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 all 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 pointed to this 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, 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 being imported every day. 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 giving the 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 collections, 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 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, 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.

Consistent 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.

Legeralizing 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.

Import 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.

Consistent with the United States paying 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 have to compete through 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. Because that means that 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 agencies. 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 decision making 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 consumer 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 improve 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 discussion 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 in order to ensure that millions of Americans can 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 50 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 being prescribed 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 on 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. Giving those drugs that are 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 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 imported pharmaceuticals 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, many 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 DONN 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. The 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 the FDA to do work in the area of 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. The 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 the authority, noting 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 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 Low-cost Act 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 patients as much as $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 Novitl 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 the same rules as small molecule drugs. 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.

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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. The system used 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 sloping 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, 225,000 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 1 million 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 system must be changed, and we must be dressed 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 international 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 as we restore public and Congress’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 this agency’s ability to ensure the safety and effectiveness of drugs and biologics, it is time that we begin to look at drugs in order to reduce overall health care costs, we need to understand how these drugs are effective—in order to reduce 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 evaluate the effectiveness of new and existing medical procedures, devices, drugs, and biologics. I am grateful for their leadership.

A mandate that Congress has repeatedly written into legislation is 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 the agency has the tools that it needs to protect the American people.

**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. (By Walt Bogdanich and Jake Hooker)

From China to Panama, a Trail of Poisoned Medicine

The kidneys fail first. Then the central nervous system begins to misfire. Paralysis sets in, 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, infant medication, injectable drugs. As a result of counterfeiters who profit by substituting the sweet-tasting solvent for a safe, more expensive syrup, used in drugs, food, toothpaste and other products. Toxic syrup has figured in at least eight mass poisonings around the world in the last 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 found an unpurified 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 the syrup 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 the way, but no one had tested the syrup to confirm what was on the label. Along the way, a certificate falsely attesting to the purity of the shipment was re-created, lettering the names of the manufacturer and previous owner. As a result, traders bought the syrup without knowing whether it came from, or who made it. When news of the trade first hit the traders that have discovered—as The Times did—that the manufacturer was not certified to make pharmaceutical ingredients.

An examination of the two poisoning 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. But the agency asked that all shipments be tested for diethylene glycol, and said it was “exploring how supplies of glycerin become contaminated.”

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 tailor, villagers say. He had already set up a textile 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 quickly discovered what others understood a small town if you are in Beijing, and many deaths later before that certification was discovered to be pure fiction.

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One company that used the syrup began importing it into interstate commerce in 2006. The F.D.A. said it was unaware of the shipments. 'With this information, the traders might know where it came from, or who made it. They could earn extra money by substituting cheaper, industrial-grade syrup—not approved for human consumption—for pharmaceutical buyers, he forged his licenses and laboratory analysis reports, records show.

Mr. Wang later told investigators that he figured the man had cheated him, because he initially tested a small quantity. He did it with the expertise of a tailor. He swallowed some of it. When nothing happened, he shipped it. 'He didn't know what he was doing,' Mr. Wang's older brother, Wang Guoping, said in an interview. 'He quickly discovered what others understood a small town if you are in Beijing, and many deaths later before that certification was discovered to be pure fiction.'
One patient of particular interest to Dr. Sosa came into the hospital with a heart attack, but no Guillain-Barré-type symptoms. The patient was a 25-year-old woman who had received several drugs, including Lisinopril. After a while, he began to exhibit the same neurological distress that was the hallmark of the most painful patients—"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." When the medical staff made him cough, he also coughed up 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.

Over the same period, hospital patients had to watch others around them die for reasons no one understood, fearing that they got outside, but it was something extraordinary, something that was obviously not something environmental, this is not something 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 counterfeit." 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 a Chinese manufacturer as Mr. Wang, the former tailor, the government investigator said. From this factory, the barrels of toxic syrup began their journey, passing from company to company, port to port and country to country, apparently without anyone testing its contents.

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 cough 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 high, adorned with an ornate 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, let alone to China. Its address locks 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 counterfeit." 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 a Chinese manufacturer as Mr. Wang, the former tailor, the government investigator said. From this factory, the barrels of toxic syrup began their journey, passing from company to company, port to port and country to country, apparently without anyone testing its 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 Pan- ama 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 state-owned business that began by supplying goods and services to Chinese personnel and business officials overseas. China's market for the cough syrup—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. McGee, a board member of the International Pharma- ceutical Exports Council. In this case, that was not done.

Fortune Way translated the certificate into English, putting its name—not the Taixing Glycerine Factory's—on the top of the document, before shipping the barrels to a second trading company, this one in Bar- celona. Li Can, managing director at Fortu ne Way, said the company was 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 state-owned business that began by supplying goods and services to Chinese personnel and business officials overseas. China's market for the cough syrup—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. McGee, a board member of the International Pharma- ceutical Exports Council. In this case, that was not done.

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A lawyer for Medicam, Valentín Jaén, said his client was a victim, too. “They were tricked by somebody,” Mr. Jaén said. “They operated in Panama.” In Panama, the 46 barrels sat unsold 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. The Panamanian government, which bought the 46 barrels and used them to make cold medicine, also failed to detect the poisons. The toxic pipes 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 partially paralyzed face and arms making small, slow movements. “I can’t walk, I can’t...I can’t do anything.” The tears, he said apologetically, were not from emotion, but from nerve damage. 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. There were 46 barrels of glycerin, Mr. Sun said, and for the 46 barrels each used to make cold medicine, also failed to detect the poisons. The toxic pipes 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.

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Mr. Wang remains in custody as the authorities wait for the Chinese government to decide if the Chinese government will hand him over to China.

The power to prosecute the counterfeiters rests not only with the Chinese authorities but also with the FDA. The FDA has the authority to bring criminal charges against those who manufacture and distribute counterfeit drugs. The FDA also has the power to seize and destroy counterfeit drugs.

A COUNTERFEITER’S CONFESSION

The thunder 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 test marketed the Tyraing Glycerine Factory made on their end, or how small. For the 46 barrels of glycerin, Rasfer admitted that China should not be selling poisonous products overseas.” Ms. Sun said the agency did not receive an official reply. Last fall, after the United States—Panama has no diplomatic relations with China—the State Food and Drug Administration of China investigated the glycerine factories, 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 had no conclusions about Fortune Way, saying that as an exporter it was not engaged in the pharmaceutical business. The agency later found evidence that either these companies had broken the law,” said Yan Jingying, a spokesperson 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 even 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 Qiang, 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 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, and improperly used. . . .” He did not comment.

One lingering mystery involves the name of the manufacturer, was hiding in plain sight. It was 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 Senate 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 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 amendments 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: the Senator from Oklahoma (Mr. INHOFE), Senator from South Dakota

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
Byrd      Graham       Mikulski
Bennett    Gregg      Murkowski
Bond       Hagel       Murray
Bunning    Hatch       Nelson (NE)
Burr       Hatchison  Roberts
Cantwell   Isaksen     Rockefeller
Carper     Kennedy     Staback
Chambliss  Kerry       Salazar
Collin      Ky  Specter
Cochran    Landrieu    Stevens
Coleman    Lautenberg  Sununu
Corzine    Lieberman   Thomas
Curray     Lincoln     Voinovich
Crapo      Logan       Warner
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
Clayton    Leahy       Stabenow
Collins    Levin       Vitter
Conrad    Lott         Webb
Craig     McCaskill   Whitehouse
Dorgan    Pryor        Wyden
Durbin    Reid

NOT VOTING—11

Allard     Ensign       Obama
Biden      Inhofe       Reed
Brownback  Johnson     Tester
Dodd      McNamara

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 vote now.

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, we reserved 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 may 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. 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 operate in 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 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.

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:

The PRESIDING OFFICER. 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. The question is the motion to invoke cloture on the substitute amendment, as modified, to S. 1082, the FDA Revitalization bill.

The PRESIDING OFFICER. Under 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.
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. ENZI), 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: [Roll Call Vote No. 152 Leg.]

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, I 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. This bill is important to 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, 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 forward.

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 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 would like to move 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. This bill is important to 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, 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 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.

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.

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 rights to learn English and 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 the 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 disabled 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 history. 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. America is the only country “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 children this English. In 1906, the. 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 fluent Chinese or Japanese.

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 we all acquire the skills to succeed 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—it 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 the 20th century, 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 as well. 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 buy 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 Enzi, Dianna Johnston, assistant legal counsel with the EEOC, adds 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 were cooking, 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 relief in offering 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 of business communications, says President Melek Pulatkonak. Many employees are immigrants who speak Turkish, German, Russian, Italian, 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 impact 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...
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 classic illustration 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. Keep in mind, prior to 1996, we didn't have direct-to-consumer advertising very much on TV and radio. Pharmaceutical companies basically marketed their products in 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 spent on only 50 brand-name 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.

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 right. I know—indeed, 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 Vioxx.

That was a drug that was advertised as a new generation of pain killers—distinguishingly 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 TV or radio, you see advertising Advil or Tylenol or a brand-name drug, and you think, maybe a green pill, maybe a purple pill, the green 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. The doctors are the ones who get the advertisement 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 people who are complaining about the pain they 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 paid 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 talk about a specific drug. You know what you ought to do? You ought to ask the doctor and ask him if the purple pill would be right for you. You don't want 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.

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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 this 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 what will be the downside? Perhaps through a beautiful meadow, where perhaps 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 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 a 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 $1.20 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 you hear individually 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 new drugs for you, life-saving 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. And, they did it. And 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 a while, you start listening 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 visual.

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 drug’s known risks 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 weeks, you could have seen this. 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 going to listen 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 treating 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.

Second, 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 companies may 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 for a disease or any other 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 state—and get this—in a clear, conspicuous, and neutral manner. A clear, conspicuous, and neutral manner.
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, 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. This 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 PRESIDENT pro tempore of the Senate said, "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 Medicare law is 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 who are investing in the research and development that is necessary to bring those types of new therapies and drugs onto the marketplace. 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 and a big part of the 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 making 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 to create the 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 Drug Enforcement 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 now been abused. It is under consideration as part of the managers’ amendment. I think this is an important amendment, one that addresses the issues we are talking about today, the high cost of prescription drugs.

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 $292.5 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 in bad faith—see the 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, is for those who 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 companies 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 that Senator from Michigan, Senator Stabenow, Senator Brown, produced—the Senator from Michigan, generally of billions and billions of dollars to allow companies to market their drugs to the tune literally of billions and billions of dollars of additional cost.

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. 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, driving down the 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. I hope this 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 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.

If I do this, another 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 support 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 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 and sale of any drug that the approval of such drug poses "no additional risk to the public health and safety." This 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 Senate at the time 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 is 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 and 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 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 challenges 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 plug I have to have a shot at assessing 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. At least in three instances 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 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. In fact, if they were selling adulterated drugs which in packages that had 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 the pharmaceutical products, were adulterated, and in some instances the adulterated drugs could have caused severe harm to the person who had 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 were shipped from 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 capacity. An 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 adult product—by selling an adult product. I emphasize 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 sees an Internet 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 in 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 in most instances have reservations in most instances have reservations reservations in most instances have reservations in most instances have reservations reservations in most instances have reservations in most instances have reservations in most instances have reservations in most instances have reservations which is that the Internet pharmacy situation is basically a “wild west” of supply. Nobody knows what they are getting.

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. They can’t actually know 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 something substantially a matter of improving 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 an 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 these sites are going to say they are safe. 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.

A 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 Northeast 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 substantially the same 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, the manufacturer 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 Pre- sideing Officer has led the charge on with Senator THUN. 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, 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 the efforts of Senator DORGAN on reimportation.

BIOEQUIVALENCE STANDARDS

Mr. HATCH. I rise to speak about the amendment I offered to S. 1082 on anti-biotics 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 make initial steps toward the important issue of drug resistant microorganisms and the need for new antibiotics. Senate Health, Education, Labor, and Pension Committee Chairman Ted KEN- NEDY and its Ranking Member Mike DORAN and Senator Enzi 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 can no longer be confident that the drugs, especially the patients who 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 colleagues on this impor- tant matter. However, I am concerned one provision of my amendment that was not included which deals with bio- equivalence standards for locally-act- ing non-absorbed drugs. In the amend- ment 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 in- dustry, I want to ensure that their bio- equivalence 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 app- propriate 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 anti- microbial 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 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 the current standard, explain the 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 ad- visor, Leigh Ann Ross, who is a phar- macist, has been very helpful in expla- ining the issues of antimicrobial science at issue here. I also want to ac- knowledge the work of my colleague from Massachusetts who has shown great leadership here and his dedicated staff, David Dorsey, who has worked tirelessly on this entire bill. I can’t stress 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 agree- ment 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 acknowl- edge 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 Sen- ator HATCH for raising this issue of antimicrobial resistance and the need for new antibiotics, an issue 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 con- tinue to address the broader issue with- in the Committee this Congress. I also agree that we need to work with FDA on this issue of account- ability and look forward to working with the Chairman and other members of the Senate on this issue.

Mr. HATCH. I thank the Senator. I agree that we need 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 estab- lishing 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 framework, asking for additional data 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? 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 enacted 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 prescription drugs. In this legislation, successfully working to include authorized generics as part of the patent settlement agreement.

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 of the settlement agreement would 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 future Senate 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 FTC fulfill its work, but I want to be clear that I do not believe Congress needs to wait on the FTC study to be completed on the program 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 support his efforts 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 Waxman-Hatch 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 FDA’s authority over 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 on the market. The language of amendment S. 1042 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, KOSHI, 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, discovery 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 any 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 it. 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 know 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 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 deposition and to provide juries with testimony. This is completely ridiculous. We should be able to provide care 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 her store 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.

Doctors and pharmacists 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. Why? Because the health care providers are measured against the pharmacy and out-of-State lawsuits brought in Jefferson County and not on product liability lawsuits when they have nothing to do with the product in question.

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 for 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,
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” (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 are frequently are named 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 the 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 taken against 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 are 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