at.

I yield the floor and reserve the remainder of the time.

The PRESIDING OFFICER. The Senator from Iowa is recognized.

Mr. HARKIN. Madam President, I join Senator ENZI in thanking Senator BURR for being not only a very valuable member of our committee but I would say the Senator's fingerprints are a lot on this bill we have before us. He has worked very hard on this bill and I think helped to improve it every step of the way over the last year.

I was looking through the list of different things here. Senator BURR was one of the leaders in our working group on the supply chain, which we have in this bill to make sure those things coming from other countries have good manufacturing practices on them and we can keep track of them.

The provision of clarifying the ''least burdensome'' standard on clinical data for device approval was also the result of the Senator's hard work. The Senator was also in the working group on the GAIN bill regarding antibiotic incentives for getting more incentives for new antibiotics. And there was a Burr-Coburn bill regarding enhanced reporting requirements for FDA, and that basically is also included in the bill we have in front of us.

So in every respect, the Senator from North Carolina is a great member of our committee, a very valuable member of our committee. As I said, we are looking at the amendment he has now brought up, and I am sure, as Senator ENZI said, we will be talking about this in the next few hours and going into tomorrow. But I again want to pay my respect to the Senator from North Carolina and thank him for all the hard work he has done on this bill.

I yield the floor.

The PRESIDING OFFICER. Who yields time?

The Senator from Minnesota is recognized.

Mr. FRANKEN. Thank you, Madam President.

Madam President, I wish to thank my friends on both sides of——

The PRESIDING OFFICER. Who yields time?

Mr. HARKIN. Madam President, an inquiry: Is the Senator bringing up—— no, the Senator does not have an amendment pending.

Mr. FRANKEN. I wish to speak on the FDA bill.

Mr. HARKIN. The Senator wishes to speak on which amendment?

Mr. FRANKEN. Not on an amendment, just on the bill overall.

Mr. HARKIN. Madam President, how much time is remaining on the Grassley amendments, the amendments offered by the Senator from Iowa?

The PRESIDING OFFICER. The Senator from Iowa has 9 minutes and the time in opposition is 15 minutes.

Mr. HARKIN. How much time does the Senator wish to take?

Mr. FRANKEN. Well, about 10 minutes.

Mr. HARKIN. I would ask that 10 minutes of the time in opposition to the Grassley amendment be allocated to the Senator from Minnesota.

The PRESIDING OFFICER. Is there objection?

Without objection, it is so ordered.

Mr. FRANKEN. I object to the Grassley amendment.

I am joking.

The PRESIDING OFFICER. The Senator from Minnesota.

Mr. FRANKEN. Thank you. I thank the Senator from Iowa for the time.

Madam President, I thank my friends on both sides of the aisle for their work on the legislation we are considering today. The Food and Drug Administration Safety and Improvement Act is not only among the most important piece of legislation we will consider this year, it is also the product of more than a year's hard work and negotiation.

This legislation will help support a culture of innovation in this country. It will help millions of Americans access the lifesaving medications and devices they need, when they need them. As a member of the HELP Committee, I am proud of the bipartisan bill before us today and look forward to passing it into law.

Let me tell you why. Of course, the Presiding Officer spoke so eloquently about this bill earlier. The Presiding Officer does not have to know why, but let me tell you a story about a little girl in Minnesota—from our State—named Josie.

Josie seemed perfectly healthy when she was born, but at 9 months of age Josie's parents found out she had a rare congenital heart disorder, a condition with the scary name of ''atrial septal defect,'' which means she had a hole in the wall between the upper two chambers of her heart.

When the doctors tested her, they found Josie had not one, not two, but three holes in her heart. It became clear that what was originally a fairly simple surgery to repair the hole was actually a lot more complicated.

But Josie was lucky. Josie's parents live in Minnesota, and Josie's doctor, Dr. Daniel Gruenstein, works at the University of Minnesota. Dr. Gruenstein was able to operate on Josie's heart because he had a brandnew device the FDA had approved only months before. The device, which was also developed in Minnesota, saved Josie's life. Because of this procedure, Josie was acting like her same old silly self the very night of her operation, and she walked out of the hospital the next day.

A few years later when Josie's little sister Jenna was born with the same congenital heart defect, Dr. Gruenstein repaired her heart using the very same device. But too many children like Josie and Jenna are not so lucky. Too many children do not have access to the medical technology they needed to save their lives or to prevent their illness or to help them recover from their rare condition. That is because too many medical devices get stuck or delayed in the agency that regulates our medical technologies. It is because we do not do enough to support a culture of innovation in this country.

The Food and Drug Administration has a tough job. The technologies they regulate are moving at the speed of light, and they do not have the workforce or the expertise to know everything about every new treatment.

In fact, the number of annual 510(k) submissions—that is the most common kind of new device application the FDA receives—has quadrupled since 1976. That is why when the HELP Committee sat down to develop this legislation, we agreed we had to streamline the FDA's processes and make them more efficient. We agreed we had to do more to support a culture of innovation which will help manufacturers get safe technologies and treatments to patients. That is exactly what the bill does. I thank both the chairman and the ranking member.

It requires the FDA to stop using ''FDA days'' and start using regular calendar days like everyone else. It lifts restrictive constraints on the FDA's consultation with outside experts, something the Presiding Officer knows well—outside experts such as are at the University of Minnesota. It creates new incentives for manufacturers that develop treatments for people with rare diseases and conditions like Josie's and Jenna's. These provisions will support innovation and will remove redtape from the process.

The three provisions I championed are included in this legislation in addition to the base bill which we negotiated as a committee. The first provision will strengthen the Food and Drug Administration's workforce by removing overly restrictive requirements that keep the FDA from consulting with outside experts, again something the Presiding Officer has been a leader

on as well. This provision will change the rules that keep the FDA from talking with many outside experts. It will make these rules consistent with those of all other agencies, including the National Institutes of Health, so as the FDA's experienced workforce retires, the FDA will be able to consult with leading experts when they are reviewing a new technology or a new treatment for a rare disease.

This provision will give the FDA the flexibility it needs to consult with experts and keep patients safe, and at the end of the day that means more patients will get the health care they need.

The second provision will require the FDA to remove new and burdensome guidance on the industry that could triple the number of required new submissions for existing devices. This provision, which Senator BURR from North Carolina also championed, will prevent this guidance from overburdening both the industry and the FDA, which could have caused innovation to come to a screeching halt.

My third provision will help companies develop innovative new products for patients across the country with rare conditions. According to the National Institutes of Health, 25 million Americans struggle with a rare disease, and these patients have to jump hurdle after hurdle to get the care they need. Many of them will go from doctor to doctor for years before they find a specialist who understands their condition.

If you live in rural Minnesota, you may have to drive hundreds of miles to find a doctor who can help you. Even for patients who find the right doctor, too often the treatment for their condition does not exist, or has not been approved. So my provision will reward companies that choose to develop treatments for patients with rare diseases.

We did this in 2007 to help companies develop devices for children with rare conditions, and we saw the number of devices that companies developed quadruple in a few years. This provision will help get treatments to adult patients with rare conditions in Minnesota and around the country and around the world.

Minnesotans know what it means to foster a culture of innovation. Our manufacturers have developed new treatments for everything from skin lacerations to brain aneurysms. This bill will go farther to support this kind of innovation by streamlining the processes that are currently impeding investment in new technologies and making the FDA more efficient and predictable.

This legislation will help patients in Minnesota access the medical technologies they need, just like Josie and Jenna. And in a time of economic hardship, it is an investment in one of our country's strongest industries, one of our State's strongest industries. This bill is a step toward a healthier future for our country. I look forward to making sure it becomes part of our law.

I yield the floor.

The PRESIDING OFFICER. The Senator from Alaska is recognized.

AMENDMENT NO. 2108

Ms. MURKOWSKI. Madam President, I ask unanimous consent to call up amendment No. 2108.

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

The clerk will report.

The bill clerk read as follows:

The Senator from Alaska [Ms. MURKOWSKI], for herself, Mr. BEGICH, Mr. MERKLEY, Mr. SANDERS, Mr. LEAHY, and Ms. CANTWELL, proposes an amendment numbered 2108.

Ms. MURKOWSKI. Madam President, I ask unanimous consent that the reading of the amendment be dispensed with.

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

The amendment is as follows:

(Purpose: To prohibit approval by the Food and Drug Administration of genetically engineered fish unless the National Oceanic and Atmospheric Administration concurs with such approval)

At the end of title XI, add the following:

SEC. 11___. ANALYSES OF APPLICATION FOR APPROVAL OF GENETICALLY-ENGINEERED FISH.

Notwithstanding any other provision of law, approval by the Secretary of Health and Human Services of an application submitted under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) for approval of any genetically modified marine or anadromous organism shall not take effect until the date that the Secretary of Commerce, acting through the Under Secretary for Oceans and Atmosphere, approves such application using standards applied by the Under Secretary under the National Environmental Policy Act of 1969 (42 U.S.C. 4321 et seq.), which shall include a Regulatory Impact Review required by Executive Order 12866 (58 Fed. Reg. 51735) and Initial Regulatory Flexibility Analyses required under chapter 6 of title 5, United States Code (commonly referred to as the ''Regulatory Flexibility Act'').

Ms. MURKOWSKI. Madam President, I rise today to speak to an amendment we will have on the floor tomorrow afternoon. This is an amendment that certainly has generated a fair amount of interest within my State, in fact, most of our coastal States, anywhere where we have an interest in seafood and the seafood industry. It has been kind of unceremoniously dubbed the frankenfish amendment, so my apologies to my colleague who just yielded the floor to me. Certainly no affront to him.

But what we are speaking about today is genetically engineered salmon. It has been somewhat affectionately dubbed frankenfish because of the images this genetically engineered fish conjures up, a fish that would literally be growing in size, doubling in size, unlike the fish we see in our streams and in our waters.

What is happening today is the FDA is on a path to approve an application for this genetically engineered fish. I want to discuss the amendment I have filed which would require NOAA to conduct a full environmental assessment and analysis of economic impact to affected fisheries before the FDA approves any of these genetically engineered fish.

I start my comments by saying I am not looking to pull the plug on the FDA. I am not looking to insert Congress's judgment into the FDA process. I am asking that when we are talking about basically a new fishery for a modified salmon, I am asking the agency that is tasked with our fisheries have some role in what is moving forward. So let me give you a little background in terms of what we are talking about with this genetically engineered fish, this frankenfish. This would be a fish, an Atlantic salmon, that has DNA spliced from a Chinook salmon with that of what they call an ocean pout, which is some kind of an eel type of a fish that apparently is in colder waters. But the technology the FDA is looking at that would allow for this genetic engineering would essentially provide for a fish that would grow to market size in about half the time of a conventional salmon. In other words, a salmon out in the wild takes about 30 months to gain full maturity. With this frankenfish, this genetically modified salmon, they could be of good market size, basically good eating size, within about 15 to 18 months.

You are thinking, okay, well, how can this be bad? We get a salmon that looks like a salmon, and it comes to us in half the time. So how can this be a bad thing? I wish to share with you why I feel this is a bad thing. When I am talking, you will hear me talking about salmon, because that is what the FDA process is engaged with right now. But I will tell you we understand that similar efforts are underway to develop a genetically modified trout, as well as a genetically modified tilapia, again, designed to grow faster than occurs in nature and out in the wild.

The pending application for the salmon would be the very first food from a transgenic animal that has been approved by the FDA, so this is precedent setting. People have suggested that, well, we see this in other forms of agriculture. But the fact is this would be the first food from a transgenic animal application that has been approved by the FDA, so this is quite precedent setting.

What is happening is this approval process for the genetically engineered fish continues to move forward as a new animal drug, rather than what it is, what I mentioned before, which is a new fishery for this modified salmon, this salmon that has been tinkered with, basically a test-tube salmon.

Here are the reasons why I think this is a bad thing, to be messing with Mother Nature, to encourage this unnatural growth. We heard on the floor this morning—the Senator from New Jersey and the Senator from New York both stood and talked about a measure

that is out there, the march that was out on the Capitol yesterday, mothers concerned about toxins in the food supply, toxins in the world around us, and knowing what is out there, knowing what we are exposed to.

Well, I, along with many consumers out there, am concerned about genetically engineered animal products that are intended for human consumption, including those that are in our marine resources. I am not the best cook in the family; my husband is. But I want to know, he wants to know, our kids want to know, that what we are eating is good and safe and sound.

At home, we eat a lot of salmon. I can stand there and tell my kids: Eat this. This is brain food. This is good for you. It is loaded with omega-3 fatty acids. It is as good as you can possibly get. I can say that with certainty.

We cannot say that, we will not be able to say that with this genetically engineered fish. As a mom, I am not going to say to my kids: Eat this frankenfish. Not quite sure what an eel pout is or an ocean pout; not quite sure how they splice this DNA together; not quite sure whether they have made it sterile.

We are not quite sure what it is, but it came to market quickly, and we are going to be able to get a cheaper price on it. I think we want to know.

The scary thing with the FDA right now is that they are reluctant to label genetically engineered products, even though it allows the public to know what they are eating. The data out there is pretty clear that there are higher human allergen effects with genetically engineered fish. If you are a mom and your kids have allergies, are you going to look at this fish and say: I wonder if this is going to set allergies off. No. You are going to stay away from it. You will not serve that to your kids or your family even though you know the wild stuff is good and healthy. But how do you know which is which if the FDA isn't moving forward to label and you are not quite sure that what you are buying in the grocery store is as advertised? How are we helping the consumer here?

The first problem I have is that this is, again, a product that is intended for human consumption, and we have some real concerns about the safety of the food in the first place. Second—and this is one that, as an Alaskan, where we have very strong fisheries, very healthy fisheries, I worry about what will happen if, in fact, there was escapement into the wild by these genetically engineered fish. You have a frankenfish that gets loose. They will tell you: They are going to be in pens, and we will make sure there is no escape. How can they make sure we are not going to see escapement? We have seen that, clearly, from the farm fish that mingle with the wild stock. We see the disease that can be transmitted. How is any of this good? Even though the genetically engineered fish supposedly is going to be kept in onshore pens, the possibility of escape is recognized, it is out there, and it exists.

Then you are going to have these genetically engineered fish that will breed year-round. They are also going to be eating year-round. They are going to be feeding year-round. What you can very possibly see is this competition with the wild stock. They will compete with one another for the food the species feeds on, and they will wreak havoc with the ecosystem. So you can introduce—granted, not intentionally—into the ecosystem that fish that just doesn't work with our wild stock. Unlike hatchery produced fish, genetically produced fish would reportedly be sterilized and their hormones altered. But many scientists believe that the FDA testing to confirm the agricultural safety and sterilization of these fish is deficient. We see this in the CRS report that has looked specifically to this issue.

Unlike other agricultural products, if you have an escape of frankenfish, it would be to an uncontrolled marine environment, exposing valued ecosystems to associated risks. If you have a cow that has been genetically modified and that cow is on land and gets out of the pen, you have more ability to control that. You don't have the ability to control in a marine environment. It is just not possible. So what is happening is that we are putting at risk the health and safety of our wild stock. Unacceptable.

Third, many find the FDA process for approving an animal product intended for human consumption as it would a veterinary drug to be insufficient. It lacks the robustness and transparency one would expect for a product that would be treated as a substitute for fish that is currently on our dinner plates in this country today.

The CRS report which I just mentioned will be introduced for the RECORD. It is a report by CRS, dated June 7 of last year, titled ''Genetically Engineered Fish and Seafood: Environmental Concerns.''

One of the concerns raised in this report is this:

> A National Research Council report stated that transgenic fish pose the ''greatest science-based concerns associated with animal biotechnology, in large part due to the uncertainty inherent in identifying environmental problems early on and the difficulty of remediation once a problem has been identified.

Our fishermen are very highly regulated, and any change to a Federal fishery, including a new GE fishery, should be analyzed for environmental effects and economic impacts to affected businesses and fishing communities. We are bringing NOAA in to be part of this process in this amendment.

The last point I will make on this is that there could be very significant economic consequences of approving genetically engineered fish. Historically, the entrance and growth of farmed salmon in the marketplace has had negative impacts on our salmon industry. We have an incredible abundance in the wild stocks, and we are very proud of it. The seafood industry in Alaska is our second largest employer, valued at $500 million with salmon alone. But the concern is that, although we have very strong wild stocks, we could see the market respond with unreasonable fear and confusion to the introduction and growth of engineered fish, particularly if it is not labeled. This, in my opinion, could have a devastating economic impact on our fish industry and the jobs it supports, clearly at a time that our Nation can't afford it.

Some will come back and say: Hey, this is a new industry, it is going to create new jobs.

I will take you back to that CRS report. One of the things I find interesting is that it says:

> To address these concerns, AquaBounty has proposed producing salmon eggs in Canada, shipping these eggs to Panama, growing and processing fish in Panama, and shipping table-ready, processed fish to the United States for retail sale.

They would ship these frankenfish to the United States for resale. So basically we get all the harm, but we don't get any jobs. But what we are doing is putting at risk the existing jobs within the seafood industry in this country—priority No. 1.

I see that my time has expired.

I commend to my colleagues this CRS Report dated June 7, 2011.

I ask unanimous consent that two letters of support for my amendment be printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

CONSUMERS UNION,
Washington, DC, May 23, 2012.

Hon. LISA A. MURKOWSKI,
U.S. Senate,
Washington, DC.

DEAR SENATOR MURKOWSKI: Consumers Union, (CU) the advocacy and public policy arm of Consumer Reports®, urges you to support Senator Murkowski's amendment to the Food and Drug Administration Safety and Innovation Act (S. 3187), which would require additional approval by the Secretary of Commerce of GE fish applications using standards applied by the Under Secretary under the National Environmental Policy Act of 1969 (42 U.S.C. 4321 et seq.).

Consumers Union has frequently spoken out on the issues and concerns surrounding the approval of genetically-engineered salmon for human consumption. Among our many concerns is that not enough research has been carried out to determine the increased potential of Aquabounty GE salmon to cause allergic reactions in humans. CU's Dr. Michael Hansen, a Ph.D. biologist, testified at the FDA hearing on this matter that Aquabounty's assessment of the potential for allergic reactions was based on just six (6) engineered fish. We believe that a much larger assessment involving hundreds to thousands of fish should be conducted. FDA has also indicated that once GE salmon are approved for human consumption, it does not intend to require labeling—a position CU strongly opposes.

We are also concerned about the potential environmental impacts of genetically-engineered fish, and particularly in regards to the impact that GE salmon would have on

the wild Alaska salmon population. Alaska wild salmon is a tasty, healthful, low-cost, and low mercury canned fish alternative. Consumers Union recommends it for pregnant women and young children who should limit mercury intake. However, some studies have shown that if GE salmon were to escape into the wild, they could potentially have serious effects upon the wild salmon population.

Consumers Union urges you to support the Murkowski amendment, in order to ensure that GE fish applications undergo an additional environmental impact review. Should you have any questions, please do not hesitate to contact me at (202) 462–6262.

Sincerely,

IOANA RUSU,
Regulatory Counsel.

TROUT UNLIMITED,
Arlington, VA, May 22, 2012.

Re Support for Murkowski genetically engineered fish amendment to S. 3187

To: U.S. SENATE

On behalf of Trout Unlimited and its 140,000 members nationwide I write to urge you to support the Murkowski amendment to ensure adequate study of genetically engineered fish prior to FDA approval. The amendment to S. 3187 prohibits approval by the FDA of genetically engineered fish unless NOAA concurs with such approval.

The acute need for this amendment is illustrated by the flawed process currently being used to review an application for commercial production of genetically modified salmon. AquaBounty Technologies has requested FDA approval for the production and marketing of genetically modified Atlantic salmon as a new animal drug. Asking the FDA to consider impacts to wild salmon is like going to a chiropractor to get your eyes checked. The FDA's pending decision has extraordinary implications for wild salmon, yet the agency with a mission to conserve and manage wild salmon—NOAA—has not been asked to analyze potential impacts, and does not have a say in the final decision. The Murkowski amendment simply states that the agency with expertise in the affected resource, NOAA, must be involved in a decision that could profoundly impact anadromous fish.

Trout Unlimited's mission is to conserve, protect and restore North America's trout and salmon fisheries and their watersheds. We work to protect healthy runs of wild salmon in places like Alaska's Bristol Bay, and restore depleted runs through habitat restoration projects on the Atlantic and Pacific coasts. Wild salmon and other anadromous fish are too important commercially, recreationally, and culturally to be put at risk by decisions that failed to adequately consider the potential impacts.

Trout Unlimited strongly supports the Murkowski amendment, and encourages you to vote Yes when the amendment is offered.

Sincerely,

KEITH CURLEY,
Director of Government Affairs.

The PRESIDING OFFICER. The Senator from Maryland.

AMENDMENT NO. 2125

Mr. CARDIN. Madam President, I ask unanimous consent that the pending amended be set aside so that I may call up amendment No. 2125.

The PRESIDING OFFICER. Without objection, it is so ordered. The clerk will report.

The legislative clerk read as follows:

The Senator from Maryland [Mr. CARDIN] proposes an amendment numbered 2125.

The amendment is as follows:

(Purpose: To ensure that adequate information is disseminated to health care providers and payors about the potential benefits and risks of medical products on all patient populations, particularly underrepresented subpopulateds, including racial subgroups)

At the end of title XI, add the following:

SEC. 11___. ENSURING ADEQUATE INFORMATION REGARDING PHARMACEUTICALS FOR ALL POPULATIONS, PARTICULARLY UNDERREPRESENTED SUBPOPULATIONS, INCLUDING RACIAL SUBGROUPS.

(a) COMMUNICATION PLAN.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary''), acting through the Commissioner of Food and Drugs, shall review and modify, as necessary, the Food and Drug Administration's communication plan to inform and educate health care providers, patients, and payors on the benefits and risks of medical products, with particular focus on underrepresented subpopulations, including racial subgroups.

(b) CONTENT.—The communication plan described under subsection (a)—

(1) shall take into account—

(A) the goals and principles set forth in the Strategic Action Plan to Reduce Racial and Ethnic Health Disparities issued by the Department of Health and Human Services;

(B) the nature of the medical product; and

(C) health and disease information available from other agencies within such Department, as well as any new means of communicating health and safety benefits and risks related to medical products;

(2) taking into account the nature of the medical product, shall address the best strategy for communicating safety alerts, labeled indications for the medical products, changes to the label or labeling of medical products (including black box warnings, health advisories, health and safety benefits and risks), particular actions to be taken by healthcare professionals and patients, any information identifying particular subpopulations, and any other relevant information as determined appropriate to enhance communication, including varied means of electronic communication; and

(3) shall include a process for implementation of any improvements or other modifications determined to be necessary.

(c) ISSUANCE AND POSTING OF COMMUNICATION PLAN.—

(1) COMMUNICATION PLAN.—Not later than 1 year after the date of enactment of this Act, the Secretary, acting through the Commissioner of Food and Drugs, shall issue the communication plan described under this section.

(2) POSTING OF COMMUNICATION PLAN ON THE OFFICE OF MINORITY HEALTH WEBSITE.—The Secretary, acting through the Commissioner of Food and Drugs, shall publicly post the communication plan on the Internet website of the Office of Minority Health of the Food and Drug Administration, and provide links to any other appropriate webpage, and seek public comment on the communication plan.

AMENDMENT NO. 2141

Mr. CARDIN. Madam President, I ask unanimous consent that that amendment be set aside so I may call up my amendment No. 2141.

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

The clerk will report.

The legislative clerk read as follows:

The Senator from Maryland [Mr. CARDIN] for himself, and Ms. LANDRIEU, proposes an amendment numbered 2141.

The amendment is as follows:

(Purpose: To require the Commissioner of Food and Drugs to report to Congress on issues with respect to small businesses)

At the end of title XI, add the following:

SEC. 11___. REPORT ON SMALL BUSINESSES.

Not later than 1 year after the date of enactment of this Act, the Commissioner of Food and Drugs shall submit a report to Congress that includes—

(1) a listing of and staffing levels of all small business offices at the Food and Drug Administration, including the small business liaison program;

(2) the status of partnership efforts between the Food and Drug Administration and the Small Business Administration;

(3) a summary of outreach efforts to small businesses and small business associations, including availability of toll-free telephone help lines;

(4) with respect to the program under the Orphan Drug Act (Public Law 97–414), the number of applications made by small businesses and number of applications approved for research grants, the amount of tax credits issued for clinical research, and the number of companies receiving protocol assistance for the development of drugs for rare diseases and disorders;

(5) with respect to waivers and reductions for small business under the Prescription Drug User Fee Act, the number of small businesses applying for and receiving waivers and reductions from drug user fees under subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379f et seq.);

(6) the number of small businesses submitting applications and receiving approval for unsolicited grant applications from the Food and Drug Administration;

(7) the number of small businesses submitting applications and receiving approval for solicited grant applications from the Food and Drug Administration;

(8) barriers small businesses encounter in the drug and medical device approval process; and

(9) recommendations for changes in the user fee structure to help alleviate generic drug shortages.

Mr. CARDIN. Madam President, I rise to discuss the FDA Safety and Innovation Act, the bill now under consideration here in the Senate.

I applaud Chairman HARKIN and Ranking Member ENZI for their leadership in moving this critical legislation through the HELP committee, and now to the Senate floor.

As an agency of the Department of Health and Human Services, the FDA has as part of its broad mission to protect Americans' health by assuring the safety of drugs, biologics, medical devices, our Nation's food supply, vaccines, tobacco, cosmetics, and animal food and drugs. Every single day, every single American depends on the vital work of FDA's employees.

There is a second key element to the FDA's work—helping to speed innovations to the marketplace through the drug, biologic, and medical device approval process. It's that component of the FDA's mission that we are addressing this week—reauthorizing the user fees that help fund the approval process.

I'm proud of the FDA's workers—the majority of the agency's more than 11,000 employees are based at its headquarters in Silver Spring, MD. It's

there that the process of medical innovation, which begins at NIH with basic research, is completed as lifesaving drugs and medical devices are approved for use.

A recent report from the IMS Institute for Healthcare Informatics found that in 2011 ''medicines with new mechanisms of action were launched in greater numbers than in prior years, with many representing significant breakthroughs and first-time therapies became available to treat several types of cancer, multiple sclerosis, hepatitis C, and cardiovascular conditions.''

At the same time, we know that greater resources are needed for the agency to be able to fulfill its mission in a timely and effective manner. For all of our Nation's investment in health care research, additional new medicines will not reach patients promptly unless the FDA has the necessary funds to perform its regulatory duties.

That's why the user fee amendments are so important. This 5-year reauthorization bill is Congress' opportunity to improve and update the regulatory process, and augment appropriations so that the agency can achieve its goals.

The purpose of the user fee program is to reduce the time in which FDA can review and make decisions on marketing applications. Lengthy review times affect drug and medical device manufacturers, who face delays in bringing their products to market, and more importantly they affect patients, who face delays in receiving needed treatments and cures.

The bill reported out of committee will move us forward. It will reauthorize the prescription drug user fee program, PDUFA, through October 1, 2017.

This is necessary so that the Federal Goverment can continue to collect application, establishment, and product fees from drug companies to support the review process for the next five years.

It will also reauthorize the medical device user fee program, MDUFA, through 2017 as well, and in an effort to ensure that the FDA's personnel needs are met, it would authorize a streamlined hiring of employees. Additionally, the Critical Path Public-Private partnerships, which are so important in encouraging medical product innovation, are reauthorized through 2017.

Two new user fee programs are established in the bill for generics and one for biosimilars. It's estimated that the monies generated from the generic user fee program will enable the FDA approval time for generics to be shortened from the current time frame of 30 months to 10, speeding savings to patients and to all taxpayers, as Medicare, Medicaid, and CHIP programs will reap considerable cost savings.

The base bill takes key first steps toward resolving the vexing issue of drug shortages. I want to acknowledge Senator KLOBUCHAR's work in this area.

All of us have heard from our community hospitals and physicians about the anguish they feel when they cannot secure medicines necessary to treat the patients in their care. I certainly have, and I have also heard from patients themselves who cannot fathom how such shortages could occur.

Carey Fitzmaurice of Bethesda, who is undergoing treatment for ovarian cancer, wrote to me:

> My doctor put me on Doxil and carboplatin to try to get rid of some tumors. Doxil was chosen because of recent research showing that it works especially well in those patients with the BRCA gene, like me.
>
> I had four treatments with both drugs and was responding very, very well. I have now missed three doses of Doxil due to the shortage. I am ''treading water'' with the Carbo but am frustrated that I am no longer making progress towards remission. Then there is all of the stress involved with the shortage—not knowing if there is anything I can do, or what will happen next or how long I will be in treatment.
>
> I am trying to continue to be a wife and mother and to hold down a job. This shortage is adding insult to injury. I wonder why we are being asked to raise money to find cures when we can't even get access to the cures that exist now.

Carey is one reason why I am a cosponsor of Senator KLOBUCHAR's bipartisan bill, the Preserving Access to Life Saving Medications Act, and I am pleased that the bill's early notification requirement provisions are included in the PDUFA bill we are considering today. It also requires the Secretary to establish a task force and create a strategic plan to address shortages.

This is also an urgent matter because shortages affect the ability to conduct clinical trials. Senator ROCKEFELLER and I worked together some years ago to get Medicare beneficiaries coverage for the routine costs associated with clinical trials.

As a result of Senator BROWN's work on the Affordable Care Act, insurance companies now must also cover the routine costs of trials. Access to trials often means the difference between life and death for cancer patients, and the availability of trials has enormous implications for the effectiveness of treatments for all patients going forward. There are more than 150 cancer clinical trials being conducted now at the NIH Clinical Center in Bethesda.

But the impact of shortages on clinical trials has not received a great deal of attention outside the research world. It is an extremely important issue for Medicare beneficiaries, who have the highest rates of cancer incidence. Cancer trials do not usually use placebos.

Rather, they compare standard of care drugs, versus, or in combination with, the experimental drug.

Doctors face difficult choices when the standard of care drug is in short supply. They must decide whether to use the limited supply of an existing drug to treat new patients, or use it in clinical trials to help find a cure for those who are seeking new therapies. Cancer trials have been delayed, limited the number of patients enrolled in the trial or stopped the trial entirely because there is simply not enough of the standard of care drug.

So I am pleased that the bill contains language requiring the Secretary's strategic plan to considering the impact of drug shortages on research and clinical trials.

The Finance Committee held hearings on drug shortages earlier this year as well, and we learned that the majority of shortages are found in the generic drug market. Some are due to a lack of raw materials, while others occur because the drugs yield lower profits than newer generics, and the interest in continuing to market those drugs is no longer there.

The notification language in this bill is a good start, but I believe it should be strengthened to better ensure compliance, and so I have cosponsored Senator BLUMENTHAL's amendment establishing civil monetary penalties for manufacturers who knowingly fail to notify the FDA of shortages for essential medicines.

I express my appreciation to Senator PRYOR for his leadership on nanotechnology. I am pleased to join him in this effort and am hopeful that the language we have sponsored can be included in this bill.

Nanotechnology has become increasingly indispensible in our daily lives—everything from cellphones and MP3 players, to packaging of our snack foods, to cancer treatments in development employ the use of nanotechnology.

As this burgeoning technology continues to power more of our consumer products and drive job creation in America, it is essential that we fully assess, understand, and address any risks that it may pose to safety, public health and our environment.

By soundly assessing the safety of nanotechnology and developing best practices, the Nanotechnology Regulatory Science Act of 2011 will further job creation, public safety and growth in the industry.

Our bill would establish a program within the FDA to assess the health and safety implications of using nanotechnology in everyday products, and develop best practices for companies using nanotechnology. This new program would bring more highly-skilled research jobs to Maryland.

FDA's laboratories and research facilities at its consolidated headquarters are ideally suited to conduct the scientific studies required under the bill.

The USDA's Beltsville Agricultural Research Center, BARC, is similarly equipped to provide innovative scientific technology, training, methods development, and technical expertise to improve public health.

Lastly, I urge my colleagues to support language addressing the lack of available information on the benefits and adverse effects of drugs and medical devices for minority populations.

Today, warnings and safety precautions are included as part of the initial approval by the FDA. The Agency

may also require them post approval—after the drug has been approved and sold for months or years. We know that additional side effects or risks may become known once a product is in the market and a much larger, diverse patient population is using it.

Ideally, a detailed conversation between physician and patient about the risks versus the potential benefit of taking a drug would always take place in a timely and informed manner. However, this is not always the case and is especially true if the warning is added after drug is initially prescribed and been on the market for an appreciable time period.

The randomized controlled trials used by the FDA when reviewing new drug applications, while the gold standard for examining efficacy, do not necessarily reflect the overall population for a variety of reasons.

For example, members of minority groups are generally underrepresented in clinical drug trials even though they are disproportionately affected by diseases such as diabetes, hypertension, colorectal, prostate and cervical cancer, stroke, congestive heart failure, acute coronary disease, and asthma.

We know that there are racial and ethnic differences in responses to pharmaceuticals, and they may not become known until the drug is in wide use, certainly beyond the constraints of a controlled clinical trial.

In today's world, post-approval surveys and studies are becoming more prevalent, and our ability to discern the effect of a drug over time on a variety of patient types is significantly improving. This information should be made available in a variety of ways to ensure that it reaches physicians, payors and patients, and I have filed an amendment that would greatly improve access to this information.

It would build on the current HHS ''Strategic Action Plan to Reduce Racial and Ethnic Health Disparities'' by directing the Secretary to develop a communications plan to ''address the best strategy for communicating safety alerts, changes to the label or labeling of drugs, including black box warnings, biological products or devices, health advisories, any information identifying particular subpopulations, and any other relevant information as determined appropriate to enhance communication, including varied means of electronic communication.''

This amendment has the support of the chairman and the ranking member, as well as the FDA and BIO, and I urge the Senate to adopt it.

Mr. President, PDUFA reauthorization is essential to furthering the Nation's health, bringing the medical innovations conceived by researchers and entrepreneurs into practice, and creating jobs. I look forward to working through the process to improve this bipartisan legislation.

Again, I thank and congratulate Senator HARKIN and Senator ENZI for their incredible work in bringing forward this bill that is so important to the public health of our Nation. We are dealing with the safety of drugs, biologics, medical devices, our Nation's food supply, vaccines, cosmetics, and the list goes on and on. It is critically important that we have the proper authorization so that the FDA has the resources it needs to advance innovation into the marketplace, products that fall within the jurisdiction of the FDA.

We know that the basic research has gone on at NIH. To get products to market, it is important that the FDA have the resources in order to move the process forward. I am proud of the 11,000-member workforce headquartered in Silver Spring, MD, for the FDA. They work very hard. This reauthorization legislation of the user fees will give them the tools in order to get the job done. I am particularly impressed that this is a 5-year reauthorization bill that will give them predictability, which is needed in order to get the job done.

I applaud Senator HARKIN and Senator ENZI. We don't see enough of these bills moving forward with the type of process our leaders have brought forward. They have resolved a lot of the issues, and we thank them for that. They have brought us a bill that enjoys broad bipartisan support and is in the best interest of our Nation. I am proud to support this legislation, and I thank them for the manner in which they have proceeded in committee and now on the floor.

Also, I point out that this bill deals with the drug shortage issues. I applaud the occupant of the chair, Senator KLOBUCHAR, and her efforts in dealing with those issues. We need more effective notification of potential shortages so that we can take appropriate action to make sure the people of this Nation have an adequate supply of medicines.

Let me share with my colleagues a letter I received from Carey Fitzmaurice of Bethesda, MD, who is undergoing treatment for ovarian cancer. She wrote:

> My doctor put me on Doxil and carboplatin to try to get rid of some tumors. Doxil was chosen because of recent research showing that it works especially well in those patients with the BRCA gene, like me.
>
> I had four treatments with both drugs and was responding very, very well. I have now missed three doses of Doxil due to the shortage. I am ''treading water'' with the Carbo but am frustrated that I am no longer making progress towards remission. Then there is all of the stress involved with the shortage—not knowing if there is anything I can do, or what will happen next, or how long I will be in treatment.
>
> I am trying to continue to be a wife and mother and to hold down a job. This shortage is adding insult to injury. I wonder why we are being asked to raise money to find cures when we can't even get access to the cures that exist now.

That is a frustration that is out there on drug shortages. I am very pleased that this legislation will move us in the right direction in answering that question.

It doesn't only affect those under active treatment, it also affects a number of clinical trials. There are currently about 150 clinical trials at NIH involving cancer and trying to find answers and cures for cancer. The problem is that on these clinical trials they don't use placebos, they use the current drug therapy that is known for the treatment against an experimental process. If there are not enough drugs available to treat people for the current protocols, how can those drugs be used in a clinical trial. As a result, we are finding it very challenging to move forward with the clinical trials that are needed. This legislation recognizes that concern and specifically deals with it. I congratulate the committee leadership for addressing that issue.

I also will mention one other issue: nanotechnology. I congratulate Senator PRYOR for his leadership in this area. Programs at FDA to access health safety facts and using nanotechnology in everyday products is something we need to do. This legislation advances that. I point out that I am proud that the lab facilities at the FDA are fully capable of dealing with the challenges presented by nanotechnology. This legislation acknowledges that.

We also, in Maryland, are proud of the Beltsville Agricultural Research Center, which will advance nanotechnology and the impact it has on everyday products and safety. Those issues will be addressed also by the underlying bill. We very much appreciate the leadership of the committee.

Let me talk for a moment about the two amendments I have brought forward. Amendment No. 2125 deals with safety warnings, particularly as they affect the minority community. Clinical trials don't always represent the diversity of our community. We know there is underrepresentation of minorities within clinical trials. Quite frankly, when the FDA gives approval, they give approval to the known risks, as I am sure you are all aware, but it doesn't always represent the impact on all communities. We also know there are racial and ethnic differences in response to pharmaceuticals, and they may not become known until the drug is in wide use, certainly beyond the constraints of a controlled clinical trial. So we do have the initial approval of FDA that includes the known risks, but we also have the capacity under FDA to do postapproval warnings. My amendment deals with that aspect.

Health and Human Services has a strategy to deal with minority health and health disparities. It is called the Strategic Action Plan to Reduce Racial and Ethnic Health Disparities. We also now have an institute at the National Institutes of Health that deals solely with minority health and health disparities. We have a commitment to do a better job as a nation in dealing with minority health disparities. This amendment would help us move forward in that regard.

One particular drug that is used to treat an inflammatory disorder has been determined by several studies to have a mortality risk that is three times higher for African-Americans than the general public. However, it is still widely prescribed, and ads for the product on the Internet and on television prominently feature African-American actors.

This is an area in which the National Medical Association and many other groups concerned about the quality of minority health have focused on for years. Beyond the black box warning, which is the most serious warning that can be issued about the side effects of approved drugs, there are other concerns about products that are marketed for the overall population that may have side effects, but the specific data has not been developed yet to warrant a black box warning.

The amendment I have offered directs the FDA to develop communication plans to address the best strategy for communicating benefits and risks, safety alerts, changes to the label or labeling of drugs, including black box warnings, biological products or devices, health advisories, any information identifying particular subpopulations, and any other relevant information as determined appropriate to enhance communication, including a variety of means of electronic communication.

I might point out this amendment has the support of the FDA and BIO, and it is budget neutral. So I would urge my colleagues to support this amendment to advance the commitment we all have made to deal with reducing and hopefully one day eliminating minority health disparities in our health care system. It is totally consistent with the Strategic Action Plan to Reduce Racial and Ethnic Health Disparities at the Department of Health and Human Services.

The second amendment I have brought forward, amendment No. 2141, deals with small businesses. This is a very appropriate amendment, as it is being considered during Small Business Week. We all acknowledge the importance of small business in the growth of our economy. Two out of every three new jobs are created through small business. We get more innovation through our small businesses on a per-employee basis than we do through larger companies. It is critically important small businesses be energized if our economy is going to rebound, as we know it needs to.

This is particularly true as we deal with innovation in drug development or medical devices. My amendment deals with the issues of coordinating the work between the FDA and small business. It provides a listing of the staffing levels at the small business offices of the FDA so that we know the capacity we have and we can evaluate that. It is our responsibility to do that. It provides an overview of the status of partnership efforts between the FDA and the SBA. We want the two agencies, the Food and Drug Administration and the Small Business Administration, to be working in concert to advance the cause for small businesses as well as the mission of the FDA.

My amendment provides a summary of all outreach efforts to small businesses and small business associations. It details the number of small businesses receiving protocol assistance. It shows the number of unsolicited and solicited grant applications to small businesses, again, so we can evaluate that. Most importantly, it calls for the examination of existing barriers, particularly as it relates to the generic drug shortages.

It is interesting that with regard to the fee schedule, the FDA has the authority to do waivers as it relates to brand names. We know a lot of the generics are where we have our shortages because of the economics of the circumstances. But the SBA has limited ability to waive the fee structure as it relates to the general development of generic drugs. My amendment would ask the SBA to report back to Congress on what impact that has on small businesses being innovative in developing generic drugs to help us generally with less costly drugs that are available for treatment, but also to make sure we deal with the drug shortage issue, which I alluded to earlier.

This amendment is also supported by Senator LANDRIEU, the chairman of the Small Business Committee, on which I have the pleasure of serving. I urge my colleagues to support both amendments I have brought forward. I believe they only enhance the strength of the bill before us and are totally consistent with the work of the chairman and the ranking member of the committee.

With that, Madam President, I would again urge my colleagues to support both amendments and to support the underlying bill.

I yield the floor, and I suggest the absence of a quorum.

The PRESIDING OFFICER (Mr. WHITEHOUSE). The clerk will call the roll.

The legislative clerk proceeded to call the roll.

Mr. HARKIN. I ask unanimous consent that the order for the quorum call be rescinded.

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

Mr. HARKIN. Mr. President, how much time remains on the two amendments offered by the Senator from Maryland?

The PRESIDING OFFICER. Six minutes for the majority on amendment No. 2125, and 15 minutes in opposition. For amendment No. 2141, 11 minutes in favor and 15 minutes in opposition.

Mr. HARKIN. Mr. President, I will speak on the time available for the amendments.

AMENDMENT NO. 2125

First of all, amendment No. 2125 will help ensure that health care providers, patients, and payers better understand the benefits and risks associated with drugs, especially with respect to those drugs by underrepresented subpopulations.

I believe this is an important and noncontroversial amendment. I hope we can support this amendment.

AMENDMENT NO. 2141

On the other amendment, No. 2141, which is the small business report, I think it is important FDA give small businesses a helping hand. I understand each FDA center has a small business office and that each of FDA's five regional offices has a small business representative. This report the FDA would have to submit on the basis of the amendment offered by Senator CARDIN would provide Congress with more information about how FDA uses its resources for small businesses to help encourage small companies.

Again, I think this is another valuable addition to our bill and, hopefully, we can support that amendment also. So I thank the Senator from Maryland for his offering these two amendments and for what I consider to be improvements to the underlying bill.

I thank him very much for that.

Mr. President, again, I would say to the Members who may be in their offices that we still have some extra time before we will be adjourning this evening. Again, I would advise Senators that by at least 2 p.m. tomorrow, when the bell rings, we will be moving to voting, if not before then. So any Senator who has an amendment to bring up and who wishes to talk about it, I wish they would come to the floor and do that now.

Mr. President, I yield the floor.

The PRESIDING OFFICER. The Senator from Wyoming.

Mr. ENZI. Mr. President, I would echo the comments of the chairman, and I, too, thank the Senator from Maryland for his amendments. I think everybody appreciates both those amendments and, hopefully, they will become a part of this bill.

I also appreciate all those who have come to speak this afternoon. I know there are still probably a couple of controversial amendments on which Senators should come and speak, and then we might have the possibility of moving some things up a little bit tomorrow so we can get this bill finished expediently.

So I hope if anyone has an amendment, they will come and use their time. I think we have a few minutes in opposition perhaps to two of the amendments that have been debated so far. But that is it, and then I think there are three controversial ones that are left to be debated. One of those has a significant amount of time allocated to it, but the others are limited to 30 minutes equally divided.

So I hope we can take care of some more of those this evening and get started on votes as soon as possible.

I yield the floor, and I suggest the absence of a quorum.

Mr. HARKIN. Mr. President, I ask unanimous consent that the time during the quorum call be divided equally.

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

The clerk will call the roll.

The legislative clerk proceeded to call the roll.

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

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

AMENDMENT NO. 2143

(Purpose: To amend the Federal Food, Drug, and Cosmetic Act concerning claims about the effects of foods and dietary supplements on health-related conditions and disease, to prohibit employees of the Food and Drug Administration from carrying firearms and making arrests without warrants, and to adjust the mens rea of certain prohibited acts under the Federal Food, Drug, and Cosmetic Act to knowing and willful)

Mr. PAUL. Mr. President, I ask unanimous consent to call up my amendment No. 2143.

The PRESIDING OFFICER. The clerk will report.

The assistant legislative clerk read as follows:

The Senator from Kentucky [Mr. PAUL] proposes an amendment numbered 2143.

Mr. PAUL. Mr. President, I ask that the reading of the amendment be waived.

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

(The amendment is printed in the RECORD of Tuesday, May 22, 2012, under ''Text of Amendments.'')

Mr. PAUL. Mr. President, today I am offering an amendment to the FDA.

I am troubled by images of armed FDA agents raiding Amish farms and preventing them from selling milk directly from the cow. I think we have bigger problems in our country without sending armed FDA agents onto peaceful farmers' land and telling them they can't sell milk directly from the cow.

My amendment has three parts.

First, it attempts to stop the FDA's overzealous regulation of vitamins, food, and supplements by codifying the first amendment prohibition on prior restraint.

What do I mean by that? The first amendment says we can't prevent speech—even commercial speech—in advance of the speech. We can't tell Cheerios they can't say that there is a health benefit to their Cheerios.

Under our current FDA laws, the FDA says that if someone wants to market prune juice, they can't say it cures constipation. They can't make a health claim about a food supplement or about a vitamin. They can do it about a pharmaceutical, but they are not allowed to do it about a health supplement. I think this should change. There have been several court cases that show this goes against not only the spirit but the letter of the law of the first amendment. So this amendment would change that.

This amendment would stop the FDA from censoring claims about curative, mitigative, or preventive effects of dietary supplements. It would also stop the FDA from prohibiting distribution of scientific articles and publications regarding the role of nutrients in protecting against disease.

Despite four court orders condemning the practice as a violation of the first amendment, the FDA continues to suppress consumers' rights to be informed and to make informed choices by denying them this particular information. It is time for Congress to put an end to FDA censorship.

Second, my amendment would disarm the FDA. Now, some of you might be surprised the FDA is armed. Well, you shouldn't be. We have nearly 40 Federal agencies that are armed.

I am not against having police. I am not against the Army, the military, or the FBI. But I think bureaucrats don't need to be carrying weapons, and I think what we ought to do is if there is a need for an armed policeman to be there, the FBI—who are trained to do this—should do it. But I don't think it is a good idea to be arming bureaucrats to go on the farms, with arms, to stop people from selling milk from a cow.

I think we have too many armed Federal agencies and that we need to put an end to this. Criminal law is increasingly used as a tool of our government bureaucracy to punish and control honest businessmen who are simply attempting to make a living. Historically, the criminal law was intended to punish only the most horrible offenses that everyone agreed were inherently wrong or evil—offenses like murder, rape, theft, arson. But now we have basically federalized thousands of activities and called them crimes.

If bureaucrats need to involve the police, let's have them use the FBI. But I see no reason to have the FDA carrying weapons.

Today, the criminal law is used to punish behavior such as even fishing without a permit, packaging a product incorrectly, or shipping something with an improper label. Simply said, the Federal Government has gone too far.

The plain language of our Constitution specifies a very few Federal crimes. In fact, the Constitution originally only had four Federal crimes, and now we have thousands of Federal crimes. We have moved beyond the original intent of the Constitution. We don't even know or have a complete list of all the Federal crimes. It is estimated there are over 4,000, but no one has an exact number.

Finally, my amendment will require adequate mens rea protection. In other words, when there is a crime, we are supposed to prove the intent. People have to have intended to harm someone. It can't be an honest mistake, where a business man or woman has broken a regulation and didn't intend to harm anyone. If we want to convict someone of a crime and put them in a jail, it should have a mens rea requirement. This is something we have had for hundreds of years that comes out of our common law tradition.

This amendment would fix this problem by strengthening the mens rea component of each of the prohibited acts in the FDA Act by including the words ''knowing'' and ''willful'' before we address and accuse someone of a crime. I think this would give protection to folks who are guilty of inadvertently breaking a regulation and would keep from overflowing our jails. We have plenty of violent criminals without putting people in for honest breaches of regulations.

If Congress is going to criminalize conduct at the Federal level, as it does with the FDA Act, then the least it can do is have an adequate mens rea requirement. My amendment will attempt to do this. It is not that we will not have rules at the Federal level, but the rules ought to be reasonable. We ought to allow people to market vitamins. There is no earthly reason why someone who markets prune juice can't advertise that it helps with constipation. We have gone too far. We have abrogated the first amendment. What we need to do is tell the FDA the courts have ruled that the first amendment does apply to commercial speech, and the FDA has been overstepping their bounds.

I hope this amendment will pass. I will ask for the yeas and nays at the appropriate time.

I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

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

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

Mr. HARKIN. Mr. President, I rise in opposition to the amendment offered by the Senator from Kentucky, and I oppose it for several reasons.

I believe I am in the court of equity now: I come with clean hands because I am one of the authors of the Dietary Supplement and Health Education Act, along with Senator HATCH, in 1994. We worked in tandem over a period of a couple of years to get the legislation through. A lot of compromises were made at that time, not only here in the Senate but also with the House when we went to conference. I believe the right balance was struck, and I think it has proven its worth over the years.

We have done some minor modifications to it over the years. As I have often said, when we write laws around here they are not chiseled in stone for all eternity. These aren't the Ten Commandments, they are laws, and sometimes they need to be modified and changed a little bit, usually tweaking. But this amendment basically turns the whole law that we had since 1994 on its head.

We have a process now where the FDA regulates the supplements as foods. These are foods, not drugs. So as

we hammered out this agreement, supplements can make nutrient, structure, function claims without any FDA preapproval. If they want to make a health claim, then it has to be approved by FDA, and FDA has to find that it is supported by appropriate scientific evidence. Under this amendment, substances that today are considered drugs and used to treat diseases as serious as cancer or HIV could be marketed without any rigorous FDA review that we have heard from many speakers here today is the gold standard of drug regulation throughout the world. It would turn our current system of drug regulation on its head. It would be a huge setback for health. It would foster a system rife with potential for health fraud. The big losers would be patients.

Frankly, as someone who is a strong supporter of the Dietary Supplement Health and Education Act, and I would say along with Senator HATCH one of its protectors for all these years, I daresay the amendment offered by the Senator from Kentucky would destroy DSHEA. It would destroy it and I don't want to see it destroyed because I think it is doing a lot of good for a lot of people in this country. It is working well. Consumers have access to a wide range of safe products. There is no reason to upset its success, because this amendment would do that.

To think that somehow you could go out and make any health claim you want? Back to the days of snake oil salesmen: ''This elixir will do everything, it will cure every ailment you have and turn the clock back 20 years on your age.'' People would buy it, and what was it? It was 80-percent alcohol and 20-percent water or something like that. They made all these crazy claims. We are going to move to that kind of system now? And the only recourse would be to take them to Federal court and then have a trial and go through all that and then, OK, then they appeal it and finally you find out, OK, the court says no, there is not enough scientific evidence to warrant it so you have to take that product off the market.

We are going to do that for every one of the thousands and thousands of different products that are out there? What a mess this would be. First of all, the Federal courts would not have the wherewithal to do every one of those. Second, who has the money to take all that to court? And it would literally destroy—bring down an industry that has done well in this country. The dietary supplement industry, the vitamins and minerals industry in this country, has done a great job and I do not want to see it ruined. This would ruin it.

Last, the Senator from Kentucky talked about increasing the mens rea, the mind; you know, in law school, what your mental condition, what your thought processes were—what was your intent. It would increase it. It would need to be shown to enjoin or prosecute serious violations of the Food, Drug, and Cosmetic Act. I find this amazing. This idea that we need to make it harder to enforce a public health protection statute, not easier, is deeply troubling. I see no legitimate reason to do this.

The goal of this amendment is clearly to render the FDA virtually incapable of addressing industry abuses. I think this amendment would have deleterious effects on the Dietary and Supplement Education Act, and the industry, and also on the FDA's ability to regulate prescription drugs. You can say just about anything about what your health claims would be on any kind of product and the only recourse, as I said, would be to go to Federal court.

Again, this is a consensus measure. We have built a very broad bipartisan support for this FDA user fee bill. It is must-pass legislation. We cannot jeopardize that consensus.

For those reasons, I oppose the amendment offered by the Senator from Kentucky.

Mr. President, I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

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

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

Mr. HARKIN. Mr. President, how much time remains on the amendments offered by the Senator from Maryland, Senator CARDIN?

The PRESIDING OFFICER. On amendment No. 2141, there is 11 minutes remaining in support and 15 minutes in opposition.

Mr. HARKIN. Mr. President, I ask the Senator from Colorado, how much time does the Senator seek?

Mr. BENNET. I would like to try for 10 minutes but if I can do it shorter——

Mr. HARKIN. I ask 10 minutes of the time from amendment No. 2141 be yielded to the Senator from Colorado.

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

Mr. BENNET. I thank the Senator from Iowa, the chairman of the HELP Committee, for his indulgence.

Yesterday I spoke about some of the process on the important issues of drug safety and making sure there is a good system for safer drugs, both in preparation and distribution. I know we seem to get close to reaching a resolution, which is tremendous. I have heard many of my colleagues praise different parts of the bill, which I will do as well in a minute. But I want to take 1 more minute again, while the chairman and the ranking member are on the floor, to recognize what an enormous accomplishment their leadership has resulted in, getting this bill to a close.

As I said yesterday, I think the work of the HELP Committee, both Democrats and Republicans, with the leadership of the chairman and the ranking member, is a model for this Congress. It is the reason why the quality of this bill is so high. We still have a few votes to go tomorrow, but people forget that it is rare to be working on a full extension of anything here. This has become the land of flickering lights, where we keep things on for 1 more month or 2 more months. Here we actually have a 5-year extension of this legislation. It is wonderful to be working in such a bipartisan and businesslike fashion. It is not lost on me how much work has been put into the bill by my colleagues on the HELP Committee, including the Presiding Officer, or the HELP Committee staff. I want to reiterate my thanks and gratitude for the work on the bill that will truly help patients and American families get the medical products they need when they need them.

That brings me to the subject of medical devices. Colorado is the sixth largest medical device sector in the country, with over 600 bioscience companies overall. We obviously need to strike a balance, as we think about this legislation, because as we speed the FDA approvals, we have to ensure that devices are safe. This year has represented a good-faith bipartisan effort among members on and off the HELP Committee to find policies that will empower the FDA to ensure safer devices and also ensure that our companies on the ground have more regulatory certainty and predictability.

The FDA has been upfront about the challenges the device center faces—reviewer turnover, young, less experienced reviewers, and management challenges. At the same time we have heard from venture capital investors who say that regulatory uncertainty at the FDA is a reason they have been hesitant about continued investments in the United States and thought about the future investment in Asia and Europe. The new medical device user fee will go a long way toward ensuring the FDA has the resources to provide safer, more effective medical devices in less time and with more predictability.

Over the course of a year we were also able to craft a balance of policies on both the innovation and safety side. This includes reinforcing regulations in place since 1997 that require the FDA to take the least burdensome approach to approving medical devices by not asking companies for unnecessary or unrelated information.

I see the Senator from Minnesota on the floor, and I thank her for her leadership on this piece of legislation. It also includes important safety provisions such as ensuring the medical devices have a tracking number so if there is any problem, doctors and patients can quickly know if their product is one that works.

I would like to say a word about drug shortage, which is a discussion issue every Member is hearing about in their States. In just the last year, the FDA was notified of about 220 drug shortages. We know that the amount of patients this affects is monumental. For

cancer alone, over 550,000 patients have been currently affected by our national drug shortage crisis.

In Colorado, our patients and providers are extremely frustrated. A pharmacist at St. Mary's Hospital in Grand Junction said that he keeps a 2-page list of 50 drugs that he cannot get or can barely get a hold of, including 12 chemotherapy drugs.

I want to share a couple of constituent stories from my home State.

Dawn Gibbs from Long Mount, CO, wrote:

Dear Senator Bennet: I am contacting you to inform you of my grave concern of the national shortage of the preservative free cancer drug Methotrexate. My 2-year-old cousin receives this drug for her newly diagnosed leukemia of October 2011. Her doctors told her that they only have a 2 week supply left at their clinic. This drug keeps her leukemia from traveling to her brain. This shortage is life threatening to her and 3,000+ like her with this cancer.

I thank you for your assistance in this matter. I know that my little 2-year-old cousin cannot speak out on her own behalf, so I am honored to be her voice. I feel my voice will not be enough alone to make a difference, and I hope that you will be our voice.

Dawn Gibbs' voice is being heard on behalf of her cousin, just as patients all across the country are lending their voices to this important debate.

Carol Gill from Morrison, CO, wrote:

Dear Senator Bennet: I have stage 4 cancer. My current treatment regimen is doing a fine job of keeping the disease stable. This regimen includes a biweekly infusion of two generic drugs—5FU and leucovorin—and two other drugs still on patent. I receive treatment at the University of Colorado Hospital. My oncologist just called me to say that the University of Colorado Hospital is out of 5FU.

Today oncologists at the University of Colorado Hospital are calling their patients to tell them some or all of their cancer treatment must be suspended.

Thank you for taking this seriously and taking immediate steps to correct it.

Carol Gill.

My hope is that this Senate bill can give some reprieve to these Coloradans in desperate need of their lifesaving drugs.

The Senate bill would give the Food and Drug Administration the much needed authority to require drug manufacturers to report any discontinuance or interruption or other adjustment that would likely result in a shortage, especially those drugs needed to provide emergency care. It would also immediately create a task force that would create a strategic plan to address drug shortages and submit recommendations to Congress as well as study the effect on drug pricing as it relates to shortages.

The people in my home State and every one of our home States need us to provide solutions to this problem yesterday. They cannot wait any longer, nor should they.

I will say again that it is because of the leadership of the two people sitting here, the ranking member of our committee and the chairman of our committee, that we have been able to get this bill to the floor for a vote. I think we should take that vote tomorrow and move forward on behalf of patients all across this country and the bioscience community.

I thank the Chair.

I yield the floor.

Mr. ENZI. I thank the Senator from Colorado, Mr. BENNET, for his comments, but he sold himself pretty short on the influence on this bill. He has worked dramatically on every portion of this bill and made some significant contributions that are now a part of the bill. He didn't have to do amendments at this point because he got them all in. That was very important across-the-aisle work that the Senator did by working with a number of people on both sides of the aisle and being faithful and helping committee and staff members, not to mention all the committee meetings held on Fridays throughout the year. This bill wouldn't have been possible without the Senator's efforts.

Mr. BENNET. I thank the ranking member.

The PRESIDING OFFICER. The Senator from Iowa.

Mr. HARKIN. Mr. President, I join Senator ENZI in thanking Senator BENNET for being a very valuable member of our committee and for all of the great work the Senator did on this bill. His fingerprints are all over this bill, and, as he pointed out, it is a great bill. There was great bipartisan support.

I thank the Senator for all of his work in our working groups, especially the drug supply chain. This is a key part of this bill. The FDA will have the authority and the wherewithal to go back up the chain to where these drugs come from. The Senator was the first one to point out to me at the committee hearing that I think about 80 percent of all of the ingredients that go into our drugs in this country come from outside this country, but we had no real idea on where and how, and now we can insist on good manufacturing practices. So I would say this singular addition to this bill can be traced right back to the Senator from Colorado, and I thank him very much for his leadership on this issue and in helping us to get this bill to where we are today. I thank the Senator.

I would like to yield 10 minutes off of the opposition of the Grassley amendment 2121 to the Senator from Minnesota.

The PRESIDING OFFICER. The Senator from Minnesota.

Ms. KLOBUCHAR. Mr. President, this bill means so much to my State. I spoke earlier today about the need to improve the approval process at the FDA, and this bill will speed that up with the agreement reached between industry and the FDA on the fees. I thank the Senator for his leadership on that issue.

We have literally tens of thousands of employees in our State who have incredibly good jobs in the high-tech industry. This is a huge potential export. It is already an export, but even more could come if we do this right as we look at the growing middle class in countries such as China and India who are going to the hospital and using medical devices. So this bill is speeding up that process but still keeping the very important safety standards in place, which couldn't be more important—as well as for patients who have been waiting for lifesaving treatment. So I thank the Senator for that.

I also thank the Senator for including, as Senator BENNET referenced, my drug shortage provision. We worked on that for 2 years. We gathered support as the years went on.

I thank Senator HARKIN for the hearing we had on that bill and for the work of his staff in bringing people together. We got Senator CASEY's and Senator COLLINS' provisions in this bill.

We all know what has been going on. As several Senators have mentioned, we are talking about 4-year-old boys with leukemia whose parents find out they have no cancer treatment drug and literally are put into a panic, so they book flights to Canada so this little child can complete his treatment, or the woman with breast cancer who has to call around for Prudoxin and is then faced with the ethical dilemma that she explained to us that she knew she was taking it away from another patient. That should not happen in the United States of America, and this early notification of the FDA, as we have seen, has been very positive.

Over 200 drug shortages have been averted because of the early notification with orphan drugs in the last few years, so this provision will truly make a difference. I thank the Senator for including that.

I am here to talk about another matter the two Senators have been involved in negotiating. These are bills that Senator SCHUMER, Senator GRASSLEY, and I have been working on. We each had one of the three bills that covered different synthetic drugs.

My drug bill covered 2C-E, which is a synthetic hallucinogen, which, sadly, is something a young man died from taking in Minnesota. There was actually a murder prosecution because of it, and, again, we have seen it go like wildfire through our State with these synthetic drugs. Senator PORTMAN and myself and Senator GRASSLEY will be offering this amendment, and I thank the Senator for his work on it. I also encourage my colleagues to support this amendment, and I hope it will pass overwhelmingly.

As members of the Judiciary Committee, Senator GRASSLEY, Senator SCHUMER, and I have been working on this, as I mentioned, for years. There have been reports from every State in the country of people acting violently while under the influence of these drugs, which leads to death or injuries to themselves and others. While taking these drugs, people can experience elevated heart rates and blood pressure,

hallucinations, seizures, and extreme agitation, which is dangerous, but they are also dangerous to themselves.

Up in Moorhead, MN, with the Fargo sheriff, we did a forum. A group of people were sitting in the front row. I actually thought they were there to object to our provisions. They were there to support them because they had lost a loved one who thought he was taking what he considered to be synthetic marijuana, and it turned out to be very different from any marijuana. It turned out to be much stronger, and he ended up hitting a tree and killing himself. They were sobbing while telling their story.

Until 2006, I was a Hennepin County attorney. During my time there we just didn't have this as an issue. We can see how quickly it has changed. Listen to these numbers. In 2011 poison control centers across America received more than 13,000 calls about synthetic drugs. How many calls did they get in 2010? They only got 3,200. Look at that—3,200 to 13,000 in just 1 year. In Minnesota there were a total of 392 calls to poison control relating to synthetic drugs in 2011 compared to 107 in 2010—a tripling of calls about this problem in just 1 year.

This all hit home, as I mentioned in my State, with the tragic death of a 19-year-old man, Trevor Robinson, in Blaine, MN, when he overdosed on 2C-E. It is a synthetic hallucinogen. Another young man was thought to have shot himself in Minnesota while under the influence of synthetic drugs. We can imagine the pain of these families, and that is why I introduced a bill to add 2C-E and similar drugs to the substance list so they will be treated in the same manner as other banned drugs they claim to represent.

I am also a cosponsor of the two bills authored by Senators GRASSLEY and SCHUMER. All three of these bills are contained in the amendment we are offering with Senator PORTMAN. These drugs can kill, and if we don't take action, they are going to become more and more prevalent. They are available on the Internet. The Federal Government has to make clear that they are illegal. That is what is going on today because people literally buy these drugs that have numbers like 2C-E. They don't really know what they are. They get them, and they turn out to be deadly. That is what happened in Blaine, MN.

I am hopeful that we vote to ban these drugs as part of the debate on this bill. We have seen what happened in Minnesota. We know the DEA has been taking action on its own, and they temporarily banned some of these drugs, but most of the substances covered in our three bills have not been banned, including all of the substances in my bill. That is why, in fact, we are offering this amendment.

On the State level, roughly 40 States have banned some synthetic drugs, including my State, where a major law regarding synthetic drugs took effect in July. We need a Federal law. This crosses State lines. A lot of it is done on the Internet. We cannot simply have this State by State, and passing a Federal law will help create the partnership we need to send a strong message that we need to eradicate these substances.

I am pleased this amendment is being offered. We need to get it done now, ban these drugs, and make a clear statement that these drugs are illegal.

I again thank Senator HARKIN and Senator ENZI for working it out so we can offer this amendment, and also my colleagues, Senators PORTMAN, SCHUMER, and GRASSLEY, for their hard work. I know we are committed to getting this done.

I yield the floor.

The PRESIDING OFFICER. The Senator from Washington.

Mrs. MURRAY. Mr. President, I ask unanimous consent to speak for 15 minutes in morning business and not to take time away from the debate on the bill.

The PRESIDING OFFICER. Is there objection?

Mr. ENZI. Mr. President, it was my understanding that because of the special event tonight, we were going to be out of here at 6 pm. I am not sure what leadership has in mind at this point.

Mrs. MURRAY. Mr. President, I have had a conversation with them——

The PRESIDING OFFICER. Is there objection to the Senator's request?

Without objection, it is so ordered.

VETERANS EMPLOYMENT

Mrs. MURRAY. Mr. President, next week Americans are going to spend time honoring and commemorating the men and women who died fighting for our great country. Memorial Day is a day to reflect on and give thanks to the sacrifices made by those who made the ultimate sacrifice. It is also a day to look forward and to think about what we all can do to help our veterans who sacrificed so much and who deserve our support when they come home.

So I come to the floor today to discuss an issue that, quite frankly, defies common sense. The high rate of unemployment among recently separated veterans is an issue that continues to make the transition home for veterans harder than ever. Despite the fact that our veterans have the leadership ability and the discipline and technical skills to not only find work but to excel in the workforce of the 21st century, our veterans continue to struggle.

Despite the skill and talent and training of our veterans, statistics continue to paint a grim picture.

According to the Department of Labor, young veterans between the ages of 18 and 24 have an unemployment rate that is nearly 20 percent. One in five of our Nation's heroes can't find a job to support their family, doesn't have an income that provides stability, and doesn't have work that provides them with the self-esteem and pride that is so critical to their transition home.

We know this should not be the case. We shouldn't let the skills and training our Nation's veterans have attained go to waste. That is why all of us joined together to overwhelmingly pass my VOW to Hire Heroes Act here in the Senate late last year. Among many other things, that law would provide tax incentives to encourage businesses to hire veterans; it makes participation in the transition assistance program mandatory for most separating servicemembers, and expands the education and training we provide to transitioning servicemembers.

Thanks to that legislation, we have been able to take real concrete steps toward putting our veterans to work. The tax credit is working, and VA is set to begin accepting applications for a retraining program that will benefit unemployed veterans ages 35 to 60 and help them get back to work.

But that bill is only that, a first step. Today I am here to talk about the next step, and that step is to build partnerships with private businesses, large and small, all across our country, to hire our Nation's heroes. Recently I was up in New York where I participated in a lively roundtable discussion hosted by the Robin Hood Foundation. This discussion on veterans employment was moderated by Tom Brokaw on the USS *Intrepid* and brought together people of various backgrounds, including former Chairman of the Joint Chiefs ADM Mike Mullen, and Housing and Urban Development Secretary Shaun Donovan, to talk about this important issue.

What is very apparent is that there is momentum to build public-private partnerships. What is also apparent is there is a lot of room for improvement in this area.

I want to first make clear that a lot of companies across the country are far ahead of the curve. In fact, many private sector companies have already joined our efforts in addressing this critical issue. J.C. Penney, one of America's largest retailers, and Joseph Abboud, a men's clothing company, partnered with Iraq and Afghanistan Veterans of America to launch the Welcome Home Joe—Thanks A Million Program.

To prepare veterans for job interviews, this program has provided 5,000 veterans with certificates to purchase business attire. For the last decade, we have expected our brave men and women in uniform to prepare for the battlefield. In the process, they have become accustomed to wearing combat boots and battle dress uniforms. Now they are expected to wear a suit and tie for job interviews—something that sometimes seems pretty foreign to them. But thanks to this program, thousands of transitioning veterans can now hang up their battle dress uniforms and dress for their next challenge.

Other companies such as Schneider National, one of America's largest

trucking companies, are realizing the skills our veterans have gained over the last decade of work are directly applicable to their business. Schneider National recognizes that a veteran who has driven a 7-ton truck across Afghanistan's dangerous and rugged terrain is more than qualified to drive a freight truck across our Nation's roads. In addition to providing many veterans with new jobs, Schneider National also provides newly separated veterans with on-the-job training through their military apprenticeship program. As part of that program, veteran employees are eligible to earn a monthly educational benefit check from the VA in addition to a paycheck. Schneider National serves as a great example of how companies can hire veterans who have proven they can perform on the job but lack proper certifications for civilian employment.

The U.S. Chamber of Commerce also should be commended for launching its Hiring Our Heroes initiative which has sponsored 150 hiring fairs in 48 of our States. At one of these recent hiring fairs, General Electric, the employer of 10,000 veterans, launched its veterans network transition assistance program. As part of that program, General Electric has vowed to hire 1,000 additional veterans every year for the next 5 years and provides job-seeking veterans with one-on-one mentoring sessions. Those sessions help transitioning veterans improve resume writing and interviewing techniques so they can capitalize on the skills they have developed during their military service.

That is just a fraction of the work being done by our Nation's employers. There are many success stories at big companies such as Home Depot and small companies such as General Plastics in my home State which has created a pipeline to hire veterans at its aerospace composite factory. All of these companies are not only examples of success stories but they have also created a roadmap about how best to find, hire, and train veterans. It is our job to make sure those lessons are being heard.

Today I am here on the floor to lay out a few things that all businesses, large and small, can do to bring our Nation's heroes into their companies. First, get the word out to companies to educate their human resources teams about the benefits of hiring veterans and how skills they learned in the military translate to the work a company does. I can't tell my colleagues how often I hear from veterans who tell me the terms they use in interviews and on resumes fail to get through to the interviewer.

Second, help our companies provide job training and resources for transitioning servicemembers. This is something I have seen done at large organizations such as Amazon and Microsoft, but also at smaller companies in conjunction with local colleges. In fact, the most successful of these programs capitalizes on skills developed during military service but also utilizes on-the-job training.

Third, let business leaders know how important it is to publicize job openings with our Veterans Service Organizations at local military bases so we can help connect veterans with jobs, and to work with local one-stop career centers.

Fourth, develop an internal veterans group within our companies to mentor recently discharged veterans.

Finally, if possible, please reach out to local community colleges and universities to help develop a pipeline of the many veterans who are using GI bill benefits to gain employment in a particular area.

If we can spread the message on just a few of these steps, I am confident we will be able to continue to build on the success we have had in hiring veterans.

There is one other even more important step we have to take to ensure that businesses are taking, and it has to do with the difficult issue that some potential employees face. I have heard repeatedly from veterans that they do not put their military service on their resume because they fear it stigmatizes them. They fear that those who have not served see them all as damaged or unstable. We have to understand what mental health challenges are and what they are not.

As we seek to employ more veterans, we need future bosses and coworkers to understand that issues such as posttraumatic stress or depression are natural responses to some of the most stressful events a person can experience. We need them to understand that these illnesses do not afflict every veteran and, most importantly, we need to understand that for those who are affected by these illnesses, they can get help, they can get better, and they can get back to their lives. We need to let businesses know if they have a veteran who is facing some challenges, we should do the right thing and encourage him or her to get help. They need to know it is OK to reach out. Help them take advantage of the excellent mental health care the VA is capable of providing. The veteran will be better and they will be an even stronger member of a company's team.

Those are some steps our employers can take, but we also need to make sure our veterans are taking steps to stand out as candidates. Unfortunately, too often our veterans don't see how the skills they learned in the military translate from the battlefield to the working world. One of the biggest reasons for that is often our veterans don't understand the vernacular of the working world.

A few weeks ago I was home in Washington State talking about this issue when I met a woman named Anne Spurte. Anne is a veteran. She helps other local veterans find work through an organization called The Unfinished Mission. Anne told me how often she has heard from veterans who told her they were not qualified for the jobs they had seen on line or in the paper. Repeatedly they told her they didn't see how their experiences mattered to employers in the area. So one day in front of a whole group of veterans, Anne pulled out this job advertisement from Boeing for a position as a fabrication specialist. Anne could once again sense that the veterans who sat there and read this ad thought they weren't qualified for this manufacturing job that is listed in Boeing's space exploration division. But then Anne concentrated all the attention of the veterans in the room on the competency and qualifications section that was listed on that job advertisement and she asked all of them: Did you spend time in the service working together to remove obstacles to help a team accomplish its goals? Did you work to fully involve others on the team in decisions and actions? Were you held responsible? Did you demonstrate your commitment to the team? Around the room, all of these veterans' heads were nodding as she read verbatim from the Boeing job announcement. Every veteran understood they had the core skills employers at Boeing were looking for, but they just didn't realize it.

What Anne made those veterans come to understand was that their skills were being lost in translation, and what many of them needed to do was simply articulate their experiences in a way that employers could understand.

So today I want to reiterate to all of our veterans that no matter what branch you served in or when you served or how long you served, the skills you learned are valuable and it is up to you to make sure employers see that.

Our veterans don't ask for a lot. Oftentimes they come home and don't even acknowledge their own sacrifice. My own father never talked about his time fighting in World War II. In fact, I never saw his Purple Heart or knew that he had a wallet with shrapnel in it from when he was hit or a diary that detailed his time in combat, until after he died and my family gathered to start sorting through his belongings. But our veterans shouldn't have to ask. We should know to provide for them.

When my father's generation came home from the war, they came home to opportunity. My father came home to a community that supported him. He came home to college and a job—a job that gave him pride and helped him start a family and one that ultimately led to me starting my own.

That is the legacy of opportunity we have to live up to for today's veterans. Together, working with the private sector, we can ensure that the brave men and women who have worn our uniform have that real opportunity. We can make sure they get a fair shot from America's employers, that they are not measured by fear or stigma but by what they can do, what they have done, and what they will do.

I thank those companies that are leading the way as our veterans transition from military service to the civilian workforce. The Veterans Affairs' Committee, which I chair, has a Web site with a list of some of those companies that are contributing to this effort. I would encourage all of our colleagues to visit that Web site and suggest companies that can be added to our list. I look forward to working with all of them, and many more of our Nation's businesses, on this important next step in bringing our veterans home to opportunity.

As we celebrate our fallen heroes on Memorial Day next week, let's all keep thinking about how we can make sure our veterans are getting everything they need after they have given so much.

Before I yield the floor, I wish to take a moment to acknowledge a young Marine reservist, an Afghanistan combat veteran, who has been working part time on my Veterans' Affairs Committee staff for the last year. Carlos Fuentes is a hard-working, well-liked young man who graduated from American University earlier this month. He has helped our committee get a better understanding of what our veterans are facing when they are looking for work, and I want to thank him for his continued service to our Nation. I need my colleagues to know that Carlos is going to be getting married this weekend and I wish him and his bride many happy years to come.

Thank you, Mr. President. I yield the floor and I suggest the absence of a quorum.

The PRESIDING OFFICER (Mr. BENNET). The clerk will call the roll.

The legislative clerk proceeded to call the roll.

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

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

AMENDMENT NO. 2151, AS MODIFIED

Mr. MANCHIN. Mr. President, I ask unanimous consent to set aside the pending amendments, so I may call up my amendment No. 2151, as modified, with the changes at the desk.

The PRESIDING OFFICER. Without objection, the clerk will report.

The legislative clerk read as follows:

The Senator from West Virginia [Mr. MANCHIN], for himself, Mr. KIRK, Mrs. GILLIBRAND, Mr. SCHUMER, and Mr. ROCKEFELLER, proposes an amendment numbered 2151, as modified.

The amendment, as modified, is as follows:

(Purpose: To amend the Controlled Substances Act to make any substance containing hydrocodone a schedule II drug)

At the end of subtitle C of title XI, add the following:

SEC. 1133. HYDROCODONE AMENDMENT.

The Controlled Substances Act is amended—

(1) in schedule III(d) in section 202(c) (21 U.S.C. 812(c)), by—

(A) striking paragraphs (3) and (4); and

(B) redesignating paragraphs (5), (6), (7), and (8) as paragraphs (3), (4), (5), and (6), respectively; and

(2) in section 401(b)(1) (21 U.S.C. 841(b)(1)), by adding at the end the following:

''(F) In the case of any material, compound, mixture, or preparation containing—

''(i) not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium; or

''(ii) not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts,

subparagraph (C) shall not apply and such case shall be subject to subparagraph (E).''.

Mr. MANCHIN. Mr. President, I wish to give a brief explanation of the amendment and hope it will be accepted. Basically, what we are doing is changing the hydrocodone combination drugs to be schedule II drugs rather than schedule III drugs. That makes it much harder for people to have access to this drug that has been wreaking havoc throughout our States and throughout the country.

I would appreciate adoption of this amendment.

The PRESIDING OFFICER. The Senator from Iowa.

Mr. HARKIN. Mr. President, as the Senator said, his amendment would amend the Controlled Substances Act to make any substance containing hydrocodone—Vicodin—a schedule II drug. As he said, this is presently a schedule III drug. The most significant difference is, for patients, schedule II drugs are not allowed to be refilled. That is the key to the amendment.

I applaud the Senator. I have great concerns regarding the increased abuse of prescription drugs. According to the Centers for Disease Control and Prevention:

Overdoses involving prescription painkillers are at epidemic levels—

Epidemic levels—

and now kill more Americans than heroin and cocaine combined.

That is a quote from the Centers for Disease Control and Prevention.

According to CDC, more than 40 people die in America every day from overdoses involving narcotic pain relievers such as hydrocodone.

For this reason, I applaud Senator MANCHIN for his amendment and the efforts he has undertaken to reschedule this drug. It is the most frequently abused narcotic and that is a strong reason to reschedule it into section II.

Again, I thank the Senator for this amendment. At the appropriate time I will ask for its adoption. Again, I thank the Senator from West Virginia. This is a great amendment. It improves the bill. It is widely accepted, and the Senator has been on the right track on this issue for a long time. I applaud him for doing this and, believe me, a lot of people in America are going to thank the Senator for getting this drug rescheduled to cut down on the terrible overuse of this drug in America. I thank the Senator very much.

The PRESIDING OFFICER. The Senator from West Virginia.

Mr. MANCHIN. Mr. President, if I may say this: Senator KIRK, as you know, has worked very closely with me on this matter, and we have many other Senators—GILLIBRAND, SCHUMER, ROCKEFELLER—so many people who are having this problem in their States. This is one way for us to fight this abuse.

I have said this: If we do nothing else—if we go to some of these communities that have been ravaged, and we speak to these young children, they will come up to us and say: Please help me to help my daddy or my mommy get off of this addiction. It will tear your heart out.

This gives us a chance—one more tool with which we can fight the drug abuse that is going on with prescription drugs. I appreciate its consideration and would ask unanimous consent that it be adopted, if we can do that.

I thank the Senator.

Mr. HARKIN. If the Senator would withhold the unanimous consent request.

Mr. MANCHIN. OK.

Mr. HARKIN. We have a number of amendments we are putting together, and at the appropriate time I will make sure that happens.

Mr. MANCHIN. Absolutely.

Mr. HARKIN. I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The legislative clerk proceeded to call the roll.

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

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

AMENDMENT NO. 2126

Mr. HARKIN. Mr. President, I ask unanimous consent to set aside all pending amendments in order to call up Reed amendment No. 2126, and I ask that the clerk report the amendment by number.

The PRESIDING OFFICER. Without objection, it is so ordered. The clerk will report.

The legislative clerk read as follows:

The Senator from Iowa [Mr. HARKIN], for Mr. REED, proposes an amendment numbered 2126.

The amendment is as follows:

(Purpose: To make effective the proposed rule of the Food and Drug Administration relating to sunscreen drug products)

At the end of title XI, add the following:

SEC. 11___. COMPLIANCE DATE FOR RULE RELATING TO SUNSCREEN DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE.

In accordance with the final rule issued by the Commissioner of Food and Drug entitled ''Labeling and Effectiveness Testing; Sunscreen Drug Products for Over-the- Counter Human Use; Delay of Compliance Dates'' (77 Fed. Reg. 27591 (May 11, 2012)), a product subject to the final rule issued by the Commissioner entitled ''Labeling and Effectiveness Testing; Sunscreen Drug Products for Over-

the-Counter Human Use'' (76 Fed. Reg. 35620 (June 17, 2011)), shall comply with such rule not later than—

(1) December 17, 2013, for products subject to such rule with annual sales of less than $25,000 and

(2) December 17, 2012, for all other products subject to such rule.

Mr. HARKIN. Mr. President, I further ask unanimous consent that the following amendments be agreed to en bloc: Cardin No. 2125; Cardin No. 2141; Grassley No. 2121; Grassley No. 2129; Manchin No. 2151, as modified; and Reed No. 2126.

The PRESIDING OFFICER. Is there objection?

Without objection, it is so ordered.

The amendments (Nos. 2125; 2141; 2121; 2129; 2151, as modified; and 2126) were agreed to.

Mr. LEAHY. Mr. President, I thank Chairman HARKIN and ranking member ENZI for including the Counterfeit Drug Penalty Enhancement Act in their substitute amendment to S. 3187. I introduced the Counterfeit Drug Penalty Act, S. 1886, last year along with Senator GRASSLEY and others, and the Senate passed it by unanimous consent in March. Unfortunately, the House of Representatives has yet to take action on it.

The Counterfeit Drug Penalty Enhancement Act has the support of industry and consumer groups and bipartisan backing in the House of Representatives. It will strengthen the provisions already included in S. 3187 that are intended to improve the safety of our supply chain and increase penalties for adulterated drugs.

This provision increases penalties for trafficking counterfeit drugs to a level commensurate with counterfeit cases in which the offender knowingly or recklessly causes or attempts to cause serious bodily injury. By strengthening the penalties appropriately, it will deter the sale of dangerous counterfeit drugs.

Few things are more important to consumer well-being than ensuring the safety of our pharmaceutical supply chain. Law enforcement is finding counterfeit versions of drugs that patients rely on to treat blood clots, cholesterol, prostate cancer, influenza, Alzheimer's, and other serious conditions. Counterfeit drugs reportedly result in 100,000 deaths globally each year and account for an estimated $75 billion in annual revenue for criminal enterprises. We must do more to prevent and deter this conduct.

In addition to protecting consumers, deterring the manufacture and sale of counterfeit drugs also protects American intellectual property, helping American workers and manufacturers. That is why this legislation has the broad support of not only the pharmaceutical industry and consumer groups such as the Alliance for Safe Online Pharmacies and Easter Seals but also the U.S. Chamber of Commerce.

I appreciate the work of Chairman HARKIN and Ranking Member ENZI to protect American consumers from adulterated and counterfeit drugs, and I thank them for including the Counterfeit Drug Penalty Enhancement Act as part of that effort in this legislation.

Mr. WHITEHOUSE. Mr. President, I rise today to speak in support of the Food and Drug Safety and Innovation Act. This measure includes a number of important reforms to promote the development of new treatments for patients in need and to ensure that drugs and other medical products are safe and effective for American families. I commend Chairman HARKIN and Ranking Member ENZI for their hard work and leadership on this bill.

As a participant in the drug supply chain integrity working group, along with the chairman and ranking member and Senators BENNET, BURR, and GRASSLEY, I am especially proud of the strong, bipartisan measures to protect patients that have been included in this bill. The not-too-distant incidents concerning adulterated Heparin and counterfeit Avastin demonstrate the critical importance of protecting Americans from unsafe medical products manufactured overseas. The new tools and authorities in this law should help safeguard Rhode Island families from dangerous drugs, while leveling the playing field for U.S. manufacturers and providing more transparency and accountability across our drug supply chain.

I particularly want to thank the chairman and ranking member for working with me to include the Expanding and Promoting Expertise in Rare Treatments Act of 2012, or EXPERT Act, which I introduced earlier this year, in the bill on the floor.

During my time in office, I have been moved by the personal stories of dozens of Rhode Islanders with rare conditions. In the last year, I have met with Rhode Island advocates who have or whose family member has a rare disease, like Fragile X, spinal muscular atrophy, and CLOVES syndrome, among many others. Treatments for these rare conditions often do not exist or are so early in the development pipeline that it will take years for patients to benefit. Rather than simply waiting for the products to come to market, these families want to play a role in educating others about the rare disease that affects their loved one and working toward a successful treatment.

The EXPERT Act is intended to give patients and experts a role in strengthening and expediting the FDA's review of new treatments for rare diseases. The measure encourages the agency to take advantage of the wisdom and insights of rare disease experts in order to speed the development of therapies for patients suffering from rare diseases. The bill also gives rare disease patients and their advocates a role in consulting with the FDA on topics like the severity of the disease, unmet medical needs, and the benefits and risks of therapies to treat the disease.

We have seen that when the FDA gets the technical and scientific assistance it needs from rare disease experts, incredible progress can be made. The Cystic Fibrosis Foundation's recent work with Vertex Pharmaceuticals on a treatment named Kalydeco, which specifically targets the underlying causes of the disease in some patients, is a good example. As a result of close consultation with the CF Foundation and renowned experts, FDA approval for this treatment was one of the fastest in the agency's history.

Rhode Islanders are already benefiting from Kalydeco. Sheri, a former resident of Narragansett, was diagnosed with cystic fibrosis when she was 16 years old. This past year, Sheri was surprised with the news that she is one of the 4 percent of cystic fibrosis patients who can be treated by the newly approved Kalydeco. For the past months Sheri has been on Kalydeco and says that she already feels the difference in her health, and, most importantly, it has given her hope to start thinking about her future. Recently engaged in February, Sheri shared, ''I can think about having children and seeing them grow up . . . even living to see my grandchildren!''

I hope the EXPERT Act will lead to more good stories for other Rhode Island patients and families afflicted with rare diseases. I have great admiration for the determination and optimism of the Rhode Islanders with rare disease I have met over the years, and I wanted to share a few more of those stories here today.

I heard from Susan, a Providence resident and mother of 3½-year-old Phoebe. Susan describes her daughter as a ''bright, happy, and beautiful'' child. When Phoebe was 5 months old, Susan and her husband noticed that their daughter did not reach for or look at objects placed on the left side of her body. After numerous tests and doctor's visits, Phoebe was finally diagnosed with developmental dyspraxia, a motor-processing disorder. Because of the rarity of their daughter's condition, Susan and her husband found that specialists ''looked at us like we had two heads when we told them what her diagnosis was.'' Phoebe is reaching milestones in her development and is continuing to improve, but because so little is known about dyspraxia, Susan and her husband have encountered several hurdles to getting Phoebe the treatment and therapy she needs. Susan said, ''It breaks our hearts to think that Phoebe is being held back from reaching her full potential because of lack of awareness and education about her disease.''

Dorrie, from Warwick, wrote to share her family's story with me. Her youngest son was diagnosed with an extremely rare disorder called atypical non-ketotic hyperglycinemia, or NKH, when he was 4 years old. He is the only child living in Rhode Island with this disorder, which has no known cure or treatment. However, doctors have

found several products can be used off label to improve their son's speech and alertness. Dorrie notes that ''he has progressed farther than we could ever have hoped possible. He is not only walking, but riding a two-wheel bicycle and playing kickball with his peers.'' Because they are using products off label, their private insurance will not cover their costs, and so they are forced to shoulder the burden of paying for their son's treatments out-of-pocket. This has caused anxiety and extreme stress on their family. As her son grows older, Dorrie is faced with more uncertainty about his future and says they are ''living on eggshells'' as he experiences increased and more severe symptoms.

For these Rhode Islanders and others like them, the challenge of having a rare disease or having a family member with a rare disease comes not just from the symptoms of the disease but the loneliness of having something that so few people understand, let alone have. The EXPERT Act is one step toward empowering patients and their families with an opportunity to participate in a process that is critically important for their future. I am pleased that the act is supported by 64 national organizations, including the Rhode Island Rare Disease Foundation. I again thank the chairman and ranking member for including this measure in this legislation so that more families in Rhode Island and around the country can receive the same kind of good news that Sheri and many other cystic fibrosis patients received earlier this year.

Mr. WARNER. Mr. President, I rise today to add my voice to the bipartisan support for the Food and Drug Administration Safety and Innovation Act, S. 3187.

In addition to continuing the fee-based funding system for timely FDA reviews, S. 3187 also calls for strengthening early scientific dialogue and transparency, promotion of innovation through enhanced communications, and modernization of regulatory science.

These provisions, including enhancing dialog between the FDA and medical device, pharmaceutical, generic and biotechnology companies early in their new product development cycle, will facilitate a clearer understanding of the specific criteria the FDA will require in its review process and provide a succinct roadmap for successful product approval.

The ultimate goal is to reduce misunderstandings and expensive superfluous testing, with the hope of reducing the time and costs to bring new medical technologies safely to patients in need.

I want to commend the chairman of the HELP committee, my friend Senator HARKIN, and the ranking member, Senator ENZI, who worked to find bipartisan consensus on these provisions.

By creating a more user friendly and accessible FDA, innovative U.S. companies built on the principle of American ingenuity, will be attracted and encouraged to develop new medical devices, technologies and pharmaceuticals.

With this new cooperation, together we will extend the quality of life for our citizens, reduce healthcare complexities and costs, create new U.S.-based jobs, and move this current national crisis to a financially manageable level for individuals, employers and tax payers.

For example, in my State of Virginia, medical and bioscience research and development is vibrant in our academic institutions and among our companies, both large and small. The biopharmaceutical companies employ nearly 77,000 workers in Virginia, both directly and indirectly. In the bioscience field alone employment has grown by 23 percent, compared to 6 percent total growth statewide and 3.5 percent across all sectors in the U.S.

We have a number of companies rushing to develop and market new products and technologies that are focused on improving healthcare delivery at a lower cost premium—companies like Engineered BioPharmaceuticals in Danville, VA, who is focused on repositioning current and future pharmaceutical therapeutics to be more effective at lower doses, with longer shelf-lives and better consumer compliance.

To help these companies, and encourage more innovation, I am glad to see that the FDA has committed to being more open with applicants about using more appropriate data, but also communicating why certain data is not able to be used. I look forward to working with stakeholders and the FDA in monitoring this issue.

One of the most exciting innovations in health care is related to mobile and health IT markets. Estimates indicate that the number of smartphone consumers using medical apps will grow to 500 million by 2015.

How these innovations are regulated matters a great deal. It is important to balance market creativity, with patient safety issues and the intended use of the medical software.

A number of agencies have jurisdiction over pieces of mobile medical applications, including FDA, Office of National Coordinator, ONC, and the Federal Communications Commission, FCC,—to properly regulate health information technology as well as address proper regulations of mobile medical applications.

I am pleased that language has been included in this bill which asks for the Secretary to work across the different agencies—the FDA, ONC, and FCC—to come up with guidance that makes sense. It also encourages an outside stakeholder group to be consulted.

I would like to thank my colleagues Senator BENNET, Senator BURR, HATCH and COBURN for their leadership on this as well.

I would also like to briefly acknowledge language in the FDA bill regarding the use of data from clinical trials conducted outside the United States. As many in industry will tell you, there are a number of countries around the world that have comparable safety standards as the U.S.

I have been interested in learning more about the application of appropriate clinical data across borders. I believe that if the FDA can do more to establish comparability between its guidelines for clinical trials and those set by countries in the European Union, for instance, we may be able to reduce the need for duplicative work and we may be able to get safe products to market sooner.

The FDA has committed to being more open with applicants about using this type of data. They have agreed to provide applicants with more information about why certain data is not appropriate for use in the U.S. The FDA will also report on regulatory science, which will specifically indicate which specific metrics can be used to determine comparability.

I am hopeful that there will soon be measurable improvement on this issue, and I look forward to working with interested stakeholders and the FDA to do more in this area in the future.

One final point I would like to make is about something that is not directly included in this bill, a new innovation—biomarkers.

Preeclampsia is a disorder that affects hundreds of thousands of pregnant women every year which undiagnosed can put a woman at risk for death and the fetus at risk of stillbirth.

Doctors currently use a mix of imprecise signs and symptoms to diagnose it but oftentimes such signs and symptoms are wrong. However, researchers have found a biomarker—a particular biological process or sign—that can accurately identify women with preeclampsia that are at risk for pregnancy complications.

Unfortunately, tests for novel biomarkers are taking 5 or more years to get approved by the FDA, delaying patients from receiving the benefits of more accurate diagnoses and treatments.

I was pleased that a recent commitment letter between FDA and industry specifically mentions the FDA's commitment to work together with industry to create a transitional IVD, or ''T–IVD'' process for the development of tests for novel biomarkers.

I look forward to seeing how this T–IVD process develops in discussions between FDA and industry and am interested in progress towards its implementation which supports advances in the sciences and promotes access to these emerging diagnostics.

If reducing healthcare costs is a national priority, we need to act today. I encourage my colleagues to pass S. 3187 and allow the FDA to work more closely with the medical industry to safely bring new technologies to the marketplace.

Let's increase the quality of life of our citizens, structurally reduce

healthcare costs without increasing risks to patients and stimulate the growth of American ingenuity and U.S.-based jobs.

Mr. HARKIN. Mr. President, we are finished with business for today. We do have some more amendments to be called up and voted on tomorrow. I understand we are coming in—I do not know exactly what time has been set for the morning, but after the leaders' time has been used, we will be back on this bill.

Again, I remind Senators and their staffs that we have until 2 p.m. for their amendments to be brought up and to be debated. The sooner we get to those in the morning, the better off we will be.

So as soon as the leader time is exhausted tomorrow morning, we will be back on our bill.

So, Mr. President, I suggest the absence of a quorum and ask unanimous consent that the time in the quorum call not be taken off our bill.

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

The clerk will call the roll.

The legislative clerk proceeded to call the roll.

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

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

MORNING BUSINESS

Mr. REID. Mr. President, I ask unanimous consent that the Senate proceed to a period of morning business with Senators allowed to speak therein for up to 10 minutes each.

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

150TH ANNIVERSARY OF USDA

Mr. INOUYE. Mr. President, last week we celebrated the 150th anniversary of the United States Department of Agriculture, also known as the USDA. On May 15, 1862, President Abraham Lincoln signed legislation to create the USDA. Since this day, the USDA has made major contributions to agriculture that have benefited the people of the United States.

Hawaii has a historic relationship with the USDA that began during Hawaii's territorial days. Our very own University of Hawaii at Manoa campus began as a land-grant college of agriculture and mechanic arts in 1907. John Washington Gilmore, the first president of the College of Hawaii, the predecessor of the University of Hawaii, was the son of a farmer who was tasked to build Hawaii's first agricultural school. During the past 100 years, the University helped Hawaii diversify its economy, sustain its environment, and build stronger families and communities.

Hawaii faces unique challenges when it comes to food security. Hawaii depends on imported food for approximately 85 percent of its food supply. For the United States as a whole, imports make up about 15 percent of total food consumption. In addition, higher energy-related transportation costs, and rapidly escalating commodity prices translate into very high food costs for Hawaii consumers. Further, if there is a shipping disruption of any kind, it is estimated that Hawaii has a 4 to 7 day food supply.

The magnitude for Hawaii of this potential and unprecedented food security crisis has prompted a restructuring of Hawaii's agriculture, with a move from large-scale plantation agriculture to smaller scale, more diversified agriculture, with an initial emphasis on import substitution. This process has been occurring over the past 20 years with many large scale plantations either closing or shifting to overseas locations. Our situation remains a struggle. There is only one sugarcane and one pineapple operation remaining in the State. There are no dairies on the Island of Oahu and the only two remaining in the State are on the Big Island. There are no slaughter or meat processing facilities on Oahu. A major employer on the Island of Molokai is gone and, with it, agricultural production and water supplies for residents. Finally, the only poultry operations remaining are four egg producers on Oahu.

The rapid closures of these farming and farm-related operations continues to pose a serious challenge for our agriculture industry in Hawaii as these operations were attempting a transition to agriculture supportive of local consumption through import substitution. Accordingly, efforts to support those remaining in agriculture to make the transition to an agriculture supportive of Hawaii food security is also critical to the continued sustainability and viability of our agriculture industry in the State of Hawaii.

The USDA plays a major role in preservation. The U.S. Forest Service, part of the USDA, protects and manages our Nation's forests and grasslands. Hawaii's rainforests contain numerous plant species that are not found anywhere else in the world, and they are part of a unique, delicate ecosystem consisting of countless native Hawaiian animal species. The Forest Service has helped protect the beauty of Hawaii's rainforests by fighting invasive species and destructive human practices.

The USDA hopes to protect the environments of Hawaii and the rest of the United States with the Animal and Plant Health Inspection Service, also known as APHIS. The mission of APHIS is to protect our Nation's agriculture and animal and plant resources from diseases and pests. APHIS plays a major role in the protection of Hawaii's environment. Invasive species such as fruit flies, coffee berry borers, and Varroa mites have been devastating to Hawaii's agriculture and fragile ecosystem. If Hawaii fails to stop potential invasive species including the Brown Tree Snake, the results will be catastrophic. Even though Hawaii may be small compared to the continental United States, our islands contain one the most diverse ecosystems in the world. It is in our country's interest to keep these protective programs. APHIS also protects the continental United States from potential destructive invasive species that can wreak havoc on our Nation's agriculture. Programs such as APHIS protect both Hawaii and the continental United States and are vital for economic and environmental security for everyone.

In addition to preservation, the USDA helps with innovation. The Agricultural Research Service is responsible for conducting basic, applied and developmental research on: soil, water, and air sciences; plant and animal productivity; commodity conversion and delivery; human nutrition; and the integration of agriculture systems. Through research, development, and other federal programs, the USDA has helped farmers produce food efficiently and sustainably. The United States is a world leader in agricultural production, and our agriculture research infrastructure continues to give our country a competitive edge.

Agriculture has been, and remains, an important pillar of the American economy. The USDA touches all Americans and will continue to contribute to our society far into the future. I wish nothing but the best for the USDA in the years to come.

HUMAN RIGHTS IN U.S. PRISONS

Mr. DURBIN. Mr. President, I rise to speak about the human rights issue of sexual assault in U.S. prisons, jails, and detention centers—and the historic release of our country's first-ever national standards to eliminate prison rape.

When the government takes people into custody, and puts them behind bars, their human rights become our responsibility. And we are accountable for the results. In studying this issue for nearly a decade, we learned that sexual assault in detention has become an epidemic. It is occurring at the hands of other inmates, and it is occurring at the hands of prison officials whose job it is to protect.

We learned that hundreds of thousands of inmates are victims of sexual assault every year. According to a Bureau of Justice Statistics report released this month, approximately one out of ten former state prisoners reported incidents of sexual victimization during their most recent stay behind bars. Approximately a third of former inmates reported other types of sexual harassment or victimization. Many say these are conservative estimates of those brave enough to report.

It is also disturbing that ''prison rape'' has become an accepted part of our culture. We hear people make light