United States of America

Congressional Record

PROCEEDINGS AND DEBATES OF THE 110th CONGRESS, FIRST SESSION

Vol. 153 WASHINGTON, MONDAY, MAY 7, 2007 No. 74

Senate

The Senate met at 2:15 p.m. and was called to order by the Honorable MARK L. PRYOR, a Senator from the State of Arkansas.

PRAYER

The Chaplain, Dr. Barry C. Black, offered the following prayer:

Let us pray.

Eternal Spirit, remind us today of truths that matter to keep us from deceiving ourselves. Help us to remember that we rarely reap what we haven't sown. Remind us that progress is seldom made on the wings of inevitability but requires prayerful plans, powerful perseverance, and loving providence. Teach us again that forgiveness still heals, truth still liberates, giving still transforms, and love still conquers.

Give the Members of this body a meaningful day. Provide them with wisdom to discern the excellent and to do what is best. Inspire them to conduct themselves in a way that honors You.

And, Lord, please remember the victims of the Kansas tornado.

We pray in Your wonderful Name. Amen.

PLEDGE OF ALLEGIANCE

The Honorable MARK L. PRYOR led the Pledge of Allegiance, as follows:

I pledge allegiance to the Flag of the United States of America, and to the Republic for which it stands, one nation under God, indivisible, with liberty and justice for all.

APPOINTMENT OF ACTING PRESIDENT PRO TEMPORE

The PRESIDING OFFICER. The clerk will please read a communication to the Senate from the President pro tempore (Mr. BYRD).

The assistant legislative clerk read the following letter:

U.S. SENATE,
PRESIDENT PRO TEMPORE,
Washington, DC, May 7, 2007.

To the Senate:

Under the provisions of rule I, paragraph 3, of the Standing Rules of the Senate, I hereby appoint the Honorable MARK L. PRYOR, a Senator from the State of Arkansas, to perform the duties of the Chair.

ROBERT C. BYRD,
President pro tempore.

Mr. PRYOR thereupon assumed the chair as Acting President pro tempore.

RECOGNITION OF THE MAJORITY LEADER

The ACTING PRESIDENT pro tempore. The majority leader is recognized.

SCHEDULE

Mr. REID. Mr. President, today, the Senate will be in a period of morning business until 4 o'clock, with the time equally divided and controlled by the respective leaders.

The Senate will resume consideration of S. 1082, the FDA bill, at 4 p.m. today. Upon resuming the bill, the Senate will begin several votes: first, the Cochran second-degree amendment to the Dorgan amendment, then the Dorgan amendment, and then the cloture vote on the substitute amendment.

I understand the managers will be here very soon to seek consent to dispose of amendments they have already worked out. Also, Members have until 3 o'clock today to file any first-degree amendments. In addition to filing cloture on the committee substitute amendment and the bill, I also filed cloture on the motion to proceed to H.R. 1495, the Water Resources Development Act, which is known as WRDA. It is a bipartisan piece of legislation, led by Senators BOXER and INHOFE. I am hopeful it will not be necessary to have that cloture vote and that we will be able to proceed to the bill once action is concluded on the FDA bill.

Members should be ready for a number of votes starting at around 4 o'clock today. The first vote will be 15 minutes, and the remaining votes will be 10-minute votes. Everyone should be alerted to that.

Another matter which I mentioned last week is going to conference with respect to the budget resolution. The House was slated to take that up this evening. I think now it may be tomorrow when they will take it up, so that message may not get to us until Wednesday.

This is a very busy week, so everyone should be aware of the different votes that may be necessary. We hope we can complete work on the FDA bill tonight. That is certainly possible; otherwise, maybe in the early morning.

IRAQ

Mr. REID. Mr. President, nearly a week has passed since the President vetoed a bipartisan proposal that fully funded our troops and also changed course in Iraq so we could responsibly end the war.

Although the President's actions thwarted the will of the American people, very clearly, they—the American people—deserve to know what their leaders in Congress are doing. We are alerting them that we, as congressional leaders, are doing everything we can to work toward an agreement on an emergency supplemental funding bill that will make America more secure, fully fund our troops, and responsibly change course in Iraq.

Our proposal called for a change in the mission and the phased redeployment of U.S. combat troops no later than October 1 of this year.

A bipartisan majority of the House and Senate made it clear they believe a timeline for the reduction of combat operations will compel the Iraqi Government to take responsibility for their own country, will reduce the specter of occupation, and will allow our forces to come home.

● This "bullet" symbol identifies statements or insertions which are not spoken by a Member of the Senate on the floor.

The American people believe this overwhelmingly. But now there are signs the Republican leadership in Congress is beginning to think a timeline is necessary as well. According to the L.A. Times, House Republican Leader JOHN BOEHNER said:

Mr. Bush risks defections in the fall if the war situation hasn't improved.

By the time we get to September or October, members are going to want to know how well this is working, and if it isn't, what's Plan B.

The House Republican leader now seems to be saying that he and his colleagues agree there must be a time limit on the President's current course in Iraq.

What is also revealing, and somewhat disturbing, is the Republican leader is willing to allow our troops to stay in Iraq with a failing strategy until he and his colleagues decide it is time to part with the President.

President Bush—the same President who vetoed our plan—said this as a candidate about his predecessor, Bill Clinton, and the war in Bosnia, in 1999:

I think it's important for the president to lay out a timetable as to how long they will be involved and when they would be withdrawn.

We hope President Bush will keep his own past words in mind as these negotiations continue.

We are pleased to see the House Republican leader, speaking on behalf of his caucus, adopt our view that this commitment in Iraq must not be openended, that there must be a timeline. It is surely no coincidence that his views come at a time when conditions in Iraq grow worse.

I am reminded of the Easter sermon of Pope Benedict, delivered only a month ago. The Pope said:

How many wounds—how much suffering there is in the world.

He continued:

Nothing positive comes from Iraq, torn apart by continual slaughter as the civilian population flees.

Since those words were spoken, conditions have indeed deteriorated.

In April, our troops suffered the deadliest month of the year and one of the deadliest of the entire 51 months of the war.

The President's own Special Inspector General for Iraq Reconstruction released its quarterly report last weekend that painted a dispiriting picture of waste, ineffectiveness, and failure to achieve even minimally satisfactory results.

Despite burning through most of the 20 billion American dollars planned for reconstruction, many Iraqis are without basic necessities such as electricity and clean drinking water. Of course, oil production is down. Only a third of Iraqi children are attending school. Seventy percent of the kids are suffering from symptoms of trauma that could paralyze an entire generation that we are counting on to harvest the seeds of democracy.

Iraqi Prime Minister al-Maliki is accused of sabotaging efforts for peace and stability by firing some of the country's top law enforcement officials for doing too good a job of combating violent Shiite militias.

President Bush speaks of pressuring the Iraqi people to take responsibility for their own future. Yet while American troops are fighting and dying to secure the country, the Iraqi Government is planning a 2-month summer vacation.

Yesterday, eight more courageous American soldiers fell; four the day before. I have no doubt these developments weighed on Leader BOEHNER's mind when he made his comments suggesting a fall timeline to the war in Iraq. But I know he is not alone. Many of my Republican friends across the aisle feel strongly that a change of course in our Iraq strategy is needed—one that holds the administration and the Iraqis accountable for real results. Many of my Republican friends across the aisle feel it is time for change. This is the time. I know many of my Republican friends also intend to be part of the solution on the way forward, and I look forward to working with them. We all look forward to continuing negotiations, which we will work on today. I have spoken to Chairman OBEY today. I talked to him Friday. I will continue to talk to him every day until we reach agreement on a bill that fully funds the troops while providing a responsible new course that makes America more secure.

No one wants to succeed in Iraq and make America more secure than I.

RESERVATION OF LEADER TIME

The ACTING PRESIDENT pro tempore. Under the previous order, the leadership time is reserved.

MORNING BUSINESS

The ACTING PRESIDENT pro tempore. Under the previous order, there will now be a period for the transaction of morning business until 4 p.m., with the time equally divided between the two leaders or their designees, with Senators permitted to speak for up to 10 minutes each.

Mr. REID. I suggest the absence of a quorum.

The ACTING PRESIDENT pro tempore. The clerk will call the roll.

The assistant 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 ACTING PRESIDENT pro tempore. Without objection, it is so ordered.

Mr. REID. Mr. President, I suggest the absence of a quorum and ask unanimous consent that the time in the quorum call be divided equally between the Democrats and the Republicans.

The ACTING PRESIDENT pro tempore. Without objection, it is so ordered.

The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

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

The ACTING PRESIDENT pro tempore. Without objection, it is so ordered.

HATCH AMENDMENT ON ANTIBIOTICS AND ENANTIOMERS

Mr. HATCH. Mr. President, I would like to discuss the amendment which deals with antibiotics and enantiomers, which is included in the managers' package we are adopting today.

I offered this amendment at the HELP Committee markup, but withdrew it with assurances that we would work it out prior to floor action. There have been constructive discussions among all interested parties and I believe we have worked language out that is acceptable.

There is a great urgency to this situation, and I want to make certain my colleagues understand it fully.

The Infectious Diseases Society of America, the Alliance for Aging Research, the Institute of Medicine, the Resources for the Future, the Centers for Disease Control, and many others have been sounding the alarm about the growing threat from resistant microorganisms and the need for innovation in the area of antibiotics.

Congress must listen.

Nobel Laureate Joshua Lederberg said it well:

We are running out of bullets for dealing with a number of (bacterial) infections. Patients are dying because we no longer in many cases have antibiotics that work.

The Hatch amendment is intended to be an initial step in the fight against these resistant strains of bacteria by increasing incentives and innovation.

Additionally, the language in the amendment requests FDA to work with companies to apply the Orphan Drug Act to antibiotics wherever possible. Hand-in-hand with this, it reauthorizes the Orphan Drug Act grant and contracts from fiscal years 2008 through 2012. As many of my colleagues know, this act has resulted in important medicines for rare diseases.

The Hatch amendment also ensures that currently existing incentives for new drugs are available for new single enantiomers in new therapeutic areas such as Alzheimer's, cancer, and type II diabetes among others. In 1997, FDA issued a Federal Register notice acknowledging that the policy needed clarification and this amendment would do that.

Let me start with the issue of antibiotics and the need for new antibiotics to fight drug-resistant infections. Many of us have become more and more concerned that there is an alarming increase in the number of drug-resistant infections—many of them serious—and we are running out of treatment options.

My first chart is based on data from the Centers for Disease Control and

Prevention and shows how resistant strains of infections have spread rapidly from 1980 to 2000. My colleagues, this is a very alarming trend and sadly, for all of us, the problem of resistance continues to grow.

A report many of us are familiar with, Bad Bugs, No Drugs, from the Infectious Diseases Society of America, IDSA, highlights the lack of R&D for new antibiotics.

Antibiotics are not profitable compared to medications that treat chronic conditions and lifestyle issues. Also, antibiotics are taken for short periods of time—unlike medications for chronic disease which may be taken daily.

And, when a new antibiotic comes on the market, it is discouraged from use to avoid the development of resistance. As a result, it is fair to say that major pharmaceutical companies have not been making significant investments in antibiotics.

Given that there are few, if any, antibiotics in the drug development pipeline, if Congress fails to act, we walk blindly into a future where we must fear basic infections we have long taken for granted are not a problem.

Medicine changed dramatically when penicillin was discovered and physicians had a tool to treat deadly infections.

Can any of my colleagues imagine life without penicillin? I am sorry to inform you, we are about there.

Over the years, many infections became resistant to penicillin, but we were OK—we moved on to the next antibiotic. We had methicillin—and now serious infections are resistant to that.

We should consider what the health professionals are telling us. Will we listen? We are taking antibiotics and our ability to treat bacterial infections for granted.

Infectious disease doctors from all over the country have been writing to their Senators to express their support for my amendment. They tell heartwrenching stories.

Dr. Helen Boucher, a physician at Tufts Medical Center in Boston, MA, wrote to tell Congress that patients are routinely lost ''to infections caused by resistant bacteria for which we have few to no options. [They] recently lost two bone marrow transplant recipients who survived all the chemo but died of multiply-resistant gram negative infections. In both cases, [physicians] pulled an old antibiotic off the shelf and gave it as a last resort, knowing how toxic it was but having NO other options for these young people. . . .''

She wrote:

> As a doc and an American, it's horrifying to know that few to no companies are investing even in discovery of new antibiotics for these infections . . . just this week [she] was presented a case of a previously completely healthy 33 year-old lady who presented to the hospital in Boston with pneumonia and died within 6 hours from community-acquired MRSA. Her story and so many others that we see ALL the time, make the need for new and powerful options to treat these infections critical.

Community-acquired MRSA is an infection that was historically acquired while in the hospital, but now is impacting young, healthy people. We have heard stories of high school, college and professional athletes losing their lives or careers as a result of these infections. Sadly, this infection has become far too common, difficult to treat and has few options to fight it. It can leave individuals disfigured, if they survive.

In my own State of Utah, the number of children with MRSA infections at the Primary Children's Medical Center in Salt Lake City has dramatically increased since 1989.

Dr. Andy Pavia of Salt Lake City told me that he ''cared for a 2 month old girl who developed MRSA pneumonia and almost died as a complication of an otherwise mild respiratory infection. She survived and will be going home to her parents, but only after 2 weeks of the most sophisticated intensive care and an additional 4 weeks of intravenous antibiotics.''

Dr. Pavia went on to explain that the Primary Children's Medical Center sees the impact of resistant bacteria almost every day.

In fact, he wrote:

> Last week a two year old girl [who] was weeks away from being cured of Burkitt's lymphoma developed shock due to a bloodstream infection with a highly resistant strain of a gram-negative bacteria. Fortunately, the bacteria was sensitive to one remaining antibiotic. If it had been resistant, she would not have left the Pediatric ICU alive.

The doctor related that MRSA is an aggressive, difficult to treat, form of staph that has spread rapidly within communities. Half of the children he sees with severe MRSA infections acquired their infection at home.

This is a picture of Bryce, whose family tells a similar story. He had his first cold 2 days before Christmas. Before then, 14-month-old Bryce Smith had never been sick. At 2 a.m. on New Year's Day, his parents took him to the emergency room, where the seriousness of their son's condition became immediately apparent.

An X-ray showed that Bryce had pneumonia. A CT scan showed that his right lung was filled with fluid. Four hours after arriving at the ER, Bryce was scheduled for surgery. Doctors found that a methicillin-resistant staph infection had eaten a hole through his lung.

For the first 12 days that Bryce was in the hospital, the doctors didn't know whether he would live. Doctors battled to force air into the child's lungs, but as they told his mom, it was like trying to pump air into a brick.

Doctors prescribed high levels of antibiotics, including vancomycin, in a desperate battle to fight the infections. For 6 weeks, the child did not wake up. During Bryce's stay in the hospital, he has suffered from several additional infections. Bryce is doing much better now, he was released from the hospital, but he still must relearn how to walk. His recovery could take several months. As of April 2007, the Smiths' total bill for Bryce's care is just under $1 million.

Fortunately, the family's insurance does not have a ceiling on payments; otherwise, the Smiths say they would be in financial ruin. Bryce's ongoing care needs are decreasing, but he still has regular visits with the pulmonologist, nephrologist, and his pediatrician. He still tires out easily with exertion.

The fact that children acquire this infection at home is significant because we used to only worry about it in the hospital.

Last month, there were numerous articles about CDC's concern that cases of resistant gonorrhea have dramatically increased and respond to only one antibiotic.

There has been much concern over the past couple months related to extensively-drug resistant—XDR–TB. Right now, there is a man in Phoenix, AZ, whom authorities took action to isolate in order to avoid the spread of the deadly XDR–TB infection he had contracted while out of the country.

This comes in addition to the numerous reports of our soldiers coming home from Iraq with Acinetobactor—a resistant infection that is especially difficult to treat and the only option is a very toxic antibiotic.

One doctor we have heard from, in a local community, indicated he has seen two patients just this month with infections resistant to every antibiotic currently available.

That is becoming a common occurrence.

Infections disease specialists can do little more than provide supportive care for those unfortunate patients. Without any new antibiotics in the pharmaceutical pipeline, there is no promise of a treatment for years to come.

Whatever we do to begin to address this serious concern, we can't hope to realize the benefit for more than a decade. Drug development takes time and money. Yet few companies are willing to invest either in the area of antibiotics.

I believe this chart shows that is the case. As you can see from this chart, the number of new antibacterial agents that have actually been approved is minimal. The market forces don't work well for antibiotics. When we cannot rely on the market, government has an obligation to step in.

The Hatch amendment focuses on incentives for research and development of antibiotics. Specifically, my amendment: Provides equitable treatment for so-called ''old'' antibiotics; promotes communication and education of current law orphan drug incentives by directing FDA to convene a public meeting to clarify what ''bad bugs'' may qualify for orphan designation; reauthorizes the Orphan Drug grants and contracts program which expired September 30, and requires FDA to establish, update and make publicly available information on antibiotic

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

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

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

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

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

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

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

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

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

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

The Hatch amendment makes it clear that development of an enantiomer for new use in a new therapeutic area based on new data would qualify for 5-year exclusivity. However, in order to address the potential for abuse the revised provision limits 5-year exclusivity to approvals in a new therapeutic class.

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

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

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

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

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

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

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

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

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

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

I submit to my colleagues, that if we had adequate antibiotics in development, we never would have had to look at these diseased feet. With passage of my amendment today, perhaps this chart can be relegated to the Russell attic forever.

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

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

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

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

RULES GOVERNING THE FDA

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

I yield the floor, and I suggest the absence of a quorum and ask unanimous consent that the time be charged equally to both sides.

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

The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

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

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

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

The PRESIDING OFFICER. The Senator is recognized.

AMENDMENTS TO THE FOOD AND DRUG ADMINISTRATION REVITALIZATION ACT

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Two members of the Institute of Medicine committee which issued the

report reiterated recommendations in an article published last week in the Journal of the American Medical Association. In particular, they stated:

The Institute of Medicine identified the imbalance in authority between the Office of New Drugs and the Office of Surveillance and Epidemiology as a major weakness in the drug safety system. In an effort to facilitate a collaborative and constructive team approach, the Institute of Medicine recommended joint authority for the Office of New Drugs and Office of Surveillance and Epidemiology in the postapproval setting.

These experts noted that the FDA's response to the Institute of Medicine's recommendations ''represent incremental progress'' but suggest that the FDA failed to embrace, among other things, ''the equality between the preapproval and postapproval activity of the agency.''

Having equality between the preapproval and postapproval activities at the FDA is fundamental to real reform. It is common sense. This is especially true when we think about what we have learned from the operation of the FDA over the past few years and those shortcomings.

As we debate this bill, we are going to hear a lot about the impressive Institute of Medicine study and its recommendations to improve the FDA. We have and will continue to hear Members talk about how S. 1082 addresses many of the Institute of Medicine's recommendations. However, this is one important and sweeping recommendation that is not addressed in the bill before us.

Amendment No. 1039 is intended to address that shortcoming. I have seen time and again in my investigations that serious adverse effects that emerge after a drug is on the market do not necessarily get the prompt attention they deserve. They are certainly not getting the attention from the Office of New Drugs.

Even the Government Accountability Office report entitled, ''Improvement Needed in FDA's Postmarket Decisionmaking and Oversight Process,'' stated:

FDA lacks clear and effective processes for making decisions about, and providing management oversight of, postmarket safety issues.

I, for one, have seen too many people suffer from the results of the Vioxx mess. I also have heard from parents whose children committed suicide on antidepressants.

This amendment is about making postmarketing safety in S. 1082 a reality, not just another byline. Identifying a safety issue after a drug is on the market is the beginning of the process of protecting the American consumer.

Once the safety questions are identified, FDA needs to be empowered and willing to take action to address those questions and to ensure timely notice to doctors and consumers of new safety risks for drugs that they are already taking.

Senator ENZI stated last Monday that with Vioxx, the Food and Drug Administration did not have enough tools to deal with the new risks that became evident only after Vioxx had been on the market for some time.

But the problem with the Vioxx mess and the antidepressant mess wasn't only about having enough tools, it was about FDA managers disregarding the concerns raised by its own scientists in the Office of Surveillance and Epidemiology and not taking action in a timely manner.

Amendment No. 1039, which is in the Institute of Medicine recommendations, is intended to curb delays when it comes to safety.

I have also been told by scientists and epidemiologists working in the FDA, as well as independent thought leaders, that S. 1082 as it stands will not prevent another Vioxx debacle.

They have told me that the Office of Surveillance and Epidemiology needs, at the minimum, joint postmarketing decisionmaking authority with the Office of New Drugs to ensure prompt postmarketing action.

I also am afraid to say, that right now, I am at the beginning of another review that will likely lead to concerns similar to those we have seen in the past—a situation where the postmarketing adverse events are severe and the public knows nothing.

The other amendment I want to talk about, amendment No. 998, is just plain common sense.

For FDA's new authorities to be meaningful, there has to be strong civil monetary penalties.

I hear that there is a lot of opposition to having stronger civil monetary penalties than those currently in S. 1082. But that just does not make sense to me.

Over the last week I have heard members talk about giving FDA some bite. Well, let's add some teeth.

Civil monetary penalties need to be more than the cost of doing business.

If civil monetary penalties are nothing more that the cost of doing business, you can't change behavior and, more importantly, you can't deter intentional bad behavior.

Amendment No. 998 would increase the penalties that can be imposed if companies fail to comply with the requirements of the ''risk evaluation and management strategies,'' such as labeling changes and requirements for postapproval studies or risk communication plans.

These requirements are at the core of S. 1082. But, FDA cannot be an effective regulator if it's all bark and no bite.

The last thing we need to do with this bill is to provide the FDA with new authorities but little enforcement capacity. That's not accountability and that won't help FDA do its job better for the American people, and it won't punish bad players.

That is why amendment Nos. 1039 and 998 make sense.

They fit into S. 1082 and its stated goal of promoting postmarketing safety.

I again thank Senators KENNEDY and ENZI for the tremendous efforts that went into bringing this bill to the floor, and I again thank them for incorporating a number of the provisions set forth in the two bills filed by Senator DODD and me.

Mr. President, I yield the floor.

ORDER OF PROCEDURE

Mr. KENNEDY. Mr. President, I understand there is a time allocation; am I correct?

The PRESIDING OFFICER. That is correct.

Mr. KENNEDY. Could the President tell us the time allocation remaining?

The PRESIDING OFFICER. The Republicans have 9 minutes remaining and the majority has 35 minutes.

Mr. KENNEDY. I note that the Senator from Maine was on the floor before I came down, and I know there are other Senators, Senator ROBERTS being one, who wanted to speak, and I think Senator BURR. We also have a number on our side.

My ranking member is here, and I imagine he will allocate the time on his side. I am glad to have the good Senator from Maine go ahead. I understand there are 9 minutes in total on her side.

Mr. President, I ask unanimous consent that I be allowed to follow her.

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

IMPORTATION OF PRESCRIPTION DRUGS

Ms. SNOWE. Mr. President, I thank the Senator from Massachusetts for his courtesy and for his cosponsorship of this initiative. I, obviously, want to also thank the sponsor of this legislation, with whom I am privileged to join, the Senator from North Dakota, who has demonstrated leadership for the last decade on this initiative which is so crucial to the American consumer.

I rise to speak today on behalf of the Dorgan-Snowe amendment regarding drug importation. I know the Senator from Mississippi, Mr. COCHRAN, has offered a second-degree amendment to require the Secretary of Health and Human Services certify both the savings and safety of drug importation. Obviously, there is concern for the safety of the American people. It is one that I appreciate strongly. It must be our highest priority. But we have been at this juncture before with respect to drug importation.

As I mentioned earlier, twice before we have seen the Congress adopt a requirement for the Secretary to certify safety and savings before implementing a program of prescription drug importation, and not a single prescription drug was imported under either the MEDS Act of 2000 or the Medicare Modernization Act of 2003. Americans deserve access to affordable medications, and that access must be safe, but

it is not made so by simply certifying with respect to drug importation. As I said, twice before we have been through this—in 2000, and of course in the Medicare Modernization Act of 2003 under the prescription drug benefit for the Part D Program.

Many who are in the Senate today supported a certification requirement in good faith, recognizing that the Secretary of Health and Human Services would certify the safety upon reviewing and evaluating circumstances, but that has not occurred. Most would not think such a certification would block Americans from legally importing medications. That is because for years we have seen our constituents—and certainly those from my State of Maine—using Canadian pharmacies, and both the safety and savings were indisputable. Yet certification did not arrive.

As a result, the former Secretary of Health and Human Services, Secretary Shalala, declined to make the certification with respect to the MEDS Act, and we know she did so because of three specific flaws in the law, each of which this legislation addresses.

After the passage of the Medicare Modernization Act, which included the prescription drug program, we saw that former Secretary Thompson could not certify importation. The fact is, it is patently unfair to ask the Secretary to make such a certification, especially as to safety. That is because you must give the Secretary the resources and the authority to implement measures to make prescription drugs and their distribution as safe as possible.

So it comes as no surprise that given no standards, no authority, and no resources, we have failed to see a Secretary provide certification over the last 7 years. Secretary Thompson understood this well. He said it simply:

> The law is this: In order to import drugs from any country, and especially Canada, I have to certify that all those drugs are safe. That is an impossible thing. If Congress wants to import drugs, they should take that provision out.

The certification of savings is no less of a red herring. In fact, it has become a persistent roadblock every time we have passed certification to allow drug importation by the Secretary of Health and Human Services. Without a doubt, Americans would not purchase imported medications if substantial savings were not being realized. Indeed, the Congressional Budget Office has told us the countries from which we would import under this bill pay 35 to 55 percent less for brand prescription drugs and that we can realize a drug savings alone of $50 billion over 10 years. It should be patently obvious the savings part of certifying importation is a nonissue.

In fact, the Congressional Budget Office has confirmed those savings again, estimating that in addition to consumer savings, the Federal Government would save $10.6 billion—including the Medicare and Medicaid Programs that would achieve indisputable savings. Every cent of that savings, the CBO estimates, will be lost if the Cochran amendment is adopted because, as we all know, there would be no legal importation.

The savings are clear. Yet the advocates of certification continue to insist certification is critical—particularly regarding safety. Yet what is needed is not a certification requirement, which simply is a stamp on the status quo, but real action to assure the safety of prescription drugs.

By way of analogy, I would like to know where we would be if we applied this simple certification approach to other areas. Consider air travel. Americans embark on thousands of flights every day, but the travel of millions is not dependent on certifying the status quo. We rely on regulation and oversight of the aircraft that fly and their maintenance—of the individuals who crew, service, and direct those aircraft—of every critical aspect of aviation. If we were waiting for the FAA and its international partners to simply say flying is safe rather than acting to make it safe, we simply wouldn't have commercial air travel.

I note that last week, as the Senate discussed problems with both the drug and food safety, I did not hear my colleagues suggest FDA certify that imported food is safe. We, instead, spoke about measures to make it so. That points to what this amendment is about—not ensuring safety but blocking fair access to imports for Americans.

The fact is, Americans simply cannot see why it is that they cannot be provided a safe and effective system, which is exactly what the Dorgan-Snowe amendment does and what this legislation has been drafted to accomplish year in and year out. We have taken every conceivable concern regarding safety and incorporated it in this legislation.

As you can see on this chart, we incorporate 31 provisions. Compare that to the Medicare Modernization Act, which included the Part D prescription drug program for seniors, that included only six safety-related provisions. We included 31 different provisions. That is crucial to understanding that this sets up a system that will allow FDA inspectors to approve registered prescription drugs imported from other countries—in fact, countries that meet or exceed our standards. Compare that, for example, to the fact that the FDA approves manufacturing facilities in other countries that actually have lower standards than our country does. We allow medications to be manufactured in other countries with lower standards than what we have. Yet we are now saying we will not allow importations of medications from countries that meet or exceed our standards.

At a time in which American consumers are paying 35 to 55 percent more for drugs than foreign consumers—in fact, paying the highest prices in the world—this amounts to $99 billion more than the foreign consumers. That is what Americans pay today. Some would say: Oh, that affects research and development. Well, no, not exactly. In fact, the pharmaceutical industry spends about 10 percent of that $99 billion. So about $10 billion in research and development more than they do in Europe. So we are not seeing the increase in prices that Americans pay being channeled into more research and development. It simply is not the case.

What this does say is that American consumers are paying more than anyone else in the world. Not only are they paying more for their drugs, but American taxpayers are underwriting the research and development, as we have seen obviously with the National Institutes of Health. The taxpayer understands how important it is that the Federal Government remain on the vanguard of research and development of life-threatening medications, and not only are they paying for the research and development that benefits foreign consumers, who are paying 35 to 55 percent less, but they are also paying the highest prices in the world.

That is why this legislation allowing for drug importation is so essential. We have addressed every safety concern. We create a regime for tracking the shipments, creating a pedigree, creating a history with FDA approval—inspected and registered. So I would urge the Members of the Senate to defeat this certification amendment and to support the Dorgan-Snowe amendment. I think we have achieved a milestone moment in the Senate, where we have finally recognized and acknowledged that the day has come to allow Americans to take advantage of more competitive prices than have been available to them before.

I yield the floor.

ORDER OF PROCEDURE

Mr. KENNEDY. Mr. President, we will speak as in morning business for 10 minutes and if the Chair would let me know when I have a minute left.

Mr. DORGAN. Mr. President, reserving the right to object, and I certainly would not object, but I want to understand the time. We have a vote at 4 o'clock, I believe, which is already ordered. Would the President tell me what the time is between the two parties, how it is divided and who controls time at this point?

The PRESIDING OFFICER. The time for morning business has been equally divided until 4 o'clock. The Republicans have no time remaining, and the majority has 33 minutes.

Mr. DORGAN. Senator KENNEDY is asking for 10 minutes in morning business?

The PRESIDING OFFICER. Senators are permitted to speak for 10 minutes.

Mr. DORGAN. Might I ask to follow Senator KENNEDY in morning business for 10 minutes?

Mr. ROBERTS. Mr. President, reserving the right to object, if that is where we are.

Mr. KENNEDY. Mr. President, could I have the attention of Members. I understand the good Senator from Kansas wanted to make a brief statement about the terrible tragedies that have affected his State, and I see my friend from Vermont is here, so if he were to take 10 minutes, we would still have 10 minutes.

Mr. SANDERS. Ten minutes would be fine.

Mr. KENNEDY. I am wondering if Senator SANDERS would be willing to take 6 minutes and let Senator ROBERTS have 4 to talk about the tragedies in his State. He mentioned this earlier to me, and I didn't think we would have this time dilemma. Would that be acceptable?

Mr. SANDERS. Yes.

Mr. ROBERTS. I could not hear the amount of time I might be permitted.

Mr. KENNEDY. We have the whole 30 minutes, but the Senator from Vermont has said that, of his 10 minutes, he would be glad to yield to you 4 minutes, and then he will take 6 minutes. Would that be agreeable?

Mr. ROBERTS. If I could plead with the Senator for 5 minutes?

Mr. SANDERS. Yes.

Mr. ROBERTS. I thank the Senator from Vermont.

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

Mr. KENNEDY. Mr. President, I will yield 1 minute of my time to Senator SANDERS.

Mr. SANDERS. I thank the Senator.

The PRESIDING OFFICER. The Senator from Massachusetts is recognized.

DRUG SAFETY

Mr. KENNEDY. Mr. President, hopefully during this afternoon we will have a chance to move irrevocably toward bringing the FDA into the 21st century, in terms of safety and security for American families. We do that with our primary focus making sure that in this time of the life sciences, the extraordinary breakthroughs we are seeing every single day, that the Food and Drug Administration is going to bring those new opportunities to American families but do it safely and do it efficaciously and do it in a way which is going to ensure that every family in America is going to have safe prescription drugs and safe products over which the FDA has jurisdiction.

I thank my friend from Wyoming for all his good work. We are going to have a series of three votes, and then we may very well set a pathway, hopefully, toward a successful conclusion of this legislation. He and I are both eager to see this legislation in the conference to work out, with the House of Representatives, the points of difference with the House. We are also eager to work out the extremely important area of the follow-on biologics. It is an enormously important area of public health, and it is going to demand a great deal of time and careful attention to make sure we get that issue correct.

It is important to not fail the American people but to see progress made in addressing this issue. The only way we can do it is make sure we get legislation that is going to pass the Senate, pass the House of Representatives, and move into conference. We are strongly committed to doing that.

I commend our colleagues for all their good work and assistance. We had a rigorous markup in our committee for several hours. There were a number of different amendments. We have addressed the issue of food safety with the Durbin amendment. This issue has been on the front pages all over this country and all over the world, particularly with regard to pet food as well as food safety generally. This legislation will go a long way toward giving assurances to American families that all of our food products are going to be safe and secure.

There are other provisions such as developing a nonprofit foundation so we can draw from the private sector and the public sector to make sure that agency is going to have the best of new techniques and new modalities, and to try to make sure the products that are before the Agency are going to be safe and secure and available as fast as possible. There will be a new emphasis in terms of science and also, as my friend from Wyoming points out, a toolbox that will be available to the FDA in order to ensure that we can get drugs more rapidly to the consumer but make sure they will be safer for American families, using the best of new technology, information technology, to make sure they are going to be more safe.

I am enormously appreciative of the work of my friend from North Dakota, Senator DORGAN, on the issue of cost and price. Part of this is making sure we are going to have drugs that will be safe, but we also want to make them accessible and available. I commend him and all those who have been a part of this process. This is certainly an aspect of the prescription drug issue that we should constantly address.

I thank Senator ROBERTS and Senator HARKIN for working with Senator ENZI and me on the important issue of DTC, direct-to-consumer advertising. We have accomplished our common goal of a constitutionally sound, effective, workable way to make sure that DTC ads provide accurate information to patients about the drugs they are taking. This amendment strikes the moratorium on DTC ads that had given rise to Constitutional concerns, and I think we have a very solid resolution. I wish to thank Senators STABENOW, BROWN, LOTT, THUNE, COBURN and HATCH for reaching agreement on the difficult issue of citizens petitions. Their amendment prohibits the abuse of the citizens petition process, a process that led to unwarranted delays in the approval process of FDA drugs, while making certain the FDA can review issues that have merit. The list also includes a novel proposal from Senator BROWNBACK and Senator BROWN to encourage the development of new therapies for neglected diseases. Under this innovative and thoughtful proposal, companies that have developed new treatments or vaccines for tropical diseases will receive a credit entitling them to a priority review at FDA for a product of their choosing. The proposal will not raise costs to consumers nor will it change safety standards. It is a very solid, imaginative, and creative approach. I commend Senator HATCH for his amendment on antibiotics, as well Senators BROWN, BURR, STABENOW and others for contributing important proposals to this amendment.

The amendment strikes the right balance between innovation and access, and closes a loophole that eliminated the incentives to bring old but never approved antibiotics to market.

If there were more time, I would describe other amendments on the list, but I simply wish to thank all our colleagues. This issue is a matter of enormous importance and incredible consequence to the safety and security of the American consumer. This legislation brings the FDA into the 21st century. I commend my friend and colleague Senator ENZI for all his work. Most of all, I want to thank our staffs. They have been tireless, over this past week, on a variety of different amendments and prior to that time as we worked our way to the floor of the Senate.

This is a very comprehensive bill. It is enormously important. We believe it will help in providing greater safety for American families, greater innovativeness in terms of breakthrough drugs and in terms of food safety, and greater opportunities for the FDA to have the best science there is.

Mr. President, whatever remaining time that I have, I yield it to the Senator from Vermont.

I yield the floor.

Mr. DORGAN. Mr. President, I will allow the Senator from Kansas, if he would prefer, to proceed for his 5 minutes, asking that I be recognized for 10 minutes following his presentation.

Mr. ROBERTS. Mr. President, I thank the distinguished Senator. I thank the distinguished Senator from Vermont for allowing me to speak.

DISASTER IN GREENSBURG, KANSAS

Mr. ROBERTS. My colleagues, last Friday evening the town of Greensburg, KS, was literally wiped off the map by an enormous, mile-and-a-half, level 5 tornado. As a result of this and storms associated with the system, 12 Kansans are confirmed dead—and I fear that number may still rise—and all of the 1,500 residents of Greensburg have been displaced.

What we have experienced in Greensburg is unlike any other event in recent Kansas history. The hospital is gone. The schools are gone. Every church is gone. Virtually every business in the community is gone, including all of Main Street. Estimates are that fully 95 percent of the structures in the town are damaged and destroyed.

But this is not all. Even as cleanup is starting, more storms continue to pound our State. Flooding and strong storms continue to compound the problem.

Too often, while government does not communicate and work well as partners in times of need and emergency, sometimes we could double that for Congress. However, this weekend my fellow Kansas Congressman and the Governor of Kansas and I all toured the devastated town of Greensburg. We were accompanied by our State's top-notch emergency officials. I spoke extensively with all levels of FEMA, in an effort to make sure they had everything they needed to move into place, and I talked to President Bush to give him a personal update from a McDonald's in Pratt, KS. Let me tell you, there is nothing quite like speaking to the President of the United States from a phonebooth in a local McDonald's to let the surrounding residents know their Government does mean business.

The President has been very supportive. We have been notified by the White House that he will be making a trip to Kansas to personally view the damage and visit with the people of Greensburg. The credit for this not only falls on Federal shoulders but those of our National Guard, all of the first responders, Red Cross, and many volunteers who, along with President Bush and the FEMA team and our State officials, are now working 24/7 to make it possible for the residents of Greensburg to rebuild and return home.

I stood here this winter, following a blizzard that buried much of western Kansas, and proclaimed the resiliency of Kansans, our willingness to help each other and our sheer determination when faced with great odds. That determination is being tested again, but I have no doubt in the coming days and weeks and months that the story of Greensburg will progress from one of horrible tragedy to one of optimism and hope for the future as we help one another rebuild, one brick at a time. It may be possible, indeed likely, that as we move forward, we may need additional emergency assistance or legislation from Congress to assist the residents of the town that no longer exists. I put our Senate leadership and all our colleagues on notice today that we will likely be coming to you with any requests for assistance to rebuild this Kansas community.

DRUG ADVERTISING

Mr. ROBERTS. Mr. President, I thank Chairman KENNEDY, Ranking Member ENZI and all of my colleagues for accepting my amendment to improve the drug advertisement provisions included in S. 1082, the Food and Drug Administration Revitalization Act.

My amendment, replaces the drug advertisement provisions in the underlying bill with what I believe is a more commonsense approach to dealing with prescription drug advertisements.

During the markup of this bill in the HELP Committee a few weeks ago, the chairman and Ranking Member ENZI committed to working with me to address my concerns on this issue. This amendment represents the result of our efforts to achieve an outcome that is acceptable to all of us.

I also want to thank Senators HARKIN, BURR, and COBURN for their leadership on this issue and for cosponsoring my amendment.

Chairman KENNEDY and Ranking Member ENZI, I want to say that I truly appreciate the hard work you both have done in putting together this bill. I know you and your staff have put in many long months of work to get us to this point.

I specifically want to thank David Bowen of Chairman KENNEDY's staff and Amy Muhlberg of Senator ENZI's staff for working so closely with me and my office on finding a resolution on the drug advertising issue. David and Amy, I appreciate your commitment and professionalism in helping us to achieve this compromise.

While I strongly support the goals of this legislation to ensure drug safety and to renew some very important prescription drug and medical device programs, I have serious concerns with provisions in the underlying bill regarding drug advertising. I believe these provisions would infringe on our first amendment rights to free speech.

Of most concern to me is a provision in the underlying bill to give the Secretary the discretion to institute a 2-year ban on advertising for new drugs and related restrictions on drug advertising.

As a former editor and reporter for several newspapers, I feel that these provisions violate the first amendment and would do nothing to address concerns that have been expressed with drug advertising. Instead, we would have a situation where the Secretary would become the editor for all prescription drug advertisements and could ban drug advertising for up to 2 years.

This would certainly put us on a slippery slope to restricting advertisements in other industries, and I don't think that is a responsible approach.

The freedom that is guaranteed to us under the first amendment demands that we carefully consider any proposal that would impose a ban or other limitation on speech. The first amendment says, ''Congress shall make no law . . . abridging the freedom of speech . . . .'' For more than three decades, this protection has been extended to speech in the form of advertising, or commercial speech.

The U.S. Supreme Court has set down an explicit four-part test—known as the Central Hudson test—to determine if a speech restriction violates the first amendment.

I believe the advertising provisions in the underlying bill fail the key parts of that test and my view is supported by constitutional experts, including the American Civil Liberties Union—ACLU, the Washington Legal Foundation and several other constitutional experts.

However, I understand that there are strong concerns with drug advertising. I agree that we have a legitimate interest in ensuring these advertisements are not false or misleading. This is why my amendment takes a reasonable and commonsense approach to deal with drug advertisements.

My amendment stresses the importance of assuring that advertising is accurate and balanced and recognizes that companies should be held accountable if their ads are false or misleading.

My amendment strikes the 2-year moratorium on advertising in the underlying bill and instead allows the Secretary to assess civil monetary penalties—up to $150,000 for the first violation and $300,000 for subsequent violations—on drug companies that produce false or misleading ads.

This will ensure that patients will know truthful and accurate information about new prescription medications in a timely manner, rather than having to wait until 2 years after their arrival in the marketplace.

My amendment also allows the Secretary to require the disclosure of a serious risk or date of approval of the drug in the advertisement if he or she believes the ad would be false or misleading without the disclosures.

My amendment requires that major statements about a drug's side effects, contraindications and effectiveness in television or radio ads be presented in a clear and conspicuous manner so as not to mislead the public.

My amendment also does not change the current language in the underlying bill which allows the Secretary to review direct-to-consumer ads before a drug company disseminates these ads to the public.

This will allow the FDA to comment and provide constructive feedback to companies to ensure their ads are appropriate and not misleading. Many companies are already submitting their ads to the FDA for review.

Truthful and accurate prescription drug ads do provide a benefit to the public. Research has shown that people are more likely to go to the doctor, ask thoughtful questions and discuss sensitive health issues with their doctors as a result of DTC ads.

My amendment ensures these positive aspects of advertising will continue, but also gives the FDA the tools

they need to protect the public from false or misleading prescription drug ads.

The agreement that was accepted today is a fair compromise that addresses the concerns of all of the Members involved.

Again, I thank the chairman and Ranking Member ENZI for their efforts to work on this important issue, and I thank all of my colleagues for accepting my amendment.

I ask unanimous consent to add Senator WEBB as a cosponsor of the Drug Safety Act.

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

DRUG IMPORTATION

Mr. DORGAN. Mr. President, if and when we pass the underlying bill, we will have advanced this country's interests, I believe. But if we pass this bill by adding the Cochran amendment, which effectively kills the underlying amendment on which we have now voted cloture last Thursday, dealing with the safe importation of FDA-approved drugs at a much lower price—if we kill that by agreeing to the Cochran amendment, we will have substantially diminished the opportunity to provide for drug safety. That is a fact.

The underlying bill doesn't have in it what we have in the Dorgan-Snowe amendment, for which we have 33 cosponsors. We have pedigree requirements. We have serial requirements to be written on the pill bottles. We have anticounterfeiting measures. We have addressed all of those issues in the amendment. None of those requirements exist today, and none of those will exist with the domestic drug supply or with imported drugs when this legislation passes.

The only way those provisions will exist is if we defeat the Cochran amendment and then pass the amendment that we have offered, allowing for the safe reimportation of prescription drugs, because we put the safety provisions in our amendment.

Mr. President, let me ask unanimous consent to show once again two bottles of Lipitor.

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

Mr. DORGAN. This is a prescription drug made in Ireland. It is made in Ireland. It is called Lipitor. It is for the reduction of cholesterol. It lowers your cholesterol—the same pill, put in the same bottle, made by the same company, made in the same FDA-approved plant. It has only one difference—only one. That is, this one costs twice as much. Why? Because this one was sent to Canada and this was sent to the United States. The U.S. consumer is told: Congratulations, you get to pay twice as much for the prescription drug.

But that is not unusual. It is happening all the time.

Let's talk about counterfeiting. This is a $20 bill. This is a new $20 bill, you know, the ones we brag about, the ones the mint has press conferences about. We have all kinds of technology in this $20 bill to prevent and prohibit counterfeiters from reproducing this $20 bill.

We can build a technology in a $20 bill to prevent counterfeiting, but we can't do it for medicine? Are you kidding me? What we have provided in this amendment is a series of steps: complete pedigree, serial numbers, RFID technology and anticounterfeiting measures. We can do it for a $20 bill but not for a bottle of medicine? Don't believe it.

We are going to vote at 4 o'clock. The question is going to be: Will the pharmaceutical industry have their way once again, as they have so often?

Let me make a point that is important. The Cochran amendment is already law. It was passed in 2003—in 2003. It already exists in law. The result is the Secretary of Health and Human Services says it can't be implemented because I can't certify there is no risk. The fact is the Secretary can't certify there is no risk with any new drug. He couldn't certify there is no risk with spinach coming from Mexico or strawberries coming from any other country. He couldn't certify there is no risk with any food product being imported. They can't certify there is no risk with the domestic drug supply. In fact, the domestic drug supply, without our amendment, will be dramatically less safe because you will not have the protections we put in this amendment.

The pharmaceutical industry has never wanted them, and the underlying bill doesn't include them. It doesn't include the anticounterfeiting provisions. It doesn't include the pedigree, the serial requirement on the individual bottles to track back. It does not include that. That is a fact.

So don't vote for the Cochran amendment and then tell people you want to allow Americans to import FDA-approved, lower priced drugs. The question is this: Should the American people be paying the highest prices in the world for prescription drugs? The answer is, no; it is not fair.

Why should that be the case, that we should pay the highest prices in the world? So we have put together a piece of legislation—bipartisan, people on both sides of the aisle, 33 cosponsors. Then we are told, well, it is unsafe to do this. It is unsafe.

That is nonsense. It is not unsafe. Europe has done it for 20 years. Europe can do it, but we can't do it? It gives consumers the opportunity to take advantage of the global marketplace.

We are talking about FDA-approved drugs, made in FDA-approved plants, sold all over the world with one difference—price. The American consumers are told they have to pay the highest price. Dr. David Kessler is the expert on this, in my judgment. He was FDA Commissioner for 8 years, the head of the Food and Drug Administration. The Dorgan-Snowe bill ''provides a sound framework for assuring that imported drugs are safe and effective.''

Safe and effective. End of story, in my judgment. I understand the pharmaceutical industry does not want this. I understand that. They want to control prices. Yes, we have price controls in America, not Government price controls but price controls by the pharmaceutical industry.

It is the only industrialized country in the world that I am aware of that says to the drug industry: Price it as you wish. It doesn't matter. You just price it as you wish.

Well, what they have done—I had a hearing. Here is what they told me. They price at the level they price prescription drugs in this country because they can. Because they can. That might sound OK for the bottom line, but what does it mean for the person walking into the grocery store tonight in a small town in the Midwest who does not have much money and has to decide—the pharmacy is at the back of the store—I better go buy the prescription drugs the doctor says I need first to find out how much money I have left for groceries?

It goes on all the time. Many of us believe, Republicans and Democrats, we ought to at least open the global marketplace for consumers to be able to pursue those FDA-approved drugs, made in FDA-approved plants, at lower prices, the prices at which they are sold in virtually every other country in the world. This is unfair to the American consumer. That is the point.

Interestingly, there was a long description of counterfeit drugs in the New York Times this weekend. None of that would be available to report, in my judgment, because it would not have happened if we had had the provisions, the safety provisions we have in the Dorgan-Snowe amendment.

The fact is, you would not have danger in the drug supply because you would have much more money going to the FDA for the purpose of making certain the drug supply is safe. I am not just talking about the imported drugs, I am talking about a drug supply sold in this country, produced here and sold here. The lack of serial numbers, the lack of a pedigree, the lack of effective anticounterfeiting technology, the lack of resources to go after RFID technology, all of that is lacking in the underlying bill.

It is not in the bill. The only way it is going to get there is if we are willing to defeat the Cochran amendment and to pass the amendment I have offered along with many of my colleagues. This is not a new issue. We have come to this issue on many occasions in the past. Each and every time the pharmaceutical industry has been able to trump us with votes on the floor of the Senate or the House. I hope—first I wish, second I hope, and finally I expect, that one of these days we will be able to prevail. One of these days we may be able to win this debate. Maybe it is today at 4 o'clock. I hope so.

Some say, well, there will be no savings with your amendment. Well, the Congressional Budget Office says it is $50 billion in 10 years—$50 billion. Is that a savings? It seems to me it is. Some say, well, this would be unsafe. You cannot prevent counterfeits from coming in.

Once again, we have all of this technology to prevent somebody from counterfeiting a twenty-dollar bill, but we cannot with respect to medicine? Of course we can.

Europe has done it for 20 years in a manner that is safe, but we cannot because we are not as smart as they are. Nonsense. Finally, at last, at long last, I hope this Senate will stand up to the pharmaceutical industry and say this: You are a good industry. We appreciate what you do. We like lifesavings drugs. But lifesavings drugs save no lives if you cannot afford to take them. We do not support your pricing policy. We believe a pricing policy that says to the American consumer: You pay the highest prices in the world, we believe that pricing policy is wrong and you have to change it. That is what I hope the message will be in this Chamber this afternoon.

It is past the time, long past the time, in my judgment, for this Congress to stand up on these issues.

In this case, let's stand up on the side of the American people who have been denied their right to participate in the global economy, to access a safe supply of drugs, FDA-approved, when it is sold in every other country for lower prices.

Let me conclude by pointing out, as I did last week, an old man sitting on a straw bale on a North Dakota farm told me one day, he said: I am in my eighties. My wife has fought breast cancer for 3 years. For 3 years we have driven to Canada to buy her Tamoxifen. Three years we have driven to Canada to buy the Tamoxifen.

You can bring a small supply across the border if you do it personally. Why? Because it costs three-fourths less than it costs in the United States. He said: I save 80 percent by buying it in Canada. Yet for 3 years my wife has had to fight breast cancer and fight the high prices here, and we have had to drive into Canada.

Well, the fact is, most Americans cannot drive to Canada. This bill is for most of the Americans who are paying prices that are too high. They want a safe drug supply, but they, for sure, finally, at long last, want a fair price, one they have not been getting, one they ought to get starting at 4 o'clock today.

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

The PRESIDING OFFICER. The Senator from Vermont is recognized.

Mr. SANDERS. Mr. President, let me congratulate the Senator for his outstanding leadership on this issue. Let me just pick up right from where he left off. He and I and Senator SNOWE and a number of us have been dealing with this issue for many years. My involvement came in 1999, when I took a busload of Vermonters, including many women who were struggling for their lives with breast cancer.

Many of those women did not have a lot of money, and they also went across the Canadian border. They also purchased Tamoxifen. In those days, the price they paid was one-tenth the price, one-tenth the price compared to what they were paying in the United States. Here you have women struggling for their lives, who do not have a lot of money, and were paying one-tenth the price.

This amendment is a big deal. This amendment will mean that Americans from one end of our country to the other, people with chronic illnesses, senior citizens who run into the doughnut hole, so-called doughnut hole on Medicare Part D, that finally these Americans, our Americans, our people, will no longer continue to be ripped off by the pharmaceutical industry and be forced to pay by far the highest prices in the industrialized world for the same exact medicine which people in Canada, people in Germany, people all over Europe receive at far lower prices—the same medicines, same companies, same factory, except we pay far higher prices.

There is very strong support for this legislation. Millions of Americans are already supporting this legislation by getting into their cars and going over the Canadian border. The AARP and other senior organizations support this amendment. My understanding is that the AARP intends to note on their scorecard that a vote for the Cochran amendment—which is clearly a poison pill—is a vote against reimportation.

I would urge my colleagues, if you disagree with reimportation, vote no. But a vote for the Cochran amendment is, in fact, a vote no.

You have heard from Senator SNOWE. You have heard from Senator DORGAN. The arguments over safety are just not accurate. This bill details in great length an entire regimen as to how we can make sure all of the prescription drugs reimported into the United States are safe and FDA approved.

I always find it remarkable that every day, huge amounts of imported food are coming into this country. I do not hear a hue and cry about whether that food is inspected.

Let me quote from the May 1st New York Times:

> More than 135 countries ship food items to the United States. Canada, Mexico and China have led the way with China shipping nearly five times as much in food items to the United States as it did in 1996.

China is importing more and more food into the United States. Where are the FDA inspectors? Are they all over the farms in China making sure these products are safe? I have not heard one word about that issue. This legislation has built in the strongest prescription drug safety regimen we have ever seen.

Let me tell you what this debate is really about. It is not about prescription drug safety. It is about the power of the pharmaceutical industry, which in a city that has enormously powerful special interests, we have the pharmaceutical industry standing uniquely alone as the most important, if you will, and, in my view, greedy lobby in the entire United States of America. Here it is. Do you want to know what the issue is? Here it is: pharmaceutical industry lobbying.

From 1998 to 2006 they spent $1.1 billion for lobbying; 1998 to 2006, $1.1 billion in lobbying.

The pharmaceutical industry has over 1,000 well-paid lobbyists right here on Capitol Hill: former heads of the Republican Party, former leaders in the Democratic Party. Whenever anybody stands up for justice, whenever anybody stands up to try to lower the cost of prescription drugs in this country so that the American people can afford these lifesaving medicines, these lobbyists descend like locusts on all of our offices in the Senate, in the House. That is what they do.

It is not just the amount of money they spend on lobbying. They spend a substantial amount of money on campaign contributions: From 1990 to 2006, $139 million in campaign contributions; 2006 alone, $19 million. That is power. What this debate is about is not just the need to lower the cost of prescription drugs in America, as important as that is. What this debate is more significantly about is whether the Congress of the United States has the courage to stand up to the greediest, most powerful special interests in this country.

In November the American people went to the polls. They said they want a change in the direction in which this country is moving. Clearly, that election had a lot to do with Iraq. It certainly did. It had a lot to do with global warming, I believe. But it also, in any view, had a lot to do with the understanding that year after year wealthy and powerful special interests have dictated the terms of the debate, have paid for the legislation which has come through the Senate and through the House.

The drug companies have managed to do something rather amazing. Virtually all of the Members of the Senate and the House look at economic issues through two lenses. No. 1, in order to protect consumers, we say: Let there be free market competition. That is the way to lower the costs of the product. And there is truth to that.

The other way that we can protect consumers is through Government regulation. There is certainly truth to that. What the pharmaceutical industry has managed to do is tell us we cannot regulate the pharmaceutical companies. We cannot have Medicare negotiating lower prices with the drug companies. We cannot do that. They have given us all kinds of reasons we cannot do that.

Then they have told us, well, we also cannot do free market competition: No,

you cannot have the local druggist going out and purchasing the product at the best price that he can get, maybe in Canada, maybe Europe. You can't do that. You cannot have regulation. You cannot have free market competition.

Then, on top of all of that, what the drug companies have managed to do is get many billions of dollars in corporate welfare, so the taxpayers of this country subsidize the research and development of many of the most important drugs, while the consumers, the American consumers, get no reasonable pricing despite the many billions of dollars that go into research and development that were paid for by them.

The drug companies get it all. That is what they get. At the end of the day, year after year after year, they are one of the most profitable industries in this country. They are very profitable, and elderly people and working people all over this country find it harder and harder to pay for the prescription drugs they desperately need.

Let us stand with the people. Let's defeat the Cochran amendment and pass the Dorgan amendment.

CONCLUSION OF MORNING BUSINESS

The PRESIDING OFFICER. Morning business is closed.

PRESCRIPTION DRUG USER FEE AMENDMENTS OF 2007

The PRESIDING OFFICER (Ms. KLOBUCHAR). Under the previous order, the Senate will resume consideration of S. 1082, which the clerk will report.

The legislative clerk read as follows:

A bill (S. 1082) to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes.

Pending:

Landrieu amendment No. 1004, to require the Food and Drug Administration to premit the sale of baby turtles as pets so long as the seller uses proven methods to effectively treat salmonella.

Dorgan amendment No. 990, to provide for the importation of prescription drugs.

Cochran amendment No. 1010 (to amendment No. 990), to protect the health and safety of the public.

Stabenow amendment No. 1011, to insert provisions related to citizens petitions.

Brown (for Brownback/Brown) amendment No. 985, to establish a priority drug review process to encourage treatments of tropical diseases.

Vitter amendment No. 983, to require counterfeit-resistant technologies for prescription drugs.

Inhofe amendment No. 988, to protect children and their parents from being coerced into administering a controlled substance in order to attend school.

Gregg/Coleman amendment No. 993, to provide for the regulation of Internet pharmacies.

Mr. GRASSLEY. Madam President, we have three critical votes ahead of us this afternoon. These votes mean that today is the day we show the American people whether we can really pass drug importation or whether we are just giving it lip service and nothing else. The Dorgan amendment is the moment American consumers have been waiting for and today is the day.

As I said last week, the Dorgan amendment is the result of a collaborative effort by myself with Senator DORGAN and with Senator SNOWE and Senator KENNEDY to finally make drug importation legal in this country.

This is the golden opportunity this year to get it done.

Now we have heard here on the floor the concerns that some have with drug importation and drug safety. Let me tell you that this is something I take seriously. Everyone who knows me knows that I care deeply about the safety of drugs, and I would not be standing here today urging support for the Dorgan amendment if I didn't think it had the right stuff on drug safety. And it does.

The fact is that the unsafe situation is what we have today.

Today, consumers are ordering drugs over the Internet from who knows where, and the FDA does not have the resources to do much of anything about it.

The fact is that legislation to legalize importation would not only help to lower the cost of prescription drugs for all Americans but also should shut down rogue Internet pharmacies selling unsafe drugs.

The Dorgan amendment would improve drug safety, not threaten it. And it would open up trade to lower cost drugs.

We see news accounts on a regular basis describing Americans who log on to the Internet to purchase drugs from Canada and elsewhere.

In 2004, my staff were briefed about an investigation by the Permanent Subcommittee on Investigations for the Senate Government Affairs Committee.

The Permanent Subcommittee on Investigations conducted an investigation into current drug importation. They found that about 40,000 parcels containing prescription drugs come through the JFK mail facility every single day of the year—40,000 packages each day.

Now, the JFK airport houses the largest International Mail Branch in the United States, but even then it is the tip of the iceberg.

Each day of the year 30,000 packages of drugs enter the United States through Miami, and 20,000 enter through Chicago. That's 50,000 more packages each day.

What is worse, about 28 percent of the drugs coming in are controlled substances.

These are addictive drugs that require close physician supervision.

While most people are ordering their prescriptions from Canada, they are also ordering prescriptions from Brazil, India, Pakistan, the Netherlands, Spain, Portugal, Mexico and Romania.

Although the Federal Food, Drug, and Cosmetic Act prohibits the importation of unapproved, misbranded, or adulterated drugs into the United States, the fact is that thousands of counterfeit and unregulated drugs are seeping through our borders. This is what is happening today.

John Taylor, Associate Commissioner of Regulatory Affairs for the Food and Drug Administration, FDA, in his testimony before the House Committee on Energy and Commerce in June 2003 stated that, ''the growing volume of unapproved imported drugs, which often are generated from sales via the Internet, presents a formidable enforcement challenge.''

Despite the hard work of both the FDA and BCBP to control our borders, the importation of illegal drugs has become an unenforceable problem. That is because today, the FDA does not have the authority or the resources to do much about it. The Dorgan amendment would change that.

The basic approach to assuring the drugs are safe in the Dorgan amendment which I coauthored with him—is to give FDA the ability to verify the drug pedigree back to the manufacturer, require FDA to inspect frequently, and require fees to give FDA the resources to do this.

For imports by individuals from Canada, the bill requires the exporters in Canada to register with FDA and to post a bond that they will lose if they send unsafe drugs. Frequent inspections by FDA ensure compliance.

For commercial imports, American wholesalers and pharmacists must register with FDA and are subject to criminal penalties if they import unsafe drugs. Again, frequent inspections by FDA ensure compliance.

The bill requires manufacturers to inform FDA whether foreign drugs meet FDA standards, and if they don't, the manufacturers have to give FDA the information necessary to evaluate the safety of the drug. If a foreign drug is manufactured in a plant the FDA has not inspected, FDA can inspect it.

The bottom line is the legislation gives the FDA the authority and resources it needs to implement safely the drug importation program set up under this bill.

The fact is that the unsafe situation is what we have today: 40,000 drug packages coming in every day in New York, 30,000 drug packages coming in every day in Miami, and 20,000 drug packages coming in every day in Chicago. That is 90,000 packages with drugs coming in from other countries every single day.

We are already saying yes to drug importation every day that we allow this unregulated and unsafe situation to exist. We say yes to it 90,000 times a day.

What we need to do and what the Dorgan amendment would accomplish is giving the FDA the resources to clean up this mess.

The Dorgan amendment gives the FDA the resources and authority to

crack down on the unsafe and unregulated importation of drugs. That is what we need. That is one of the key reasons I have been working with Senator DORGAN and Senator SNOWE and Senator KENNEDY on this legislation. One of our key aims is to improve drug safety.

I have been doing a lot of work in the area of drug safety, as my colleagues know, and I felt that I should talk about why the Dorgan amendment is important for improving drug safety.

A vote against the Dorgan amendment is a vote in favor of the unsafe situation we have today.

I must also say that a vote for the Cochran amendment is a vote to kill the Dorgan amendment. So a vote in favor of the Cochran amendment is a vote in favor of doing nothing. It is a vote for keeping the unsafe situation we have today.

Congress must act now on legislation that will not only shut down rogue Internet pharmacies selling unsafe drugs to consumers but will also lower the cost of prescription drugs.

Legalizing the importation of prescription drugs through a highly regulated system overseen by FDA will stem the tide of unregulated pharmaceuticals coming into the United States and create a safe and effective system for obtaining low-cost prescription drugs.

The bill before us is the vehicle this year to get it done. The bill we are debating is a must-pass FDA bill. The Senate should send a strong message that we are committed to finally getting it done this year.

And that is what we are working together to do today.

Making it legal for Americans to import their prescription drugs is a top priority at the grassroots. It needs to be a top priority here in Washington.

I have long advocated allowing American consumers access to safe drugs from other countries. I have always considered it a free-trade issue.

Imports create competition and keep domestic industry more responsive to consumers.

In the United States, we import everything consumers want. So that should be the case on prescription drugs.

We need to do it legally and safely. We need to give the FDA the authority and resources to do it. That is what the Dorgan amendment would do.

Consumers in the United States pay far more for prescription drugs than those in other counties.

If Americans could legally and safely access prescription drugs outside the United States, then drug companies will be forced to reevaluate their pricing strategies. They would no longer be able to gouge American consumers by making them pay more than their fair share of the high cost of research and development.

Now, it is true that pharmaceutical companies do not like the idea of opening up America to the global marketplace.

They want to keep the United States closed to other markets in order to charge higher prices here. However, with the Dorgan amendment, prescription drug companies will be forced to compete and establish fair prices here in America.

Now some don't want this to happen. And I want to reiterate that there is an attempt to kill drug importation as has been done many times before in this Chamber. I am referring to an amendment by my good friend from Mississippi, Senator COCHRAN. His amendment would require a certification about health and safety. That amendment is designed to kill drug importation once again. It is a clever amendment but it is a poison pill.

Our effort develops an effective and safe system that gives Americans access to lower prices. This amendment requires that all imported drugs be approved by the FDA. The amendment sets a stringent set of safety requirements that must be met before Americans can import drugs from that country. And there are stiff penalties for violating the safety requirements.

Don't be fooled by the Cochran amendment. Voting for the Cochran amendment is a vote to kill drug importation.

With the Dorgan amendment, we are working to get the job done.

We need to make sure Americans have even greater, more affordable access to wonder drugs by further opening the doors to competition in the global pharmaceutical industry.

Americans are waiting. We must make sure they have access to affordable prescription drugs.

I urge my colleagues to vote against the Cochran amendment and in favor of the Dorgan amendment.

Mrs. CLINTON. Madam President, for many years, the FDA has been considered the gold standard among the world's drug safety bodies. And no one here doubts the desire of the agency's many career employees to continue to carry out its mission of keeping our drug supply safe for all Americans. In the legislation we are considering today, S. 1082, the Food and Drug Administration Revitalization Act, we provide these dedicated employees with the resources necessary to continue their work to ensure the safety and efficacy of drugs and biologic products for Americans.

Despite the dedication of the FDA's employees, we know there have been breakdowns at the agency. We know that, at times, it has taken too long to act when a drug may pose a threat. It took many months from the point when scientists became aware of the elevated risk of adverse cardiovascular events associated with Vioxx and the point when it was withdrawn from the market, during which time the FDA had multiple opportunities to engage in stronger actions to protect consumers.

In recent years, we have seen the scientific process unduly influenced by political or economic factors. When Senator PATTY MURRAY and I worked to secure a decision for over-the-counter availability of Plan B, we saw the ways in which science-based decisionmaking was compromised. The Government Accountability Office has confirmed that the FDA's 2004 decision not to approve over-the-counter sales of Plan B was politically motivated. Concerns about undue influence from factors other than science extend beyond this one example. According to a Union of Concerned Scientists survey, 61 percent of FDA scientists could cite examples of when ''Health and Human Services or FDA political appointees have inappropriately injected themselves into FDA determinations of actions.'' Twenty percent of those responding had been ''asked explicitly by FDA decision makers to provide incomplete, inaccurate, or misleading information ''

Because of these examples, I believe that the American public lost a great deal of confidence in the ability of the agency to ensure the safety of their medications. With this legislation, we can begin the process of rebuilding consumers' confidence in the FDA. Through this bill, we are taking concrete steps to improve drug safety. S. 1082 establishes steps to establish a routine active surveillance system for medications and sets up a process through which the FDA can better manage risks for a range of drugs, from requiring postmarket studies to improving communication about the risks and benefits associated with medications.

In addition to establishing a framework to increase drug safety, we are also working to implement an atmosphere where science guides the agency's decisions. We need to put into place the systems to ensure that employees can engage in the open, evidence-based discourse needed as part of the drug approval and review process—discourse not unduly influenced by political concerns. This legislation goes a long way to doing some of that by increasing the transparency around drug approval decisions, addressing conflicts of interests on advisory committees, and creating a climate that protects the rights of employees to publish in peer-reviewed scientific journals.

I know that many of my colleagues have raised concerns about safety in the context of reimportation of drugs, and I am pleased to note that on this legislation, we have found a way to allow for safe drug reimportation. S. 1082 contains the provisions of Senator DORGAN and SNOWE's Pharmaceutical Access and Drug Safety Act, legislation I am proud to cosponsor. This amendment would establish the framework through which we could phase in drug reimportation from other nations where regulatory authority is similar to that in our country, allowing millions of Americans to safely obtain medically necessary drugs at lower cost.

Americans pay higher prices for the exact same prescription drugs being taken by their counterparts in Canada and Europe. The Congressional Budget Office has found that prices for brand-name prescription drugs are 35 percent to 55 percent higher in the United States. This price disparity affects millions of Americans. Our seniors, many of whom are on fixed incomes, end up spending larger portions of their income on drugs, especially when falling into the ''doughnut hole'' or wrestling with other gaps in a Medicare Part D benefit. And this isn't only a problem for seniors—we have 46 million uninsured individuals in our country, many of whom are unable to afford prescription drugs. Without these drugs, manageable chronic conditions, like asthma or high blood pressure, spiral out of control into serious health problems.

The lack of affordable drugs does not just hurt those who are uninsured or underinsured, but it also places greater pressure upon our health care system. The cost of treating someone in the emergency room is much higher than the cost of a prescription. But the way our system is set up, we don't help people engage in cost-effective disease management by making those drugs affordable, and I believe that we need to examine the ways in which importation can lower costs not only for consumers but for our overall system.

The Dorgan-Snowe amendment contains many provisions that will ensure safety while giving Americans access to cheaper drugs. This bipartisan provision will allow seniors to safely access drugs from Canada starting 90 days after enactment. It will provide the needed authority and funding to the FDA to regulate foreign pharmacies and wholesalers, so that we can be sure that any drugs that enter the United States are safe for our citizens. And it will increase the consumer protections involved with internet pharmacies, so that people who don't live near the border can access imported drugs without being defrauded.

We need to make drug reimportation safe, we need to make drug reimportation unambiguously legal, and we need to do so as quickly as possible. The Dorgan-Snowe amendment would allow us to do all of those things, and I would urge all of my colleagues to support this amendment to the bill.

In addition to the provisions of this legislation dealing with drug safety and reimportation, I am proud to note that the Food and Drug Administration Revitalization Act has an entire title devoted to pediatric issues. I worked with Senators DODD, KENNEDY, and ENZI to craft these provisions, which will be of great benefit to children. The pediatric device provisions will help us improve the number and types of medical devices designed for pediatric populations, and the reauthorization of the Best Pharmaceuticals for Children Act improves the applicability of the pediatric exclusivity incentive and increases the speed through which these studies can be requested by the FDA. When this bill was passed in 2002, I was able to work with Senator DODD and the HELP Committee to increase provisions to assist pediatric cancer research, and I am pleased to be a cosponsor of this legislation this time around.

S. 1082 also contains most of the provisions of the Pediatric Research Improvement Act, a bill that I introduced earlier this year to reauthorize the pediatric rule. Because of this authority, the Food and Drug Administration is able to ensure that drugs that are marketed for children are safe and effective in children.

For the past decade, I have been working to ensure that drugs that are marketed to children are safe and effective in children. As of the early 1990s, only about 20 percent of drugs contained specific pediatric dosing information, but since 1998, we have had over 1,000 drugs fall under the scope of the pediatric rule, resulting in hundreds of studies that have helped us gain valuable data about drugs commonly used by kids.

The reauthorization of the pediatric rule contained in this larger bill will allow us to make additional strides in improving pediatric drug development. We will be able to remove unnecessary bureaucratic barriers and improve the ability of the Food and Drug Administration to require testing on already-marketed drugs when sponsors refuse to carry out such testing under the incentive provided by the Best Pharmaceuticals for Children Act.

It will improve our ability to collect and analyze data about pediatric clinical trials so that we can better evaluate the impact of such trials upon children's health overall, and it will improve the FDA's ability to coordinate the incentives provided under Best Pharmaceuticals for Children Act with the pediatric rule so that these two pediatric programs of the agency can work together more seamlessly.

However, I must note that I am disappointed that this bill does not consider what I believe to be a critical part of the Pediatric Research Improvement Act—the provision which would have made permanent the authority of the FDA to obtain important data through the pediatric rule.

Instead, the legislation before the Senate today contains a sunset of this authority, meaning that if this provision isn't reauthorized 5 years from now, the FDA will no longer be able to ensure that drugs used in children are safe and effective in children.

We would never dream of placing a sunset on the FDA's authority to certify the safety and efficacy of drugs used in adults, and I fail to understand why we impose a different standard on drugs for children, and I will seek to address this issue as the bill moves forward.

We must also improve the FDA's authority in the realm of follow-on biologics. While there is nothing in the version of the legislation that is on the floor today that addresses this issue, Senators KENNEDY and ENZI have made a commitment that we will mark up legislation on this issue on June 13 in the HELP Committee and that we will incorporate this legislation into the conference negotiations on this drug safety bill.

Earlier this year, in conjunction with a number of bipartisan cosponsors, I introduced the Access to Life-Saving Medicine Act, legislation to provide FDA with the authority to approve safe and effective generic versions of biotech drugs. By bringing safe and effective follow-on biologics to the market, we can provide significant savings to patients, employers, and the government.

More than $10 billion worth of biopharmaceuticals will come off patent in the next 5 years, and without this legislation, the manufacturers of these biotech drugs can continue to charge monopoly prices indefinitely. In 2005, the costs of biologics grew 17.5 percent compared to traditional drugs, which increased 10 percent. And in 2006, the Medicare Part B Program spent more than $5 billion on biologic drugs. It is clear that biotech drugs hold great promise, but this promise is wasted if we don't take action to ensure that all Americans have access to safe, effective, and affordable generic versions of these drugs.

According to a report released by Engel and Novitt to the Pharmaceutical Care Management Association, PCMA, passage of this legislation could conservatively save an estimated $14 billion over the next 10 years.

I look forward to working with Senator KENNEDY and my colleagues on the HELP Committee to ensure that we enact legislation that provides the FDA with the authority and flexibility to approve biopharmaceuticals subject to a workable, abbreviated approval pathway that is efficient, effective, and scientifically grounded and that includes measures to ensure timely resolution of patent disputes, as well as adequate incentives for continued innovation.

Another issue that has come up during debate on the Food and Drug Administration Revitalization Act is food safety. Recent illnesses involving E. coli in spinach and lettuce, the discovery of Salmonella in peanut butter, and the importation of unsafe pet food ingredients from China illustrate the continued vulnerability of the American food supply and expose weakness in the FDA's food safety program.

In the latest case, a chemical used in plastic manufacturing was placed in feed material from China, causing the deaths of an unknown number of pets. This chemical was also consumed by 2.7 million chickens and 345 pigs that were slaughtered for human consumption. Our food system must be prepared to effectively prevent the chemicals found in these animals from endangering the health of consumers.

That is why I supported the inclusion of certain provisions in this bill to begin to address many of the agency's problems with food safety, as a prelude to overall committee action on this issue.

I have long been concerned about the siloing of authority at the FDA and Department of Agriculture, and I filed an amendment to this bill which would establish a joint task force between the FDA, U.S. Department of Agriculture, USDA, and the Centers for Disease Control and Prevention (CDC) to improve our response to foodborne illnesses.

According to the CDC, unsafe foods cause an estimated 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths each year. Despite these statistics, safety tests for domestically produced food have dropped nearly 75 percent when compared to the number conducted in 2003. Meanwhile, the number of food imports has grown from under 4 million food import line items in 1993 to nearly 20 million in 2007. We have a situation where inspections are declining, yet the number of outbreaks and contaminations in our food supply is on the rise. The fragmentation in our food safety system must be addressed in order to protect consumers.

With several of my colleagues, I have repeatedly written to the Secretary of Agriculture, the Commissioner of the FDA and the Director of the CDC urging them to create an interagency task force to better enable us to prevent such illnesses. To date, no action has been taken to grant my request. If the delay is due to concerns that these agencies do not have the authority to pursue such authority, I stand prepared, along with many others in the Senate, to provide these agencies with such authority. I look forward to working with my colleagues in the HELP Committee to address concerns about food safety and help restore our Nation's confidence in the ability of both these agencies to protect American consumers.

I would like to close by noting that while the Food and Drug Administration Revitalization Act takes several steps that will improve the agency's ability to ensure the safety and effectiveness of drugs and biologics, it is time that we begin to look at drugs in a new way.

It is not enough that we have drugs that are effective—in order to reduce overall health care costs, we need to understand how these drugs are effective in comparison to each other, in order to assist providers and patients make the best health care decisions.

While the Vioxx controversy highlighted the need for additional safety protections, many of which are contained in the Food and Drug Administration Revitalization Act, it also demonstrates the role comparative effectiveness can play in ensuring the use of the most appropriate treatment for a specific condition. I pushed for inclusion of comparative effectiveness studies in the Medicare Modernization Act. One of the first studies to be carried out under this provision was a systematic review of osteoarthritis drugs, including Cox-2 drugs. If this information had been compiled earlier, it could have helped many evaluate whether to use these drugs, as opposed to other pain relievers, many of which are available at a lower cost without a doctor's prescription.

Comparative effectiveness assists physicians and patients in selecting the best treatment and helps to reduce inappropriate uses of treatments that pose unnecessary safety risks to patients—and more and more people are recognizing its potential in improving health care. Earlier today, the Blue Cross and Blue Shield Association announced their support to create a new, independent entity to explore the effectiveness of new and existing medical procedures, drugs, devices, and biologics. I am grateful for their leadership, and I will be introducing legislation shortly to expand comparative effectiveness research and its use at the Federal level.

I have been involved in the debate over the Food and Drug Administration Revitalization Act for several months now and believe that the product we have produced represents a step forward for safety. I will be supporting this legislation and look forward to working with my colleagues to ensure that we can continue to strengthen this agency, lower prescription drug costs, and maintain a strong commitment to consumer protection and scientific innovation.

AMENDMENT NO. 1010

The PRESIDING OFFICER. Under the previous order, there will be 2 minutes for debate equally divided on amendment No. 1010 offered by the Senator from Mississippi.

The Senator from Mississippi.

Mr. COCHRAN. Madam President, Americans deserve Continued access to safe and effective drugs which are approved by the Food and Drug Administration. A number of recent reports demonstrate that serious problems exist with products from other countries. The New York Times ran a front-page story yesterday about how counterfeit drugs contaminated with an industrial solvent have poisoned hundreds, if not thousands, of people around the world. The toxic syrup has been involved in at least eight mass poisonings around the world in the past two decades, and researchers estimate thousands have died as a result. Most recently an epidemic of contaminated cough syrup was traced back to counterfeit medication from China. The FDA last week issued a warning to U.S. consumers to be especially vigilant because of the risk of the poison reaching the United States. The New York Times article is entitled ''From China to Panama, a Trail of Poisoned Medicine.''

Counterfeit products, those that have been tampered with, or those of unknown origin, should not be brought into this country.

The amendment proposed by the Senator from North Dakota will put in jeopardy the process we now have to ensure the safety of prescription medications and protect the health of the American people.

I have offered a second degree amendment, with bipartisan support, that requires the Secretary of Health and Human Services to certify that the importation of drug products will not pose additional risks to Americans and will indeed lower costs to consumers.

We have had this issue before the Senate on several previous occasions. In all of these cases, the Senate has adopted this certification amendment overwhelmingly. Safeguards continue to be necessary and are even more important now considering the terrorist threats we face.

I urge the Senate to again support this amendment.

I ask unanimous consent that a copy of the New York Times article to which I referred be printed in the RECORD.

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

[From the New York Times, May 6, 2007]

FROM CHINA TO PANAMA, A TRAIL OF POISONED MEDICINE

(By Walt Bogdanich and Jake Hooker)

The kidneys fail first. Then the central nervous system begins to misfire. Paralysis spreads, making breathing difficult, then often impossible without assistance. In the end, most victims die. Many of them are children, poisoned at the hands of their unsuspecting parents. The syrupy poison, diethylene glycol, is an indispensable part of the modern world, an industrial solvent and prime ingredient in some antifreeze. It is also a killer. And the deaths, if not intentional, are often no accident.

Over the years, the poison has been loaded into all varieties of medicine—cough syrup, fever medication, injectable drugs—a result of counterfeiters who profit by substituting the sweet-tasting solvent for a safe, more expensive syrup, usually glycerin, commonly used in drugs, food, toothpaste and other products. Toxic syrup has figured in at least eight mass poisonings around the world in the past two decades. Researchers estimate that thousands have died. In many cases, the precise origin of the poison has never been determined. But records and interviews show that in three of the last four cases it was made in China, a major source of counterfeit drugs.

Panama is the most recent victim. Last year, government officials there unwittingly mixed diethylene glycol into 260,000 bottles of cold medicine—with devastating results. Families have reported 365 deaths from the poison, 100 of which have been confirmed so far. With the onset of the rainy season, investigators are racing to exhume as many potential victims as possible before bodies decompose even more. Panama's death toll leads directly to Chinese companies that made and exported the poison as 99.5 percent pure glycerin.

Forty-six barrels of the toxic syrup arrived via a poison pipeline stretching halfway around the world. Through shipping records and interviews with government officials, The New York Times traced this pipeline from the Panamanian port of Colón, back through trading companies in Barcelona,

Spain, and Beijing, to its beginning near the Yangtze Delta in a place local people call ''chemical country.'' The counterfeit glycerin passed through three trading companies on three continents, yet not one of them tested the syrup to confirm what was on the label. Along the way, a certificate falsely attesting to the purity of the shipment was repeatedly altered, eliminating the name of the manufacturer and previous owner. As a result, traders bought the syrup without knowing where it came from, or who made it. With this information, the traders might have discovered—as The Times did—that the manufacturer was not certified to make pharmaceutical ingredients.

An examination of the two poisoning cases last year—in Panama and earlier in China—shows how China's safety regulations have lagged behind its growing role as low-cost supplier to the world. It also demonstrates how a poorly policed chain of traders in country after country allows counterfeit medicine to contaminate the global market.

Last week, the United States Food and Drug Administration warned drug makers and suppliers in the United States ''to be especially vigilant'' in watching for diethylene glycol. The warning did not specifically mention China, and it said there was ''no reason to believe'' that glycerin in this country was tainted. Even so, the agency asked that all glycerin shipments be tested for diethylene glycol, and said it was ''exploring how supplies of glycerin become contaminated.''

China is already being accused by United States authorities of exporting wheat gluten containing an industrial chemical, melamine, that ended up in pet food and livestock feed. The F.D.A recently banned imports of Chinese-made wheat gluten after it was linked to pet deaths in the United States. Beyond Panama and China, toxic syrup has caused mass poisonings in Haiti, Bangladesh, Argentina, Nigeria and twice in India.

In Bangladesh, investigators found poison in seven brands of fever medication in 1992, but only after countless children died. A Massachusetts laboratory detected the contamination after Dr. Michael L. Bennish, a pediatrician who works in developing countries, smuggled samples of the tainted syrup out of the country in a suitcase. Dr. Bennish, who investigated the Bangladesh epidemic and helped write a 1995 article about it for BMJ, formerly known as the British Medical Journal, said that given the amount of medication distributed, deaths ''must be in the thousands or tens of thousands.''

''It's vastly underreported,'' Dr. Bennish said of diethylene glycol poisoning. Doctors might not suspect toxic medicine, particularly in poor countries with limited resources and a generally unhealthy population, he said, adding, ''Most people who die don't come to a medical facility.'' The makers of counterfeit glycerin, which superficially looks and acts like the real thing but generally costs considerably less, are rarely identified, much less prosecuted, given the difficulty of tracing shipments across borders. ''This is really a global problem, and it needs to be handled in a global way,'' said Dr. Henk Bekedam, the World Health Organization's top representative in Beijing.

Seventy years ago, medicine laced with diethylene glycol killed more than 100 people in the United States, leading to the passage of the toughest drug regulations of that era and the creation of the modern Food and Drug Administration. The F.D.A. has tried to help in poisoning cases around the world, but there is only so much it can do. When at least 88 children died in Haiti a decade ago, F.D.A. investigators traced the poison to the Manchurian city of Dalian, but their attempts to visit the suspected manufacturer were repeatedly blocked by Chinese officials, according to internal State Department records. Permission was granted more than a year later, but by then the plant had moved and its records had been destroyed.

''Chinese officials we contacted on this matter were all reluctant to become involved,'' the American Embassy in Beijing wrote in a confidential cable. ''We cannot be optimistic about our chances for success in tracking down the other possible glycerin shipments.''

In fact, The Times found records showing that the same Chinese company implicated in the Haiti poisoning also shipped about 50 tons of counterfeit glycerin to the United States in 1995. Some of it was later resold to another American customer, Avatar Corporation, before the deception was discovered. ''Thank God we caught it when we did,'' said Phil Ternes, chief operating officer of Avatar, a Chicago-area supplier of bulk pharmaceutical and nonmedicinal products. The F.D.A. said it was unaware of the shipment.

In China, the government is vowing to clean up its pharmaceutical industry, in part because of criticism over counterfeit drugs flooding the world markets. In December, two top drug regulators were arrested on charges of taking bribes to approve drugs. In addition, 440 counterfeiting operations were closed down last year, the World Health Organization said.

But when Chinese officials investigated the role of Chinese companies in the Panama deaths, they found that no laws had been broken, according to an official of the nation's drug enforcement agency. China's drug regulation is ''a black hole,'' said one trader who has done business through CNSC Fortune Way, the Beijing-based broker that investigators say was a crucial conduit for the Panama poison.

In this environment, Wang Guiping, a tailor with a ninth-grade education and access to a chemistry book, found it easy to enter the pharmaceutical supply business as a middleman. He quickly discovered what others had before him: that counterfeiting was a simple way to increase profits. And then people in China began to die.

CHEATING THE SYSTEM

Mr. Wang spent years as a tailor in the manufacturing towns of the Yangtze Delta, in eastern China. But he did not want to remain a common craftsman, villagers say. He set his sights on trading chemicals, a business rooted in the many small chemical plants that have sprouted in the region. ''He didn't know what he was doing,'' Mr. Wang's older brother, Wang Guoping, said in an interview. ''He didn't understand chemicals.'' But he did understand how to cheat the system. Wang Guiping, 41, realized he could earn extra money by substituting cheaper, industrial-grade syrup—not approved for human consumption—for pharmaceutical grade syrup. To trick pharmaceutical buyers, he forged his licenses and laboratory analysis reports, records show.

Mr. Wang later told investigators that he figured no harm would come from the substitution, because he initially tested a small quantity. He did it with the expertise of a former tailor. He swallowed some of it. When nothing happened, he shipped it.

One company that used the syrup beginning in early 2005 was Qiqihar No.2 Pharmaceutical, about 1,000 miles away in Heilongjiang Province in the northeast. A buyer for the factory had seen a posting for Mr. Wang's syrup on an industry Web site.

After a while, Mr. Wang set out to find an even cheaper substitute syrup so he could increase his profit even more, according to a Chinese investigator. In a chemical book he found what he was looking for: another odorless syrup—diethylene glycol. At the time, it sold for 6,000 to 7,000 yuan a ton, or about $725 to $845, while pharmaceutical-grade syrup cost 15,000 yuan, or about $1,815, according to the investigator.

Mr. Wang did not taste-test this second batch of syrup before shipping it to Qiqihar Pharmaceutical, the government investigator said, adding, ''He knew it was dangerous, but he didn't know that it could kill.''

The manufacturer used the toxic syrup in five drug products: ampules of Amillarisin A for gall bladder problems; a special enema fluid for children; an injection for blood vessel diseases; an intravenous pain reliever; and an arthritis treatment.

In April 2006, one of southern China's finest hospitals, in Guangzhou, Guangdong Province, began administering Amillarisin A. Within a month or so, at least 18 people had died after taking the medicine, though some had already been quite sick.

Zhou Jianhong, 33, said his father took his first dose of Amillarisin A on April 19. A week later he was in critical condition. ''If you are going to die, you want to die at home,'' Mr. Zhou said. ''So we checked him out of the hospital.'' He died the next day. ''Everybody wants to invest in the pharmaceutical industry and it is growing, but the regulators can't keep up,'' Mr. Zhou said. ''We need a system to assure our safety.'' The final death count is unclear, since some people who took the medicine may have died in less populated areas.

In a small town in Sichuan Province, a man named Zhou Lianghui said the authorities would not acknowledge that his wife had died from taking tainted Amillarisin A. But Mr. Zhou, 38, said he matched the identification number on the batch of medicine his wife received with a warning circular distributed by drug officials. ''You probably cannot understand a small town if you are in Beijing,'' Zhou Lianghui said in a telephone interview. ''The sky is high, and the emperor is far away. There are a lot of problems here that the law cannot speak to.''

The failure of the government to stop poison from contaminating the drug supply caused one of the bigger domestic scandals of the year. Last May, China's premier, Wen Jiabao, ordered an investigation of the deaths, declaring, ''The pharmaceutical market is in disorder.''

At about the same time, 9,000 miles away in Panama, the long rainy season had begun. Anticipating colds and coughs, the government health program began manufacturing cough and antihistamine syrup. The cough medicine was sugarless so that even diabetics could use it. The medicine was mixed with a pale yellow, almost translucent syrup that had arrived in 46 barrels from Barcelona on the container ship Tobias Maersk. Shipping records showed the contents to be 99.5 percent pure glycerin. It would be months and many deaths later before that certification was discovered to be pure fiction.

A MYSTERIOUS ILLNESS

Early last September, doctors at Panama City's big public hospital began to notice patients exhibiting unusual symptoms. They initially appeared to have Guillain-Barré syndrome, a relatively rare neurological disorder that first shows up as a weakness or tingling sensation in the legs. That weakness often intensifies, spreading upward to the arms and chest, sometimes causing total paralysis and an inability to breathe.

The new patients had paralysis, but it did not spread upward. They also quickly lost their ability to urinate, a condition not associated with Guillain-Barré. Even more unusual was the number of cases. In a full year,

doctors might see eight cases of Guillain-Barré, yet they saw that many in just two weeks. Doctors sought help from an infectious disease specialist, Nestor Sosa, an intense, driven doctor who competes in triathlons and high-level chess.

Dr. Sosa's medical specialty had a long, rich history in Panama, once known as one of the world's unhealthiest places. In one year in the late 1800s, a lethal mix of yellow fever and malaria killed nearly 1 in every 10 residents of Panama City. Only after the United States managed to overcome those mosquito-borne diseases was it able to build the Panama Canal without the devastation that undermined an earlier attempt by the French. The suspected Guillain-Barré cases worried Dr. Sosa. ''It was something really extraordinary, something that was obviously reaching epidemic dimensions in our hospital,'' he said.

With the death rate from the mystery illness near 50 percent, Dr. Sosa alerted the hospital management, which asked him to set up and run a task force to handle the situation. The assignment, a daunting around-the-clock dash to catch a killer, was one he eagerly embraced. Several years earlier, Dr. Sosa had watched as other doctors identified the cause of another epidemic, later identified as hantavirus, a pathogen spread by infected rodents. ''I took care of patients but I somehow felt I did not do enough,'' he said. The next time, he vowed, would be different. Dr. Sosa set up a 24–hour ''war room'' in the hospital, where doctors could compare notes and theories as they scoured medical records for clues. As a precaution, the patients with the mystery illness were segregated and placed in a large empty room awaiting renovation. Health care workers wore masks, heightening fears in the hospital and the community.

''That spread a lot of panic,'' said Dr. Jorge Motta, a cardiologist who runs the Gorgas Memorial Institute, a widely respected medical research center in Panama. ''That is always a terrifying thought, that you will be the epicenter of a new infectious disease, and especially a new infectious disease that kills with a high rate of death, like this.'' Meanwhile, patients kept coming, and hospital personnel could barely keep up. ''I ended up giving C.P.R.,'' Dr. Sosa said. ''I haven't given C.P.R. since I was a resident, but there were so many crises going on.'' Frightened hospital patients had to watch others around them die for reasons no one understood, fearing that they might be next. As reports of strange Guillain-Barré symptoms started coming in from other parts of the country, doctors realized they were not just dealing with a localized outbreak.

Pascuala Pérez de González, 67, sought treatment for a cold at a clinic in Coclé Province, about a three-hour drive from Panama City. In late September she was treated and sent home. Within days, she could no longer eat; she stopped urinating and went into convulsions. A decision was made to take her to the public hospital in Panama City, but on the way she stopped breathing and had to be resuscitated. She arrived at the hospital in a deep coma and later died.

Medical records contained clues but also plenty of false leads. Early victims tended to be males older than 60 and diabetic with high blood pressure. About half had been given Lisinopril, a blood pressure medicine distributed by the public health system. But many who did not receive Lisinopril still got sick. On the chance that those patients might have forgotten that they had taken the drug, doctors pulled Lisinopril from pharmacy shelves—only to return it after tests found nothing wrong. Investigators would later discover that Lisinopril did play an important, if indirect role in the epidemic, but not in the way they had imagined.

A MAJOR CLUE

One patient of particular interest to Dr. Sosa came into the hospital with a heart attack, but no Guillain-Barré-type symptoms. While undergoing treatment, the patient received several drugs, including Lisinopril. After a while, he began to exhibit the same neurological distress that was the hallmark of the mystery illness. ''This patient is a major clue,'' Dr. Sosa recalled saying. ''This is not something environmental, this is not a folk medicine that's been taken by the patients at home. This patient developed the disease in the hospital, in front of us.'' Soon after, another patient told Dr. Sosa that he, too, developed symptoms after taking Lisinopril, but because the medicine made him cough, he also took cough syrup—the same syrup, it turned out, that had been given to the heart patient. ''I said this has got to be it,'' Dr. Sosa recalled. ''We need to investigate this cough syrup.'' The cough medicine had not initially aroused much suspicion because many victims did not remember taking it. ''Twenty-five percent of those people affected denied that they had taken cough syrup, because it's a nonevent in their lives,'' Dr. Motta said.

Investigators from the United States Centers for Disease Control and Prevention, who were in Panama helping out, quickly put the bottles on a government jet and flew them to the United States for testing. The next day, Oct. 11, as Panamanian health officials were attending a news conference, a Blackberry in the room went off. The tests, the C.D.C. was reporting, had turned up diethylene glycol in the cough syrup. The mystery had been solved. The barrels labeled glycerin turned out to contain poison.

Dr. Sosa's exhilaration at learning the cause did not last long. ''It's our medication that is killing these people,'' he said he thought. ''It's not a virus, it's not something that they got outside, but it was something we actually manufactured.''

A nationwide campaign was quickly begun to stop people from using the cough syrup. Neighborhoods were searched, but thousands of bottles either had been discarded or could not be found. As the search wound down, two major tasks remained: count the dead and assign blame. Neither has been easy. A precise accounting is all but impossible because, medical authorities say, victims were buried before the cause was known, and poor patients might not have seen doctors. Another problem is that finding traces of diethylene glycol in decomposing bodies is difficult at best, medical experts say. Nonetheless, an Argentine pathologist who has studied diethylene glycol poisonings helped develop a test for the poison in exhumed bodies. Seven of the first nine bodies tested showed traces of the poison, Panamanian authorities said.

With the rainy season returning, though, the exhumations are about to end. Dr. José Vicente Pachar, director of Panama's Institute of Legal Medicine and Forensic Sciences, said that as a scientist he would like a final count of the dead. But he added, ''I should accept the reality that in the case of Panama we are not going to know the exact number.''

Local prosecutors have made some arrests and are investigating others connected to the case, including officials of the import company and the government agency that mixed and distributed the cold medicine. ''Our responsibilities are to establish or discover the truth,'' said Dimas Guevara, the homicide investigator guiding the inquiry. But prosecutors have yet to charge anyone with actually making the counterfeit glycerin. And if the Panama investigation unfolds as other inquiries have, it is highly unlikely that they ever will.

A SUSPECT FACTORY

Panamanians wanting to see where their toxic nightmare began could look up the Web site of the company in Hengxiang, China, that investigators in four countries have identified as having made the syrup—the Taixing Glycerine Factory. There, under the words ''About Us,'' they would see a picture of a modern white building nearly a dozen stories tall, adorned by three arches at the entrance. The factory, the Web site boasts, ''can strictly obey the contract and keep its word.'' But like the factory's syrup, all is not as it seems.

There are no tall buildings in Hengxiang, a country town with one main road. The factory is not certified to sell any medical ingredients, Chinese officials say. And it looks nothing like the picture on the Internet. In reality, its chemicals are mixed in a plain, one-story brick building. The factory is in a walled compound, surrounded by small shops and farms. In the spring, nearby fields of rape paint the countryside yellow. Near the front gate, a sign over the road warns, ''Beware of counterfeits.'' But it was posted by a nearby noodle machine factory that appears to be worried about competition. The Taixing Glycerine Factory bought its diethylene glycol from the same manufacturer as Mr. Wang, the former tailor, the government investigator said. From this spot in China's chemical country, the 46 barrels of toxic syrup began their journey, passing from company to company, port to port and country to country, apparently without anyone testing their contents.

Traders should be thoroughly familiar with their suppliers, United States health officials say. ''One simply does not assume that what is labeled is indeed what it is,'' said Dr. Murray Lumpkin, deputy commissioner for international and special programs for the Food and Drug Administration. In the Panama Case, names of suppliers were removed from shipping documents as they passed from one entity to the next, according to records and investigators. That is a practice some traders use to prevent customers from bypassing them on future purchases, but it also hides the provenance of the product. The first distributor was the Beijing trading company, CNSC Fortune Way, a unit of a state-owned business that began by supplying goods and services to Chinese personnel and business officials overseas.

As China's market reach expanded, Fortune Way focused its business on pharmaceutical ingredients, and in 2003, it brokered the sale of the suspect syrup made by the Taixing Glycerine Factory. The manufacturer's certificate of analysis showed the batch to be 99.5 percent pure. Whether the Taixing Glycerine Factory actually performed the test has not been publicly disclosed. Original certificates of analysis should be passed on to each new buyer, said Kevin J. McGlue, a board member of the International Pharmaceutical Excipients Council. In this case, that was not done.

Fortune Way translated the certificate into English, putting its name—not the Taixing Glycerine Factory's—at the top of the document, before shipping the barrels to a second trading company, this one in Barcelona. Li Can, managing director at Fortune Way, said he did not remember the transaction and could not comment, adding, ''There is a high volume of trade.'' Upon receiving the barrels in September 2003, the Spanish company, Rasfer International, did not test the contents, either. It copied the chemical analysis provided by Fortune Way, then put its logo on it. Ascension Criado, Rasfer's manager, said in an e-mail response to written questions that when Fortune Way shipped the syrup, it did not say who made

it. Several weeks later, Rasfer shipped the drums to a Panamanian broker, the Medicom Business Group. ''Medicom never asked us for the name of the manufacturer,'' Ms. Criado said.

A lawyer for Medicam, Valentín Jaén, said his client was a victim, too. ''They were tricked by somebody,'' Mr. Jaén said. ''They operated in good faith.'' In Panama, the barrels sat unused for more than two years, and officials said Medicam improperly changed the expiration date on the syrup. During that time, the company never tested the product. And the Panamanian government, which bought the 46 barrels and used them to make cold medicine, also failed to detect the poison, officials said. The toxic pipeline ultimately emptied into the bloodstream of people like Ernesto Osorio, a former high school teacher in Panama City. He spent two months in the hospital after ingesting poison cough syrup last September.

Just before Christmas, after a kidney dialysis treatment, Mr. Osorio stood outside the city's big public hospital in a tear-splattered shirt, describing what his life had become. ''I'm not an eighth of what I used to be,'' Mr. Osorio said, his partly paralyzed face hanging like a slab of meat. ''I have trouble walking. Look at my face, look at my tears.'' The tears, he said apologetically, were not from emotion, but from nerve damage. And yet, Mr. Osorio knows he is one of the lucky victims. ''They didn't know how to keep the killer out of the medicine,'' he said simply.

While the suffering in Panama was great, the potential profit—at least for the Spanish trading company, Rasfer—was surprisingly small. For the 46 barrels of glycerin, Rasfer paid Fortune Way $9,900, then sold them to Medicom for $11,322, according to records.

Chinese authorities have not disclosed how much Fortune Way and the Taixing Glycerine Factory made on their end, or how much they knew about what was in the barrels.

''The fault has to be traced back to areas of production,'' said Dr. Motta, the cardiologist in Panama who helped uncover the source of the epidemic. ''This was my plea—please, this thing is happening to us, make sure whoever did this down the line is not doing it to Peru or Sierra Leone or some other place.''

A COUNTERFEITER'S CONFESSION

The power to prosecute the counterfeiters is now in the hands of the Chinese. Last spring, the government moved quickly against Mr. Wang, the former tailor who poisoned Chinese residents. The authorities caught up with him at a roadblock in Taizhou, a city just north of Taixing, in chemical country. He was weak and sick, and he had not eaten in two days. Inside his white sedan was a bankbook and cash. He had fled without his wife and teenage son.

Chinese patients were dead, a political scandal was brewing and the authorities wanted answers. Mr. Wang was taken to a hospital. Then, in long sessions with investigators, he gave them what they wanted, explaining his scheme, how he tested industrial syrup by drinking it, how he decided to use diethylene glycol and how he conned pharmaceutical companies into buying his syrup, according to a government official who was present for his interrogation. ''He made a fortune, but none of it went to his family,'' said Wang Xiaodong, a former village official who knows Mr. Wang and his siblings. ''He liked to gamble.''

Mr. Wang remains in custody as the authorities decide whether he should be put to death. The Qiqihar drug plant that made the poisonous medicine has been closed, and five employees are now being prosecuted for causing ''a serious accident.'' In contrast to the Wang Guiping investigation, Chinese authorities have been tentative in acknowledging China's link to the Panama tragedy, which involved a state-owned trading company. No one in China has been charged with committing the fraud that ended up killing so many in Panama.

Sun Jing, the pharmaceutical program officer for the World Health Organization in Beijing, said the health agency sent a fax ''to remind the Chinese government that China should not be selling poisonous products overseas.'' Ms. Sun said the agency did not receive an official reply.

Last fall, at the request of the United States—Panama has no diplomatic relations with China—the State Food and Drug Administration of China investigated the Taixing Glycerine Factory and Fortune Way. The agency tested one batch of glycerin from the factory, and found no glycerin, only diethylene glycol and two other substances, a drug official said. Since then, the Chinese drug administration has concluded that it has no jurisdiction in the case because the factory is not certified to make medicine. The agency reached a similar conclusion about Fortune Way, saying that as an exporter it was not engaged in the pharmaceutical business. ''We did not find any evidence that either of these companies had broken the law,'' said Yan Jiangying, a spokeswoman for the drug administration. ''So a criminal investigation was never opened.''

A drug official said the investigation was subsequently handed off to an agency that tests and certifies commercial products—the General Administration of Quality Supervision, Inspection and Quarantine. But the agency acted surprised to learn that it was now in charge. ''What investigation?'' asked Wang Jian, director of its Taixing branch. ''I'm not aware of any investigation involving a glycerin factory.'' Besides, Huang Tong, an investigator in that office, said, ''We rarely get involved in products that are sold for export. '' Wan Qigang, the legal representative for the Taixing Glycerine Factory, said in an interview late last year that the authorities had not questioned him about the Panama poisoning, and that his company made only industrial-grade glycerin. ''I can tell you for certain that we have no connection with Panama or Spain,'' Mr. Wan said. But in recent months, the Glycerine Factory has advertised 99.5 percent pure glycerin on the Internet.

Mr. Wan recently declined to answer any more questions. ''If you come here as a guest, I will welcome you,'' Mr . Wan said. ''But if you come again wanting to talk about this matter, I will make a telephone call.'' A local government official said Mr. Wan was told not to grant interviews. A five-minute walk away, another manufacturer, the Taixing White Oil Factory, also advertises medical glycerin on the Internet, yet it, too, has no authorization to make it. The company's Web site says its products have been exported to America, Australia and Italy.''

Ding Xiang, who represents the White Oil Factory, denied that his company made pharmaceutical-grade glycerin, but he said chemical trading companies in Beijing often called, asking for it. ''They want us to mark the barrels glycerin,'' Mr. Ding said in late December. ''I tell them we cannot do that.'' Mr. Ding said he stopped answering calls from Beijing. ''If this stuff is taken overseas and improperly used. . . .'' He did not complete the thought. In chemical country, product names are not always what they seem. ''The only two factories in Taixing that make glycerin don't even make glycerin,'' said Jiang Peng, who oversees inspections and investigations in the Taixing branch of the State Food and Drug Administration. ''It is a different product.''

ALL IN A NAME

One lingering mystery involves the name of the product made by the Taixing Glycerine Factory. The factory had called its syrup ''TD'' glycerin. The letters TD were in virtually all the shipping documents. What did TD mean?

Spanish medical authorities concluded that it stood for a manufacturing process. Chinese inspectors thought it was the manufacturer's secret formula. But Yuan Kailin, a former salesman for the factory, said he knew what the TD meant because a friend and former manager of the factory, Ding Yuming, had once told him. TD stood for the Chinese word ''tidai'' (pronounced tee-die), said Mr. Yuan, who left his job in 1998 and still lives about a mile from the factory. In Chinese, tidai means substitute. A clue that might have revealed the poison, the counterfeit product, was hiding in plain sight. It was in the product name.

Mr. KENNEDY. Madam President, if I could have the attention of the Senate, I was going to ask consent about a managers' amendment. Is it the intention of the Senator from North Dakota to object?

Mr. DORGAN. Am I to be recognized for 1 minute at this point?

Mr. COCHRAN. Madam President, point of order: What is the order?

The PRESIDING OFFICER. The order is 2 minutes of debate equally divided.

Mr. COCHRAN. One minute is consumed so that is all that remains; is that correct?

The PRESIDING OFFICER. The Senator is correct.

Mr. DORGAN. The Senator's point is I am entitled to 1 minute.

The PRESIDING OFFICER. The Senator is entitled to 1 minute.

Mr. KENNEDY. I yield a minute to the Senator from North Dakota.

Mr. DORGAN. Madam President, I rise in opposition to the Cochran amendment. The Cochran amendment has been law since 2003. The Secretary cannot certify as a result of it. So it is an amendment that will void anything that is in the bipartisan legislation we have offered to try to make imported drugs, FDA-approved drugs, at a lower price available to American consumers. All Senator COCHRAN described would be dealt with by the safety amendments in our amendment. If his amendment prevails, none of the safety issues—pedigree, certification, anti-counterfeiting—in our amendment will survive. That is the problem. If we stand with the American people who want lower drug prices—a safe drug supply, FDA approved—and believe they should not be paying the highest prices in the world, vote against the Cochran amendment and for the underlying Dorgan-Snowe amendment.

The PRESIDING OFFICER. Under the previous order, the question is on agreeing to amendment No. 1010.

Mr. KENNEDY. I ask for the yeas and nays.

The PRESIDING OFFICER. Is there a sufficient second?

There appears to be a sufficient second.

The clerk will call the roll.

The legislative clerk called the roll.

Mr. DURBIN. I announce that the Senator from Delaware (Mr. BIDEN), the Senator from Connecticut (Mr. DODD), the Senator from South Dakota (Mr. JOHNSON), the Senator from Illinois (Mr. OBAMA), the Senator from Rhode Island (Mr. REED), and the Senator from Montana (Mr. TESTER) are necessarily absent.

Mr. LOTT. The following Senators are necessarily absent: the Senator from Colorado (Mr. ALLARD), the Senator from Kansas (Mr. BROWNBACK), the Senator from Nevada (Mr. ENSIGN), the Senator from Oklahoma (Mr. INHOFE), and the Senator from Arizona (Mr. MCCAIN).

Further, if present and voting, the Senator from Oklahoma (Mr. INHOFE) would have voted ''yea.''

The result was announced—yeas 49, nays 40, as follows:

[Rollcall Vote No. 151 Leg.]

YEAS—49

Alexander	Domenici	McConnell
Baucus	Enzi	Menendez
Bayh	Graham	Mikulski
Bennett	Gregg	Murkowski
Bond	Hagel	Murray
Bunning	Hatch	Nelson (NE)
Burr	Hutchison	Roberts
Cantwell	Isakson	Rockefeller
Carper	Kennedy	Salazar
Chambliss	Kerry	Specter
Coburn	Kyl	Stevens
Cochran	Landrieu	Sununu
Coleman	Lautenberg	Thomas
Corker	Lieberman	Voinovich
Cornyn	Lincoln	Warner
Crapo	Lugar	
Dole	Martinez	

NAYS—40

Akaka	Feingold	Sanders
Bingaman	Feinstein	Schumer
Boxer	Grassley	Sessions
Brown	Harkin	Shelby
Byrd	Inouye	Smith
Cardin	Klobuchar	Snowe
Casey	Kohl	Stabenow
Clinton	Leahy	Thune
Collins	Levin	Vitter
Conrad	Lott	Webb
Craig	McCaskill	Whitehouse
DeMint	Nelson (FL)	Wyden
Dorgan	Pryor	
Durbin	Reid	

NOT VOTING—11

Allard	Ensign	Obama
Biden	Inhofe	Reed
Brownback	Johnson	Tester
Dodd	McCain	

The amendment (No. 1010) was agreed to.

Mr. COCHRAN. Madam President, I move to reconsider the vote, and I move to lay that motion on the table.

The motion to lay on the table was agreed to.

The PRESIDING OFFICER. The Senator from Massachusetts.

Mr. KENNEDY. Madam President, I request that the next vote be a 10-minute vote.

The PRESIDING OFFICER. That request has been granted.

AMENDMENT NO. 990

The PRESIDING OFFICER. Under the previous order, there will be 2 minutes for debate, equally divided, on amendment No. 990, offered by the Senator from North Dakota, as amended.

Who yields time?

Since no one yields time, time will be equally charged to both sides.

Mr. KENNEDY. Madam President, we yield back the remaining time, all time.

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

Mr. KENNEDY. I think we are ready to voice vote.

The PRESIDING OFFICER. The question is on agreeing to amendment No. 990, as amended.

The amendment (No. 990), as amended, was agreed to.

Mr. REID. Madam President, I move to reconsider the vote.

Mr. NELSON of Florida. I move to lay that motion on the table.

The motion to lay on the table was agreed to.

Mr. KENNEDY. Madam President, I ask unanimous consent that the managers' amendments be agreed to en bloc.

The PRESIDING OFFICER. Is there objection?

Mr. DORGAN. Madam President, reserving the right to object, we received the managers' amendment about 30 minutes ago and I am still reviewing some of the amendments. I object at this point.

The PRESIDING OFFICER. Objection is heard.

Under the previous order, there will be 2 minutes for debate equally divided prior to the vote on the motion to invoke cloture on the substitute amendment to S. 1082.

Who yields time?

Mr. BYRD. May we have order. May we have order.

The PRESIDING OFFICER. The Senate will be in order.

Mr. KENNEDY. Madam President, again, I thank all of the membership for their cooperation. We have been on this legislation for 1 week. We believe we have a managers' amendment which reflects the best judgment of Senator ENZI and myself and we will offer that at the appropriate time. I mentioned earlier during the debate and discussion, the essence of the managers' amendment. I think we probably have possibly two more votes that might require rollcall votes and then we would go to final passage. I think we have broad support for this legislation which is so essential if we are going to bring the FDA into the 21st century, and if we are going to assure safety for the prescription drugs our families take, insist on a safe food supply, and ensure that the FDA has the best in terms of science.

I again thank my friend and colleague from Wyoming. I hope we can get a strong vote in favor of this bill.

Mr. BYRD. Madam President, may we have order.

The PRESIDING OFFICER. Could we please have order.

Mr. BYRD. Would the Senator mind saying that again, please.

Mr. KENNEDY. Madam President, 30 seconds. I was reminding the membership, as the Senator from West Virginia knows, this bill is going to ensure the safety of our pharmaceutical products. It is going to ensure the safety of our food products. It is going to insist that the FDA promote the latest in terms of science. We need to push the FDA into the 21st century, and this legislation will do it.

The PRESIDING OFFICER. Who yields time?

The Senator from North Dakota is recognized.

Mr. DORGAN. Madam President, I am all for pulling or pushing the FDA into whatever century we determine at this point. I only pointed out that I wish to review some of the managers' package that deals with ginseng, baby turtles, tanning beds, and more, and I want a bit of time—and perhaps others would if they don't know these amendments exist—to take a look at the amendments.

The PRESIDING OFFICER. The Senator from Wyoming is recognized.

Mr. ENZI. Madam President, on our side of the aisle I do appreciate the tremendous amount of effort Senator KENNEDY and his staff and many others on the other side of the aisle who have worked with those of us on this side of the aisle to get particularly the major concerns that were brought up during the markup in committee taken care of. There are tremendous amounts of things in here both sides have worked on and in some cases come up with a third way of doing it. I think we are on the right track here. The product will make a huge difference in the bill, and I hope we can move forward.

CLOTURE MOTION

The PRESIDING OFFICER. Under the previous order and pursuant to rule XXII, the Chair lays before the Senate the pending cloture motion, which the clerk will state.

The assistant legislative clerk read as follows:

CLOTURE MOTION

We, the undersigned Senators, in accordance with the provisions of rule XXII of the Standing Rules of the Senate, hereby move to bring to a close debate on the committee substitute amendment, as modified, to S. 1082, the FDA Revitalization bill.

Ted Kennedy, Dick Durbin, Byron L. Dorgan, B.A. Mikulski, Patty Murray, Claire McCaskill, Amy Klobuchar, Sherrod Brown, Jack Reed, Herb Kohl, Charles Schumer, Christopher Dodd, Barbara Boxer, Bill Nelson, Jeff Bingaman, Debbie Stabenow.

The PRESIDING OFFICER. By unanimous consent, the mandatory quorum call has been waived.

The question is, Is it the sense of the Senate that debate on the committee substitute amendment to S. 1082, as modified, shall be brought to a close?

The yeas and nays are mandatory under the rule.

The clerk will call the roll.

The legislative clerk called the roll.

Mr. DURBIN. I announce that the Senator from Delaware (Mr. BIDEN),

the Senator from Connecticut (Mr. DODD), the Senator from South Dakota (Mr. JOHNSON), the Senator from Illinois (Mr. OBAMA), and the Senator from Montana (Mr. TESTER) are necessarily absent.

Mr. LOTT. The following Senators are necessarily absent: the Senator from Colorado (Mr. ALLARD), the Senator from Kansas (Mr. BROWNBACK), the Senator from Nevada (Mr. ENSIGN), the Senator from Oklahoma (Mr. INHOFE), and the Senator from Arizona (Mr. MCCAIN).

Further, if present and voting, the Senator from Oklahoma (Mr. INHOFE) would have voted ''nay.''

The yeas and nays resulted—yeas 82, nays 8, as follows:

[Rollcall Vote No. 152 Leg.]

YEAS—82

Akaka	Durbin	Menendez
Alexander	Enzi	Mikulski
Baucus	Feingold	Murkowski
Bayh	Feinstein	Murray
Bennett	Graham	Nelson (FL)
Bingaman	Gregg	Nelson (NE)
Bond	Hagel	Pryor
Boxer	Harkin	Reed
Brown	Hatch	Reid
Bunning	Hutchison	Roberts
Burr	Inouye	Rockefeller
Byrd	Isakson	Salazar
Cantwell	Kennedy	Schumer
Cardin	Kerry	Sessions
Carper	Klobuchar	Shelby
Chambliss	Kohl	Smith
Clinton	Kyl	Specter
Coburn	Landrieu	Stabenow
Cochran	Lautenberg	Stevens
Coleman	Leahy	Sununu
Collins	Levin	Thomas
Conrad	Lieberman	Thune
Corker	Lincoln	Voinovich
Cornyn	Lott	Warner
Craig	Lugar	Whitehouse
Crapo	Martinez	Wyden
Dole	McCaskill	
Domenici	McConnell	

NAYS—8

Casey	Grassley	Vitter
DeMint	Sanders	Webb
Dorgan	Snowe	

NOT VOTING—10

Allard	Ensign	Obama
Biden	Inhofe	Tester
Brownback	Johnson	
Dodd	McCain	

The PRESIDING OFFICER. On this question, the yeas are 82, the nays are 8. Three-fifths of the Senators duly chosen and sworn having voted in the affirmative, the motion is agreed to.

Mr. KENNEDY. Madam President, as far as I know, on this side, I think we have one amendment. We are inquiring of the Senator to see whether it will be offered. I think Senator ENZI can speak for the other side. We still have to work through the managers' amendment. I want to make it very clear that we are glad to get into the details of all that. I tried to summarize the managers' amendment. It involves a great many ideas from our side of the aisle. So, hopefully, we will be able to move that process.

I know Members want to know how we are going to proceed now through the afternoon. We have good attendance, and we would like to at least give the membership an idea about how we are going to proceed. We have been on this legislation now for a week, and we have made very good progress. I think the vote on cloture demonstrates the strong support for this underlying legislation.

We would like to move this legislation in a timely way and not delay it needlessly. So we will inquire of our colleagues further—if they have amendments, hopefully, they will let us know. Hopefully, we will have the opportunity to deal with the managers' amendment in a timely way. It would be unfortunate if we did not, since we have given assurance to Members on both sides of the aisle and worked long and hard with them to try to get this through. Obviously, any Senator is entitled to review the managers' amendment. We are getting very close to the point where we are prepared to move along with this legislation. This would seriously compromise a lot of colleagues who voted with the assurance that we were going to move ahead. We are more than delighted to get into the description of these various amendments and explain why we have recommended them. I hope we will not have delay for delay's sake, but that we will find a way to move forward.

The PRESIDING OFFICER. The Senator from Tennessee is recognized.

Mr. ALEXANDER. Madam President, I ask the managers through the Chair—I have about a 10-minute speech on another subject I would like to make at an appropriate time. I don't want to interfere with the progress of the bill. I ask the Chair whether now would be an appropriate time or whether they would like me to wait.

Mr. KENNEDY. Madam President, I think it would be appropriate for the Senator to speak now. I thank him for his courtesy.

Mr. ALEXANDER. Madam President, I ask unanimous consent to speak for up to 10 minutes as in morning business.

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

ENGLISH: OUR NATIONAL LANGUAGE

Mr. ALEXANDER. Madam President, at the end of March, the U.S. Equal Employment Opportunity Commission sued the Salvation Army for allegedly discriminating against two of the Salvation Army's employees in a Boston-area thrift store by requiring them to speak English on the job. This lawsuit means that every business in America, from the shoe shop to Wal-Mart, will need to hire lawyers to prove it has a legitimate business purpose if that business wants to require employees to speak our national language while at work.

I asked the chair of the EEOC in what language she holds staff meetings. She said, in English.

We conduct Senate debates in English.

Since 1906, no immigrant has been able to become an American citizen without first learning English. At Hillsboro High School in Nashville, where my daughter graduated, students speak 28 native languages, but classes are conducted in English.

Federal law requires that all children in public schools be tested in English, and that if they do not know English, they must learn it as soon as possible.

Over the last 40 years, I have voted for or supported, I believe, almost every civil rights or anti-discrimination law that has been offered. But in America, requiring English in the workplace is not discrimination; it is common sense. More important, it is our common language. Our common language helps unite the diversity in this Nation of immigrants.

That is why, during the debate on immigration a year ago, the Senate adopted my proposals: First, to provide $500 grants to help prospective citizens learn basic English; second, to allow someone who becomes fluent in English to become a citizen after 4 years instead of 5.

The Senate also declared English to be America's national language and provided that anyone illegally here must first learn English before gaining legal status.

A few Senators said we were wasting our time debating national unity and language. But other nations are discovering just how important and difficult it is to unite one's country. Look at how today Turkey is struggling with whether to become more secular or more Muslim, struggling with what to do about its Kurdish minority. Germans are struggling to absorb Turkish workers. Italians are establishing agencies to help new Muslim residents ''feel Italian.'' Three alienated British citizens, children of Pakistani immigrants, blew up a London subway 2 years ago. The children of disaffected Muslim immigrants in France burned cars during that country's elections this weekend, a small echo of much larger riots 2 years ago.

We Americans are rightly proud of our diversity. But Iraq and Jerusalem and the Balkans are also diverse. America's greatest accomplishment is not our magnificent diversity. Our greatest accomplishment is that we have united that diversity into one country.

Our original national motto inscribed in the wall right above the Presiding Officer's chair is ''One from Many,'' not ''Many from One.''

Most nations unite around ancestry or race, making it hard for newcomers. Imagine ''becoming Japanese'' or ''becoming German.'' In other words, the United States Constitution says race or ancestry can have nothing to do with someone becoming an American. Instead, American unity is based upon ideas, principles found in our founding documents—such as liberty, equal opportunity, and the rule of law. New citizens must, therefore, pass an exam, which was recently improved, about the Declaration of Independence, our Constitution, and United States history.

The first Europeans in America were French and Spanish, but our cultural beginnings and primary institutions

and laws were Protestant and English. So English became the way Americans of many backgrounds communicated with one another.

In the 20th century, according to the late president of the American Federation of Teachers, Albert Shanker, American common—or public—schools were created primarily to help immigrant children learn arithmetic and to read and write in English with the hope that they would go home and teach their parents. Then, in 1906, all new citizens were required to know English.

That has turned out to be a fortunate choice. English has also become a unifying language internationally. For example, every Chinese student is expected to study English. When Carlos Ghosn, who speaks several languages, became chief executive officer of Nissan, he began conducting business meetings in Nissan's Tokyo headquarters in English.

The most fortunate children in our country are those who grow up learning more than one language, but American parents know that one of those must be English. Mastering English is how an American succeeds in school, in the workplace, on the computer, and in international affairs.

A century ago, many American companies and private associations led an effort to Americanize new immigrants. They taught their employees English and the National Anthem. Today, the EEOC is suing the Salvation Army for doing the very same thing, insisting that its employees learn and speak this country's common language.

According to an article that appeared today in USA Today:

> The number of charges filed with the Federal Equal Employment Opportunity Commission (EEOC) alleging discrimination based on such English-only policies is . . . six times as large as 10 years ago, [growing] from 32 charges in 1996 to about 200 in 2006.

This is not only an astonishing waste of the EEOC's time and taxpayers' money—the EEOC has a backlog of 56,000 cases—but it is also contrary to everything we know about the importance of achieving unity in our country.

Speaking English is not a punitive requirement; it is a requirement to help us communicate with one another. A 9–1–1 telephone call isn't of much help to a Chinese-speaking person if the employee answering the phone speaks only Spanish.

In this case, the Salvation Army posted its requirements that employees in thrift stores speak English. The two employees in question had worked for the Salvation Army for 5 years. They were then given an extra year to learn English. When they didn't, they were let go.

I intend to introduce legislation to put an end to these lawsuits by making it clear that requiring employees to speak English is not illegal discrimination as long as the policy is clearly posted.

More than that, I can think of nothing that would be more in our national interest than helping anyone in our country learn our common language. That is why later this month, when the immigration legislation comes to the floor, I will introduce again my amendment that the Senate adopted last year giving every adult immigrant a $500 voucher to receive English instruction and allowing those immigrants who want to become citizens to do that in 4 years instead of 5 if they become proficient—rather than just achieve a basic level—in English.

Senator KENNEDY and I have discussed the fact that there are too many adults eager to learn English standing in line in Boston and Nashville for adult learning programs. They need help learning English, and I hope we can rectify that soon.

For 10 years I have suggested, most recently to Bill Gates at a hearing, that I would like to see established a private foundation that would loan $500 to any person living in this country who wants to spend it at an accredited institution learning English, with the hope that someday that student would pay it back. The payoff to American unity would be worth the cost by itself. But I believe such a bank would eventually grow to a huge size funded by grateful new Americans.

Without our common language we would be a giant Tower of Babel. It would be difficult for Americans to talk with one another, to debate political issues, and to vote. It would be harder to function as a democracy and to unite as one country. Without English, we would risk becoming just another United Nations instead of the United States of America.

Madam President, I ask unanimous consent to have printed in the RECORD the article from the USA Today to which I made reference.

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

[From USA Today, May 7, 2007]

ENGLISH-ONLY WORKPLACES SPARK LAWSUITS

(By Stephanie Armour)

Some companies are adopting policies that require employees to speak only English on the job, spurring a backlash of lawsuits alleging that such rules can discriminate against immigrants.

The English-only policies are coming as the number of immigrants in the USA soars: Nearly 11 million residents are not fluent in English, according to U.S. Census data, up from 6.6 million in 1990. Nearly 34 million residents are foreign-born, according to 2003 U.S. Census data. That's up from 24.6 million in 1996.

''This is becoming a much bigger issue,'' says Amy McAndrew, an employment lawyer at Philadelphia-based Pepper Hamilton. ''Employers want to have policies because of safety and customer service, but they have to be careful not to be discriminatory.''

Employers may legally adopt an English-only speaking rule if they can show it is a business necessity, such as the need for communication with co-workers and customers or safety-sensitive situations where use of a common language could prevent an emergency, she says.

But Ronna Timpa, owner of Workplace ESL Solutions in Henderson, Nev., says employers go too far in adopting strict policies that prevent co-workers from talking in their native language even during lunch.

''Imagine how you would feel if you couldn't speak your own language in the bathroom,'' she says.

The issue typically comes up in lower-wage and service-sector jobs.

The number of charges filed with the federal Equal Employment Opportunity Commission (EEOC) alleging discrimination based on such English-only policies is small but six times as large as 10 years ago, from 32 charges in 1996 to about 200 in 2006.

''If the rules enter work breaks, they will be difficult to defend or justify,'' says Dianna Johnston, assistant legal counsel with the EEOC, adding that some employers also have policies requiring employees to be fluent in English.

Employers have faced lawsuits for enforcing English-only policies. In April, Flushing Manor Geriatric Center agreed to pay $900,000 to settle an EEOC lawsuit based in part on the company's English-only policy. The New York-based geriatric center barred Haitian employees from speaking in Creole while allowing other foreign languages to be spoken, according to the EEOC.

That prohibition also included that no Creole be spoken during breaks, and largely affected employees who worked in nursing, food service and housekeeping, the EEOC says.

''There was no justifiable reason when there's not a specific business necessity,'' says Stella Yamada, an EEOC lawyer.

Marc Wenger, a New York-based lawyer representing the geriatric center, says the EEOC characterization is inaccurate and it believes its language policies are consistent with EEOC guidelines. He says there was no restriction on using other languages during breaks, adding the consent decree was not an admission of wrongdoing.

Some employers have extended the policy to customers, too. Geno's Steaks, a Philadelphia landmark, generated a storm of media and blogger attention in 2006 when its owner posted a sign requesting that customers order only in English.

At New York-based Hakia, which provides an Internet-based search engine, employees who are hired must speak English, and English is the language used for all business communications, says President Melek Pulatkonak. Many employees are immigrants who speak Turkish, German, Russian, Indian, Romanian or Spanish. Employees are free to speak their native language in private conversations.

''We have a very international team,'' Pulatkonak says. ''Sometimes we have slips, and we just e-mail them back in English.''

The PRESIDING OFFICER. The Senator from Iowa.

Mr. HARKIN. Madam President, I wish to discuss the amendment Senator ROBERTS and I have worked on, along with Senator KENNEDY and Senator ENZI, regarding direct-to-consumer advertising of prescription drugs. I am concerned about the proliferation of this kind of advertising, its effect on public health and health care spending, how much money we are spending on health care. Senator ROBERTS and I want to make sure they are done in a responsible way so that consumers have good information and it deals with safety and efficacy. I believe, along with Senator KENNEDY and Senator ENZI, we have crafted an amendment that addresses any first amendment concerns, and I believe we

have also crafted an amendment that will help the FDA get better safety and efficacy information to consumers who see these ads.

I wish to take this time to discuss my concerns with direct-to-consumer advertising of prescription drugs. Keep in mind, we are talking about ads you see on television, you hear on the radio, you see in newspapers and magazines for drugs that you cannot buy unless you get a prescription. It raises all kinds of questions. Why would you advertise drugs that you can't buy? I can see advertising Advil or Tylenol or a host of other over-the-counter-type drugs that you can go into a drugstore and buy, such as cold pills and antihistamines. But for prescription drugs, it raises an interesting question: Why would these drug companies be spending so much money advertising directly to you if you can't even buy it unless you get a prescription?

Let's look at the history of what has happened. Information that is conveyed in these ads is supposed to balance risks and benefits of a specific drug and provide information to the public. But what we have seen happening over the last several years is less and less information and more and more promotion—ads that minimize the risks associated with the drugs and maximize the benefits. They are not balanced. As a result, in exchange for an increased market share for a drug company, the consumer is left with an incomplete and even a dangerous understanding of a drug's risks and benefits.

More often than not, these ads do not provide consumers with accurate comparisons between new drugs or even older drugs that are still effective.

For example, in a 2002 FDA survey of physicians, 65 percent of physicians thought patients were confused by the relative risks and benefits of drugs they saw advertised; 75 percent of the doctors believed the ads led patients to overestimate the efficacy of advertised drugs. All of this can only lead to one conclusion, that there is not a fair balance of risks and benefits in these ads.

Worse still, 86 percent of physicians had a patient who asked about a specific drug. They didn't ask about something for their back pain or for allergies, they asked about a specific drug. Eighty-six percent of physicians said the patients asked about specific drugs. As it turns out, the patient usually got that drug.

Seventy-seven percent of primary care physicians prescribed a drug a patient asked for; 74 percent of specialists did.

Let's look at some of these drugs and what happened. We all know what happened when Vioxx, a pain reliever now associated with heart attacks, was pulled from the market after being heavily marketed to consumers. Consumers never had a clear picture of the risks and benefits associated with the drug. Millions of consumers were put at risk.

One wonders how many doctors said to a patient who came in: You know, if Advil works for you now, you probably don't need Vioxx.

Look what happened with Vioxx: 2 million Americans took it. It was marketed in 80 countries. Madam President, $100 million per year was spent on direct-to-consumer advertising of the prescription drug Vioxx over about 5 years. So about a half billion dollars was spent to tell you Vioxx was good for you.

What happened? Because of all this heavy advertising, there was $2.3 billion in sales in 2003. We all know what happened. It was pulled from the market in 2004. Why? Because thousands of people died of heart attacks because they took Vioxx. Yet this product was subject to heavy direct-to-consumer advertising.

We all remember the Vioxx ads, how good it was for you. Then we find out it was causing heart attacks. Again, this is a clear indication of the irresponsibility of these drug companies in direct-to-consumer advertising. It has just gotten out of hand. It has totally gotten out of hand.

I will show on the next chart what I mean by getting out of hand. Here is the spending on direct-to-consumer advertising. Keep in mind, prior to 1996, we didn't have direct-to-consumer advertising very much on TV and radio. Pharmaceutical companies basically marketed to doctors. You went into the doctor's office. You saw things in the doctor's office. But the doctors were the ones who got the advertisements.

In 1997, the FDA promulgated some rules which opened up the system. Then, all of a sudden, the drug companies started marketing to consumers. In the first year, they spent $791 million. Look what has happened every year. More and more and more. In 2003, $3.2 billion was spent on advertising. I made the chart before I got the latest figures, but today I got the 2005 figures. It is now $4.2 billion. Madam President, $4.2 billion was spent in 2005 advertising drugs you can't buy unless you get a prescription. Keep in mind, these are drugs for which you have to have a prescription. So it has gotten out of hand.

To make matters even worse, most of this money that is spent, $4.2 billion in 2005, was for the promotion of only 50 brand-name drugs. As a GAO study found out, these drugs are most often for chronic conditions, not for cancer—not for life-threatening diseases—but for chronic conditions. GAO found the ads tend to be for antihistamines, sleep aids, acid reflux, and—as we all know too well from watching evening television—things like impotence. We all know this is true. We know it. Look at the ads on TV every night.

It is no coincidence these advertisements are for drugs that you must take repeatedly. It is so you will get hooked on a brand and then you have to keep taking it and taking it and taking it.

Mr. DORGAN. Madam President, will the Senator yield for a question?

Mr. HARKIN. I will yield.

Mr. DORGAN. The Senator held up one or two charts dealing with Vioxx, a pain medicine. He is aware, I know—and I believe it was Dr. Graham from the FDA who testified—that somewhere around 50,000 to 75,000 Americans died of heart attacks as a result of that drug. I know Senator HARKIN is talking about the advertising of these drugs. That was a drug that was advertised as a new generation of pain killers—distinctly different and distinctly better. Not only was that not the case, but it turns out that it posed a very substantial risk to tens of thousands of people, in the FDA's own testimony, who died.

If I might make one additional point. The Senator is raising a question I have raised on the floor in the last week or so about this issue. You turn on the television in the morning while you are brushing your teeth—if you have a little television in your bathroom—and you are minding your own business, when a commercial comes on and says: You know what you ought to be doing? You ought to go to your doctor and ask him if the purple pill would be right for you. You don't know what the purple pill is, but there is a lot of advertising saying you are somehow unworthy if you don't go to the doctor to see if the purple pill isn't right for you because life would be a lot better if you were taking the purple pill.

That is the way this advertising goes. You can only get these drugs by a doctor's prescription. Yet the television set is giving us all this advertising from a pharmaceutical industry saying: You know what you need to do, you need to ask your doctor if you shouldn't be taking more prescription drugs. Maybe a green pill, maybe a purple pill, but life will be better if you would do this.

The reason I wanted you to yield, is that doctors are saying that what they are finding in their offices these days is patients are coming in and the patients are saying: Here is the medicine I want because I saw it on television. Obviously, the doctors aren't happy about that because they are the ones who should be diagnosing and prescribing.

I wanted to make the point that I think your presentation is right. I think there are only two countries in the world, us and New Zealand, that allow virtually unrestricted, complete public advertising on prescription drugs that can only be prescribed by doctors.

Mr. HARKIN. The GAO did this study which found that 86 percent of physicians responded that patients came in to ask about a specific drug—the purple pill, the green pill. You might say: Why are the doctors doing it? One doctor said to me: You are right. They shouldn't be advertising this. Patients coming in would be just as well served by taking an aspirin or something like that, very cheap and readily available, and I tell them that. The doctor is telling me this. I tell them that, and they

say, no, no, they saw this ad. They want this. I tell them no, but they say: Well, Doctor, if it is all the same with you, I would just as soon have that pill. So he says: Well, if you want it, I will prescribe it.

So there is an undue amount of pressure being put on doctors right now to prescribe these drugs because patients are demanding it.

Mr. DORGAN. It is the case with this advertising that if you take this purple drug, you know, you will be riding in a convertible, perhaps through a beautiful meadow, where the Sun is shining and the birds are singing and life is wonderful. Why? Because you took the purple drug. And by the way, go ask the doctor if you shouldn't have some of this.

The Senator is raising a very important question, especially about the dramatic growth in direct-to-consumer advertising about a product that can only be achieved through a prescription by a doctor.

Mr. HARKIN. Well, I thank the Senator for his great leadership in all these areas on drugs, on reimportation, which I was proud to support him on. We have to get a handle on this.

We all have first amendment concerns. People have the right to advertise, but I question whether they can advertise in a way, like with Vioxx, where they tell you all the benefits, but they do not tell you the risks, or they put them in such little fine print that it takes a 50-power magnifying glass to read them.

On television, how many of you have seen the ads where they come on with this wonderful advertisement of a drug, and then in the end it says: Not to be taken by, and it goes so fast you can't understand what they are saying. It is akin to listening to an auctioneer. You can't understand what they are saying. So you see all the benefits of it, but you don't get any of the downsides.

One might ask: Why are companies doing it? Well, simple. They make money. The Kaiser Family Foundation found an additional $4.20 in savings for every dollar spent on advertising. There you go. If you could spend a dollar and make $4.20, who wouldn't?

So we have to ask some questions. What happens when we create an artificial demand? What is the effect on our budget? Some people might say: Well, that is OK, but people are spending their own money or the insurance company is. That is not so. Think of all the money we are spending on Medicare and Medicaid for these drugs that people are being beaten over the head with every day on these ads on television. Think about the baby boomers retiring.

I said that by 2005 the spending had gone to $4.2 billion. Think of what it is going to be this year. I will bet it will be over $5 billion this year, spent on advertising alone, for drugs you can't buy unless you get a prescription. So it is clear to me it has very little to do with patient care and very much to do with making money. I don't mind drug companies making money. That is fine. They do good things. They invest money in research—not as much as I wish they would—and they come up with good drugs. We all take them when we get sick or when we have a disease. The problem is it has gotten out of hand.

It was OK when they did a little bit of advertising, but now it has gotten out of hand. It has gotten to the point now where an individual from a drug company—I will not mention who—said to me: Well, yes, you want to turn the clock back to 1996, when we didn't advertise much on TV. He said: That would be nice, but you could never get it done because not everyone would agree. Because, you see, the big drug companies, the big ones that have some major portion of these 50 drugs that are basically the ones being advertised, they have got the power. The little drug companies out there, which may have good drugs for you, lifesaving drugs and things such as that, they have to get in the game too. They have to compete. So it keeps ratcheting itself up every year. Every year it ratchets itself up with more and more advertising.

Before I yield the floor, I wish to review a little bit the history, so we are clear on how we got to this point. In 1962, Congress gave the FDA the authority to regulate prescription drug advertising which, at that point, in 1962, consisted of ads in medical journals. Regulations followed from the FDA, after 1962, which required that all drug ads include ''a brief summary statement that discloses all the drug's known risks.'' That was done, and all the medical journals, whenever the drug company would put an ad in a medical journal about the benefits of the drug, they had to include, and they did include—they were very responsible for a long time—all the known risks. After all, they were advertising to doctors, people who were knowledgeable in the field.

Until 1997, there was no real guidance beyond that as to what was required. Today, based on guidance that was finalized in 1999, an ad sponsor is only required to disclose ''the most important risks'' in a ''major statement'' in the audio portion of a TV or radio ad. The FDA does not require that all risks be read in the ad.

Think about that. You can tout all the wonderful benefits, but you don't have to tell what all the risks are. The FDA requires that an ad sponsor provide other places to find the list of all the risks. So you could have an ad on TV tell you Vioxx is great—there may be a problem with irregular heartbeat, maybe—but if you want to know all the known risks, you can call this toll-free number or you can go to a health care provider and ask your doctor or print ads.

As I said earlier, it can be very easy for a statement about risks and benefits to get lost in the creative content of the ads. It is no wonder consumers demand newer drugs from their doctors. They don't have a clear idea of the true safety or the efficacy profile. Over time, it has become clear that sometimes the creative content of the drug ads has the effect of minimizing the safety profile of a drug while artificially spurring the demand.

I have one other chart I wish to show. This ad right here. Here is an ad for Cialis. If you have ever watched television in the evening in the last several months, you have seen this ad. You could have seen it in the last few weeks. It seems like I can't turn on the TV that I don't see this ad, so I put it on a chart in case someone might have missed it. It is talking about Cialis. It has this wonderful scene at the end, with a woman in a bathtub, a man in a bathtub, and a beautiful valley scene—maybe Napa Valley, I don't know where it is—and they say: If a relaxing moment turns into the right moment, will you be ready?

While this is on the screen and you are looking at this beautiful scene and thinking how wonderful it is, they come on and give you a couple of known risks. Are you going to listen to that? Or are you paying attention to how wonderful Cialis is for you?

This is another example of the amount of money being put into advertising. This is not a drug preventing a disease someone might have. It is not for a life-threatening disease or anything like that. Not at all. Yet that is where the money is going. That is what the problem is with a lot of these ads.

What our amendment does is it tries to fix some of these problems and to help the FDA and the companies to provide better information so that consumers can make real choices, not a choice based on a movie endorsement or a slick advertisement. So our amendment does four things:

First, the 2-year moratorium on direct-to-consumer advertisements found in the underlying bill is dropped. While I believe this provision is constitutional, I understand and respect the concerns others have on this point.

Secondly, in the underlying bill, every ad may be prereviewed by the FDA. In this amendment, as part of that process, the FDA may require specific safety information in the content of an advertisement as part of a risk evaluation and mitigation strategy. In addition, the company must include any changes the FDA requests about a serious risk in the content of the ad or they are subject to civil penalties.

Third, civil monetary penalties can be assessed against a company for an ad that is false and misleading in the way it presents its safety and efficacy information.

Fourth, the major statement relating to side effects, contraindications, and effectiveness that is included in every TV and radio ad must now be stated—and get this—in a clear, conspicuous, and neutral manner. A clear, conspicuous, and neutral manner.

Hopefully, this will clarify the major statement about risk and benefits, which is paramount, and that the creative wonderful scenery will not distract from it. I think it is a good compromise. It is a step in the right direction. Hopefully, we will get the bill through, this will be a part of it, and we will see if the drug companies want to be responsible.

We don't need to spend $5 billion a year advertising for drugs for which you have to get a prescription. I would rather they put that money into research, research on drugs that really are lifesaving and helpful to more people.

I hope this amendment will be accepted. As I said, it is a compromise, obviously. It is not everything I wanted to do, but I think, again, it is a step in the right direction, and it will give us a yardstick. If, a couple of years from now, we see that the spending has gone from $4.2 billion to $5 billion to $5.5 billion to $6 billion, then we will really have to come back here and tighten down on it even more.

This is a shot across the bow to the drug companies—rein it in, be responsible, or tougher things are coming in the future. So it is really up to the drug companies to now start to be responsible. It is up to FDA to use their authority to make sure the contraindications, the safety measures, the drug interactions—all the things that may happen to people—are presented in a clear, conspicuous, and balanced and fair manner. That is the essence of the amendment. I hope it will be adopted.

I yield the floor.

The PRESIDING OFFICER (Ms. STABENOW). The Senator from South Dakota.

Mr. THUNE. Madam President, one of the biggest drivers of health care costs today is the cost of prescription drugs. This debate over reauthorization of the FDA has given us an opportunity to really home in on some of the reasons for those high costs of prescription drugs. We say we spend somewhere around $2.2 trillion on health care today or about 16 or 17 percent of our gross domestic product. Of that amount, about 15 to 20 percent of what we spend on health care is for prescription drugs. It is an enormous industry in this country.

Frankly, some remarkable things have happened. We have wonderful therapies that have prolonged life, have improved the quality of life, and for that we can be grateful to those companies which are investing in the research and development that is necessary to bring these types of new therapies and drugs onto the market.

At the same time, we have to be very concerned about the cost of these things. Everybody has to be concerned about that. The taxpayers, who underwrite the cost of Medicare and Medicaid, which is a big part of the cost of health care in this country, have a stake in this debate, as does every consumer who, for prescription drugs—whenever they are diagnosed with something and a doctor prescribes a certain medication, a certain drug, and they have to go get it, obviously that cost is borne by them as consumers and by their health care provider, their insurer. Everybody has a stake in the cost of prescription drugs and doing everything we can to lower their costs, to make them more affordable to average people in this country.

We have an amendment, the Stabenow-Thune-Brown-Lott amendment having to do with citizen petitions, which was just debated. It has been debated. It is under consideration as part of the managers' amendment. I thank the managers, Senators KENNEDY and ENZI, for giving us an opportunity to perhaps have it included in the managers' amendment. I think this is an important amendment, one that addresses the issue we are talking about today, the high cost of prescription drugs.

The amendment will reduce the filing of frivolous ''citizen petitions'' that delay entry of generic drugs to the market and unnecessarily increase drug costs for both taxpayers and consumers. My colleague from Michigan, the distinguished Presiding Officer, has discussed this earlier.

A citizen petition is intended to be just that—it is a petition that is filed by an individual or a group in order to raise potential concerns. If you look at what has happened with that, that process has been abused. You can see that even from what the FDA Chief Counsel has said about this process:

> These petitions appear designed not to raise timely concerns with respect to the legality or scientific soundness of approving a drug application, but rather to delay approval.

What has happened in this process is it has become hijacked and is being used for purposes for which it was not intended.

Under current FDA regulations, the simple act of filing a petition, no matter how meritorious or frivolous that petition may be, automatically delays the approval of a generic drug. Under current regulations, there is no risk or cost associated with filing a citizen petition. Yet the benefit to a brand-name company in maintaining their market share for even a few months is enormous.

I want to show another chart which I think further defines why there is so much advantage for a company to use this process in a frivolous way, to delay the introduction of generic drugs into the marketplace. Take Flonase, for example. The delay caused by using the citizen petition was 645 days. During that period, the additional sales that were generated were over $1 billion—$1.6 billion. If you look at DuoNeb, another drug, 420 days' delay yielded $262.5 million additional revenue generated during that delay period.

The amendment will allow the FDA to verify that citizen petitions are legitimate by requiring applicants to verify that they have not received compensation from another organization to file such a petition. It will also prohibit delays of generic drug approvals unless the FDA determines within the first 25 days that a petition is filed that the petition raises a genuine public health concern. This amendment helps to remove the incentive for drug companies to file unnecessary or illegitimate citizen petitions.

Even the FDA has said the citizen petition process is inefficient and is often abused by pharmaceutical companies. This is troubling to me because the rising cost of prescription drugs is one of the largest drivers, as I said earlier, of health care costs in our country today. These costs contribute directly to the rising cost of health insurance premiums for families and small businesses and the cost to all taxpayers for what we pay for Medicare and Medicaid.

As a Member of the House of Representatives in 2002, I sponsored legislation that would help speed access to lower cost generics. Back then, one of the major issues of concern to Congress and consumers was the automatic 30-month stay brand-name companies could request whenever a challenge was raised to the patent. FDA regulations at the time essentially allowed a pharmaceutical company to ask the FDA for an unlimited number of 30-month stays as generics sought entry into the market, effectively delaying their approval. Now we are looking at yet another loophole the industry has found to delay access to lower cost generic drugs.

Access to generic drugs is one crucial part of the solution to controlling prescription drug costs. As I said earlier, in overall health care costs, what continues to increase over time is the cost of prescription drugs. As I said earlier, there are also some wonderful therapies, some medications that were brought onto the market that are doing remarkable things for health care in this country. But there is also a long period where drug companies that develop these types of medications and therapies have the exclusive right to market those. During that period, they have an opportunity to recover the cost of the research and development that goes into that particular drug. But there is a point at which that period comes to an end. When that period comes to an end and it is opened to competition, then other generic drug manufacturers can enter the marketplace. What you generally see happen is drug costs go down dramatically when competition takes hold.

I am a big believer in the market. The market works when there is competition. What we will need, if we want to do something about the high cost of prescription drugs and the impact they are having in driving health care costs in this country, is to create more competition in the marketplace.

What this particular loophole does, the citizen petition loophole, is it allows drug companies to take advantage and in a frivolous way use something that was intended for legitimate purposes; that is, to allow citizens to challenge this process, to extend the period in which they can continue to exclusively market a drug to the tune literally of billions and billions of dollars of additional cost. That is wrong.

The amendment we have introduced—the Senator from Michigan, Senator STABENOW, Senator BROWN, Senator LOTT, myself—would simply bring some clarity to this and make sure, when the FDA has an opportunity to determine, to take a look at these citizen petitions, that petition does, in fact, raise a genuine public health concern. I believe this amendment will help remove the incentive drug companies have to file unnecessary or illegitimate citizen petitions in order to continue to reap some of these profits and take advantage of a loophole that exists today that needs to be closed.

I hope the managers of the bill, those who have been working with us throughout the course of this process, will find their way to accept this amendment into the managers' package, allow it to be adopted as part of the FDA reauthorization and to do something that in a very significant and meaningful way will address what is a serious problem in America today; that is, the high cost of health care which is driving more and more people into the ranks of the uninsured, becoming a higher cost and burden on small businesses, and, as I said earlier, a big component of that cost of health care is the cost of prescription drugs.

I think this amendment, along with others we have debated here today as well—and I happen to support allowing for the reimportation of drugs from Canada and Europe and places such as that, which will help bring drug costs down in this country—these things will all add competition to the marketplace. Competition drives down costs, it drives down costs for consumers, it drives down costs for taxpayers. That is a good thing. This particular amendment closes a loophole that needs to be closed that will bring about lower costs for consumers in this country.

I thank the sponsors and the managers of the legislation for their cooperation and willingness to work with us, and I hope in the end we can have this amendment adopted and do something that is serious and meaningful in terms of eliminating unnecessary delays in allowing for generic drug approvals, getting them into the marketplace, and driving down the cost of prescription drugs.

I yield the floor.

The PRESIDING OFFICER. The Senator from North Dakota is recognized.

Mr. DORGAN. Madam President, I have been trying to review the managers' package, as I indicated before. I read a number of the provisions. The one on domestic pet turtles—I looked that over. I guess I don't have an issue with that. Ginseng is all right. Tanning beds—we have a number of amendments, some small, some large, some important, some perhaps not. I have looked through them.

I do think there a couple that ought to be added. I noticed in the managers' amendment that there is a note that there is additional language coming on several of them. I don't know what that would be.

I suggested two additions to the managers' package that I hope will be considered. One is country-of-origin labeling with respect to prescription drugs:

Any prescription drug dispensed in the United States shall affix on each dispenser or container of the prescription drug a label that includes the country in which the drug was manufactured.

The reason for that is there has been an assertion here that somehow the importation of prescription drugs would be unsafe because it comes from another country. In fact, a substantial portion of our prescription drugs comes from other countries. It would probably be useful for consumers to know that. I do not suggest they know that because it is apparently unsafe, as some seem to suggest with reimportation, but nonetheless I think that would be a useful thing.

The second is the Secretary shall certify prior to the approval for marketing any new prescription drug that the approval of such drug poses ''no additional risk to the public health and safety,'' which is the identical provision in the Cochran amendment dealing with reimportation of prescription drugs. I would provide the same requirement for the new prescription drugs that are approved for use in this country.

These are at least, to the extent there is validity in the Cochran amendment, as judged at least by a small majority of the Members of the Senate today—to the extent there is validity in that, it seems to me there might be some use for some consistency, and the consistency would be we would want to be able to have the same approval process with respect to no substantial risk from new drugs as they are suggesting would be the case when a U.S. consumer is trying to purchase a prescription drug, FDA approved prescription drug from another country.

The second, the country-of-origin labeling just makes sense to me inasmuch as every time we debate this subject, we have people implying that there is something inherently unsafe about importing a prescription drug from another country. As I have indicated time and time again, they do this routinely in Europe and have done it for 20 years. If you are in Italy and you want to buy a prescription drug in Spain or if you are in Germany and you want to buy a prescription drug in France, there is no problem. There is something called parallel trading, and you can easily, as a consumer, access the best price on that approved drug.

It is just, if they can do it in Europe, we are told by our colleagues we do not have the capability or the wherewithal or the knowledge or whatever to be able to do it in our country.

That, of course, I think, seriously shortchanges the ability of the American people to develop a system that the Europeans have used for 20 years, a system that would help consumers. It would allow the global economy to work for consumers. Maybe the little guy ought to have a shot at accessing the benefits of the global economy.

So I think both of those amendments have merit. I would ask that those who are working on the managers' amendment consider adding these two amendments to the managers' package. I hope between now and perhaps tomorrow, over either supper or breakfast, they might have some sort of an epiphany and believe that consistency is a virtue in the Senate, and as a matter of consistency include both of these amendments in the managers' amendment.

I yield the floor.

The PRESIDING OFFICER. The Senator from New Hampshire.

AMENDMENT NO. 993

Mr. GREGG. Madam President, I appreciate the Senator from Ohio who was going to move to morning business by giving me a little respite and let me speak.

I rise relative to the amendment I have offered on this bill, which is the effort to try to protect people who purchase pharmaceuticals from Internet pharmacies. This is a major concern today. In fact, just last week I entered into the RECORD that the FDA reported they had identified 24 different Internet pharmaceutical sites that appeared to be selling adulterated drugs to people. At least in three instances they were selling adulterated drugs which came in packages that had a lot number on them, they had an expiration number on them, and they looked exactly like the drugs the individual would have bought had they bought them through a pharmacy in the United States.

But it turned out those drugs, when they were opened by the FDA and tested by the producer of these pharmaceutical products, were adulterated, and in some instances the adulterated drugs could have caused severe harm to the person had they taken those drugs. In other instances, the drugs were simply sugar. They had no chemical compound in them.

We have had a lot of instances of this occurring. The FDA has literally hundreds of instances of people purchasing drugs over the Internet sites which come in from international locations, which the FDA has no jurisdiction over. When the person received those drugs, they took them and they were harmed. In several instances, death has actually occurred as a result.

So what I think is important is that we create a system where, when somebody uses the Internet—because everybody uses the Internet today, or just

about everyone uses the Internet—to purchase the pharmaceutical product, that they be able to be fairly confident, in fact very confident, in fact assured that product is FDA approved.

This is doable. This is not an impossible exercise. This capacity to make Internet pharmaceutical sites subject to FDA oversight and give consumers the information they need in order to ensure that the pharmaceutical site is FDA approved is a very doable event. That is what my amendment creates.

Essentially what it will say is that the FDA will receive the resources necessary to be able to inspect and review and manage and overview Internet pharmaceutical sites after they have put an Internet pharmaceutical site through the system of testing and make sure that site first has responsibility in the United States, so that they are not in Russia or Albania or Pakistan or someplace and can't be reached if they do harm by selling an adulterated drug to an American citizen, that that site has a bonded individual in the United States who is responsible for actions taken by that site in selling products in the United States.

Second, that the products that are sold through that site are FDA approved and have a review process which assures that they have been FDA approved. At that point the FDA will put a tamperproof recognition symbol on that site so that a person who goes on the Internet and looks up a pharmaceutical site will immediately see this tamperproof identification that it has been FDA approved, sort of like in the old days when you used to have the Good Housekeeping seal of approval on a product. That is what this will do so that an American citizen buying through an Internet site will know that the product coming through that site is FDA approved, that it is what they say it is, what the pharmaceutical site says it is. This is a step which needs to be taken, obviously, in order to assure that American consumers are safe.

As we see, American consumers are more and more going to the Internet for purposes of buying their products. Now, regrettably, some fairly large pharmaceutical—not pharmaceutical companies but some fairly large drug retail companies which run Internet sites in most instances have reservations about this language because they are concerned about the fee system which is set up to pay for it. I can understand that. I am willing to look at ways of addressing that so that we can alleviate, to some degree, their concern.

But the simple fact is, you have to come up with a system which assures that resources are available for the FDA to be able to go out and monitor these sites. It should be a consumer-producer retail sales-fee system so that the people who are taking advantage of this site and the people who are benefiting from the site, both economically and through purchasing the product, are essentially bearing the cost of making sure the FDA has the resources necessary to monitor the site.

That is a reasonable approach. It is something we do on most issues of this type. So there is a fee system in this proposal which would basically pay for the resources necessary and give the FDA the support it needs financially so that it can expand its review process to cover these pharmaceutical products which are being sold over the Internet. This is a step we have to take. This is not something where we can sort of bury our heads in the sand and say, well, we are just going to let this happen. We are going to let these sites continue to function, and we are going to ignore their existence because more and more Americans are moving to this process of purchasing drugs.

You cannot have, in the United States, two different streams of supply of pharmaceuticals for American citizens: one which is absolutely safe and when American citizens are purchasing that product they are sure that it is not going to harm them; and, two, where they are basically rolling the dice, playing Russian roulette with what they purchase when they use an Internet site but thinking they are actually purchasing something that is claimed to be the medication they need.

You cannot do that and claim we have a safe and efficient system, a safe system which has efficacy in the quality of the drugs and have those drugs be safe when they are delivered to the consumer. We cannot have two different systems and still make that claim. We are basically undermining one of our great strengths as a culture, which is that we have a very strong system for protecting the food that Americans eat and the drugs America uses.

So it is critical that we face up to this very significant problem we have, which is that the Internet pharmacy situation is basically a ''wild west'' of supply. Nobody knows what they are getting. Well, they think they know what they are getting, but nobody actually knows what they are getting. They can be harmed as a result. So I believe this proposal is a reasoned proposal. It is one I hope we will take a hard look at as a Congress because I believe it is our responsibility. This is an area where the Federal Government has chosen to legislate and has done quite well over the years, FDA proposals dealing with the safety of drugs and food in our country and in our supply chain. We have a lot of history. We can take considerable pride in it. But the market has changed. We need to change the process by which we review the quality of the drugs as they come through this new market structure, which is called the Internet. This is not a partisan or political issue. This is just a question of how we substantially improve FDA's capacity on oversight of the delivery of drugs to the American citizen.

So it should, I hope, be accepted at some point. I understand it is going to be opposed, regrettably, by the other side of the aisle. This makes no sense to me. I think it has something to do with the fee system that is in place and the fact that the large drug delivery companies in this country are opposed to this type of system. But as I stated, this is negotiable. There should be some way to deal with that.

But, in any event, at some point I hope we face up to the reality of needing this type of an amendment and giving the FDA this type of authority. At this point I am not going to ask for a vote on the amendment. I may before we move to final passage. But I am also considering other approaches to getting this type of language considered.

I will review the situation as we go down the road. But I did want to speak tonight to outline again the need for this type of protection. As I said, just last week the FDA sent out a warning, actual warning to American consumers, that said: Do not use these 24 Internet sites because we cannot tell you that the drugs you purchase over these sites are going to be safe, that they are going to be what they say they are. In fact, we can tell you in these three incidents that they were not.

That means people were put at risk by purchasing drugs from these sites. So we need to give the FDA this authority, and hopefully we will. If not now, at least before this bill completes the whole process and comes back from the conference committee.

I yield the floor.

The PRESIDING OFFICER. The Senator from Ohio is recognized.

Mr. BROWN. Madam President, I have a few comments on this afternoon's proceedings. I was disappointed, as I know many in the Chamber were, in the passage of the Cochran amendment and what that means to the price of prescription drugs.

An awful lot of us believed—those of us running for election last fall, those of us who were just observers of the American political scene—understand that the drug industry has had way too much influence in the Senate and the House and particularly the White House in the last many years.

Many of us talked about reimportation of prescription drugs, particularly from Canada. Many of us—I know the Presiding Officer has done this. I have, from my Northeastern Ohio Congressional District before I was elected to the Senate last fall, taken busloads of senior citizens to Canada to buy less expensive but identical—same drugs, same dosage, same packaging, same manufacturing,—drugs in Canadian drugstores.

We all thought that it made no sense for Americans to leave our country to buy drugs, often made in the United States, but certainly drugs that are safe as those at a drugstore in Elyria, Ashtabula or Toledo or Dayton.

Many of us were disappointed at the passage of the Cochran amendment,

which is what the drug companies wanted, and what again stands in the way of direct reimportation so that American seniors and other Americans could get less expensive drugs. There is simply no reason the Canadian drugs—that our drugs should cost two, three, four times what people pay for the same drug, same manufacturer, same dosage, the same packaging in Canada.

I am intrigued by Senator DORGAN's idea of country-of-origin labeling on prescription drugs. We know, for example, that a doctor prescribes Lipitor, and the patient buys Lipitor; that these actual drugs were manufactured—that medicine was manufactured in Ireland. We do not seem to think there is anything wrong with that. So it makes sense to me to put on country-of-origin labeling because then Americans would see that these drugs, whether they are made in Ireland, whether they are made in Canada, whether they are made in Germany, whether they are made in the UK, whether they are made in the United States, that because of the FDA we know those drugs are safe in our country. We know they are safe if they are coming from Britain or Ireland or Canada.

I am intrigued by Senator DORGAN's idea. I also, for a moment, wanted to speak on the amendment that the Presiding Officer has led the charge on with Senator THUNE and with Senator LOTT and myself, on the citizen petition issue. That, I understand, is in the managers' amendment. I am hopeful that will become part of this bill as it moves through the process.

We know of abuse of the citizen petition process. We know that while, of course, we want to protect peoples' rights in this country to petition their Government always, we also note the drug companies have gamed that system, turned that system to their advantage and used that petition process to block the generics getting on the market.

We know the drug companies will do darn near anything to get their way, to keep their prices higher. It is the most profitable industry in the country—return on investment, return on sales, return on equity—for almost a generation, almost every year except for when the oil industry does slightly better than the pharmaceutical industry. We know they will try almost anything.

But Senator STABENOW's work on this issue and this amendment will draw a balance so that citizen petition rights are protected, that consumers are protected, which will mean generics are earlier to market, safe generics, identical generics that will mean lower prices for our consumers.

I am hopeful we can get this bill in better shape than it has been. I appreciate particularly the efforts of Senator DORGAN on reimportation.

BIOEQUIVALENCE STANDARDS

Mr. HATCH. I rise to speak about the amendment I offered to S. 1082 on antibiotics access and innovation. My amendment is supported by the Infectious Diseases Society of America, IDSA, the Alliance for Aging Research, the National Organization of Rare Disorders, and the Immune Deficiency Foundation. It is intended to take initial steps to address the important issue of drug resistant microorganisms and the need for new antibiotics. Senate Health, Education, Labor, and Pensions Committee Chairman TED KENNEDY and its Ranking Member MIKE ENZI have worked with me on the provision as well as Senators BURR, BROWN, and COCHRAN. I appreciate all their efforts to address this important issue and am pleased that we have reached an agreement on language to include in S. 1082.

Mr. KENNEDY. I want to thank the Senator from Utah for introducing this important amendment. I am concerned with the alarming increase in the number of drug-resistant infections. Physicians from Massachusetts have written me in support of this amendment saying that patients are routinely lost to infections caused by resistant bacteria for which we have few to no options. I appreciate the efforts of infectious disease experts from the Infectious Diseases Society of America to raise these concerns and propose solutions.

Mr. HATCH. Senator KENNEDY has always been a leader in public health issues and I appreciate the efforts of him and his staff to address this important matter. However, I am concerned one provision of my amendment that was not included which deals with bioequivalence standards for locally-acting non-absorbed drugs. In the amendment I filed for Committee, I had asked for the Food and Drug Administration to establish a new bioequivalence standard for these drugs through a guidance allowing for transparency and a public process. The underlying bill deals with drug safety and although I am a supporter of the generic drug industry, I want to ensure that their bioequivalence standards are based on science—we need to ensure that FDA is applying high scientific standards and allowing for public input when these standards are developed by the Office of Generic Drugs.

Mr. BROWN. I appreciate his leadership on this matter and want to work with him to ensure that we exercise appropriate oversight over FDA and hold the agency, and in this case, the Office of Generic Drugs, accountable for its decisions. I also appreciate working with him and other members of the HELP Committee on the issue of antimicrobial resistance. So my question is, isn't this a public health crisis that requires immediate action?

Mr. HATCH. Yes, it is. I appreciate the remarks of the Senator from Ohio. I yield to the Senator from Mississippi.

Mr. COCHRAN. I want to thank the Senator from Utah for his leadership on this issue. I have been working on this issue of FDA standard setting and process for bioequivalence standards for almost a year now. We have not yet had resolution to concerns regarding bioequivalence standards and I had hoped to include language in this bill requiring FDA to engage in a process to inform the public of a change in standard, explain their scientific rationale, and allow for public input before a new standard is implemented. I understand we have agreed to continue to work with FDA on this issue and defer including the provision in this bill. I am hopeful that we can address these concerns through our continued work with the FDA. However, I think we all understand that if FDA does not sufficiently answer our questions, Congress will revisit this issue.

Mr. HATCH. I thank the Senator from Mississippi for his leadership on this matter. I agree that we need to pursue this further if we don't get good answers from the FDA. The agency's lack of a response is a big concern to me.

I might also add that your health advisor, Leigh Ann Ross, who is a pharmacist, has been very helpful in explaining the issues of pharmaceutical science at issue here. I also want to acknowledge the work of my colleague from Massachusetts who has shown great leadership here and his dedicated staffer, David Dorsey, who has worked tirelessly on this entire bill and this issue in particular. I also appreciate the hard work of Senator ENZI's staff person, David Schmickel, who has made great efforts to reach an agreement on this issue. We would not have been able to reach this point without Senator KENNEDY's and Senator ENZI's leadership on the entire bill.

In addition, I would like to acknowledge Senator BROWN's health staffer, Ellie Dehoney, who has made valuable contributions to this discussion.

Mr. ENZI. Would the Senator yield for a moment? I want to commend Senator HATCH for raising this issue of antimicrobial resistance and the need for innovation. The problem that the Senator is addressing here is a real threat to public health. The Director of the CDC reports that more than 63,000 patients in the United States die every year from hospital-acquired, antibiotic resistant infections. Although I strongly support this amendment as it is an excellent first step, a comprehensive response is needed. I hope we can continue to address the broader issue within the Committee this Congress. I also agree that we need to continue to work with FDA on this issue of accountability and look forward to working with the Chairman and other members of the Senate on this issue.

Mr. HATCH. I thank the Senator. I appreciate my colleagues' willingness to work with me on this important issue. Although the language on the bioequivalence issue is not in the agreed-to version of the amendment, by accepting the revised amendment, I want to make it perfectly clear that we want to have clear answers from the FDA on its current process in establishing a bioequivalence standard for

locally-acting non-absorbed drugs. It is certainly not my intent or the intent of my colleagues to suggest that we have concluded the oversight of FDA on this issue. Instead, we have agreed to engage with FDA through the oversight function of the HELP Committee to ensure that the scientific standards and procedures used in establishing bioequivalence for this life-threatening antibiotic are appropriate.

Mr. SPECTER. Would the Senator yield for a question? My office has also been in contact with FDA on this issue of bioequivalence for a life-saving antibiotic because leading infectious disease experts in my state have expressed concern that FDA did not take appropriate steps to establish this new standard for demonstrating bioequivalence. I would like to work with my colleagues on this important issue as well.

Mr. HATCH. I thank the Senator from Pennsylvania and I know that he has been in communication with FDA regarding this issue. His contributions to this dialog have been considerable. I look forward to working with him, Senator COCHRAN and my HELP Committee colleagues in getting some answers from the FDA on this situation.

AUTHORIZED GENERICS

Mr. ROCKEFELLER. Madam President, I rise today with my colleagues to speak about so-called authorized generics. An authorized generic drug is a brand-name prescription drug produced by the same brand manufacturer on the same manufacturing lines, yet repackaged as a generic in order to confuse consumers and shut true generics out of the market. Because it is not a true generic drug and does not require an additional FDA approval, an authorized generic can be marketed during the federally mandated 6-month exclusivity period for generics. This discourages true generic companies from entering the market and offering lower priced prescription drugs. I have introduced legislation—the Fair Prescription Drug Competition Act—in order to ban authorized generics during this protected 180-day period, and I had hoped that this legislation could be accepted as part of this bill.

Mr. KENNEDY. I appreciate the leadership of the Senator from West Virginia on this important issue. He has been a staunch advocate of consumer access to lower cost generic prescriptions, successfully working to include authorized generics in the Medicaid best price calculation. I support his efforts and believe that the bill before us includes significant provisions to lower prescription drug costs. While I know that our legislation does not directly address the Senator's concerns, I want to continue to work with him on this important issue and believe that we can reach consensus on authorized generics as part of the patent settlement debate.

Mr. ENZI. As the Senator from West Virginia knows, we included language in the underlying bill on authorized generics in part due to his urging. Our bill would require the Food and Drug Administration to keep track of authorized generics marketed since January 1, 1999, and to make such data publicly available in electronic form. The language in our bill will help the Federal Trade Commission complete its study in a timely fashion, and it will also help to shed some light on this elusive marketing practice. Let me be clear: I do not agree with the other policy statements being made regarding authorized generics because I don't believe we have enough information yet to make those assessments. However, I do agree that we need more information to shed light onto this subject. That is why I supported the language in the underlying bill to allow us to have that data and to provide a strong platform for future discussions.

Mr. ROCKEFELLER. I appreciate the chairman and ranking member's interest in looking into this deceptive marketing practice. And, while I had hoped that we could reach agreement on my legislation as part of this bill, I appreciate the chairman's commitment to working with me to solve this problem as part of the patent settlements discussion. I am also grateful for Senators KENNEDY, ENZI, and HATCH's support of the authorized generics language Senator BROWN and I worked to include in the underlying bill. This language will undoubtedly help the FTC finish its work, but I want to be clear that I do not believe Congress needs to wait on the FTC study to be completed to act on the problem of authorized generics. At the very least, Congress should impose a moratorium on authorized generic drugs until such time as the FTC study is complete.

Mr. HATCH. My friend from West Virginia has had a longstanding interest in looking into this issue, and I certainly don't fault his tenacity in this area. When Congressman HENRY WAXMAN and I wrote the Drug Price Competition and Patent Term Restoration Act in 1984, our intent was to improve generic competition, while preserving the ability of brand-name manufacturers to discover and market new and innovative products. I think this legislation has worked fairly well at achieving its intended goals. I know there have been a few problems along the way, but I think we addressed many of them in the Medicare Modernization Act of 2003. In that law, Congress closed several loopholes that were delaying generic competition and hindering consumer access to lower cost generic drugs. The law also clarified the 180-day period of market exclusivity for generic manufacturers. Now, I know Senator ROCKEFELLER is very concerned about authorized generics, and I think we should have updated data on the number of authorized generic drugs are on the market. The language already included in S. 1082 will help the Federal Trade Commission complete its authorized generics study, which I know Senator ROCKEFELLER requested along with Senators GRASSLEY and LEAHY. I support the completion of that study; however, Congress shouldn't contemplate additional legislation before having necessary data on authorized generics. I will work with my good friend and colleague from West Virginia to ensure that the FTC has the data needed to complete its study. So, I want to let my friend from West Virginia know that I want to continue to have a dialogue about this issue.

Mr. ROCKEFELLER. I thank my colleagues for these commitments. I look forward to working together with Chairman KENNEDY, Senator ENZI, Senator HATCH, and the cosponsors of this amendment Senators SCHUMER, LEAHY, KOHL, and STABENOW to develop strong consensus language that can be enacted as part of the patent settlements legislation.

AMENDMENT NO. 1042

Mr. ENSIGN. Madam President, prescription drugs and medical technology save lives. Advances in medicine have given patients who are fighting deadly diseases or managing chronic conditions hope for a healthier future.

Prescription drugs are working to meet the emerging diabetes epidemic, save the lives of cancer patients, and forestall the terrible burden of Alzheimer's. These advances in medicine are helping patients today.

Although these lifesaving drugs have the enormous potential to improve lives, at times they also have the potential to harm. We all know that no prescription medication is absolutely safe. There is always some degree of safety and health risks.

Drug companies selling products in the United States must comply with regulations and procedures mandated by the Food and Drug Administration. FDA approval, however, does not always guarantee drug safety.

The bill we are debating today intends to improve drug safety and will significantly change the drug approval process at the FDA. I believe it is important to improve the drug approval process and, at the same time, ensure patients access to new and innovative therapies. In order to achieve this goal, a carefully balanced approach is necessary.

As we debate how to improve the drug approval process, it is important for Congress to take actions to ensure that legal efforts to enforce drug safety are directed toward the appropriate parties.

I am particularly concerned that this bill does nothing to protect physicians and pharmacists from being named in product liability lawsuits. We cannot allow for additional waste in our legal system by naming doctors and pharmacists to these lawsuits—especially when these professionals have nothing to do with the design or manufacture of the product in question. It is for that reason that I rise to speak on amendment No. 1042.

Product liability lawsuits usually involve claims that a product is unreasonably dangerous, either in its design, manufacture, or its lack of a proper warning or instructions regarding use.

Historically, trial lawyers name the product manufacturer as well as each party that handled the product in the stream of commerce as a defendant. This includes the shipper of the product, as well as the store owner who sells the product. In most cases, the store owner is never liable for a design defect, manufacturing defect, or failure to warn. Why? Because these cases have nothing to do with the negligence of the store owner.

Doctors and pharmacists are similar to store owners. They have nothing to do with the design or manufacture of a product. Yet time and time again, doctors and other health care providers are named as parties to product liability lawsuits involving prescription drugs and medical devices. Why? Because class action lawyers are constantly looking for the best courtrooms to file their lawsuits. These lawyers routinely shop for venues that are known for siding with the patient who has been harmed. By bringing their cases in front of plaintiff-friendly judges and juries, these lawyers immeasurably enhance their probability of securing a jackpot jury award.

Judgments are virtually never entered against doctors and pharmacists in product liability lawsuits. Yet these health care professionals are often forced to spend thousands of dollars in legal costs and take valuable time off from work, time away from the patients who need them, to provide lawyers with rounds and rounds of depositions and to provide juries with testimony. This is completely ridiculous. We need doctors in our emergency rooms and family practice centers—not in the courtrooms when they have nothing to do with the product in question.

I want to tell you about a woman named Hilda Bankston. Hilda owned a pharmacy in Jefferson County, MS, and has been named as a defendant in so many lawsuits that she has lost count. In each instance, Hilda was sued for doing nothing more than filling legal prescriptions. In other words, she wasn't doing anything wrong. Nevertheless, Hilda has been dragged into court to testify in hundreds of national lawsuits brought in Jefferson County against the pharmacy and out-of-State manufacturers of drugs. Why is this? Because the party who initiated the lawsuit was shopping for a friendly court in order to file their national lawsuit in that county.

Does this bill we are considering today provide any protection to Hilda Bankston? No, it does not. Does the bill provide any protection to doctors and pharmacists with respect to product liability lawsuits? No. It doesn't do that either. The bill allows these health care providers to continue to be named in product liability cases. This is outrageous.

My amendment is simple. It prohibits a health care provider, including a doctor or a pharmacist, from being named in a product liability lawsuit or in a class action lawsuit merely because the health care provider prescribed or sold a drug or device that was approved by the Food and Drug Administration.

My amendment does not deprive patients of the right to sue a physician or a pharmacist who behaves in a negligent manner. It does not provide blanket immunity to a physician or pharmacist who behaves in a negligent manner. That would be a separate cause of action, which lies outside the scope of my amendment. What my amendment does say is that health care providers should not be dragged into a product lawsuit that they have no business being in. Doctors and pharmacists are routinely named in product liability lawsuits and are virtually always removed from these cases without having damages assessed against them. They are not responsible for the design or manufacture of drugs and devices and should not be dragged into these types of lawsuits.

Patients pay for product liability lawsuits in the form of higher health benefits and premiums.

I urge my colleagues to join me in taking action to curb this abuse of our legal system. Let's protect our health care providers from incurring frivolous unnecessary costs. Our health care providers should be focused on providing the best care possible to their patients, not on product liability lawsuits when they have nothing to do with the product in question.

I ask unanimous consent to have printed in the RECORD letters of support for my amendment from the American Medical Association and the American Osteopathic Association.

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

AMERICAN MEDICAL ASSOCIATION,
Chicago, IL, May 3, 2007.

Hon. JOHN ENSIGN,
U.S. Senate, Russell Senate Office Building, Washington, DC.

DEAR SENATOR ENSIGN: The physician and student members of the American Medical Association (AMA) commend you for introducing an amendment to S. 1082, the ''Prescription Drug User Fee Amendments of 2007,'' that would clarify physician and other health care provider liability.

Specifically, the amendment would prevent physicians and other healthcare providers who prescribe or dispense a drug, biologic product, or medical device approved, licensed, or cleared by the Food and Drug Administration from being named in class action product liability lawsuits for forum-shopping purposes. The amendment would address situations in which a local physician or other health care provider is named as a defendant as a way to file a lawsuit in a legal jurisdiction more likely to award large damage awards, even though such jurisdiction has little or no connection to the local defendants. In such cases, the local physician or other health care provider is often dropped from the suit or not found liable for damages. Instead, liability attaches to the manufacturer, whose conduct is the real subject of the litigation. Nonetheless, physicians and other health care providers are exposed to the significant legal costs, distress, and time away from their patients.

The AMA is pleased to offer its support for this amendment and looks forward to continuing to work with you to bring about common sense liability reforms, such as this amendment.

Sincerely,

MICHAEL D. MAVES, *MD, MBA.*

AMERICAN OSTEOPATHIC ASSOCIATION,
Washington, DC, May 3, 2007.

Hon. JOHN ENSIGN,
U.S. Senate, Russell Senate Office Building, Washington, DC.

DEAR SENATOR ENSIGN: As President of the American Osteopathic Association (AOA), I am pleased to inform you of our support for your amendment to the ''Prescription Drug User Fee Amendments of 2007'' (S. 1082), which would provide clarification on physician liability.

Your amendment seeks to clarify that a physician who prescribes a drug, biological product, or medical device, which has cleared successfully the Food and Drug Administration's approval process, cannot be named as a party in a class action lawsuit. The AOA shares our concerns that physicians and other health care providers frequently are names as defendants in such cases as a means of securing a venue which is more likely to produce larger monetary awards. In most cases, physicians are dismissed from he lawsuit or found not liable for damages. Regardless of the ultimate outcome, physicians face significant legal costs and time away from their patients as a result of this practice.

We believe your amendment takes the appropriate steps to ensure that future class action lawsuits are targeted at those whose conduct is in question. Additionally, we believe your amendment rightfully prevents attorneys from using physicians as a means to pursue legal action in venues they deem more favorable. For these reasons, we re pleased to offer our support.

Sincerely,

JOHN A. STROSNIDER, *DO, President.*

MORNING BUSINESS

Mr. BROWN. I ask unanimous consent that there now be a period of morning business with Senators permitted to speak for up to 10 minutes each.

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

ADDITIONAL STATEMENTS

REMEMBERING HAWAII'S DON HO

• Mr. AKAKA. Mr. President, I wish to pay tribute to a remarkable son of Hawaii, entertainment legend, Don Ho. Don's big heart gave out on April 14, in Waikiki. He was 76 years old. On Saturday, May 5, Hawaii bid a fond aloha to Don Ho, during a ceremony on Waikiki Beach in celebration of his life. Thousands of people attended his memorial.

Don didn't plan on a career in entertainment. After his college graduation, he served in the U.S. Air Force, attaining the rank of first lieutenant. When

he returned home, he began helping at his mother's quiet neighborhood bar, playing music with friends. That was the beginning of a show business career spanning more than four decades including hit records, motion pictures, television, and sold out performances world-wide.

Hawaii was still a young State when Don Ho became an international star, and in many ways he helped put Hawaii on the map. In my travels around the world, people always ask me about Don Ho. Don was a big star wherever he went. He even played in Washington, DC, when I was in the House. And I can tell you, it was a big show.

Despite his stature as an entertainment icon, Don was never too busy to spend a few minutes with his fans; young honeymooners, servicemen and women stationed in the islands, or senior citizens on a dream vacation. He had tremendous charisma and talent and because of that he touched many people. Hawaii has lost a beloved son and he will be sorely missed.●

MESSAGES FROM THE PRESIDENT

Messages from the President of the United States were communicated to the Senate by Ms. Evans, one of his secretaries.

EXECUTIVE MESSAGES REFERRED

As in executive session the Presiding Officer laid before the Senate messages from the President of the United States submitting sundry nominations which were referred to the appropriate committees.

(The nominations received today are printed at the end of the Senate proceedings.)

MESSAGE FROM THE HOUSE

At 2:15 p.m., a message from the House of Representatives, delivered by Ms. Niland, one of its reading clerks, announced that the House has passed the following bills, in which it requests the concurrence of the Senate:

H.R. 1429. An act to reauthorize the Head Start Act, to improve program quality, to expand access, and for other purposes.

H.R. 1592. An act to provide Federal assistance to States, local jurisdictions, and Indian tribes to prosecute hate crimes, and for other purposes.

H.R. 1867. An act to authorize appropriations for fiscal years 2008, 2009, and 2010 for the National Science Foundation, and for other purposes.

H.R. 1868. An act to authorize appropriations for the National Institute of Standards and Technology for fiscal years 2008, 2009, and 2010, and for other purposes.

MEASURES REFERRED

The following bills were read the first and the second times by unanimous consent, and referred as indicated:

H.R. 1592. An act to provide Federal assistance to States, local jurisdictions, and Indian tribes to prosecute hate crimes, and for other purposes; to the Committee on the Judiciary.

H.R. 1868. An act to authorize appropriations for the National Institute of Standards and Technology for fiscal years 2008, 2009, and 2010, and for other purposes; to the Committee on Commerce, Science, and Transportation.

MEASURES PLACED ON THE CALENDAR

The following bills were read the first and second times by unanimous consent, and placed on the calendar:

H.R. 1429. An act to reauthorize the Head Start Act, to improve program quality, to expand access, and for other purposes.

H.R. 1867. An act to authorize appropriations for fiscal years 2008, 2009, and 2010 for the National Science Foundation, and for other purposes.

MEASURES READ THE FIRST TIME

The following bill was read the first time:

S. 1312. A bill to amend the National Labor Relations Act to ensure the right of employees to a secret-ballot election conducted by the National Labor Relations Board.

EXECUTIVE AND OTHER COMMUNICATIONS

The following communications were laid before the Senate, together with accompanying papers, reports, and documents, and were referred as indicated:

EC–1742. A communication from the Acting Administrator, Food Safety and Inspection Service, Department of Agriculture, transmitting, pursuant to law, the report of a rule entitled ''Uniform Compliance Date for Food Labeling Regulations'' (RIN0583–AD05) received on May 2, 2007; to the Committee on Agriculture, Nutrition, and Forestry.

EC–1743. A communication from the Under Secretary of Defense (Comptroller), transmitting, pursuant to law, the report of a violation of the Antideficiency Act by the Department of the Army, case number 04–12; to the Committee on Appropriations.

EC–1744. A communication from the Under Secretary of Defense (Comptroller), transmitting, pursuant to law, the report of a violation of the Antideficiency Act by the Department of the Army, case number 06–01; to the Committee on Appropriations.

EC–1745. A communication from the Under Secretary of Defense (Acquisition, Technology and Logistics), transmitting, pursuant to law, a report relative to a review of the Guided Multiple Launch Rocket System program; to the Committee on Armed Services.

EC–1746. A communication from the Under Secretary of Defense (Acquisition, Technology and Logistics), transmitting, pursuant to law, the annual report on the Department's Chemical and Biological Defense Program; to the Committee on Armed Services.

EC–1747. A communication from the Under Secretary of Defense (Personnel and Readiness), transmitting, pursuant to law, a report relative to the Secretary's plan for improving recruitment, placement, and retention within the Department of individuals who receive scholarships and fellowships; to the Committee on Armed Services.

EC–1748. A communication from the Director of Defense Research and Engineering, transmitting, a report relative to the management and adequacy of biometrics programs; to the Committee on Armed Services.

EC–1749. A communication from the Under Secretary of Defense (Acquisition, Technology and Logistics), transmitting, pursuant to law, a report relative to the funds expended during fiscal year 2006 and the funds that are expected to be expended during fiscal years 2007 and 2008; to the Committee on Armed Services.

EC–1750. A communication from the Principal Deputy, Office of the Under Secretary of Defense (Personnel and Readiness), transmitting, pursuant to law, a report relative to the effects of Aviation Continuation Pay on retention of qualified aviators during fiscal year 2006; to the Committee on Armed Services.

EC–1751. A communication from the Secretary of the Air Force, transmitting, pursuant to law, the report of a critical breach in Average Procurement Unit Cost for the Joint Air-to-Surface Standoff Missile; to the Committee on Armed Services.

EC–1752. A communication from the Secretary of the Treasury, transmitting, pursuant to law, a six-month periodic report on the national emergency relative to Syria that was declared in Executive Order 13338 of May 11, 2004; to the Committee on Banking, Housing, and Urban Affairs.

EC–1753. A communication from the Secretary of Commerce, transmitting, the report of a draft bill intended to ''revise and extend the Export Administration Act of 1979, amended''; to the Committee on Banking, Housing, and Urban Affairs.

EC–1754. A communication from the Assistant Administrator for Fisheries, National Marine Fisheries Service, Department of Commerce, transmitting, pursuant to law, the report of a rule entitled ''Annual Management Measures for the 2007 Pacific Halibut Fisheries and Changes to the Catch Sharing Plan for Area 2A'' (RIN0648–AV03) received on May 2, 2007; to the Committee on Commerce, Science, and Transportation.

EC–1755. A communication from the Deputy Assistant Administrator for Operations, National Marine Fisheries Service, Department of Commerce, transmitting, pursuant to law, the report of a rule entitled ''Atlantic Herring Fishery; 2007–2009 Specifications'' (RIN0648–AT66) received on May 2, 2007; to the Committee on Commerce, Science, and Transportation.

EC–1756. A communication from the Director, Office of Sustainable Fisheries, Department of Commerce, transmitting, pursuant to law, the report of a rule entitled ''Closure of the Hook-and-Line Commercial Fishery for Gulf Group King Mackerel in the Southern Florida West Coast Subzone'' (Docket No. 001005281–0369–02) received on May 2, 2007; to the Committee on Commerce, Science, and Transportation.

EC–1757. A communication from the Director, Office of Sustainable Fisheries, Department of Commerce, transmitting, pursuant to law, the report of a rule entitled ''Fisheries of the Exclusive Economic Zone Off Alaska; Reallocation of Pacific Cod in the Bering Sea and Aleutian Islands Management Area'' (ID No. 040607A) received on May 2, 2007; to the Committee on Commerce, Science, and Transportation.

EC–1758. A communication from the Director, Office of Sustainable Fisheries, Department of Commerce, transmitting, pursuant to law, the report of a rule entitled ''Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Cod by Catcher Vessels Using Trawl Gear in the Bering Sea and Aleutian Islands Management Area'' (ID No. 040607B) received on May 2, 2007; to the Committee on Commerce, Science, and Transportation.

EC–1759. A communication from the Director, Office of Sustainable Fisheries, Department of Commerce, transmitting, pursuant to law, the report of a rule entitled ''Fisheries of the Exclusive Economic Zone Off

Alaska; Rock Sole, Flathead Sole, and 'Other Flatfish' by Vessels Using Trawl Gear in Bering Sea and Aleutian Islands Management Area'' (ID No. 040607E) received on May 2, 2007; to the Committee on Commerce, Science , and Transportation.

EC–1760. A communication from the Acting Director, Office of Sustainable Fisheries, Department of Commerce, transmitting, pursuant to law, the report of a rule entitled ''Increase of Landing Limit for Georges Bank Yellowtail Flounder'' (ID No. 040407D) received on May 2, 2007; to the Committee on Commerce, Science, and Transportation.

EC–1761. A communication from the Acting Director, Office of Sustainable Fisheries, Department of Commerce, transmitting, pursuant to law, the report of a rule entitled ''Fisheries of the Economic Exclusive Zone Off Alaska; Pacific Cod in the Bering Sea and Aleutian Islands'' (ID No. 040907D) received on May 2, 2007; to the Committee on Commerce, Science, and Transportation.

EC–1762. A communication from the Acting Director, Office of Sustainable Fisheries, Department of Commerce, transmitting, pursuant to law, the report of a rule entitled ''Temporary Rule; Closure (Closure of Trimester I Fishery for Loligo Squid)'' (ID No. 112106A) received on May 2, 2007; to the Committee on Commerce, Science, and Transportation.

EC–1763. A communication from the Acting Director, Office of Sustainable Fisheries, Department of Commerce, transmitting, pursuant to law, the report of a rule entitled ''Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Commercial Tilefish Fishery of the Gulf of Mexico; Closure'' (ID No. 040607F) received on May 2, 2007; to the Committee on Commerce, Science, and Transportation.

EC–1764. A communication from the Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service, Department of Commerce, transmitting, pursuant to law, the report of a rule entitled ''Pacific Albacore Tuna Fisheries; Vessel List to Establish Eligibility to Fish for Albacore Tuna in Canadian Waters Under the U.S.-Canada Albacore Tuna Treaty'' (RIN0648–AU78) received on May 2, 2007; to the Committee on Commerce, Science, and Transportation.

EC–1765. A communication from the Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service, Department of Commerce, transmitting, pursuant to law, the report of a rule entitled ''Fisheries in the Western Pacific; Optional Use of Electronic Logbook Forms'' (RIN0648–AS29) received on May 2, 2007; to the Committee on Commerce, Science, and Transportation.

EC–1766. A communication from the Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service, Department of Commerce, transmitting, pursuant to law, the report of a rule entitled ''Final Rule to Implement Regulations to Establish and Govern Seafood Marketing Councils'' (RIN0648–AS09) received on May 2, 2007; to the Committee on Commerce, Science, and Transportation.

EC–1767. A communication from the Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service, Department of Commerce, transmitting, pursuant to law, the report of a rule entitled ''Final Rule for 2007 Pacific Whiting Harvest Specifications and Inseason Adjustments to Groundfish Management Measures'' (RIN0648–AU57) received on May 2, 2007; to the Committee on Commerce, Science, and Transportation.

EC–1768. A communication from the Assistant Administrator for Human Capital Management, National Aeronautics and Space Administration, transmitting, pursuant to law, the report of a vacancy and the designation of an acting officer for the position of Chief Financial Officer, received on May 2, 2007; to the Committee on Commerce, Science, and Transportation.

EC–1769. A communication from the Deputy Chief Counsel, National Telecommunications and Information Administration, Department of Commerce, transmitting, pursuant to law, the report of a rule entitled ''Rules to Implement and Administer a Coupon Program for Digital-to-Analog Converter Boxes'' (RIN0660–AA16) received on May 2, 2007; to the Committee on Commerce, Science, and Transportation.

EC–1770. A communication from the General Counsel, Department of Commerce, transmitting, the report of draft legislation intended to amend the Communications Act of 1934 to terminate the Telecommunications Development Fund for various reasons; to the Committee on Commerce, Science, and Transportation.

EC–1771. A communication from the Acting Director, Office of Surface Mining, Department of the Interior, transmitting, pursuant to law, the report of a rule entitled ''Ohio Regulatory Program'' (Docket No. OH–251–FOR) received on May 4, 2007; to the Committee on Energy and Natural Resources.

EC–1772. A communication from the Director, Office of Congressional and Intergovernmental Affairs, Department of Energy, transmitting, pursuant to law, the report of a vacancy and designation of an acting officer for the position of Assistant Secretary for Congressional and Intergovernmental Affairs, received on May 2, 2007; to the Committee on Energy and Natural Resources.

EC–1773. A communication from the Director of Land and Minerals Management, Minerals Management Service, Department of the Interior, transmitting, pursuant to law, the report of a rule entitled ''Oil and Gas and Sulphur Operations and Leasing in the Outer Continental Shelf—Corrections and Amendments'' (RIN1010–AD42) received on May 3, 2007; to the Committee on Energy and Natural Resources.

EC–1774. A communication from the Secretary of Energy, transmitting, the report of a legislative proposal that would amend two sections of the Energy Policy and Conservation Act; to the Committee on Energy and Natural Resources.

EC–1775. A communication from the Assistant Secretary for Water and Science, Department of the Interior, transmitting, the report of a draft bill entitled ''Reclamation Water Management Improvement Act''; to the Committee on Energy and Natural Resources.

EC–1776. A communication from the Assistant Secretary of the Army (Civil Works), transmitting, pursuant to law, a report relative to an investigation of opportunities to address near-term water resources needs for coastal Mississippi resulting from the hurricane season of 2005 that was conducted by the Army Corps of Engineers; to the Committee on Environment and Public Works.

EC–1777. A communication from the Principal Deputy Associate Administrator, Office of Policy, Economics and Innovation, Environmental Protection Agency, transmitting, the Uniform Resource Locator for a document entitled ''Audit Policy; Frequently Asked Questions (2007)''; to the Committee on Environment and Public Works.

EC–1778. A communication from the Assistant Secretary of the Army (Civil Works), transmitting, pursuant to law, a report relative to an evaluation by the Army Corps of Engineers of the damage reduction measures for Montauk Point, New York; to the Committee on Environment and Public Works.

EC–1779. A communication from the Principal Deputy Associate Administrator, Office of Policy, Economics and Innovation, Environmental Protection Agency, transmitting, pursuant to law, the report of a rule entitled ''Delegation of National Emission Standards for Hazardous Air Pollutants for Source Categories; State of Arizona, Arizona Department of Environmental Quality, State of Nevada, Nevada Division of Environmental Protection'' (FRL No. 8309–7) received on May 3, 2007; to the Committee on Environment and Public Works.

EC–1780. A communication from the Principal Deputy Associate Administrator, Office of Policy, Economics and Innovation, Environmental Protection Agency, transmitting, pursuant to law, the report of a rule entitled ''Ambient Air Monitoring Regulations: Correcting and Other Amendments'' (FRL No. 8308–7) received on May 3, 2007; to the Committee on Environment and Public Works.

EC–1781. A communication from the Principal Deputy Associate Administrator, Office of Policy, Economics and Innovation, Environmental Protection Agency, transmitting, pursuant to law, the report of a rule entitled ''Approval and Promulgation of Implementation Plans and Designation of Areas for Air Quality Planning Purposes; California'' (FRL No. 8308–4) received on May 3, 2007; to the Committee on Environment and Public Works.

EC–1782. A communication from the Principal Deputy Associate Administrator, Office of Policy, Economics and Innovation, Environmental Protection Agency, transmitting, pursuant to law, the report of a rule entitled ''Approval and Promulgation of Implementation Plans; Missouri; Interstate Transport of Pollution'' (FRL No. 8310–6) received on May 3, 2007; to the Committee on Environment and Public Works.

EC–1783. A communication from the Principal Deputy Associate Administrator, Office of Policy, Economics and Innovation, Environmental Protection Agency, transmitting, pursuant to law, the report of a rule entitled ''Approval and Promulgation of Implementation Plans; Revisions to the Nevada State Implementation Plan; Visible Emissions and Particulate Matter Rules'' (FRL No. 8308–2) received on May 3, 2007; to the Committee on Environment and Public Works.

EC–1784. A communication from the Principal Deputy Associate Administrator, Office of Policy, Economics and Innovation, Environmental Protection Agency, transmitting, pursuant to law, the report of a rule entitled ''Approval and Promulgation of Implementation Plans; State of Missouri'' (FRL No. 8309–3) received on May 3, 2007; to the Committee on Environment and Public Works.

EC–1785. A communication from the Principal Deputy Associate Administrator, Office of Policy, Economics and Innovation, Environmental Protection Agency, transmitting, pursuant to law, the report of a rule entitled ''Approval and Promulgation of Air Quality Implementation Plans; West Virginia; Redesignation of the Parkersburg, West Virginia Portion of the Parkersburg-Marietta, WV–OH 8–Hour Ozone Nonattainment Area to Attainment and Approval of the Maintenance Plan'' (FRL No. 8309–9) received on May 3, 2007; to the Committee on Environment and Public Works.

EC–1786. A communication from the Principal Deputy Associate Administrator, Office of Policy, Economics and Innovation, Environmental Protection Agency, transmitting, pursuant to law, the report of a rule entitled ''Approval and Promulgation of State Plans for Designated Facilities and Pollutants; States of Iowa, Kansas, and Missouri'' (FRL No. 8310–8) received on May 3, 2007; to the Committee on Environment and Public Works.

EC–1787. A communication from the Principal Deputy Associate Administrator, Office

of Policy, Economics and Innovation, Environmental Protection Agency, transmitting, pursuant to law, the report of a rule entitled ''Revisions to the Arizona State Implementation Plan, Maricopa County Environmental Services Department'' (FRL No. 8302–9) received on May 3, 2007; to the Committee on Environment and Public Works.

EC–1788. A communication from the Principal Deputy Associate Administrator, Office of Policy, Economics and Innovation, Environmental Protection Agency, transmitting, pursuant to law, the report of a rule entitled ''Revisions to the Nevada State Implementation Plan, Washoe County'' (FRL No. 8303–2) received on May 3, 2007; to the Committee on Environment and Public Works.

EC–1789. A communication from the Principal Deputy Associate Administrator, Office of Policy, Economics and Innovation, Environmental Protection Agency, transmitting, pursuant to law, the report of a rule entitled ''Source-Specific Federal Implementation Plan for Four Corners Power Plant; Navajo Nation'' ((RIN2009–AA01)(FRL No. 8308–6)) received on May 3, 2007; to the Committee on Environment and Public Works.

EC–1790. A communication from the Chief of the Publications and Regulations Branch, Internal Revenue Service, Department of the Treasury, transmitting, pursuant to law, the report of a rule entitled ''Section 1035—Certain Exchanges of Insurance Policies'' (Rev. Rul. 2007–24) received on May 4, 2007; to the Committee on Finance.

EC–1791. A communication from the Chief of the Publications and Regulations Branch, Internal Revenue Service, Department of the Treasury, transmitting, pursuant to law, the report of a rule entitled ''Accrual of Interest on Nonperforming Loans'' (Rev. Rul. 2007–32) received on May 4, 2007; to the Committee on Finance.

EC–1792. A communication from the Chief of the Publications and Regulations Branch, Internal Revenue Service, Department of the Treasury, transmitting, pursuant to law, the report of a rule entitled ''Credit for Alternative Fuel Vehicle Refueling Property'' (Notice 2007–43) received on May 4, 2007; to the Committee on Finance.

EC–1793. A communication from the Commissioner, Social Security Administration, transmitting, pursuant to law, the Administration's Federal Activities Inventory Reform Act Inventory for fiscal year 2006; to the Committee on Finance.

EC–1794. A communication from the Regulations Coordinator, Centers for Medicare and Medicaid Services, Department of Health and Human Services, transmitting, pursuant to law, the report of a rule entitled ''Medicare Program; Prospective Payment System for Long-Term Care Hospitals RY 2008: Annual Payment Rate Updates and Policy Changes; and Hospital Direct and Indirect Graduate Medical Education Policy Changes'' (RIN0938–AO30) received on May 3, 2007; to the Committee on Finance.

EC–1795. A communication from the President and Chief Executive Officer of the Overseas Private Investment Corporation, transmitting, the report of draft legislation intended to ''amend the Foreign Assistance Act of 1961 with respect to the activities of the Overseas Private Investment Corporation''; to the Committee on Foreign Relations.

EC–1796. A communication from the Assistant Director-General, Technical Cooperation Department, Food and Agriculture Organization of the United Nations, transmitting, copies of letters intended to raise awareness among parliamentarians and mobilize their support for the efforts of developing countries to foster agriculture and rural development; to the Committee on Foreign Relations.

EC–1797. A communication from the Assistant General Counsel for Regulations, Office of Elementary and Secondary Education, Department of Education, transmitting, pursuant to law, the report of a rule entitled ''Title I—Improving the Academic Achievement of the Disadvantaged; Individuals With Disabilities Education Act—Assistance to States for the Education of Children With Disabilities'' (RIN1810–AA98) received on May 1, 2007; to the Committee on Health, Education, Labor, and Pensions.

EC–1798. A communication from the Director, Regulations Policy and Management Staff, Department of Health and Human Services, transmitting, pursuant to law, the report of a rule entitled ''Laxative Drug Products for Over-the-Counter Human Use; Psyllium Ingredients in Granular Dosage Forms'' ((RIN0910–AF36)(Docket No. 1978N–0036L)) received on May 2, 2007; to the Committee on Health, Education, Labor, and Pensions.

EC–1799. A communication from the Regulations Coordinator, Centers for Medicare and Medicaid Services, Department of Health and Human Services, transmitting, pursuant to law, the report of a rule entitled ''Inpatient Psychiatric Facility Prospective Payment System Payment Update for Rate Year'' (RIN0938–AO40) received on May 3, 2007; to the Committee on Health, Education, Labor, and Pensions.

EC–1800. A communication from the White House Liaison, Department of Health and Human Services, transmitting, pursuant to law, the report of a vacancy and designation of an acting officer for the position of Assistant Secretary for Children and Families, received on May 2, 2007; to the Committee on Health, Education, Labor, and Pensions.

EC–1801. A communication from the Director of Legislative Affairs, Railroad Retirement Board, transmitting, pursuant to law, the Board's report relative to the Sunshine Act; to the Committee on Homeland Security and Governmental Affairs.

EC–1802. A communication from the Director of Legislative Affairs, Railroad Retirement Board, transmitting, pursuant to law, the Board's report relative to the No Fear Act; to the Committee on Homeland Security and Governmental Affairs.

EC–1803. A communication from the Chief of the Border Security Regulations Branch, Customs and Border Protection, Department of Homeland Security, transmitting, pursuant to law, the report of a rule entitled ''Advance Electronic Presentation of Cargo Information for Truck Carriers Required to be Transmitted Through ACE Truck Manifest at Ports in the States of Idaho and Montana'' (CBP Dec. 07–25) received on May 2, 2007; to the Committee on Homeland Security and Governmental Affairs.

EC–1804. A communication from the Administrator, General Services Administration, transmitting, pursuant to law, prospectuses that support the Administration's fiscal year 2008 Capital Investment Program; to the Committee on Homeland Security and Governmental Affairs .

EC–1805. A communication from the Administrator, General Services Administration, transmitting, pursuant to law, additional prospectuses that support the Administration's fiscal year 2008 Capital Investment and Leasing Program; to the Committee on Homeland Security and Governmental Affairs.

EC–1806. A communication from the Associate General Counsel for General Law, Department of Homeland Security, transmitting, pursuant to law, the report of a nomination for the position of Deputy Administrator for National Preparedness, received on May 2, 2007; to the Committee on Homeland Security and Governmental Affairs.

EC–1807. A communication from the Chairman, U.S. Parole Commission, Department of Justice, transmitting, pursuant to law, the Commission's annual report for calendar year 2005; to the Committee on Homeland Security and Governmental Affairs.

EC–1808. A communication from the Chairman, Occupational Safety and Health Review Commission, transmitting, pursuant to law, a report relative to the amount of acquisitions made by the agency from entities that manufacture the articles, materials, or supplies outside of the U.S. in that fiscal year; to the Committee on Homeland Security and Governmental Affairs.

EC–1809. A communication from the Administrator, General Services Administration, transmitting, pursuant to law, the report of a request for reimbursement under the Meritorious Claims Act for Patrick J. Truver; to the Committee on Homeland Security and Governmental Affairs.

EC–1810. A communication from the Principal Deputy Assistant Attorney General, Office of Legislative Affairs, Department of Justice, transmitting, pursuant to law, a report relative to the use and effectiveness of court-authorized Title III interceptions conducted during calendar year 2006; to the Committee on the Judiciary.

EC–1811. A communication from the Director, Administrative Office of the United States Courts, an annual report relative to crime victims' rights; to the Committee on the Judiciary.

EC–1812. A communication from the Acting Assistant Attorney General, Office of Legislative Affairs, Department of Justice, transmitting, pursuant to law, a report relative to all applications made by the Government during calendar year 2006 for authority to conduct electronic surveillance and physical search for foreign purposes under the Foreign Intelligence Surveillance Act of 1978; to the Committee on the Judiciary.

EC–1813. A communication from the Chair, U.S. Sentencing Commission, transmitting, pursuant to law, the report of the amendments to the federal sentencing guidelines and policy statements made during the 2006–2007 amendment cycle; to the Committee on the Judiciary.

EC–1814. A communication from the Deputy Assistant Administrator, Office of Diversion Control, Department of Justice, transmitting, pursuant to law, the report of a rule entitled ''Implementation of the Combat Methamphetamine Epidemic Act of 2005 Notice of Transfers Following Importation or Exportation'' (RIN1117–AB06) received on May 2, 2007; to the Committee on the Judiciary.

EC–1815. A communication from the Deputy Assistant Administrator, Office of Diversion Control, Department of Justice, transmitting, pursuant to law, the report of a rule entitled ''Exemption of Chemical Mixtures'' (RIN1117–AA31) received on May 2, 2007; to the Committee on the Judiciary.

EC–1816. A communication from the Director, Administrative Office of the United States Courts, transmitting, pursuant to law, the fiscal year 2007 update to the ''Long Range Plan for Information Technology in the Federal Judiciary'' and the ''Judiciary Information Technology Fund Annual Report for Fiscal Year 2006''; to the Committee on the Judiciary.

EC–1817. A communication from the Secretary of Labor, transmitting, the report of a draft bill intended to ''establish a fee for processing applications for permanent employment certification for immigrant aliens in the United States, to enhance program integrity, and for other purposes''; to the Committee on the Judiciary.

EC–1818. A communication from the Director of Regulatory Management, Veterans

Benefits Administration, Department of Veterans Affairs, transmitting, pursuant to law, the report of a rule entitled ''Administration of VA Educational Benefits—Centralized Certification'' (RIN2900–AL43) received on May 2, 2007; to the Committee on Veterans' Affairs.

REPORTS OF COMMITTEES

The following reports of committees were submitted:

By Mrs. BOXER, from the Committee on Environment and Public Works, with amendments:

S. 496. A bill to reauthorize and improve the program authorized by the Appalachian Regional Development Act of 1965 (Rept. No. 110–63).

By Mr. KERRY, from the Committee on Small Business and Entrepreneurship, with an amendment in the nature of a substitute:

S. 163. A bill to improve the disaster loan program of the Small Business Administration, and for other purposes (Rept. No. 110–64).

By Mr. BINGAMAN, from the Committee on Energy and Natural Resources, without amendment:

S. 1321. An original bill to enhance the energy security of the United States by promoting biofuels, energy efficiency, and carbon capture and storage, and for other purposes (Rept. No. 110–65).

INTRODUCTION OF BILLS AND JOINT RESOLUTIONS

The following bills and joint resolutions were introduced, read the first and second times by unanimous consent, and referred as indicated:

By Mr. DEMINT (for himself, Mr. ALEXANDER, Mr. ALLARD, Mr. BROWNBACK, Mr. BUNNING, Mr. BURR, Mr. CHAMBLISS, Mr. COBURN, Mr. CORNYN, Mr. CRAIG, Mrs. DOLE, Mr. ENZI, Mr. GRASSLEY, Mr. INHOFE, Mr. KYL, Mr. LOTT, Mr. MARTINEZ, Mr. MCCAIN, Mr. MCCONNELL, Mr. ROBERTS, Mr. SESSIONS, Mr. THOMAS, Mr. VITTER, and Mr. WARNER):

S. 1312. A bill to amend the National Labor Relations Act to ensure the right of employees to a secret-ballot election conducted by the National Labor Relations Board; read the first time.

By Mr. FEINGOLD:

S. 1313. A bill to amend the Servicemembers Civil Relief Act to provide relief for servicemembers with respect to contracts for cellular phone service, and for other purposes; to the Committee on Veterans' Affairs.

By Mr. FEINGOLD (for himself and Mr. BURR):

S. 1314. A bill to amend title 38, United States Code, to improve the outreach activities of the Department of Veterans Affairs, and for other purposes; to the Committee on Veterans' Affairs.

By Mr. AKAKA:

S. 1315. A bill to amend title 38, United States Code, to enhance life insurance benefits for disabled veterans, and for other purposes; to the Committee on Veterans' Affairs.

By Mrs. FEINSTEIN (for herself, Mr. DURBIN, and Mr. KENNEDY):

S. 1316. A bill to establish and clarify that Congress does not authorize persons convicted of dangerous crimes in foreign courts to freely possess firearms in the United States; to the Committee on the Judiciary.

By Mr. SCHUMER (for himself, Mrs. CLINTON, Mrs. BOXER, Mr. OBAMA, Mr. BAYH, Mr. LEAHY, Mr. LEVIN, Ms. LANDRIEU, Mr. FEINGOLD, Mr. LIEBERMAN, Mr. DURBIN, Mr. VOINOVICH, Mr. KENNEDY, Mr. SALAZAR, Mr. COCHRAN, Mr. PRYOR, Ms. MIKULSKI, Mr. HAGEL, Mrs. FEINSTEIN, Mr. ENZI, Mr. REID, Ms. STABENOW, and Mr. REED):

S. 1317. A bill to posthumously award a congressional gold medal to Constance Baker Motley; to the Committee on Banking, Housing, and Urban Affairs.

By Mr. SCHUMER (for himself, Mr. SMITH, Mr. BOND, Mr. REED, Mrs. MURRAY, Mr. CARDIN, and Ms. SNOWE):

S. 1318. A bill to amend the Internal Revenue Code of 1986 to provide an incentive to preserve affordable housing in multifamily housing units which are sold or exchanged; to the Committee on Finance.

By Mr. INOUYE (for himself and Mr. AKAKA):

S. 1319. A bill to provide for the conversion of a temporary judgeship for the district of Hawaii to a permanent judgeship; to the Committee on the Judiciary.

By Mr. KYL:

S. 1320. A bill to prohibit the rewarding of suicide bombings, to prohibit terrorist kidnappings and sexual assaults, and for other purposes; to the Committee on the Judiciary.

By Mr. BINGAMAN:

S. 1321. An original bill to enhance the energy security of the United States by promoting biofuels, energy efficiency, and carbon capture and storage, and for other purposes; from the Committee on Energy and Natural Resources; placed on the calendar.

By Mrs. LINCOLN:

S. 1322. A bill to amend the Internal Revenue Code of 1986 to improve the operation of employee stock ownership plans, and for other purposes; to the Committee on Finance.

By Mr. MCCONNELL (for himself, Mr. PRYOR, Mr. GRAHAM, Mr. BAUCUS, Mr. CORNYN, Mrs. LINCOLN, Mr. ALEXANDER, Mrs. DOLE, and Mr. BUNNING):

S. 1323. A bill to prevent legislative and regulatory functions from being usurped by civil liability actions brought or continued against food manufacturers, marketers, distributors, advertisers, sellers, and trade associations for claims of injury relating to a person's weight gain, obesity, or any health condition associated with weight gain or obesity; to the Committee on the Judiciary.

By Mr. REID (for Mr. OBAMA (for himself and Mr. HARKIN)):

S. 1324. A bill to amend the Clean Air Act to reduce greenhouse gas emissions from transportation fuel sold in the United States; to the Committee on Environment and Public Works.

SUBMISSION OF CONCURRENT AND SENATE RESOLUTIONS

The following concurrent resolutions and Senate resolutions were read, and referred (or acted upon), as indicated:

By Mr. REID (for himself and Mr. MCCONNELL):

S. Res. 189. A resolution to authorize testimony and legal representation in District of Columbia v. Ellen E. Barfield, Eve-Leona Tetaz, Jeffrey A. Leys, and Jerome A. Zawada; considered and agreed to.

By Mr. ROBERTS (for himself and Mr. BROWNBACK):

S. Res. 190. A resolution expressing the condolences of the Nation to the community of Greensburg, Kansas; considered and agreed to.

By Mr. ALEXANDER (for himself, Mr. DODD, and Mr. KENNEDY):

S. Con. Res. 33. A concurrent resolution recognizing the benefits and importance of school-based music education; to the Committee on Health, Education, Labor, and Pensions.

ADDITIONAL COSPONSORS

S. 147

At the request of Mrs. BOXER, the name of the Senator from Washington (Mrs. MURRAY) was added as a cosponsor of S. 147, a bill to empower women in Afghanistan, and for other purposes.

S. 185

At the request of Mr. SPECTER, the name of the Senator from Washington (Ms. CANTWELL) was added as a cosponsor of S. 185, a bill to restore habeas corpus for those detained by the United States.

S. 231

At the request of Mrs. FEINSTEIN, the names of the Senator from Rhode Island (Mr. WHITEHOUSE), the Senator from Vermont (Mr. SANDERS) and the Senator from Hawaii (Mr. INOUYE) were added as cosponsors of S. 231, a bill to authorize the Edward Byrne Memorial Justice Assistance Grant Program at fiscal year 2006 levels through 2012.

S. 242

At the request of Mr. DORGAN, the name of the Senator from Virginia (Mr. WEBB) was added as a cosponsor of S. 242, a bill to amend the Federal Food, Drug, and Cosmetic Act with respect to the importation of prescription drugs, and for other purposes.

S. 276

At the request of Mrs. FEINSTEIN, the name of the Senator from Arizona (Mr. KYL) was added as a cosponsor of S. 276, a bill to strengthen the consequences of the fraudulent use of United States or foreign passports and for other purposes.

S. 309

At the request of Mr. SANDERS, the name of the Senator from Maryland (Ms. MIKULSKI) was added as a cosponsor of S. 309, a bill to amend the Clean Air Act to reduce emissions of carbon dioxide, and for other purposes.

S. 382

At the request of Ms. COLLINS, the names of the Senator from New York (Mrs. CLINTON) and the Senator from Pennsylvania (Mr. CASEY) were added as cosponsors of S. 382, a bill to amend the Public Health Service Act to establish a State family support grant program to end the practice of parents giving legal custody of their seriously emotionally disturbed children to State agencies for the purpose of obtaining mental health services for those children.

S. 392

At the request of Mr. BIDEN, the name of the Senator from Ohio (Mr. VOINOVICH) was added as a cosponsor of S. 392, a bill to ensure payment of United States assessments for United Nations peacekeeping operations for the 2005 through 2008 time period.

S. 413

At the request of Mrs. CLINTON, the name of the Senator from Georgia (Mr. CHAMBLISS) was added as a cosponsor of S. 413, a bill to amend the Bank Holding Company Act of 1956 and the Revised Statutes of the United States to prohibit financial holding companies and national banks from engaging, directly or indirectly, in real estate brokerage or real estate management activities, and for other purposes.

S. 430

At the request of Mr. LEAHY, the name of the Senator from New York (Mr. SCHUMER) was added as a cosponsor of S. 430, a bill to amend title 10, United States Code, to enhance the national defense through empowerment of the Chief of the National Guard Bureau and the enhancement of the functions of the National Guard Bureau, and for other purposes.

S. 442

At the request of Mr. DURBIN, the name of the Senator from Hawaii (Mr. INOUYE) was added as a cosponsor of S. 442, a bill to provide for loan repayment for prosecutors and public defenders.

S. 502

At the request of Mr. CRAPO, the name of the Senator from New Hampshire (Mr. GREGG) was added as a cosponsor of S. 502, a bill to repeal the sunset on the reduction of capital gains rates for individuals and on the taxation of dividends of individuals at capital gains rates.

S. 579

At the request of Mr. REID, the names of the Senator from Ohio (Mr. BROWN) and the Senator from Connecticut (Mr. LIEBERMAN) were added as cosponsors of S. 579, a bill to amend the Public Health Service Act to authorize the Director of the National Institute of Environmental Health Sciences to make grants for the development and operation of research centers regarding environmental factors that may be related to the etiology of breast cancer.

S. 588

At the request of Mr. NELSON of Florida, the names of the Senator from Arkansas (Mr. PRYOR) and the Senator from Arkansas (Mrs. LINCOLN) were added as cosponsors of S. 588, a bill to amend title XVIII of the Social Security Act to increase the Medicare caps on graduate medical education positions for States with a shortage of residents.

S. 616

At the request of Ms. COLLINS, the name of the Senator from Nevada (Mr. ENSIGN) was added as a cosponsor of S. 616, a bill to promote health care coverage parity for individuals participating in legal recreational activities or legal transportation activities.

S. 638

At the request of Mr. ROBERTS, the name of the Senator from Mississippi (Mr. COCHRAN) was added as a cosponsor of S. 638, a bill to amend the Internal Revenue Code of 1986 to provide for collegiate housing and infrastructure grants.

S. 648

At the request of Mr. CHAMBLISS, the name of the Senator from Arkansas (Mr. PRYOR) was added as a cosponsor of S. 648, a bill to amend title 10, United States Code, to reduce the eligibility age for receipt of non-regular military service retired pay for members of the Ready Reserve in active federal status or on active duty for significant periods.

S. 678

At the request of Mrs. BOXER, the name of the Senator from Washington (Ms. CANTWELL) was added as a cosponsor of S. 678, a bill to amend title 49, United States Code, to ensure air passengers have access to necessary services while on a grounded air carrier and are not unnecessarily held on a grounded air carrier before or after a flight, and for other purposes.

S. 691

At the request of Mr. CONRAD, the name of the Senator from New Jersey (Mr. LAUTENBERG) was added as a cosponsor of S. 691, a bill to amend title XVIII of the Social Security Act to improve the benefits under the Medicare program for beneficiaries with kidney disease, and for other purposes.

S. 901

At the request of Mr. KENNEDY, the name of the Senator from Georgia (Mr. ISAKSON) was added as a cosponsor of S. 901, a bill to amend the Public Health Service Act to provide additional authorizations of appropriations for the health centers program under section 330 of such Act.

S. 953

At the request of Mr. ROCKEFELLER, the name of the Senator from South Dakota (Mr. JOHNSON) was added as a cosponsor of S. 953, a bill to amend title 49, United States Code, to ensure competition in the rail industry, enable rail customers to obtain reliable rail service, and provide those customers with a reasonable process for challenging rate and service disputes.

S. 961

At the request of Mr. NELSON of Nebraska, the name of the Senator from North Dakota (Mr. CONRAD) was added as a cosponsor of S. 961, a bill to amend title 46, United States Code, to provide benefits to certain individuals who served in the United States merchant marine (including the Army Transport Service and the Naval Transport Service) during World War II, and for other purposes.

S. 970

At the request of Mr. SMITH, the names of the Senator from Texas (Mr. CORNYN), the Senator from Nevada (Mr. ENSIGN), and the Senator from Montana (Mr. TESTER), were added as cosponsors of S. 970, a bill to impose sanctions on Iran and on other countries for assisting Iran in developing a nuclear program, and for other purposes.

S. 971

At the request of Mr. BOND, the name of the Senator from Minnesota (Mr. COLEMAN) was added as a cosponsor of S. 971, a bill to establish the National Institute of Food and Agriculture, to provide funding for the support of fundamental agricultural research of the highest quality, and for other purposes.

S. 1062

At the request of Mr. DURBIN, the name of the Senator from Georgia (Mr. ISAKSON) was added as a cosponsor of S. 1062, a bill to establish a congressional commemorative medal for organ donors and their families.

S. 1113

At the request of Mr. BAYH, the names of the Senator from Massachusetts (Mr. KENNEDY), the Senator from Massachusetts (Mr. KERRY), the Senator from Maryland (Ms. MIKULSKI), the Senator from Ohio (Mr. BROWN), the Senator from New Jersey (Mr. MENENDEZ), and the Senator from Minnesota (Ms. KLOBUCHAR), were added as cosponsors of S. 1113, a bill to facilitate the provision of care and services for members of the Armed Forces for traumatic brain injury, and for other purposes.

S. 1117

At the request of Mr. BOND, the name of the Senator from North Dakota (Mr. CONRAD) was added as a cosponsor of S. 1117, a bill to establish a grant program to provide vision care to children, and for other purposes.

S. 1161

At the request of Mr. CRAIG, the name of the Senator from Mississippi (Mr. COCHRAN) was added as a cosponsor of S. 1161, a bill to amend title XVIII of the Social Security Act to authorize the expansion of medicare coverage of medical nutrition therapy services.

S. 1164

At the request of Mr. CARDIN, the name of the Senator from Mississippi (Mr. COCHRAN) was added as a cosponsor of S. 1164, a bill to amend title XVIII of the Social Security Act to improve patient access to, and utilization of, the colorectal cancer screening benefit under the Medicare Program.

S. 1233

At the request of Mr. AKAKA, the name of the Senator from Pennsylvania (Mr. SPECTER) was added as a cosponsor of S. 1233, a bill to provide and enhance intervention, rehabilitative treatment, and services to veterans with traumatic brain injury, and for other purposes.

S. 1237

At the request of Mr. LAUTENBERG, the name of the Senator from New York (Mrs. CLINTON) was added as a cosponsor of S. 1237, a bill to increase public safety by permitting the Attorney General to deny the transfer of firearms or the issuance of firearms and explosives licenses to known or suspected dangerous terrorists.

S. 1249

At the request of Mrs. FEINSTEIN, the name of the Senator from Connecticut (Mr. DODD) was added as a cosponsor of S. 1249, a bill to require the President to close the Department of Defense detention facility at Guantanamo Bay, Cuba, and for other purposes.

S. 1257

At the request of Mr. LIEBERMAN, the name of the Senator from Maryland (Ms. MIKULSKI) was added as a cosponsor of S. 1257, a bill to provide the District of Columbia a voting seat and the State of Utah an additional seat in the House of Representatives.

S. 1263

At the request of Ms. CANTWELL, the name of the Senator from Hawaii (Mr. INOUYE) was added as a cosponsor of S. 1263, a bill to protect the welfare of consumers by prohibiting price gouging with respect to gasoline and petroleum distillates during natural disasters and abnormal market disruptions, and for other purposes.

S. 1276

At the request of Mr. DURBIN, the name of the Senator from California (Mrs. FEINSTEIN) was added as a cosponsor of S. 1276, a bill to establish a grant program to facilitate the creation of methamphetamine precursor electronic logbook systems, and for other purposes.

S. 1305

At the request of Mr. COBURN, the names of the Senator from South Carolina (Mr. DEMINT), the Senator from Wyoming (Mr. ENZI) and the Senator from Arizona (Mr. KYL) were added as cosponsors of S. 1305, a bill making emergency war appropriations for American troops overseas, without unnecessary pork barrel spending and without mandating surrender or retreat in Iraq, for the fiscal year ending September 30, 2007, and for other purposes.

S. CON. RES. 29

At the request of Mr. NELSON of Florida, the names of the Senator from Ohio (Mr. BROWN), the Senator from New York (Mr. SCHUMER), the Senator from Michigan (Ms. STABENOW), the Senator from Massachusetts (Mr. KERRY), the Senator from Tennessee (Mr. CORKER) and the Senator from Virginia (Mr. WARNER) were added as cosponsors of S. Con. Res. 29, a concurrent resolution encouraging the recognition of the Negro Baseball Leagues and their players on May 20th of each year.

S. RES. 30

At the request of Mr. BIDEN, the name of the Senator from Virginia (Mr. WARNER) was added as a cosponsor of S. Res. 30, a resolution expressing the sense of the Senate regarding the need for the United States to address global climate change through the negotiation of fair and effective international commitments.

S. RES. 106

At the request of Mr. DURBIN, the name of the Senator from Maryland (Mr. CARDIN) was added as a cosponsor of S. Res. 106, a resolution calling on the President to ensure that the foreign policy of the United States reflects appropriate understanding and sensitivity concerning issues related to human rights, ethnic cleansing, and genocide documented in the United States record relating to the Armenian Genocide.

S. RES. 171

At the request of Ms. COLLINS, the name of the Senator from Idaho (Mr. CRAPO) was added as a cosponsor of S. Res. 171, a resolution memorializing fallen firefighters by lowering the United States flag to half-staff on the day of the National Fallen Firefighter Memorial Service in Emmitsburg, Maryland.

AMENDMENT NO. 1009

At the request of Mr. HATCH, the name of the Senator from Connecticut (Mr. DODD) was added as a cosponsor of amendment No. 1009 intended to be proposed to S. 1082, a bill to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes.

AMENDMENT NO. 1043

At the request of Mr. REED, the name of the Senator from New York (Mrs. CLINTON) was added as a cosponsor of amendment No. 1043 intended to be proposed to S. 1082, a bill to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes.

STATEMENTS ON INTRODUCED BILLS AND JOINT RESOLUTIONS

By Mr. AKAKA:

S. 1315. A bill to amend title 38, United States Code, to enhance life insurance benefits for disabled veterans, and for other purposes; to the Committee on Veterans' Affairs.

Mr. AKAKA. Mr. President, today I introduce the Disabled Veterans Insurance Improvement Act of 2007.

The purpose of this legislation is to make certain improvements in the insurance programs available to service-connected disabled veterans. It has two main components.

First, this legislation would increase the maximum amount of Veterans Mortgage Life Insurance, VMLI, that a service-connected disabled veteran may purchase from the current maximum of $90,000 to $200,000. The VMLI program was established in 1971 and is available to those service-connected disabled veterans who have received specially adapted housing grants from VA. In the event of the veteran's death, the veteran's family is protected because the Department of Veterans Affairs will pay the balance of the mortgage owed up to the maximum amount of insurance purchased.

The need for this increase is obvious in today's housing market where, during February, the median sale price of a home in the United States was estimated by the Bureau of Census to be $250,000. My legislation would ensure that this important benefit, which helps secure the financial future of many veterans and their families, keeps pace with changes in the economy.

My bill would also establish a new program of insurance for service-connected disabled veterans that would provide up to a maximum of $50,000 in level premium term life insurance coverage. This new program would be available to service-connected disabled veterans who are less than 65 years of age at the time of application.

Under the new program, eligible service-connected veterans would be able to purchase, in increments of $10,000, up to a maximum amount of $50,000 in insurance. Importantly, unlike existing life insurance programs, the premium rates for this program would be based on the 2001 Commissioners Standard Ordinary Basic Table of Mortality rather than the 1941 mortality table that the Service-Disabled Veterans Insurance, S-DVI, program is based upon.

When an insured veteran reaches age 70, two things would occur under this new program of insurance. First, the amount of insurance would be reduced to 20 percent of the amount of insurance in force prior to the veteran's 70th birthday. Second, the veteran would cease making premium payments. This means that during those years where the family's financial obligations would be commensurately higher because of children, mortgages, and the potential impact of any loss of income, the veteran's family would be able to purchase the maximum amount of term life insurance. At age 70, when resources are likely to be most restricted and the need for substantial insurance to take care of a family's needs after the veteran's death have lessened, the veteran would no longer have an obligation to continue to pay any insurance premiums.

My proposal provides that application for this insurance would need to be submitted by an eligible veteran within 2 years from the date on which VA establishes a service-connected disability to exist but not later than 10 years after a veteran's release from active duty. It would further provide that during the first year of the program, any eligible veteran who is presently insured under the S-DVI program could convert that insurance to a policy under this new program.

Both of the proposals contained in the legislation I am introducing today are compatible with the provisions of S. 643, the proposed Disabled Veterans Insurance Act of 2007, which I introduced on February 15 of this year.

I ask unanimous consent that the text of the bill be printed in the RECORD.

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

S. 1315

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Disabled Veterans Insurance Improvement Act of 2007''.

SEC. 2. ENHANCEMENT OF VETERANS' MORTGAGE LIFE INSURANCE.

Section 2106(b) of title 38, United States Code, is amended by striking ''$90,000'' and inserting ''$200,000''.

SEC. 3. LEVEL-PREMIUM TERM LIFE INSURANCE FOR VETERANS WITH SERVICE-CONNECTED DISABILITIES.

(a) IN GENERAL.—Chapter 19 of title 38, United States Code, is amended by inserting after section 1922A the following new section:

''§ 1922B. Level-premium term life insurance for veterans with service-connected disabilities

''(a) IN GENERAL.—In accordance with the provisions of this section, the Secretary shall grant insurance to each eligible veteran who seeks such insurance against the death of such veteran occurring while such insurance is in force.

''(b) ELIGIBLE VETERANS.—For purposes of this section, an eligible veteran is any veteran less than 65 years of age who has a service-connected disability.

''(c) AMOUNT OF INSURANCE.—(1) Subject to paragraph (2), the amount of insurance granted an eligible veteran under this section shall be $50,000 or such lesser amount as the veteran shall elect. The amount of insurance so elected shall be evenly divisible by $10,000.

''(2) The aggregate amount of insurance of an eligible veteran under this section, section 1922 of this title, and section 1922A of this title may not exceed $50,000.

''(d) REDUCED AMOUNT FOR VETERANS AGE 70 OR OLDER.—In the case of a veteran insured under this section who turns age 70, the amount of insurance of such veteran under this section after the date such veteran turns age 70 shall be the amount equal to 20 percent of the amount of insurance of the veteran under this section as of the day before such date.

''(e) PREMIUMS.—(1) Premium rates for insurance under this section shall be based on the 2001 Commissioners Standard Ordinary Basic Table of Mortality and interest at the rate of 4.5 per centum per annum.

''(2) The amount of the premium charged a veteran for insurance under this section may not increase while such insurance is in force for such veteran.

''(3) The Secretary may not charge a premium for insurance under this section for a veteran as follows:

''(A) A veteran who has a service-connected disability rated as total and is eligible for a waiver of premiums under section 1912 of this title.

''(B) A veteran who is 70 years of age or older.

''(4) Insurance granted under this section shall be on a nonparticipating basis and all premiums and other collections therefor shall be credited directly to a revolving fund in the Treasury of the United States, and any payments on such insurance shall be made directly from such fund. Appropriations to such fund are hereby authorized.

''(5) Administrative costs to the Government for the costs of the program of insurance under this section shall be paid from premiums credited to the fund under paragraph (4), and payments for claims against the fund under paragraph (4) for amounts in excess of amounts credited to such fund under that paragraph (after such administrative costs have been paid) shall be paid from appropriations to the fund.

''(f) APPLICATION REQUIRED.—An eligible veteran seeking insurance under this section shall file with the Secretary an application therefor. Such application shall be filed not later than the earlier of—

''(1) the end of the two-year period beginning on the date on which the Secretary notifies the veteran that the veteran has a service-connected disability; and

''(2) the end of the 10-year period beginning on the date of the separation of the veteran from the Armed Forces, whichever is earlier.''.

(b) CLERICAL AMENDMENT.—The table of sections at the beginning of chapter 19 of such title is amended by inserting after the item related to section 1922A the following new item:

''1922B. Level-premium term life insurance for veterans with service-connected disabilities.''.

(c) EXCHANGE OF SERVICE DISABLED VETERANS' INSURANCE.—During the one-year period beginning on the date of the enactment of this Act, any veteran insured under section 1922 of title 38, United States Code, who is eligible for insurance under section 1922B of title 38, United States Code (as added by subsection (a)), may exchange insurance coverage under such section 1922 for insurance coverage under such section 1922B.

SEC. 4. ADMINISTRATIVE COSTS OF SERVICE DISABLED VETERANS' INSURANCE.

Section 1922(a) of title 38, United States Code, is amended by striking ''date of such insurance'' and inserting ''date of such insurance; (5) administrative costs to the Government for the costs of the program of insurance under this section shall be paid from premiums credited to the fund under paragraph (4), and payments for claims against the fund under paragraph (4) for amounts in excess of amounts credited to such fund under that paragraph (after such administrative costs have been paid) shall be paid from appropriations to the fund''.

SEC. 5. MODIFICATION OF SERVICEMEMBERS' GROUP LIFE INSURANCE COVERAGE.

(a) EXPANSION OF SERVICEMEMBERS' GROUP LIFE INSURANCE TO INCLUDE CERTAIN MEMBERS OF INDIVIDUAL READY RESERVE.—

(1) IN GENERAL.—Paragraph (1)(C) of section 1967(a) of title 38, United States Code, is amended by striking ''section 1965(5)(B) of this title'' and inserting ''subparagraph (B) or (C) of section 1965(5) of this title''.

(2) CONFORMING AMENDMENT.—Paragraph (5)(C) of such section 1967(a) is amended by striking ''section 1965(5)(B) of this title'' and inserting ''subparagraph (B) or (C) of section 1965(5) of this title''.

(b) REDUCTION IN PERIOD OF COVERAGE FOR DEPENDENTS AFTER MEMBER SEPARATES.—Section 1968(a)(5)(B)(ii) of such title is amended by striking ''120 days after''.

By Mrs. FEINSTEIN (for herself, Mr. DURBIN, and Mr. KENNEDY)

S. 1316. A bill to establish and clarify that Congress does not authorize persons convicted of dangerous crimes in foreign courts to freely possess firearms in the United States; to the Committee on the Judiciary.

Mrs. FEINSTEIN. Mr. President, today I am pleased to join with Senators DURBIN and KENNEDY in introducing the Firearms by Foreign Convicts Clarification Act. This bill would close a loophole that exists in current law, by stating that people convicted of foreign felonies and domestic violence, just like people convicted of similar American crimes, cannot possess firearms in the United States.

I imagine that most Americans may be surprised, as I was, to learn that foreign felons actually have greater gun rights than American citizens who have been convicted of felonies and domestic violence in our own courts. Our country has been trying to keep guns out of the hands of criminals for at least the last 40 years, since the landmark Gun Control Act of 1968. Unfortunately, in 2005 the Supreme Court created a gaping loophole in this longstanding felon-in-possession law.

That happened in the case of Small v. United States, where a majority of the Court essentially held that foreign convictions don't count for the purpose of being a felon in possession of a firearm. This was not because the Justices somehow thought that exempting foreign convictions from our felon-in-possession laws was wise public policy. In fact, as Justice Thomas noted in his dissent, ''the majority's interpretation permits those convicted overseas of murder, rape, assault, kidnapping, terrorism and other dangerous crimes to possess firearms freely in the United States.''

The problem in Small was that a majority of the Court felt that our 1968 law had not been written clearly enough. Although Congress had said that a person convicted of a felony ''in any court'' could not possess a firearm, the majority said that this phrase, ''any court,'' might have been meant to apply only to ''any American court'' rather than what the legislation actually said—''any court.''

The Federal felon-in-possession law had already been applied to foreign felons in several prosecutions since 1968, but the Court found unpersuasive both this history and the statute's express language. Dissenting Justices Thomas, Scalia and Kennedy accused the majority of creating a novel canon of legal construction that will ''wreak havoc'' with established rules of extraterritorial construction. But whatever we may think of the Court's analysis, there is no doubt that the Small decision is now the law of the land. And if we want to close this legal loophole, it is clear that we need to pass some clarifying legislation. The bill I introduce today would do just that.

Under this bill, section 921 of Title 18, the definitions section, would be amended to state clearly that ''[t]he term 'any court' includes any Federal, State, or foreign court.'' Similar changes would be made in other sections of the Gun Control Act, where there are references to ''state offenses'' or ''offenses under state law, the bill would expand these terms to include convictions of foreign offenses and offenses under foreign law.

In other words, the bill would make clear that if someone is convicted in a foreign court of an offense that would have disqualified him from possessing a gun if that conviction had been handed

down in the U.S., the same laws relating to gun possession will be applied. The only exception will be if there is reason to think the conviction entered by the foreign jurisdiction is somehow invalid.

In that situation, this bill would create an exemption, allowing a person convicted in a foreign jurisdiction to challenge its validity. Under the bill, a foreign conviction will not constitute a ''conviction'' for purposes of the felon-in-possession laws, if the foreign conviction either (1) resulted from a denial of fundamental fairness that would violate due process if committed in the United States, or (2) if the conduct on which the foreign conviction was based would be legal if committed in the United States.

I expect that these circumstances will be fairly rare, but the bill does take them into account and will provide a complete defense to anyone with an invalid foreign conviction. And in any event, it is clear that we should not keep in place a policy in which the tail wags the dog. The current state of the law is that we essentially treat every foreign conviction as invalid. And that is simply illogical.

An example of why we need to fix this law occurred in 2001, when U.S. agents with bulletproof vests raided the New York hotel room of suspect Rohan Ingram. Ingram was found with 13 firearms and had an extensive criminal background, including at least 18 convictions for crimes such as assault and use of firearms during crimes. Law enforcement had flagged him as ''armed and dangerous.'' But because all of his convictions had occurred in foreign courts, his felon-in-possession charge was eventually thrown out of court. That is simply not a tolerable state of affairs in a post- 9/11 world.

Particularly in these times, America cannot continue to give foreign-convicted murderers, rapists and even terrorists an unlimited right to buy firearms in the United States, including even assault weapons that they might try to send to colleagues abroad, or use to develop a cache of weapons to use to kill our citizens within the United States. American citizens convicted of identical crimes at home are denied the ability to buy and possess such firearms, and the time has come to fix this loophole so that foreign convicts are placed in the same category.

I urge my colleagues to support this legislation. I ask unanimous consent that the text of the bill be printed in the RECORD.

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

S. 1316

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Firearms by Foreign Convicts Clarification Act of 2007''.

SEC. 2. DEFINITIONS.

(a) COURTS.—Section 921(a) of title 18, United States Code, is amended by adding at the end the following:

''(36) The term 'any court' includes any Federal, State, or foreign court.''.

(b) EXCLUSION OF CERTAIN FELONIES.—Section 921(a)(20) of title 18, United States Code, is amended—

(1) in subparagraph (A), by striking ''any Federal or State offenses'' and inserting ''any Federal, State, or foreign offenses'';

(2) in subparagraph (B), by striking ''any State offense classified by the laws of the State'' and inserting ''any State or foreign offense classified by the laws of that jurisdiction''; and

(3) in the matter following subparagraph (B), in the first sentence, by inserting before the period the following: '', except that a foreign conviction shall not constitute a conviction of such a crime if the convicted person establishes that the foreign conviction resulted from a denial of fundamental fairness that would violate due process if committed in the United States or from conduct that would be legal if committed in the United States''.

(c) DOMESTIC VIOLENCE CRIMES.—Section 921(a)(33) of title 18, United States Code, is amended—

(1) in subparagraph (A), by striking ''subparagraph (C)'' and inserting ''subparagraph (B)''; and

(2) in subparagraph (B)(ii), by striking ''if the conviction has'' and inserting the following: ''if the conviction—

''(I) occurred in a foreign jurisdiction and the convicted person establishes that the foreign conviction resulted from a denial of fundamental fairness that would violate due process if committed in the United States or from conduct that would be legal if committed in the United States; or

''(II) has''.

SEC. 3. PENALTIES.

Section 924(e)(2)(A)(ii) of title 18, United States Code, is amended—

(1) by striking ''an offense under State law'' and inserting ''an offense under State or foreign law''; and

(2) by inserting before the semicolon the following: '', except that a foreign conviction shall not constitute a conviction of such a crime if the convicted person establishes that the foreign conviction resulted from a denial of fundamental fairness that would violate due process if committed in the United States or from conduct that would be legal if committed in the United States''.

By Mr. INOUYE (for himself and Mr. AKAKA):

S. 1319. A bill to provide for the conversion of a temporary judgeship for the district of Hawaii to a permanent judgeship; to the Committee on the Judiciary.

Mr. INOUYE. Mr. President, I rise today to support this bill addressing the need for a fourth permanent judgeship for the District of Hawaii.

Hawaii currently has four active District Court judges. However, if any of its four active judges either accepts senior status and retires, or becomes otherwise unable to serve, the District of Hawaii will not be able to replace that vacancy with another active judge. This will pose a problem for not only the active judges, as their workload will increase, but also for the public because an unfilled vacancy may have a disastrous effect on our court's caseloads. This bill ensures the continued efficiency of Hawaii's District court system.

Thank you for allowing me this opportunity to share with you the importance of this legislation.

I ask unanimous consent that the text of the bill be printed in the RECORD.

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

S. 1319

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. CONVERSION OF TEMPORARY JUDGESHIP TO PERMANENT JUDGESHIP FOR THE DISTRICT OF HAWAII.

(a) IN GENERAL.—The existing judgeship for the district of Hawaii authorized by section 203(c) of the Judicial Improvements Act of 1990 (28 U.S.C. 133 note; Public Law 101–650; 104 Stat. 5089) shall, as of the date of enactment of this Act, be authorized under section 133 of title 28, United States Code, and the incumbent in that office shall hold the office under section 133 of title 28, United States Code, as amended by this Act.

(b) TABLES.—In order that the table contained in section 133(a) of title 28, United States Code, will reflect the change in the total number of permanent district judgeships authorized as a result of subsection (a) of this section, the item relating to Hawaii is amended to read as follows:

''Hawaii ..... 4''.

Mr. AKAKA. Mr. President, I rise today with my colleague from Hawaii, Senator DANIEL INOUYE, to introduce legislation to convert a temporary judgeship for the U.S. District Court for the District of Hawaii to a permanent position.

There are currently 3 permanent Federal judgeships and one temporary Federal judgeship in the U.S. District Court, District of Hawaii. The Judicial Improvement Act of 1990, P.L. 101–650 created the temporary position and mandates that the first vacancy occurring in Hawaii after October 2004 cannot be filled. The District of Hawaii will be left with only 3 Federal judge positions upon a judge vacating his or her position. The loss of a judgeship will severely impact Hawaii's judicial system.

In March 2007, the Judicial Conference recommended that Congress convert 5 temporary judgeships, one of which is in the District of Hawaii, to permanent status. Their recommendation is largely based on the significant increase in weighted filings that would occur if a judgeship is lost. The Conference projects that the current weighted filing of 380 per judgeship would climb to 507 per judgeship, which is 18 percent above the Conference standard, should the District of Hawaii lose a judgeship.

In addition, the Conference reported that the median time from filing to disposition for criminal cases in Hawaii has continued to increase from 1999 to 2005, making Hawaii's case processing times the second slowest in the nation. Since 2001, the District Court of Hawaii has completed an average of 50 trials per year, significantly less than the national average. Although Hawaii has 4 judgeships, 2 are senior judges

who only handle a small number of civil cases. The limited assistance provided by these senior judges is likely to decline further in the near future. These judges are not able to retire due to the constraints put forth by the loss of the temporary judgeship seat, should one of the current judges decide to leave. Furthermore, receiving assistance from visiting judges is made difficult by the high cost of travel to Hawaii. For these, and many other reasons, the Judicial Council of the Ninth Circuit supports the Judicial Conference's recommendation to convert this temporary judgeship to a permanent position.

I share the concern of many in Hawaii's legal community that the lack of a fourth permanent position will delay the timely issuance of justice in matters pending before the U.S. District Court, District of Hawaii. This is a disservice to all. The economic impact of extending trials and prolonging time spent in jail will burden Hawaii's taxpayers. Moreover, the lack of timely judicial review will have negative social impacts by prolonging the disruption in individuals' families and lives. The bill we introduce today would ensure 4 Federal judgeships remain active in Hawaii to address the needs of the District Court of Hawaii and the people of Hawaii.

By Mr. REID (for Mr. OBAMA (for himself and Mr. HARKIN)):

S. 1324. A bill to amend the Clean Air Act to reduce greenhouse gas emissions from transportation fuel sold in the United States; to the Committee on Environment and Public Works.

Mr. OBAMA. Mr. President, we heard from a panel of top climate change experts from around the world earlier this year that global warming is a certainty and that most of the temperature increase is very likely due to rising greenhouse gas concentrations. Reducing America's dependence on oil should be one of our top priorities, but any policy that affects our production and consumption of fuel must also address the pressing problem of global warming. Because the oil used in the U.S. transportation sector accounts for about one-third of our nation's emissions of greenhouse gases, we must adopt a policy that curtails these emissions in an effective manner.

Today, along with Senator HARKIN, I am introducing the National Low-Carbon Fuel Standard Act of 2007, which calls for a reduction in the lifecycle greenhouse gas emissions of the transportation fuels sold in the U.S. of 5 percent in 2015 and 10 percent in 2020. These reductions can play an important role in stemming the dangerous transformation of our climate.

According to one estimate, the National Low-Carbon Fuel Standard, NLCFS, would reduce annual greenhouse gas emissions by about 180 million metric tons in 2020. This is the equivalent of taking over 30 million cars off the road. If enacted in conjunction with the bill I introduced earlier this year to raise fuel efficiency standards, the NLCFS would reduce greenhouse gas emissions by about 530 million metric tons in 2020, the equivalent of taking over 50 million cars off the road.

The effect on our oil imports would also be dramatic. By making greater use of home-grown, renewable fuels, the NLCFS could reduce the annual consumption of gasoline derived from foreign oil imports by about 30 billion gallons in 2020.

The NLCFS will greatly expand the market for domestic renewable fuels such as corn-based ethanol, cellulosic ethanol, and biodiesel. By one estimate, the NLCFS will create a market for over 40 billion gallons of biofuels by 2020. To provide near-term demand certainty for renewable fuel producers, the bill expands the Renewable Fuel Standard established in the Energy Policy Act of 2005 to require 15 billion gallons of renewable fuel by 2012.

The bill also contains a minimum requirement for fuels with lifecycle greenhouse gas emissions that are 50 and 75 percent lower than gasoline. This requirement signals to investors that there will be a market for advanced fuels with ultra-low carbon emissions, but still allows significant leeway for fuel blenders to choose the optimal mix of fuels to meet their overall greenhouse gas emissions targets.

Because the NLCFS will encourage a rapid expansion of our domestic renewable fuels production capacity, the bill contains provisions that protect sensitive areas like national wildlife refuges, national parks, old-growth forests, national grasslands, and national forests. The bill calls for an assessment of the impacts of the expansion compared to the business-as-usual scenario of continued reliance on petroleum-based transportation fuels, and the development of standards by 2012 to protect air, land, and water quality. This approach strikes a balance between the need to rapidly expand our domestic renewable fuel production capacity and the need to ensure sustainability and environmental protection. I urge my colleagues to support the National Low-Carbon Fuel Standard Act.

SUBMITTED RESOLUTIONS

SENATE RESOLUTION 189—TO AUTHORIZE TESTIMONY AND LEGAL REPRESENTATION IN DISTRICT OF COLUMBIA V. ELLEN E. BARFIELD, EVE-LEONA TETAZ, JEFFREY A. LEYS, AND JEROME A. ZAWADA

Mr. REID (for himself and Mr. MCCONNELL) submitted the following resolution; which was considered and agreed to:

S. RES. 189

Whereas, in the cases of District of Columbia v. Ellen E. Barfield (Cr. No. 07–3133), Eve-Leona Tetaz (Cr. No. 07–3144), Jeffrey A. Leys (Cr. No. 07–5009), and Jerome A. Zawada (Cr. No. 07–5088), pending in the Superior Court for the District of Columbia, testimony has been requested from Katie Landi, an employee in the office of Senator John McCain;

Whereas, pursuant to sections 703(a) and 704(a)(2) of the Ethics in Government Act of 1978, 2 U.S.C. 288b(a) and 288c(a)(2), the Senate may direct its counsel to represent employees of the Senate with respect to any subpoena, order, or request for testimony relating to their official responsibilities;

Whereas, by the privileges of the Senate of the United States and Rule XI of the Standing Rules of the Senate, no evidence under the control or in the possession of the Senate may, by the judicial or administrative process, be taken from such control or possession but by permission of the Senate;

Whereas, when it appears that evidence under the control or in the possession of the Senate may promote the administration of justice, the Senate will take such action as will promote the ends of justice consistent with the privileges of the Senate: Now, therefore, be it

Resolved, That Katie Landi and any other employees of Senator McCain's office from whom testimony may be required are authorized to testify in the cases of District of Columbia v. Ellen E. Barfield, Eve-Leona Tetaz, Jeffrey A. Leys, and Jerome A. Zawada, except concerning matters for which a privilege should be asserted.

SEC. 2. The Senate Legal Counsel is authorized to represent Katie Landi and other employees of Senator McCain's staff in the actions referenced in section one of this resolution.

SENATE RESOLUTION 190—EXPRESSING THE CONDOLENCES OF THE NATION TO THE COMMUNITY OF GREENSBURG, KANSAS

Mr. ROBERTS (for himself and Mr. BROWNBACK) submitted the following resolution, which was considered and agreed to:

S. RES. 190

Whereas, on Friday, May 4, 2007, a tornado struck the community of Greensburg, Kansas;

Whereas this tornado was classified as an EF-5, the strongest possible type, by the National Weather Service, with winds estimated at 205 miles per hour;

Whereas the tornado is the first EF-5 on the Enhanced Fujita scale, and the first F-5 on the previous scale since 1999;

Whereas approximately 95 percent of Greensburg is destroyed;

Whereas 1,500 residents have been displaced from their homes; and

Whereas, in response to the declaration by the President of a major disaster, the Administrator of the Federal Emergency Management Agency has made Federal disaster assistance available for the State of Kansas to assist in local recovery efforts: Now, therefore, be it

Resolved, That the Senate expresses the condolences of the Nation to the community of Greensburg, Kansas, and its gratitude to local, State, and National law enforcement and emergency responders conducting search and rescue operations.

SENATE CONCURRENT RESOLUTION 33—RECOGNIZING THE BENEFITS AND IMPORTANCE OF SCHOOL-BASED MUSIC EDUCATION

Mr. ALEXANDER (for himself, Mr. DODD, and Mr. KENNEDY) submitted the

following concurrent resolution, which was referred to the Committee on Health, Education, Labor, and Pensions:

S. CON. RES. 33

Whereas school music programs enhance intellectual development and enrich the academic environment for students of all ages;

Whereas students who participate in school music programs are less likely to be involved with drugs, gangs, or alcohol, and have better attendance in school;

Whereas the skills gained through sequential music instruction, including discipline and the ability to analyze, solve problems, communicate, and work cooperatively, are vital for success in the 21st century workplace;

Whereas the majority of students attending public schools in inner city neighborhoods have virtually no access to music education, which places them at a disadvantage compared to their peers in other communities;

Whereas the arts are a core academic subject, and music is an essential element of the arts; and

Whereas every student in the United States should have an opportunity to reap the benefits of music education: Now, therefore, be it

Resolved by the Senate (the House of Representatives concurring), That it is the sense of Congress that music education grounded in rigorous instruction is an important component of a well-rounded academic curriculum and should be available to every student in every school in the United States.

AMENDMENTS SUBMITTED AND PROPOSED

SA 1045. Mr. REID (for Mr. OBAMA) submitted an amendment intended to be proposed by Mr. REID to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table.

SA 1046. Ms. STABENOW (for herself, Mr. KOHL, Mr. HATCH, and Mr. COBURN) submitted an amendment intended to be proposed by her to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1047. Mr. ROBERTS (for himself, Mr. HARKIN, Mr. BURR, and Mr. COBURN) submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1048. Ms. SNOWE submitted an amendment intended to be proposed by her to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1049. Mr. ENZI (for himself and Mr. KENNEDY) submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1050. Mr. ENZI (for himself and Mr. KENNEDY) submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1051. Mr. STEVENS (for himself and Ms. MURKOWSKI) submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1052. Mr. CORKER submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1053. Mr. ENZI (for himself, Mr. KENNEDY, Mr. DODD, and Mrs. CLINTON) submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1054. Mr. FEINGOLD submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1055. Mr. LEVIN submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1056. Mr. REED (for himself and Mr. ISAKSON) submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1057. Mr. GREGG submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1058. Mr. DEMINT (for himself, Mr. COBURN, and Mr. MARTINEZ) submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1059. Mr. SESSIONS (for himself, Mrs. LINCOLN, Mr. COCHRAN, Mr. PRYOR, Mr. LOTT, and Mr. SHELBY) submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1060. Mr. HATCH (for himself and Mr. KENNEDY) submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

TEXT OF AMENDMENTS

SA 1045. Mr. REID (for Mr. OBAMA) submitted an amendment intended to be proposed by Mr. Reid to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ___. IMPROVING GENETIC TEST SAFETY AND QUALITY.

Not later than 30 days after the date of enactment of this Act, the Secretary shall enter into a contract with the Institute of Medicine to conduct a study to assess the overall safety and quality of genetic tests and prepare a report that includes recommendations to improve Federal oversight and regulation of genetic tests. Such study shall take into consideration relevant reports by the Secretary's Advisory Committee on Genetic Testing and other groups and shall be completed not later than 1 year after the date on which the Secretary entered into such contract.

SA 1046. Ms. STABENOW (for herself, Mr. KOHL, Mr. HATCH, and Mr. COBURN) submitted an amendment intended to be proposed by her to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ___. CITIZENS PETITIONS AND PETITIONS FOR STAY OF AGENCY ACTION.

Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), as amended by this Act, is amended by adding at the end the following:

''(s) CITIZEN PETITIONS AND PETITIONS FOR STAY OF AGENCY ACTION.—

''(1) IN GENERAL.—

''(A) NO DELAY OF CONSIDERATION OR APPROVAL.—

''(i) IN GENERAL.—With respect to a pending application submitted under subsection (b)(2) or (j), if a petition is submitted to the Secretary that seeks to have the Secretary take, or refrain from taking, any form of action relating to the approval of the application, including a delay in the effective date of the application, clauses (ii) and (iii) shall apply.

''(ii) NO DELAY OF CONSIDERATION OR APPROVAL.—Except as provided in clause (iii), the receipt and consideration of a petition described in clause (i) shall not delay consideration or approval of an application submitted under subsection (b)(2) or (j).

''(iii) NO DELAY OF APPROVAL WITHOUT DETERMINATION.—The Secretary shall not delay approval of an application submitted under subsection (b)(2) or (j) while a petition described in clause (i) is reviewed and considered unless the Secretary determines, not later than 25 business days after the submission of the petition, that a delay is necessary to protect the public health.

''(B) DETERMINATION OF DELAY.—With respect to a determination by the Secretary under subparagraph (A)(iii) that a delay is necessary to protect the public health the following shall apply:

''(i) Not later than 5 days after making such determination, the Secretary shall publish on the Internet website of the Food and Drug Administration a detailed statement providing the reasons underlying the determination. The detailed statement shall include a summary of the petition and comments and supplements, the specific substantive issues that the petition raises which need to be considered prior to approving a pending application submitted under subsection (b)(2) or (j), and any clarifications and additional data that is needed by the Secretary to promptly review the petition.

''(ii) Not later than 10 days after making such determination, the Secretary shall provide notice to the sponsor of the pending application submitted under subsection (b)(2) or (j) and provide an opportunity for a meeting with appropriate staff as determined by the Commissioner to discuss the determination.

''(2) TIMING OF FINAL AGENCY ACTION ON PETITIONS.—

''(A) IN GENERAL.—Notwithstanding a determination made by the Secretary under paragraph (1)(A)(iii), the Secretary shall take final agency action with respect to a petition not later than 180 days of submission of that petition unless the Secretary determines, prior to the date that is 180 days after the date of submission of the petition, that a delay is necessary to protect the public health.

''(B) DETERMINATION OF DELAY.—With respect to a determination by the Secretary under subparagraph (A) that a delay is necessary to protect the public health the following shall apply:

''(i) Not later than 5 days after making the determination under subparagraph (A), the Secretary shall publish on the Internet website of the Food and Drug Administration a detailed statement providing the reasons underlying the determination. The detailed statement should include the state of the review of the petition, the specific outstanding issues that still need to be resolved, a proposed timeframe to resolve the issues, and any additional information that has been requested by the Secretary of the petitioner or needed by the Secretary in order to resolve the petition and not further delay an application filed under subsection (b)(2) or (j).

''(ii) Not later than 10 days after making the determination under subparagraph (A), the Secretary shall provide notice to the sponsor of the pending application submitted

under subsection (b)(2) or (j) and provide an opportunity for a meeting with appropriate staff as determined by the Commissioner to discuss the determination.

''(3) VERIFICATIONS.—

''(A) PETITIONS FOR REVIEW.—The Secretary shall not accept a petition for review unless it is signed and contains the following verification: 'I certify that, to my best knowledge and belief: (a) this petition includes all information and views upon which the petition relies; (b) this petition includes representative data and/or information known to the petitioner which are unfavorable to the petition; and (c) information upon which I have based the action requested herein first became known to the party on whose behalf this petition is filed on or about _____. I received or expect to receive payments, including cash and other forms of consideration, from the following persons or organizations to file this petition: _____. I verify under penalty of perjury that the foregoing is true and correct.', with the date of the filing of such petition and the signature of the petitioner inserted in the first and second blank space, respectively.

''(B) SUPPLEMENTAL INFORMATION.—The Secretary shall not accept for review any supplemental information or comments on a petition unless the party submitting such information or comments does so in written form and that the subject document is signed and contains the following verification: 'I certify that, to my best knowledge and belief: (a) I have not intentionally delayed submission of this document or its contents; and (b) the information upon which I have based the action requested herein first became known to me on or about _____. I received or expect to receive payments, including cash and other forms of consideration, from the following persons or organizations to submit this information or its contents: _____. I verify under penalty of perjury that the foregoing is true and correct.', with the date of the submission of such document and the signature of the petitioner inserted in the first and second blank space, respectively.

''(4) ANNUAL REPORT ON DELAYS IN APPROVALS PER PETITION.—The Secretary shall annually submit to the Congress a report that specifies—

''(A) the number of applications under subsection (b)(2) and (j) that were approved during the preceding 1-year period;

''(B) the number of petitions that were submitted during such period;

''(C) the number of applications whose effective dates were delayed by petitions during such period and the number of days by which the applications were so delayed; and

''(D) the number of petitions that were filed under this subsection that were deemed by the Secretary under paragraph (1)(A)(iii) to require delaying an application under subsection (b)(2) or (j) and the number of days by which the applications were so delayed.

''(5) EXCEPTION.—This subsection does not apply to a petition that is made by the sponsor of the application under subsection (b)(2) or (j) and that seeks only to have the Secretary take or refrain from taking any form of action with respect to that application.

''(6) REPORT BY INSPECTOR GENERAL.—The Office of Inspector General of the Department of Health and Human Services shall issue a report not later than 2 years after the date of enactment of this subsection evaluating evidence of the compliance of the Food and Drug Administration with the requirement that the consideration by the Secretary of petitions that do not raise public health concerns remain separate and apart from the review and approval of an application submitted under subsection (b)(2) or (j).

''(7) DEFINITION.—For purposes of this subsection, the term 'petition' includes any request for an action described in paragraph (1)(A)(i) to the Secretary, without regard to whether the request is characterized as a petition.''.

SA 1047. Mr. ROBERTS (for himself, Mr. HARKIN, Mr. BURR, and Mr. COBURN) submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

Strike subparagraphs (E) and (F) of section 505(o)(5) of the Federal Food, Drug, and Cosmetic Act, as added by this Act, and insert the following:

''(E) SPECIFIC DISCLOSURES.—

''(i) SERIOUS RISK; SAFETY PROTOCOL.—If the Secretary determines that advertisements lacking a specific disclosure about a serious risk listed in the labeling of a drug or about a protocol to ensure safe use described in the labeling of the drug would be false or misleading, the risk evaluation and mitigation strategy for the drug may require that the applicant include in advertisements of the drug such disclosure.

''(ii) DATE OF APPROVAL.—If the Secretary determines that advertisements lacking a specific disclosure of the date a drug was approved and disclosure of a serious risk would be false or misleading, the risk evaluation and mitigation strategy for the drug may require that the applicant include in advertisements of the drug such disclosure.

''(iii) SPECIFICATION OF ADVERTISEMENTS.—The Secretary may specify the advertisements required to include a specific disclosure under clause (i) or (ii).

''(iv) REQUIRED SAFETY SURVEILLANCE.—If the approved risk evaluation and mitigation strategy for a drug requires the specific disclosure under clause (ii), the Secretary shall—

''(I) consider identifying and assessing all serious risks of using the drug to be a priority safety question under subsection (k)(3)(B);

''(II) not less frequently than every 3 months, evaluate the reports under subsection (k)(1) and the routine active surveillance as available under subsection (k)(3) with respect to such priority drug safety question to determine whether serious risks that might occur among patients expected to be treated with the drug have been adequately identified and assessed;

''(III) remove such specific disclosure requirement as an element of such strategy if such serious risks have been adequately identified and assessed; and

''(IV) consider whether a specific disclosure under clause (i) should be required.

On page 101, strike lines 7 through 9.

At the end of the bill, add the following:

SEC. ____. CIVIL PENALTIES; DIRECT-TO-CONSUMER ADVERTISEMENT.

(a) CIVIL PENALTIES.—Section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333) is amended by adding at the end the following:

''(g)(1) Any applicant (as such term is used in section 505(o)) who disseminates a direct-to-consumer advertisement for a prescription drug that is false or misleading and a violation of section 502(n) shall be liable to the United States for a civil penalty in an amount not to exceed $150,000 for the first such violation in any 3-year period, and not to exceed $300,000 for each subsequent violation committed after the applicant has been penalized under this paragraph any time in the preceding 3-year period. For the purposes of this paragraph, repeated dissemination of the same or similar advertisement prior to the receipt of the written notice referred to in paragraph (2) for such advertisements shall be considered as 1 violation.

''(2) A civil penalty under paragraph (1) shall be assessed by the Secretary by an order made on the record after providing written notice to the applicant to be assessed a civil penalty and an opportunity for a hearing in accordance with this paragraph and section 554 of title 5, United States Code. If upon receipt of the written notice, the applicant to be assessed a civil penalty objects and requests a hearing, then in the course of any investigation related to such hearing, the Secretary may issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation, including information pertaining to the factors described in paragraph (3).

''(3) Upon the request of the applicant to be assessed a civil penalty, the Secretary, in determining the amount of a civil penalty, shall take into account the nature, circumstances, extent, and gravity of the violation or violations, including the following factors:

''(A) Whether the applicant submitted the advertisement or a similar advertisement for review under section 736A.

''(B) Whether the applicant submitted the advertisement for prereview if required under section 505(o)(5)(D).

''(C) Whether, after submission of the advertisement as described in subparagraph (A) or (B), the applicant disseminated the advertisement before the end of the 45-day comment period.

''(D) Whether the applicant failed to incorporate any comments made by the Secretary with regard to the advertisement or a similar advertisement into the advertisement prior to its dissemination.

''(E) Whether the applicant ceased distribution of the advertisement upon receipt of the written notice referred to in paragraph (2) for such advertisement.

''(F) Whether the applicant had the advertisement reviewed by qualified medical, regulatory, and legal reviewers prior to its dissemination.

''(G) Whether the violations were material.

''(H) Whether the applicant who created the advertisement acted in good faith.

''(I) Whether the applicant who created the advertisement has been assessed a civil penalty under this provision within the previous 1-year period.

''(J) The scope and extent of any voluntary, subsequent remedial action by the applicant.

''(K) Such other matters, as justice may require.

''(4)(A) Subject to subparagraph (B), no applicant shall be required to pay a civil penalty under paragraph (1) if the applicant submitted the advertisement to the Secretary and disseminated such advertisement after incorporating any comment received from the Secretary.

''(B) The Secretary may retract or modify any prior comments the Secretary has provided to an advertisement submitted to the Secretary based on new information or changed circumstances, so long as the Secretary provides written notice to the applicant of the new views of the Secretary on the advertisement and provides a reasonable time for modification or correction of the advertisement prior to seeking any civil penalty under paragraph (1).

''(5) The Secretary may compromise, modify, remit, with or without conditions, any civil penalty which may be assessed under

paragraph (1). The amount of such penalty, when finally determined, or the amount charged upon in compromise, may be deducted from any sums owned by the United States to the applicant charged.

''(6) Any applicant who requested, in accordance with paragraph (2), a hearing with respect to the assessment of a civil penalty and who is aggrieved by an order assessing a civil penalty, may file a petition for de novo judicial review of such order with the United States Court of Appeals for the District of Columbia Circuit or for any other circuit in which such applicant resides or transacts business. Such a petition may only be filed within the 60-day period beginning on the date the order making such assessments was issued.

''(7) If any applicant fails to pay an assessment of a civil penalty—

''(A) after the order making the assessment becomes final, and if such applicant does not file a petition for judicial review of the order in accordance with paragraph (6); or

''(B) after a court in an action brought under paragraph (6) has entered a final judgment in favor of the Secretary,

the Attorney General shall recover the amount assessed (plus interest at currently prevailing rates from the date of the expiration of the 60-day period referred to in paragraph (6) or date of such final judgment, as the case may be) in an action brought in any appropriate district court of the United States. In such an action, the validity, amount, and appropriateness of such penalty shall not be subject to review.''.

(b) DIRECT-TO-CONSUMER ADVERTISEMENT.—

(1) IN GENERAL.—Section 502(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(n)) is amended by inserting after the first sentence the following: ''In the case of an advertisement for a prescription drug presented directly to consumers in television or radio format that states the name of the drug and its conditions of use, the major statement relating to side effects, contraindications, and effectiveness referred to in the previous sentence shall be stated in a clear and conspicuous (neutral) manner.''.

(2) REGULATIONS TO DETERMINE NEUTRAL MANNER.—The Secretary of Health and Human Services shall by regulation establish standards for determining whether a major statement, relating to side effects, contraindications, and effectiveness of a drug, described in section 502(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(n)) (as amended by paragraph (1)) is presented in the manner required under such section.

SA 1048. Ms. SNOWE submitted an amendment intended to be proposed by her to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ___. MARKETING OF CERTAIN CRUSTACEANS.

(a) IN GENERAL.—Notwithstanding any other provision of law, for purposes of the Federal Food, Drug, and, Costmetic Act (21 U.S.C. 301 et seq.) the term ''lobster'' may not be used to label or advertise the sale of any seafood product from the infraorder Garidea or Anomura.

(b) MISBRANDED FOOD.—Section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343) is amended by adding at the end the following:

(y) LOBSTER.—If it purports to be, or is represented as being, lobster but is from the infraorder Caridea or Anomura.''.

SA 1049. Mr. ENZI (for himself and Mr. KENNEDY) submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

Beginning on page 104, strike line 23 and all that follows through line 14 on page 105 and insert the following:

''(II) the amount equal to one-fifth of the excess amount in item (bb), provided that—

''(aa) the amount of the total appropriation for the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) exceeds the amount of the total appropriation for the Food and Drug Administration for fiscal year 2007 (excluding the amount of fees appropriated for such fiscal year), adjusted as provided under subsection (c)(1); and

''(bb) the amount of the total appropriations for the process of human drug review at the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) exceeds the amount of appropriations for the process of human drug review at the Food and Drug Administration for fiscal year 2007 (excluding the amount of fees appropriated for such fiscal year), adjusted as provided under subsection (c)(1).

In making the adjustment under subclause (II) for any fiscal year 2008 through 2012, subsection (c)(1) shall be applied by substituting '2007' for '2008.'''.

SA 1050. Mr. ENZI (for himself and Mr. KENNEDY) submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the end of the bill, add the following:

SEC. ___. COLOR CERTIFICATION REPORTS.

Section 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379e) is amended by adding at the end the following:

''(g) COLOR CERTIFICATION REPORTS.—Not later than—

''(1) 90 days after the close of a fiscal year in which color certification fees are collected, the Secretary shall submit to Congress a performance report for such fiscal year on the number of batches of color additives approved, the average turn around time for approval, and quantifiable goals for improving laboratory efficiencies; and

''(2) 120 days after the close of a fiscal year in which color certification fees are collected, the Secretary shall submit to Congress a financial report for such fiscal year that includes all fees and expenses of the color certification program, the balance remaining in the fund at the end of the fiscal year, and anticipated costs during the next fiscal year for equipment needs and laboratory improvements of such program.''.

SA 1051. Mr. STEVENS (for himself and Ms. MURKOWSKI) submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the end of the bill, add the following:

SEC. ___. CONSULTATION REGARDING GENETICALLY ENGINEERED SEAFOOD PRODUCTS.

The Commissioner of Food and Drugs shall consult with the Assistant Administrator of the National Marine Fisheries Service of the National Oceanic and Atmospheric Administration before granting final approval to use or produce a genetically engineered seafood product.

SA 1052. Mr. CORKER submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

''SEC. ___. PROHIBITION ON COMMINGLING.

''(a) IN GENERAL.—Notwithstanding any other provision of this Act (or an amendment made by this Act) a registered importer shall not commingle a prescription drug imported into the United States under this Act (or amendment) with another prescription drug, regardless of whether such other drug is a domestic prescription drug or a prescription drug from a permitted country.

''(b) LABEL.—A registered importer (including an Internet pharmacy) that dispenses a prescription drug imported from a permitted country shall affix on each dispensed container of the prescription drug the label required under subsection (c), unless such a label is already affixed to the container.

''(c) REQUIREMENTS.—Each prescription drug imported under this Act (or an amendment made by this Act) shall be in a container that bears a label stating, in prominent and conspicuous type—

''(1) the following statement: 'This drug has been imported from _____.' with the name of the permitted country from which the prescription drug has imported in the blank space; and

''(2) that the container complies with any other applicable requirement of this Act.''.

SA 1053. Mr. ENZI (for himself, Mr. KENNEDY, Mr. DODD, and Mrs. CLINTON) submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

On page 226, line 4, strike ''later'' and insert ''if the determination made under subsection (d)(3) is made less''.

On page 228, line 3, strike ''later'' and insert ''if the determination made under subsection (d)(3) is made less''.

On page 233, line 12, insert '', such as expertise in child and adolescent psychiatry,'' after ''expertise''.

On page 233, line 15, strike ''including'' and insert ''which may include''.

On page 233, between lines 18 and 19, insert the following:

''(C) ACTION BY COMMITTEE.—The committee established under this paragraph may perform a function under this section using appropriate members of the committee under subparagraph (B) and need not convene all members of the committee under subparagraph (B) in order to perform a function under this section.

''(D) DOCUMENTATION OF COMMITTEE ACTION.—The committee established under this

paragraph shall document for each function under paragraphs (2) and (3), which members of the committee participated in such function.

On page 234, line 1, strike ''determine'' and insert ''make a recommendation to the Secretary''.

On page 235, line 2, strike ''and''.

On page 235, line 6, strike ''.'';'' and insert ''; and''

On page 235, between lines 6 and 7, insert the following:

''(H) the number of times the committee established under paragraph (1) made a recommendation to the Secretary under paragraph (3), the number of times the Secretary did not follow such a recommendation to accept reports under subsection (d)(3), and the number of times the Secretary did not follow such a recommendation to reject such reports under section (d)(3).

''(5) COMMITTEE.—The committee established under paragraph (1) is the committee established under section 505B(f)(1).'';

On page 260, lines 17 through 19, strike ''of a letter, or a written request under section 505A that was declined by the sponsor or holder'' and insert ''of a written request under section 505A that was declined by the sponsor or holder, or a letter referencing such declined written request,''.

On page 261, line 3, strike ''appropriate'' and insert ''appropriate, for the labeled indication or indications,''.

On page 263, line 14, insert '', such as expertise in child and adolescent psychiatry,'' after ''expertise''

On page 263, between lines 19 and 20, insert the following and redesignate the remaining paragraphs accordingly:

''(2) ACTION BY THE COMMITTEE.—The committee established under paragraph (1) may perform a function under this section using appropriate members of the committee under paragraph (1) and need not convene all members of the committee under paragraph (1) in order to perform a function under this section.

''(3) DOCUMENTATION OF COMMITTEE ACTION.—For each drug or biological product, the committee established under this paragraph shall document for each function under paragraph (4) or (5), which members of the committee participated in such function.

On page 265, between lines 18 and 19, insert the following:

''(7) COMMITTEE.—The committee established under paragraph (1) is the committee established under section 505A(f)(1).

On page 289, line 16, strike ''**SURVEILLANCES**'' and insert ''**POSTMARKET SURVEILLANCE**''.

On page 289, line 17, strike ''SURVEILLANCES'' and insert ''SURVEILLANCE''.

On page 290, strike lines 9 through 12 and insert the following:

''(iii) that is intended to be—

''(I) implanted in the human body for more than 1 year; or

''(II) a life-sustaining or life-supporting device used outside a device user facility.

On page 290, line 15, strike ''of an'' and all that follows through ''section 510(k) only for'' on line 19, and insert ''or clearance of''.

SA 1054. Mr. FEINGOLD submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ___. PUBLICATION OF ANNUAL REPORTS.

(a) IN GENERAL.—The Commissioner on Food and Drugs shall annually submit to Congress and publish on the Internet website of the Food and Drug Administration, a report concerning the results of the Administration's pesticide residue monitoring program, that includes—

(1) information and analysis similar to that contained in the report entitled ''Food and Drug Administration Pesticide Program Residue Monitoring 2003'' as released in June of 2005;

(2) based on an analysis of previous samples, an identification of products or countries (for imports) that require special attention and additional study based on a comparison with equivalent products manufactured, distributed, or sold in the U.S. (including details on the plans for such additional studies), including in the initial report (and subsequent reports as determined necessary) the results and analysis of the Ginseng Dietary Supplements Special Survey as described on page 13 of the report entitled ''Food and Drug Administration Pesticide Program Residue Monitoring 2003'';

(3) information on the relative number of interstate and imported shipments of each tested commodity that were sampled, including recommendations on whether sampling is statistically significant, provides confidence intervals or other related statistical information, and whether the number of samples should be increased and the details of any plans to provide for such increase; and

(4) a description of whether certain commodities are being improperly imported as another commodity, including a description of additional steps that are being planned to prevent such smuggling.

(b) INITIAL REPORTS.—Annual reports under subsection (a) for fiscal years 2004 through 2006 may be combined into a single report, by not later than June 1, 2008, for purposes of publication under subsection (a). Thereafter such reports shall be completed by June 1 of each year for the data collected for the year that was 2-years prior to the year in which the report is published.

(c) MEMORANDUM OF UNDERSTANDING.—The Commissioner of Food and Drugs, the Administrator of the Food Safety and Inspection Service, the Department of Commerce, and the head of the Agricultural Marketing Service shall enter into a memorandum of understanding to permit inclusion of data in the reports under subsection (a) relating to testing carried out by the Food Safety and Inspection Service and the Agricultural Marketing Service on meat, poultry, eggs, and certain raw agricultural products, respectively.

SA 1055. Mr. LEVIN submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ___. SAFETY OF FOOD ADDITIVES.

Not later than 90 days after the date of enactment of this Act, the Food and Drug Administration shall issue a report on the question of whether substances used to preserve the appearance of fresh meat may create any health risks, or mislead consumers.

SA 1056. Mr. REED (for himself, and Mr. ISAKSON) submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ___. REPORT BY THE FOOD AND DRUG ADMINISTRATION REGARDING LABELING INFORMATION ON THE RELATIONSHIP BETWEEN THE USE OF INDOOR TANNING DEVICES AND DEVELOPMENT OF SKIN CANCER OR OTHER SKIN DAMAGE.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary''), acting through the Commissioner of Food and Drugs, shall determine—

(1) whether the labeling requirements for indoor tanning devices, including the positioning requirements, provide sufficient information to consumers regarding the risks that the use of such devices pose for the development of irreversible damage to the eyes and skin, including skin cancer; and

(2)(A) whether modifying the warning label required on tanning beds to read, ''Ultraviolet radiation can cause skin cancer'', or any other additional warning, would communicate the risks of indoor tanning more effectively; or

(B) whether there is no warning that would be capable of adequately communicating such risks.

(b) CONSUMER TESTING.—In making the determinations under subsection (a), the Secretary shall conduct appropriate consumer testing, using the best available methods for determining consumer understanding of label warnings.

(c) PUBLIC HEARINGS; PUBLIC COMMENT.—The Secretary shall hold public hearings and solicit comments from the public in making the determinations under subsection (a).

(d) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall submit to the Congress a report that provides the determinations under subsection (a). In addition, the Secretary shall include in the report the measures being implemented by the Secretary to significantly reduce the risks associated with indoor tanning devices.

SA 1057. Mr. GREGG submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

TITLE __—INTERNET PHARMACIES

SEC. __01. SHORT TITLE.

This title may be cited as the ''Safe Internet Pharmacy Act of 2007''.

SEC. __02. INTERNET PHARMACIES.

(a) INTERNET PHARMACIES.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 510 the following:

''SEC. 511. INTERNET PHARMACIES.

''(a) DEFINITIONS.—In this section:

''(1) ADVERTISING SERVICE PROVIDER.—The term 'advertising service provider' means an advertising company that contracts with a provider of an interactive computer service (as defined in section 230(f) of the Communications Act of 1934 (47 U.S.C. 230(f)) to provide advertising on the Internet.

''(2) DESIGNATED PAYMENT SYSTEM.—

''(A) IN GENERAL.—The term 'designated payment system' means a system used by a person described in subparagraph (B) to effect a credit transaction, electronic fund

transfer, or money transmitting service that the Board determines, by regulation or order, is regularly used in connection with, or to facilitate restricted transactions.

''(B) PERSONS DESCRIBED.—A person referred to in subparagraph (A) is—

''(i) a creditor;

''(ii) a credit card issuer;

''(iii) a financial institution;

''(iv) an operator of a terminal at which an electronic fund transfer may be initiated;

''(v) a money transmitting business; or

''(vi) a participant in an international, national, regional, or local network constructed primarily to effect a credit transaction, electronic fund transfer, or money transmitting service.

''(3) FEDERAL FUNCTIONAL REGULATOR.—The term 'Federal functional regulator' has the meaning given the term in section 509 of the Gramm-Leach-Bliley Act (15 U.S.C. 6809).

''(4) INTERNET PHARMACY.—The term 'Internet pharmacy' means a person that offers to dispense or dispenses in the United States a prescription drug through an Internet website in interstate commerce, regardless of whether the physical location of the principal place of business of the Internet pharmacy is in the United States or in another country.

''(5) PRESCRIPTION DRUG.—The term 'prescription drug' means a drug described in section 503(b) that is approved by the Secretary under section 505.

''(6) RESTRICTED TRANSACTION.—The term 'restricted transaction' means a transaction or transmittal, on behalf of a individual who places an unlawful Internet pharmacy request to any person engaged in the operation of an unlicensed Internet pharmacy, of—

''(A) credit, or the proceeds of credit, extended to or on behalf of the individual for the purpose of the unlawful Internet request (including credit extended through the use of a credit card);

''(B) an electronic fund transfer or funds transmitted by or through a money transmitting business, or the proceeds of an electronic fund transfer or money transmitting service, from or on behalf of the individual for the purpose of the unlawful Internet request;

''(C) a check, draft, or similar instrument which is drawn by or on behalf of the individual for the purpose of the unlawful Internet request and is drawn on or payable at or through any financial institution; or

''(D) the proceeds of any other form of financial transaction (identified by the Board by regulation) that involves a financial institution as a payor or financial intermediary on behalf of or for the benefit of the individual for the purpose of the unlawful Internet request.

''(7) TREATING PROVIDER.—The term 'treating provider' means a health care provider licensed in the United States who is authorized to prescribe medications and who—

''(A)(i) performs a documented patient evaluation (including a patient history and physical examination) of an individual, portions of which may be conducted by other health professionals;

''(ii) discusses with the individual the treatment options of the individual and the risks and benefits of treatment; and

''(iii) maintains contemporaneous medical records concerning the individual; or

''(B) provides care to an individual as part of an on-call or cross-coverage arrangement with a health care provider described in subparagraph (A).

''(8) UNLAWFUL INTERNET PHARMACY REQUEST.—The term 'unlawful Internet pharmacy request' means the request, or transmittal of a request, made to an unlicensed Internet pharmacy for a prescription drug by mail (including a private carrier), facsimile, telephone, or electronic mail, or by a means that involves the use, in whole or in part, of the Internet.

''(9) UNLICENSED INTERNET PHARMACY.—The term 'unlicensed Internet pharmacy' means an Internet pharmacy that is not licensed under this section.

''(10) OTHER DEFINITIONS.—

''(A) BOARD.—The term 'Board' means the Board of Governors of the Federal Reserve System.

''(B) CREDIT; CREDITOR; CREDIT CARD.—The terms 'credit', 'creditor', and 'credit card' have the meanings given the terms in section 103 of the Truth in Lending Act (15 U.S.C. 1602).

''(C) ELECTRONIC FUND TRANSFER.—The term 'electronic fund transfer'—

''(i) has the meaning given the term in section 903 of the Electronic Fund Transfer Act (15 U.S.C. 1693a); and

''(ii) includes any fund transfer covered under article 4A of the Uniform Commercial Code, as in effect in any State.

''(D) FINANCIAL INSTITUTION.—The term 'financial institution'—

''(i) has the meaning given the term in section 903 of the Electronic Transfer Fund Act (15 U.S.C. 1693a); and

''(ii) includes a financial institution (as defined in section 509 of the Gramm-Leach-Bliley Act (15 U.S.C. 6809)).

''(E) MONEY TRANSMITTING BUSINESS; MONEY TRANSMITTING SERVICE.—The terms 'money transmitting business' and 'money transmitting service' have the meanings given the terms in section 5330(d) of title 31, United States Code.

''(b) IN GENERAL.—An Internet pharmacy may only dispense or offer to dispense a prescription drug to a person in the United States in accordance with this section.

''(c) LICENSING OF INTERNET PHARMACIES.—

''(1) IN GENERAL.—An Internet pharmacy shall be licensed by the Secretary in accordance with this section prior to offering to dispense or dispensing a prescription drug to an individual.

''(2) CONDITIONS FOR LICENSING.—

''(A) APPLICATION REQUIREMENTS.—An Internet pharmacy shall submit to the Secretary an application that includes—

''(i)(I) in the case of an Internet pharmacy located in the United States, verification that, in each State in which the Internet pharmacy engages in dispensing or offering to dispense prescription drugs, the Internet pharmacy, and all employees and agents of the Internet pharmacy, is in compliance with applicable Federal and State laws regarding—

''(aa) the practice of pharmacy, including licensing laws and inspection requirements; and

''(bb) the manufacturing and distribution of controlled substances, including with respect to mailing or shipping controlled substances to consumers; or

''(II) in the case of an Internet pharmacy whose principal place of business is located outside the United States, verification that—

''(aa) all employees and agents of the Internet pharmacy are in compliance with applicable Federal and State laws regarding the practice of pharmacy, including licensing laws and inspection requirements;

''(bb) the Internet pharmacy is in compliance with applicable Federal and State laws regarding the practice of pharmacy, including licensing laws and inspection requirements;

''(cc) the Internet pharmacy expressly and affirmatively agrees to provide and maintain an agent for service of process in the United States;

''(dd) the Internet pharmacy expressly and affirmatively agrees to be subject to the jurisdiction of the United States and any of its States or territories where it engages in commerce; and

''(ee) the Internet pharmacy agrees to affix to each shipping container of drugs to be shipped in the United States such markings as the Secretary determines to be necessary to identify that the shipment is from a licensed Internet pharmacy, which may include anticounterfeiting or track-and-trace technologies;

''(ii) verification that the person that owns the Internet pharmacy has not had a license for an Internet pharmacy terminated by the Secretary, and that no other Internet pharmacy owned by the person has had a license under this subsection that has been terminated by the Secretary;

''(iii) verification from the person that owns the Internet pharmacy that the person will permit inspection of the facilities and business practices of the Internet pharmacy by the Secretary to the extent necessary to determine whether the Internet pharmacy is in compliance with this subsection;

''(iv) in the case of an agreement between a patient and an Internet pharmacy that releases the Internet pharmacy, and any employee or agent of the Internet pharmacy, from liability for damages arising out of the negligence of the Internet pharmacy, an assurance that such a limitation of liability shall be null and void;

''(v) verification that the Internet pharmacy expressly and affirmatively agrees to provide the Secretary with the identity of any providers of interactive computer services that provide host services or advertising services for the Internet pharmacy; and

''(vi) assurance that the Internet pharmacy will comply with the requirements under subparagraphs (B) and (C).

''(B) IDENTIFICATION REQUIREMENTS.—An Internet pharmacy shall post in a clear and visible manner, on each page of the website of the Internet pharmacy or by a link to a separate page, the following information:

''(i) The street address, city, ZIP Code or comparable mail code, State (or comparable entity), country, and telephone number of—

''(I) each place of business of the Internet pharmacy; and

''(II) the name of the supervising pharmacist of the Internet pharmacy and each individual who serves as a pharmacist for purposes of the Internet pharmacy website.

''(ii) The names of all States in which the Internet pharmacy and the pharmacists employed by the Internet pharmacy are licensed or otherwise authorized to dispense prescription drugs.

''(iii) If the Internet pharmacy makes referrals to, or solicits on behalf of, a health care practitioner or group of practitioners in the United States for prescription services—

''(I) the name, street address, city, ZIP Code or comparable mail code, State, and telephone number of the practitioner or group; and

''(II) the name of each State in which each practitioner is licensed or otherwise authorized to prescribe drugs.

''(iv) A statement that the Internet pharmacy will dispense prescription drugs only after receipt of a valid prescription from a treating provider.

''(v) A distinctive tamper resistant seal to identify that the Internet pharmacy is licensed.

''(C) PROFESSIONAL SERVICES REQUIREMENTS.—An Internet pharmacy shall carry out the following:

''(i) Maintain patient medication profiles and other related data in a readily accessible format organized to facilitate consultation with treating providers, caregivers, and patients.

''(ii) Conduct prospective drug use reviews before dispensing medications or medical devices.

''(iii) Ensure patient confidentiality and the protection of patient identity and patient-specific information, in accordance with the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996.

''(iv) Offer interactive and meaningful consultation by a licensed pharmacist to the caregiver or patient before and after the time at which the Internet pharmacy dispenses the drug.

''(v)(I) Establish a mechanism for patients to report errors and suspected adverse drug reactions.

''(II) Document in the reporting mechanism the response of the Internet pharmacy to those reports.

''(III) Submit those reports within 3 days of receipt and the response of the Internet pharmacy to the Food and Drug Administration in a manner determined appropriate by the Secretary.

''(vi) Develop a system to inform caregivers and patients about drug recalls.

''(vii) Educate caregivers and patients about the appropriate means of disposing of expired, damaged, or unusable medications.

''(viii) Assure that the sale of a prescription drug is in accordance with a valid prescription from the treating provider of the individual.

''(ix)(I) Verify the validity of the prescription of an individual by using 1 of the following methods:

''(aa) If the prescription for any drug other than a controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802)) is received from an individual or the treating provider of the individual by mail (including a private carrier), or from the treating provider of the individual by electronic mail, the validity of the prescription shall be confirmed in accordance with all applicable Federal and State laws.

''(bb) If the prescription is for a controlled substance (as defined in section 102 of the Controlled Substances Act), the validity of the prescription shall be confirmed with the treating provider as described in subclause (II).

''(II) When seeking verification of a prescription of an individual under subclause (I)(bb), an Internet pharmacy shall provide to the treating provider the following information:

''(aa) The full name and address of the individual.

''(bb) Identification of the prescription drug.

''(cc) The quantity of the prescription drug to be dispensed.

''(dd) The date on which the individual presented the prescription to the Internet pharmacy.

''(ee) The date and time of the verification request.

''(ff) The name of a contact person at the Internet pharmacy, including a voice telephone number, electronic mail address, and facsimile telephone number.

''(III) A prescription is verified under subclause (I)(bb) only if 1 of the following occurs:

''(aa) The treating provider confirms, by direct communication with the Internet pharmacy, that the prescription is accurate.

''(bb) The treating provider informs the Internet pharmacy that the prescription is inaccurate and provides the accurate prescription.

''(IV) An Internet pharmacy shall not fill a prescription if—

''(aa) a treating provider informs the Internet pharmacy within 72 hours after receipt of a communication under subclause (I)(bb) that the prescription is inaccurate or expired; or

''(bb) the treating provider does not respond within that time.

''(x) Maintain, for such period of time as the Secretary shall prescribe by regulation, a record of all direct communications with a treating provider regarding the dispensing of a prescription drug, including verification of the prescription.

''(3) LICENSURE PROCEDURE.—

''(A) ACTION BY SECRETARY.—On receipt of a complete licensing application from an Internet pharmacy under paragraph (2), the Secretary shall—

''(i) assign an identification number to the Internet pharmacy;

''(ii) notify the applicant of the receipt of the licensing application; and

''(iii) if the Internet pharmacy is in compliance with the conditions under paragraph (2), issue a license not later than 60 days after receipt of a licensing application from the Internet pharmacy.

''(B) ELECTRONIC FILING.—

''(i) IN GENERAL.—For the purpose of reducing paperwork and reporting burdens, the Secretary shall require the use of electronic methods of submitting to the Secretary a licensing application required under this section and provide for electronic methods of receiving the applications.

''(ii) AUTHENTICATION.—In providing for the electronic submission of such licensing applications under this section, the Secretary shall ensure that adequate authentication protocols are used to allow identification of the Internet pharmacy and validation of the data as appropriate.

''(4) DATABASE.—

''(A) IN GENERAL.—The Secretary shall compile, maintain, and periodically update a database of the Internet pharmacies licensed under this section.

''(B) AVAILABILITY.—The Secretary shall make the database described under subparagraph (A) and information submitted by the licensee under paragraph (2)(B) available to the public on an Internet website and through a toll-free telephone number.

''(5) FEES.—

''(A) IN GENERAL.—

''(i) LICENSING APPLICATION FEE.—The Secretary shall establish a licensing application fee to be paid by all applicants.

''(ii) RENEWAL FEE.—The Secretary shall establish a yearly renewal fee to be paid by all Internet pharmacies licensed under this section.

''(B) COLLECTION.—

''(i) COLLECTION OF LICENSING APPLICATION FEE.—A licensing application fee payable for the fiscal year in which the Internet pharmacy submits a licensing application, as established under subparagraph (C), shall be payable upon the submission to the Secretary of such licensing application.

''(ii) COLLECTION OF RENEWAL FEES.—After the licensing application fee is paid for the first fiscal year of licensure, the yearly renewal fee, as established under subparagraph (C), shall be payable on or before October 1 of each subsequent fiscal year.

''(iii) ONE FEE PER INTERNET PHARMACY.—The licensing application fee and yearly renewal fee shall be paid only once for each Internet pharmacy for a fiscal year in which the fee is payable.

''(iv) EXCESS FEES.—Any amount collected by the Secretary under this paragraph for a fiscal year that is in excess of the costs of enforcing the requirements of this section for such fiscal year shall be deposited in the Treasury.

''(C) FEE AMOUNT.—The amount of the licensing application fee and the yearly renewal fee for an Internet pharmacy shall be determined each year by the Secretary based on 133 percent of the anticipated costs to the Secretary of enforcing the requirements of this section in the subsequent fiscal year.

''(D) ANNUAL FEE DETERMINATION.—

''(i) IN GENERAL.—Not later than 60 days before the beginning of each fiscal year beginning after September 30, 2007, the Secretary shall determine the amount of the licensing application fee and the yearly renewal fee for that fiscal year.

''(ii) PUBLICATION OF FEE AMOUNT.—Not later than 60 days before each fiscal year, the Secretary shall publish the amount of the licensing application fee and the yearly renewal fee under this section for that fiscal year and provide for a period of 30 days for the public to provide written comments on the fees.

''(E) USE OF FEES.—The fees collected under this section shall be used, without further appropriation, to carry out this section.

''(F) FAILURE TO PAY FEE.—

''(i) DUE DATE.—A fee payable under this section shall be paid by the date that is 30 days after the date on which the fee is due.

''(ii) FAILURE TO PAY.—If an Internet pharmacy subject to a fee under this section fails to pay the fee by the date specified under clause (i), the Secretary shall not permit the Internet pharmacy to engage in the dispensing of drugs as described under this section until all such fees owed by the Internet pharmacy are paid.

''(G) REPORTS.—Beginning with fiscal year 2008, not later than 60 days after the end of each fiscal year during which licensing application fees are collected under this section, the Secretary 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 that describes—

''(i) implementation of the licensing fee authority during the fiscal year; and

''(ii) the use by the Secretary of the licensing fees collected during the fiscal year for which the report is made.

''(6) SUSPENSION.—

''(A) IN GENERAL.—If the Secretary determines that an Internet pharmacy is engaged in a pattern of violations of any of the requirements of this Act, the Secretary may immediately order the suspension of the license of the Internet pharmacy.

''(B) APPEAL OF SUSPENSION ORDER.—An Internet pharmacy subject to a suspension order under subparagraph (A) may appeal the suspension order to the Secretary. Not later than 30 days after an appeal is filed, the Secretary, after providing opportunity for an informal hearing, shall affirm or terminate the order.

''(C) FAILURE TO ACT.—If, during the 30-day period specified in subparagraph (B), the Secretary fails to provide an opportunity for a hearing or to affirm or terminate the order, the order shall be deemed to be terminated.

''(D) NO JUDICIAL REVIEW.—An order under this paragraph shall not be subject to judicial review.

''(7) TERMINATION OF LICENSE.—The Secretary may terminate a license issued under this subsection, after notice to the Internet pharmacy and an opportunity for a hearing, and if the Secretary determines that the Internet pharmacy—

''(A) has demonstrated a pattern of noncompliance with this section;

''(B) has made an untrue statement of material fact in its licensing application; or

''(C) is in violation of any applicable Federal or State law relating to the dispensing of a prescription drug.

''(8) RENEWAL EVALUATION.—

''(A) IN GENERAL.—Before renewing a license of an Internet pharmacy under this subsection, the Secretary shall conduct an

evaluation to determine whether the Internet pharmacy is in compliance with this section.

''(B) EVALUATION OF INTERNET PHARMACIES.—At the discretion of the Secretary and as applicable, an evaluation under subparagraph (A) may include testing of the Internet pharmacy website or other systems through which the Internet pharmacy communicates with consumers, and a physical inspection of the records and premises of the pharmacy.

''(9) CONTRACT FOR OPERATION OF PROGRAM.—

''(A) IN GENERAL.—The Secretary may award a contract under this subsection for the operation of the licensing program.

''(B) TERM.—The duration of a contract under subparagraph (A) shall not exceed 5 years and may be renewable.

''(C) PERFORMANCE REVIEW.—The Secretary shall annually review performance under a contract under subparagraph (A).

''(d) PROVIDERS OF INTERACTIVE COMPUTER SERVICES OR ADVERTISING SERVICES.—No provider of interactive computer services (as defined in section 230(f) of the Communications Act of 1934 (47 U.S.C. 230(f)) or an advertising service provider shall be liable under this section on account of another person's selling or dispensing of a prescription drug, so long as the provider of the interactive computer service or the advertising service provider does not own or exercise corporate control over such person.

''(e) POLICIES AND PROCEDURES REQUIRED TO PREVENT PAYMENTS FOR UNLAWFUL INTERNET PHARMACY REQUESTS.—

''(1) REGULATIONS.—Not later than 180 days after designating a system under subsection (a)(2), the Board shall promulgate regulations that require—

''(A) an operator of a credit card system that is a designated payment system, an operator of an international, national, or local network used to effect a credit transaction, electronic fund transfer, or money transmitting service that is a designated payment system, and an operator of any other designated payment system specified by the Board that is centrally managed and is primarily engaged in the transmission and settlement of credit transactions, electronic transfers, or money transmitting services where at least 1 party to the transaction or transfer is an individual; and

''(B) in the case of a designated payment system, other than a designated payment system described in subparagraph (A), a person described in subsection (a)(2)(B);

to establish policies and procedures that are reasonably designed to prevent the introduction of restricted transactions into a designated payment system or the completion of restricted transactions using a designated payment system.

''(2) REQUIREMENTS FOR POLICIES AND PROCEDURES.—In promulgating regulations under paragraph (1), the Board shall—

''(A) identify types of policies and procedures, including nonexclusive examples, that shall be considered to be reasonably designed to identify and reasonably designed to prevent the introduction of a restricted transaction in a designated payment or the completion of restricted transactions using a designated payment system; and

''(B) to the extent practicable, permit any designated payment system, or person described in subsection (a)(2)(B), as applicable, to choose among alternative means of preventing the introduction or completion of restricted transactions.

''(3) NO LIABILITY FOR BLOCKING OR REFUSING TO HONOR RESTRICTED TRANSACTION.—

''(A) IN GENERAL.—A designated payment system, or a person described in subsection (a)(2)(B), that is subject to a regulation or an order issued under this subsection, and any participant in such payment system, that—

''(i) prevents or otherwise refuses to honor restricted transactions, in an effort to implement the policies and procedures required under this subsection or to otherwise comply with this section, shall not be liable to any party for such action; and

''(ii) prevents or otherwise refuses to honor a nonrestricted transaction in an effort to implement the policies and procedures under this subsection or to otherwise comply with this section, shall not be liable to any party for such action.

''(B) COMPLIANCE WITH THIS SUBSECTION.—A person described in subsection (a)(2)(B) meets the requirements of this subsection, if any, if the person relies on and complies with the policies and procedures of a designated payment system of which the person is a member or in which the person is a participant, and such policies and procedures of the designated payment system comply with the requirements of the regulations under paragraph (1)(B).

''(4) ENFORCEMENT.—

''(A) IN GENERAL.—This subsection shall be enforced by the Federal functional regulators and the Federal Trade Commission under applicable law in the manner provided in section 505(a) of the Gramm-Leach-Bliley Act (21 U.S.C. 6805(a)).

''(B) FACTORS TO BE CONSIDERED.—In considering any enforcement action under this subsection against a payment system or person described in subsection (a)(2)(B), the Federal functional regulators and the Federal Trade Commission shall consider the following factors:

''(i) The extent to which the payment system or person knowingly permits restricted transactions.

''(ii) The history of the payment system or person in connection with permitting restricted transactions.

''(iii) The extent to which the payment system or person has established and is maintaining policies and procedures in compliance with regulations prescribed under this subsection.

''(iv) The feasibility that any specific remedy prescribed can be implemented by the payment system or person without substantial deviation from normal business practice.

''(v) The costs and burdens the specific remedy will have on the payment system or person.

''(f) REPORTS REGARDING INTERNET-RELATED VIOLATIONS OF FEDERAL AND STATE LAWS ON DISPENSING OF DRUGS.—The Secretary shall, pursuant to the submission of an application meeting criteria prescribed by the Secretary, make an award of a grant or contract to an entity with experience in developing and maintaining systems for the purpose of—

''(1) identifying Internet pharmacy websites that are not licensed or that appear to be operating in violation of Federal or State laws concerning the dispensing of drugs;

''(2) reporting such Internet pharmacy websites to State medical licensing boards and State pharmacy licensing boards, and to the Attorney General and the Secretary, for further investigation; and

''(3) submitting, for each fiscal year for which the award under this subsection is made, a report to the Secretary describing investigations undertaken with respect to violations described in paragraph (1).

''(g) TRANSACTIONS PERMITTED.—A designated payment system or person subject to a regulation or an order issued under subsection (e) may engage in transactions with licensed and unlicensed Internet pharmacies in connection with investigating violations or potential violations of any rule or requirement adopted by the payment system or person in connection with complying with subsection (e). A person subject to a regulation or an order issued under subsection (e) and the agents and employees of that person shall not be found to be in violation of, or liable under, any Federal, State, or other law for engaging in any such transaction.

''(h) RELATION TO STATE LAWS.—No requirement, prohibition, or liability may be imposed on a designated payment system or person subject to a regulation or an order issued under subsection (e) under the laws of any State with respect to any payment transaction by an individual because the payment transaction involves a payment to an Internet pharmacy.

''(i) TIMING OF REQUIREMENTS.—A designated payment system or a person subject to a regulation under subsection (e) shall adopt policies and procedures reasonably designed to comply with any regulations required under subsection (e) not later than 180 days after the date on which such final regulations are issued.''.

(b) PROHIBITED ACTS.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following:

''(hh)(1) The sale, under section 511, of a drug that is not a prescription drug, the sale of such a prescription drug without a valid prescription from a treating provider, or the ownership or operation of an Internet pharmacy, in violation of section 511.

''(2) The representation by advertisement, sales presentation, direct communication (including telephone, facsimile, or electronic mail), or otherwise by an Internet pharmacy, that a prescription drug may be obtained from the Internet pharmacy without a prescription, in violation of section 511.

''(3) The advertisement related to a prescription drug through any media including sales presentation, direct communication (including telephone, facsimile, or electronic mail), by an unlicensed Internet pharmacy.

''(4) The provision of an untrue statement of material fact in the licensing application of an Internet pharmacy.

''(5) For purposes of this subsection, any term used in this subsection that is also used in section 511 shall have the meaning given that term in section 511.''.

(c) LINKS TO UNLICENSED INTERNET PHARMACIES.—Section 302 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 332) is amended by adding at the end the following:

''(c)(1) In the case of a violation of section 511 relating to an unlicensed Internet pharmacy (as defined in such section 511), the district courts of the United States and the United States courts of the territories shall have jurisdiction to order a provider of an interactive computer service to remove, or disable access to, links to a website violating that section that resides on a computer server that the provider controls or operates.

''(2) Relief under paragraph (1)—

''(A) shall be available only after provision to the provider of notice and an opportunity to appear;

''(B) shall not impose any obligation on the provider to monitor its service or to affirmatively seek facts indicating activity violating section 511;

''(C) shall specify the provider to which the relief applies; and

''(D) shall specifically identify the location of the website to be removed or to which access is to be disabled.''.

(d) REGULATIONS.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this title, the Secretary of Health and Human Services shall promulgate interim final regulations to carry out the amendments made by this section.

(2) EFFECTIVE DATE.—The requirement of licensure under section 511 of the Federal Food, Drug, and Cosmetic Act (as added by this section) shall take effect on the date determined by the Secretary of Health and Human Services but in no event later than 90 days after the effective date of the interim final regulations under paragraph (1).

(e) PENALTIES.—Section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333) is amended by adding at the end the following:

''(g) Notwithstanding subsection (a), any person who knowingly violates paragraph (1), (2), (3), or (4) of section 301(hh) shall be imprisoned for not more than 10 years or fined in accordance with title 18, United States Code, or both.''.

SA 1058. Mr. DEMINT (for himself, Mr. COBURN, and Mr. MARTINEZ) submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ___. SENSE OF THE SENATE REGARDING CERTAIN PATENT INFRINGEMENTS.

(a) FINDINGS.—The Senate makes the following findings:

(1) The value of American innovation in developing life-saving prescription drugs saves millions of lives around the world each year.

(2) The protection of intellectual property is vital to the continued development of new and life-saving drugs and future growth of the United States economy.

(3) In order to maintain the global competitiveness of the United States, the United States Trade Representative's Office of Intellectual Property and Innovation develops and implements trade policy in support of vital American innovations, including innovation in the pharmaceutical and medical technology industries.

(4) The United States Trade Representative also provides trade policy leadership and expertise across the full range of interagency initiatives to enhance protection and enforcement of intellectual property rights.

(5) When other countries do not respect the intellectual property of American drug companies, all patients suffer because of diminished incentives to develop new life-saving medications and the American economy is unfairly harmed.

(6) Strong intellectual property protection, including patent, copyright, trademark, and data protection plays an integral role in fostering economic growth and development and ensuring patient access to the most effective medicines around the world.

(7) Certain countries have engaged in unfair price manipulation and abuse of compulsory licensing. This results in Americans bearing the majority of research and development costs for the world, undermines the value of existing United States pharmaceutical patents and could impede access to important therapies.

(8) There is a growing global threat of counterfeit medicines and increased need for the United States Trade Representative and other United States agencies to use available trade policy measures to strengthen laws and enforcement abroad to prevent harm to United States patients and patients around the world.

(b) SENSE OF THE SENATE.—It is the sense of the Senate that—

(1) the United States Trade Representative should use all the tools at the disposal of the Trade Representative to deal with violations of intellectual property rights, including—

(A) bilateral engagement with United States trading partners;

(B) transparency of the annual ''Special 301'' review and reviews of compliance with the intellectual property requirements of countries with respect to which the United States grants trade preferences;

(C) negotiation of intellectual property provisions as part of bilateral and regional trade agreements; and

(D) multilateral engagement through the World Trade Organization (WTO); and

(2) the United States Trade Representative should develop and implement a strategic plan to address the problem of countries that infringe upon American pharmaceutical intellectual property rights and the problem of countries that engage in price manipulation.

SA 1059. Mr. SESSIONS (for himself, Mrs. LINCOLN, Mr. COCHRAN, Mr. PRYOR, Mr. LOTT, and Mr. SHELBY) submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ___. ENHANCED AQUACULTURE AND SEAFOOD INSPECTION.

(a) FINDINGS.—Congress finds the following:

(1) In 2007, there has been an overwhelming increase in the volume of aquaculture and seafood that has been found to contain substances that are not approved for use in food in the United States.

(2) As of May 2007, inspection programs are not able to satisfactorily accomplish the goals of ensuring the food safety of the United States.

(3) To protect the health and safety of consumers in the United States, the ability of the Secretary of Health and Human Services to perform inspection functions must be enhanced.

(b) HEIGHTENED INSPECTIONS.—

(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall, by regulation, enhance, as necessary, the inspection regime of the Food and Drug Administration for aquaculture and seafood, consistent with obligations of the United States under international agreements and United States law.

(2) CONTENT.—The Secretary shall ensure that the regulations promulgated under paragraph (1) to enhance the inspection regime—

(A) ensure that aquaculture and seafood products are not contaminated with substances that are not approved for use in food in the United States;

(B) include the authority to refuse imports of such products from a foreign facility if a requested inspection of the foreign facility is refused or unnecessarily delayed;

(C) take into account whether the United States has a cooperative agreement regarding aquaculture and seafood inspection; and

(D) provide for an assessment of the risk associated with particular contaminants.

(c) REPORT TO CONGRESS.—Not later than 90 days after the date of enactment of this Act, the Secretary shall submit to Congress a report that describes—

(1) the specifics of the aquaculture and seafood inspection program; and

(2) the feasibility of developing a traceability system for all catfish and seafood products, both domestic and imported, for the purpose of identifying the processing plant of origin of such products.

(d) PARTNERSHIPS WITH STATES.—Upon the request by any State, the Secretary may enter into partnership agreements, as soon as practicable after the request is made, to implement inspection programs regarding the importation of aquaculture and seafood.

(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary to carry out this section.

SA 1060. Mr. HATCH (for himself and Mr. KENNEDY) submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ___. FOOD AND DRUG ADMINISTRATION FUNDING SUBMISSION.

Subchapter A of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371 et seq.), as amended by this Act, is amended by adding at the end the following:

''SEC. 714. FOOD AND DRUG ADMINISTRATION FUNDING SUBMISSION.

''For each of fiscal years 2009 through 2013, the Commissioner of Food and Drugs shall prepare and submit, directly to the President for review and transmittal to Congress, an annual Food and Drug Administration funding submission estimate (including the number and type of personnel needs for the Food and Drug Administration), after reasonable opportunity for comment (but without change) by the Secretary.''.

NOTICE OF HEARING

SUBCOMMITTEE ON PUBLIC LANDS AND FORESTS

Mr. BINGAMAN. Mr. President, I would like to announce for the information of the Senate and the public that a hearing has been scheduled before the Subcommittee on Public Lands and Forests of the Committee on Energy and Natural Resources.

The hearing will be held on Wednesday, May 30, at 12 p.m. in the Medford City Council Chambers at 411 West 8th Street in Medford, Oregon.

The purpose of the hearing is to receive testimony on the impacts of the Chinese hardwood plywood trade on the National Forest System and other public lands, and the communities that depend on them.

Because of the limited time available for the hearing, witnesses may testify by invitation only. However, those wishing to submit written testimony for the hearing record should send it to the Committee on Energy and Natural Resources, United States Senate, Washington, DC 20510–6150, or by e-mail to rachel_pasternack@energy.senate.gov.

For further information, please contact Scott Miller at (202) 224–5488 or Rachel Pasternack at (202) 224–0883.

UNANIMOUS-CONSENT AGREEMENT—EXECUTIVE CALENDAR

Mr. BROWN. Mr. President, I ask unanimous consent that at 11:50 tomorrow, the Senate proceed to executive

session to consider Executive Calendar No. 84, the nomination of Frederick J. Kapala to be a U.S. district judge, there be 20 minutes of debate equally divided between the chairman and ranking member of the Judiciary Committee or their designees, and at the conclusion or yielding back of time, the Senate vote without any intervening action on the nomination; that the motion to reconsider be laid on the table, the President be immediately notified of the Senate's action, and the Senate then return to legislative session.

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

ORDER FOR STAR PRINT—S. 1138

Mr. BROWN. I ask unanimous consent that S. 1138 be star printed with the changes at the desk.

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

BY SENATE LEGAL COUNSEL AUTHORIZATION

Mr. BROWN. I ask unanimous consent that the Senate proceed to the immediate consideration of S. Res. 189 submitted earlier today.

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

The legislative clerk read as follows:

A resolution (S. Res. 189) to authorize testimony and legal representation in the District of Columbia v. Ellen E. Barfield, Eve-Leona Tetaz, Jeffrey A. Leys, and Jerome A. Zawada.

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

Mr. REID. Mr. President, this resolution concerns a request for testimony and representation in actions pending in the Superior Court for the District of Columbia. In these actions, anti-war protesters have been charged with unlawful assembly for refusing repeated requests to leave Senator MCCAIN's Washington, DC., office on or about February 5, 2007. Trials of these defendants are scheduled to commence on May 11, 2007. The prosecution has requested that a member of the Senator's staff who had conversations with the defendants during the events in question testify in this case. Senator MCCAIN would like to cooperate by providing testimony from his staff. This resolution would authorize that staff member, and any other employee of Senator MCCAIN's office from whom evidence may be required, to testify in this action, with representation by the Senate Legal Counsel.

Mr. BROWN. I ask unanimous consent that the resolution be agreed to, the preamble agreed to, the motion to reconsider be laid upon the table, and that any statements relating thereto be printed in the RECORD.

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

The resolution (S. Res. 189) was agreed to.

The preamble was agreed to.

The resolution, with its preamble, reads as follows:

S. RES. 189

Whereas, in the cases of District of Columbia v. Ellen E. Barfield (Cr. No. 07–3133), Eve-Leona Tetaz (Cr. No. 07–3144), Jeffrey A. Leys (Cr. No. 07–5009), and Jerome A. Zawada (Cr. No. 07–5088), pending in the Superior Court for the District of Columbia, testimony has been requested from Katie Landi, an employee in the office of Senator John McCain;

Whereas, pursuant to sections 703(a) and 704(a)(2) of the Ethics in Government Act of 1978,2 U.S.C. §§288b(a) and 288c(a)(2), the Senate may direct its counsel to represent employees of the Senate with respect to any subpoena, order, or request for testimony relating to their official responsibilities;

Whereas, by the privileges of the Senate of the United States and Rule XI of the Standing Rules of the Senate, no evidence under the control or in the possession of the Senate may, by the judicial or administrative process, be taken from such control or possession but by permission of the Senate;

Whereas, when it appears that evidence under the control or in the possession of the Senate may promote the administration of justice, the Senate will take such action as will promote the ends of justice consistent with the privileges of the Senate: Now, therefore, be it

Resolved, That Katie Landi and any other employees of Senator McCain's office from whom testimony may be required are authorized to testify in the cases of District of Columbia v. Ellen E. Barfield, Eve-Leona Tetaz, Jeffrey A. Leys, and Jerome A. Zawada, except concerning matters for which a privilege should be asserted.

SEC. 2. The Senate Legal Counsel is authorized to represent Katie Landi and other employees of Senator McCain's staff in the actions referenced in section one of this resolution.

EXPRESSING CONDOLENCES TO GREENSBURG, KS

Mr. BROWN. I ask unanimous consent that the Senate now proceed to the consideration of S. Res. 190 which was submitted earlier today.

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

The legislative clerk read as follows:

A resolution (S. Res. 190) expressing the condolences of the Nation to the community of Greensburg, Kansas.

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

Mr. BROWN. I ask unanimous consent that the resolution be agreed to, the preamble be agreed to, and the motion to reconsider be laid upon the table.

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

The resolution (S. Res. 190) was agreed to.

The preamble was agreed to.

The resolution, with its preamble, reads as follows:

S. RES. 190

Whereas, on Friday, May 4, 2007, a tornado struck the community of Greensburg, Kansas;

Whereas this tornado was classified as an EF-5, the strongest possible type, by the National Weather Service, with winds estimated at 205 miles per hour;

Whereas the tornado is the first EF-5 on the Enhanced Fujita scale, and the first F-5 on the previous scale since 1999;

Whereas approximately 95 percent of Greensburg is destroyed;

Whereas 1,500 residents have been displaced from their homes; and

Whereas, in response to the declaration by the President of a major disaster, the Administrator of the Federal Emergency Management Agency has made Federal disaster assistance available for the State of Kansas to assist in local recovery efforts: Now, therefore, be it

Resolved, That the Senate expresses the condolences of the Nation to the community of Greensburg, Kansas, and its gratitude to local, State, and National law enforcement and emergency responders conducting search and rescue operations.

MEASURE READ THE FIRST TIME

Mr. BROWN. I understand that S. 1312, introduced earlier today by Senator DEMINT and others, is at the desk, and I ask for its first reading.

The PRESIDING OFFICER. The clerk will read the bill by title for the first time.

The legislative clerk read as follows:

A bill (S. 1312) to amend the National Labor Relations Act to ensure the right of employees to a secret-ballot election conducted by the National Labor Relations Board.

Mr. BROWN. I now ask for its second reading and object to my own request.

The PRESIDING OFFICER. Objection is heard.

ORDERS FOR TUESDAY, MAY 8, 2007

Mr. BROWN. Mr. President, I ask unanimous consent that when the Senate completes its business today, it stand adjourned until 10 a.m., Tuesday, May 8; that on Tuesday, following the prayer and pledge, the Journal of proceedings be approved to date, the morning hour be deemed expired, and the time for the two leaders reserved for their use later in the day; that there then be a period of morning business for 60 minutes, with Senators permitted to speak therein for up to 10 minutes each, with the first half under the control of the majority and the second half under the control of the Republicans; that at the close of morning business, the Senate resume consideration of S. 1082; that on Tuesday, following the vote on the judicial nomination, the Senate stand in recess until 2:15 p.m., in order to accommodate the regular party conference meetings; that all time during any recess, adjournment, and period of morning business count postcloture, and that any time used in morning business by any Member be charged against their hour postcloture; provided further that Members have until 10:30 a.m. Tuesday to file any second-degree amendments, notwithstanding rule XXII.

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

ORDER FOR ADJOURNMENT

Mr. BROWN. If there is no further business to come before the Senate today, I ask unanimous consent that the Senate stand adjourned under the previous order, following the remarks of the Senator from Alabama.

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

The Senator from Alabama.

IMMIGRATION REFORM

Mr. SESSIONS. Mr. President, I hope we are not moving forward with a plan that would introduce the immigration bill we considered in the Senate last year. That is what I am hearing. I believe there are talks ongoing today—bipartisan talks—talks in which the White House and other members of the President's Cabinet are participating where they are at least talking about a framework of a comprehensive immigration reform of which we could be proud.

The bill that was introduced last year was fatally flawed. It was not the kind of legislation we should have passed. If it had been passed, it would never have worked and would have been an embarrassment to the Senate. I cannot say how strongly I believe that to be true. There was no way we could repair that bill by amendment. I talked about that last year. It was important that we start over with a new piece of legislation. We worked on it, and a majority of the Republicans in the Senate, last year, voted against the bill. The House refused to even consider it. They would not take it up. Four Democrats voted against the bill last year.

So the only way to enact comprehensive immigration legislation is to start over and write a new bill on which both the Democrats and a majority of Republicans can agree. Until this week, I had hopes that was ongoing. I have not been in the detailed negotiations, but I have been briefed on some of the framework for reform that, to me, is very consistent with what I pleaded with my colleagues last year to do.

Now, over the past several weeks, up to 10 Members of the Senate have been actively meeting to write a new bill. They started with the principles laid out by the White House in a 23-page Powerpoint that promptly got leaked. Maybe they wanted it leaked. I don't know. Those Powerpoints just have one or two lines. They do not have fine print. But they do set fourth agenda items and principles.

The principles laid out in that Powerpoint are much closer to a bill I could support and I think the American people would be willing to support.

This is what they included in that presentation. Although I am not involved in the details, I think it is what Members are discussing at this moment—have been discussing, at least. Apparently, people periodically walk away from the discussions, and they say this isn't good enough or I don't like this, but that is negotiation, hopefully, and we can work forward with it. Let me just tell you some of the things that are in this bill that were not in last year's legislation.

There is an enforcement trigger. Before any new immigration programs or green card adjustments could begin, the principles in the Powerpoint would require an ''enforcement trigger'' to be met. Senator ISAKSON from Georgia offered that. He basically said: We are not going to trust you this time—the American people are not. We want to see that you follow through on the things that are critical to a lawful immigration system before we pass the green card adjustments and deal with those other issues.

It also requires that the Border Patrol be increased to the numbers agreed upon—with a total of 18,300. It is one thing to say we are going to authorize 18,000 Border Patrol agents, which I think is a minimum, really not sufficient to cover the border—but it is an increase of significance. We are not going to go forward with the bill until you actually hire them and put them on the payroll and train them and they are out there.

Also, 200 miles of vehicle barriers and 370 miles of fencing must be constructed. We talked about that, and I offered the amendment. It passed several times and eventually was passed last year.

The catch and release at the border must be ended. This idea of catching people at the border who have violated our immigration laws and have come into the country illegally—they are being taken inland, taken before some administrative officer or judge and released on bail and asked to come back. Well, 95 percent are not showing up. That is what they wanted to do: to be brought into America. They were released on bail. Nobody ever went out and found them or looked for them. It is just a broken system. It is not working. Those are things that are part of the trigger as to what has to be fixed before we go forward with the legislation. That would be in the principles.

The future flow of temporary workers is critical. As to the future flow temporary worker program, the so-called Y visas—the principles outline a new program for truly temporary workers. The White House plan would admit new workers for 2 years and could be renewed three times, for a total of 6 years.

Between each 2-year period, workers would be required to return to their home countries for 6 months. Workers could not bring their spouses or their children but could return home to visit them if they choose. They would be able to go back and forth as often as they liked. There is no cap specified in the White House plan, but the plan envisions an annual cap set by the Secretary of Homeland Security in consultation with the Secretaries of Labor and Commerce, depending on American needs.

Workers would be eligible to apply for green cards through regular channels. Regular channels are adjusted to a more merit-based system. It would include a merit-based system. I think this is a great improvement over last year's legislation. But I have to tell you, I am concerned about people coming to stay more than 1 year because I think it becomes more and more difficult for them to leave. They are less likely to leave. Many of them are more likely to violate the law and just embed and stay. I think a 1-year plan would be far better. But those are things that are being talked about which would be substantially better than last year's legislation.

There is a seasonal worker program that makes much more sense than what was in last year's bill. The principles also contain a ''new and improved'' seasonal worker program that would combine the current agricultural—the H–2A plan—and unskilled—H–2B—seasonal worker programs. We combine those two programs, as they should be combined, because they are each for temporary workers.

Workers could remain in this country for 9 months at a time, under this proposal, and would be required to return to their home countries for 3 months in between. This is a temporary worker program that appears to be actually temporary, unlike last year's legislation, in which the temporary guest worker program in last year's immigration bill said an individual could come to this country temporarily, but they could bring their wife and children. They could come for 3 years. That 3 years could be extended again and again and again. And they could apply for citizenship within the first year they got here. That was the temporary worker program last year. How broken was that? It would never have worked. People bring their children, they get settled in the country, a decade goes by. Who is going to be able to ask them to leave? What kind of painful scene would that be? Teachers, preachers, family members, neighbors—they have gotten to know people. They have a whole new mindset, an incorrect mindset.

The bill, last year, said ''temporary guest worker program,'' and this is what it was. It was really a permanent entry into the country for very extended periods of time where it could be difficult for people to leave.

Under this plan, the outline that is being discussed, they could actually work—and it is what I suggested last year—and spouses and children would remain in the worker's home country.

Renewals under the seasonal program would be unlimited, which may be problematic. We would need to discuss that some.

But these workers would also be eligible to apply for green cards under regular channels, if they are willing to compete against others on a merit-

based basis to see whether or not they could come.

Then the principles focus on a more merit-based entry policy into the United States. The principles I hear being discussed would eliminate the Diversity Visa Lottery and some chain migration categories, such as brothers and sisters and adult siblings of U.S. citizens.

Green cards that have been given out for those individuals would be transferred over to a point system which selects legal permanent resident applicants based on merit. So I am concerned that the White House plan also appears to increase the total number of green cards available each year. Page 21 of the Powerpoint indicates that 1.4 million green cards would be available each year. We are at about 1 million now. That would be a 40-percent increase. I want to look at that carefully. But I like the idea of the entry being based on a more meritorious program.

They have a plan to clear the current backlog of green card applications, which also has dangers in that it could substantially increase the number of people who would come. I am not sure comprehensive immigration reform is designed to increase—at least the American people have an idea that it is designed to increase dramatically the number of people who come legally today. I don't think that is what most people have in mind when they think about immigration reform.

What about the population that is here today illegally? This plan that is being discussed would have given legal status to illegal aliens currently in the country through a new ''Z'' visa, which would be renewable indefinitely. Those holding Z visas will be eligible to apply for green cards through regular channels after they go back, ''touchback,'' across the border. But regular channels are adjusted to a more merit-based system. So they would have to compete with people who have other qualities and merits that may make them less likely to be admitted.

If these principles are the ones that form the framework for a newly drafted, bipartisan bill, then I think it is possible that we could successfully enact immigration reform this year.

Now, I cannot tell you that I am going to be able to vote for this plan in the end because I intend to read the fine print. That is what I learned last year. The rubric, the caption in the bill last year was ''temporary guest worker program'' in big print right in the middle of the bill. Then, when you read it, what did you find? We found that the individuals came here for 3 years, with their family, and they could reup, reup for 3 years, time and time again, and, frankly were never going to leave this country.

It was not a temporary guest worker program at all. It was a scheme to confuse the American people about the real meaning of it. In fact, I think it confused Senators. I think they thought it was a temporary worker program, and it absolutely was not. It would never have worked. But the people who wrote it—I think that was their plan. They never wanted it to work to begin with. That is the true fact about it. So the fine print could contain things that will not work.

So I think the framework, the outline, if we are honest and serious, could be the basis for a historic reform of immigration that could actually work, that we could actually be proud of. It is possible. But there are forces, special interests that are driving this process, and they do not respect the views of the American people. They want to ram it through on their terms, and they want to have it say what they want it to say.

This is what the news reports are saying, and I am getting very concerned about it. It is now being reported that instead of being patient and waiting for this new bipartisan bill to be completed and actually written up so people can read it, the majority leader, Senator REID, is forcing the immigration bill to this floor Wednesday, May 9, the day after tomorrow. According to Roll Call, this morning:

> According to an aide to Reid, the Majority leader is expected to bring up the . . . package passed by the Judiciary Committee last year . . . if negotiations produce a deal he will allow lawmakers to propose it as a substitute amendment. . . .

Now, this plan is not a wise approach. Why do we want to bring up a piece of legislation that is fatally flawed, that should never, ever become law? I see no reason. I have one idea, though, or one suspicion I am going to discuss.

It puts undue pressure, an artificial timeline, on those who are trying to work through this extremely complex and important piece of legislation we do not need. We don't have to set that kind of deadline. What we need them to do is to spend the necessary time to produce a strong, thoughtful, bipartisan product that will actually work. That is what we need to do. Then we can vote for it with pride instead of trying to sneak it through this Senate without anybody knowing what is actually in it. As I said last week when I heard about this plan, the Democratic leadership acts as if this is another piece of everyday legislation, but it is not. The immigration bill is one of the most important to come through the Senate in the decade I have been here. I believe that. I think the American people understand that. So this option is not new.

In April, we heard news reports that the Democratic majority would be abandoning efforts to write a new bill and would be starting with the fatally flawed bill produced by the Judiciary Committee last Congress.

''Immigration Daily,'' an online immigration law publication, reported:

> There is good reason to believe that the CIR—that is the Comprehensive Immigration Reform—
>
> Language will finally be introduced on the Senate floor within 2 weeks or less. What will the CIR language look like? CIR begins with S. 2611, the McCain-Kennedy bill which cleared the Senate last year.

The New York Times reported a similar story:

> Senator Edward M. Kennedy has abandoned efforts to produce a new immigration bill and is proposing using legislation produced last March by the Senate Judiciary Committee as the starting point for negotiations this year. Mr. Kennedy dismissed the notion that his efforts to produce a new immigration bill had failed. He said he had decided that the committee report was the best starting point.
>
> We have had extensive hearings on the essential aspects of this bill,
>
> Mr. KENNEDY said.
>
> We are effectively ready to mark up and for going to the floor.

I am very disappointed—beyond disappointed—to hear those news reports. I have been pleased, I guess, today that so far these plans haven't come to fruition, that the majority has begun to engage or has continued to engage Republican Senators and the White House in a real effort to write a good bill. I hope that is what the majority will continue to do.

I hope the majority will abandon last year's fatally flawed bill, not start with it. It cannot be amended and an effective bill created. It means this cannot be the starting point to come to the floor with a new bill this Congress. I implore our leadership to continue trying to write a bill that a majority of Republicans could support, that is possible if we follow through on the real principles people are talking about and saying they can agree to.

It is not a question of the principles we are dealing with. The question is: Will we write the bill in such a way that the principles are carried out? That is the key thing. It was not done last year. In 1986, it was to be the amnesty to end all amnesties. They had 3 million people—I think they thought there were 2 million people—here illegally. They created amnesty for them and they promised we would pass a new law and that this new law would be such that we wouldn't have to do amnesty again. That was in 1986, 20 years ago. We had, it turned out, 3 million people who claimed the amnesty.

What has happened since? Now we have 12 million people here illegally—maybe 20 million—who knows for sure. So why wouldn't we learn from that? Why wouldn't we understand this is not a political football to be kicked down the field? This is important legislation that ought to be passed and written correctly, so 5 years from now, we can go to our constituents and say: We did something good. It is working as we promised you it would work. Why not?

Well, I will tell my colleagues what appears to me to be happening. By bringing up the old bill, last year's bill, which many people in this Senate voted for and probably still believe is good legislation, though it certainly is not, they can start it—they can start it and go forward with this bill that perhaps they never intend to be offered as the final legislation. You burn the time

on the motion to proceed to the bill for the bill to be discussed, and they can go past that and move to proceed to the bill, and then file for cloture on the bill, and then offer a substitute, 700, 800 pages. That is how many pages it was last year—over 600. If they write this one well this year, it should be more than that. They drop a 700, 800-page bill and substitute the old bill, and there is no time to debate it, and they slide it right through, railroad time. I am telling my colleagues, that appears to me to be what it is about. That would be an abrogation of our responsibility.

The American people care about this legislation. The American people are not unengaged. They know something compassionate is going to have to be done about the 12 million people, but I think most people agree with me that someone who came here illegally should not be given every single benefit we give to somebody who comes here legally. We need to set a principle that we are not going to reward illegal behavior in the future. So you work something out on that, and you work something out on these other complex issues, and we set up a policy of immigration for the future that reflects some of the principles Canada has: its point system, its merit-based system. That was never discussed last year. Not one hint of it is in the bill Senator REID is apparently intending to bring up on Wednesday.

How can we possibly talk about comprehensive immigration reform and never consider a merit-based immigration system? Isn't America based on merit? Don't we know far more people want to come here than can be accepted? Don't we know Australia does that, New Zealand does that, the United Kingdom is looking at that—all developed and highly sophisticated nations committed to humanity and civil rights, world leaders in that regard. Are their proposals somehow immoral and unfit? Of course not. Those ideas were not even discussed in last year's bill. So they say we might have something such as that in this legislation. Well, let's see it. Let's see what the words say. What is it going to say? Is it going to be like last year when it said ''temporary guest worker,'' and that was nothing but a sham when you read the fine print under it? Is that what we are going to get this year, a bill they ram through at the last minute, burning the time for debate so we have only the most minimal time to debate? Is that the plan? I hope the American people are keeping their eye on this one. They deserve more. The American people are concerned about immigration. It is an important issue. It is a very important issue to us.

We had a group from Ireland testify at the Judiciary Committee last year and they told us only 2,000 people got into our country from Ireland last year. We had over 1 million come in legally. What is this? How do we create a system that does not give people throughout the world an equal chance, an opportunity to apply to come to America? We need to work on that. We can do it. There is a framework here that, if fleshed out with good legislation, good language, enforceability, we can be proud of.

I am afraid that is not what we are doing. I am afraid there is an attempt here to move a fast one. I am afraid the masters of the universe who run this place, some on both sides of the aisle, don't want the American people to know what is in the bill. They don't trust them to be in on the negotiations. They want to do it and slide it through.

I remember last year we offered—someone offered a good amendment, I think it was the Isakson amendment, on a trigger, and one of the Senators said: Oh, we can't accept that amendment. Why not? We can't accept it because it would upset that delicate balance of negotiations with the parties who put this bill together. So I asked: Who were they? Who are these parties who put the bill together? Where did they meet? Did they have votes? Did people elect them to go in this caucus to write this piece of junk that was the bill last year? Who was that? Oh, they wouldn't talk about who actually wrote the bill. They wanted to ram it through, and nobody could amend it because it would upset their delicate compromise. Well, phooey on that. We need to do this in the light of day. We need to stand up and explain to our constituents and ask them to support a good bill, and we need to stand up and oppose a bill that is a bad bill. We are going to live with it, as we have lived for over 20 years now with 1986, that failed piece of legislation that had so much promise and people were so happy about when it passed, and it never worked.

There are several reasons we need to be cautious. You can put in a piece of legislation an authorization to add a bunch of Border Patrol officers or workplace enforcement rules, or you can put in an authorization to spend money to create a computer system that will actually work, and it can. We can create a system that will work, but authorizing doesn't mean anything. That doesn't mean anything. You have to come up with money, and the money comes up in the years to come. If this Congress isn't serious about what it is doing and we pass a bill that authorizes a bunch of provisions that could actually help and be worthwhile and we never come up with the money to do it, the system is going to collapse as badly as it is right now.

We need a national debate, a national consensus on a good piece of legislation. The President needs to be committed to leading instead of undermining the enforcement of laws. They are getting a little better in the White House now, but Presidents in the past have had no interest whatsoever in seeing immigration laws passed. If they did, they would have come to Congress and said: We need more border enforcement, we need fencing, we need more Border Patrol, we need an end catch and release. They never came to Congress and said the law was not being enforced. American constituents talk to Members of Congress and the Members of the Senate and explain about the plain as day illegality that is going on, and the Congress is trying to make the system be enforced. My colleague, the Presiding Officer, is a former U.S. attorney. The President, the executive branch has the responsibility to enforce the law, not the Congress. What do we know about how to catch all these people. They ought to be asking us for the laws. They should be telling us what is needed. But no, no, because nobody, not any President since 1986, has ever taken his responsibility to enforce the laws of the United States seriously as they apply to immigration. So that is what we have.

I have points I will not go into tonight that detail the incredible flaws that existed in last year's bill.

Senator SPECTER offered a bill that I didn't favor, but it was better—he was chairman of the Judiciary Committee last year—it was better than the other two that arose. After he offered it in Judiciary Committee, we went on in a day or so, or two or three, and we had this deadline. Like Senator REID, Senator FRIST said: I have to have the bill out Monday. If you don't bring it out Monday, I am going to introduce another bill—a pretty good bill, actually, which was an enforcement-oriented bill. Also, the Judiciary Committee got in a flutter, and we ran around, and Senator KENNEDY offered the substitute—Kennedy-McCain. The Specter bill was gone, and an entirely new Kennedy-McCain bill was on the floor. Then the controversial AgJOBS portion of immigration that had been floating around here and had been blocked over the years was offered up as an amendment to Kennedy-McCain, and it was added with no debate. We voted this out and it was on the floor, and the next day we were debating this 600-page bill.

That is not the way to do business in the Senate. My chief counsel here studied this legislation, and we read the fine print, that 600 pages, and when we looked at it, we were shocked at the loopholes it contained. We identified—and I spoke here several hours on it—17 loopholes in that legislation. It began to lose steam. We found out just, for example—mind you, Senator REID, I understand from the New York Times and others, is talking about introducing the Judiciary Committee bill. This is what the Judiciary Committee bill would have done last year, the one that passed out of the Committee, the so-called McCain-Kennedy bill. Under current law, over the next 20 years, this Nation would issue 18.9 million green cards—quite a substantial number. Under the Kennedy-McCain bill passed out of committee last year—hold your hat—it would have been, at a minimum, 78 million over 20 years to

as many as 200 million. That is two-thirds of the current population of the United States of America. They tried to move that bill without amendments. I cannot recall the gymnastics they went through, but they were even denying Senators KYL and CORNYN amendments they wanted to have, and Senator REID wanted no amendments.

Finally, we began to have amendments. Senator BINGAMAN offered two amendments, eventually, as time went by. It was brought back the third time. They brought those numbers down from 78 million and 200 million to 53 million, almost 3 times the current rate of immigration.

So Senator REID, as I understand it, according to a news report, is talking about bringing up the Judiciary Committee bill. This is not the 53 million people being brought in here permanently with a green card—permanent residents—but we would go back to the 78 million to 200 million. How amazing is that?

So I am just flabbergasted by the way this matter is being treated. There is only one way to do it; that is, we stand up like real Senators and we write a bill and work out a bill, and we give the Members of the Senate the time to read it, time for the American people to understand what is in it, and see if it can be amended and made better, and make sure it will actually work, not just be a political show—not some political sham but a piece of legislation that would actually work, and then we would pass it. We would be responsible to our constituents for a ''yes'' or ''no'' vote because we do need to pass comprehensive reform. I said that many times last year. Of course, we need that.

The whole system is broken. Nothing about it works. Of course, we need to reform it from the ground up. But the legislation last year is no place to start. We don't need to be using some gimmick to get the bill up, with last year's language, and then substitute new language that nobody has read and ram it through the Senate. The American people should not be happy with that.

Mr. President, I thank the Chair for his patience and those who listened to my remarks. I believe we can do something better. I support real and genuine reform of immigration in America. I will support legislation that provides a compassionate solution to the people who have been here for years and have been dutiful, law-abiding people except for their illegal presence. We can work through those things.

We need a future flow system, much more like Canada's, much more like New Zealand's. We need a temporary worker program that is really temporary. We need a workplace enforcement system that the average employer will have no problem in following. We need a biometric, identifying cards for immigrant workers so they cannot be illegally forged. That is all possible to do if we want to do it—unless the people who are driving this bill, the architects of this, just want to go through the motions of creating an immigration system that would work, unless that is their plan, to just go through the motions and pass a bill that has no chance of being successful, just like we did in 1986, and 8 or 10 years later, they can say: We are heartbroken; we thought it was going to work.

I think we can do it, and I think we ought to do it. I hope the majority leader will not bring up the last year's bills—any one of them—and that he will bring up the bill that was drafted through this compromise process because I think it at least has some possibility to be a bill we could support, unlike the one last year, and then we can study it and debate it. The American people could be engaged in it, and we ought to stand up and vote and do the right thing for America.

I yield the floor.

ADJOURNMENT UNTIL 10 A.M. TOMORROW

The PRESIDING OFFICER. Under the previous order, the Senate stands adjourned until 10 a.m. tomorrow.

Thereupon, the Senate, at 6:51 p.m., adjourned until Tuesday, May 8, 2007, at 10 a.m.

NOMINATIONS

Executive nominations received by the Senate May 7, 2007:

DEPARTMENT OF COMMERCE

WILLIAM G. SUTTON, JR., OF VIRGINIA, TO BE AN ASSISTANT SECRETARY OF COMMERCE, VICE ALBERT A. FRINK, JR.

FOREIGN SERVICE

THE FOLLOWING-NAMED CAREER MEMBERS OF THE SENIOR FOREIGN SERVICE OF THE AGENCY FOR INTERNATIONAL DEVELOPMENT FOR PROMOTION WITHIN AND INTO THE SENIOR FOREIGN SERVICE TO THE CLASSES INDICATED:

CAREER MEMBER OF THE SENIOR FOREIGN SERVICE, CLASS OF CAREER MINISTER:

JOHN E. PETERS, OF FLORIDA

CAREER MEMBER OF THE SENIOR FOREIGN SERVICE, CLASS OF MINISTER-COUNSELOR:

WILLIAM A. BREKKE, OF SOUTH DAKOTA
IRA E. KASOFF, OF CALIFORNIA

CAREER MEMBER OF THE SENIOR FOREIGN SERVICE, CLASS OF COUNSELOR:

JOHN D. BREIDENSTINE, OF PENNSYLVANIA
JANICE A. CORBETT, OF OHIO
AMER M. KAYANI, OF CALIFORNIA
MARGARET A. KESHISHIAN, OF CALIFORNIA
ANDREW P. WYLEGALA, OF WASHINGTON

IN THE ARMY

THE FOLLOWING NAMED OFFICER FOR APPOINTMENT TO THE GRADE INDICATED IN THE UNITED STATES ARMY UNDER TITLE 10, U.S.C., SECTION 624:

To be brigadier general

COL. CHARLES W. HOOPER, 0000

THE FOLLOWING NAMED OFFICER FOR APPOINTMENT IN THE UNITED STATES ARMY TO THE GRADE INDICATED UNDER TITLE 10, U.S.C., SECTIONS 624 AND 3064:

To be brigadier general

COL. LOREE K. SUTTON, 0000

THE FOLLOWING NAMED OFFICER FOR APPOINTMENT AS CHIEF OF CHAPLAINS, UNITED STATES ARMY AND APPOINTMENT TO THE GRADE INDICATED UNDER TITLE 10, U.S.C., SECTION 3036:

To be major general

BRIG. GEN. DOUGLAS L. CARVER, 0000