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

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

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

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

CONCLUSION OF MORNING BUSINESS

The PRESIDING OFFICER. Morning business is closed.

PRESCRIPTION DRUG USER FEE AMENDMENTS OF 2007

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

The legislative clerk read as follows:

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

Pending:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

These are addictive drugs that require close physician supervision.

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

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

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

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

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

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

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

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

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

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

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

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

The Dorgan amendment gives the FDA the resources and authority to

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

AMENDMENT NO. 1010

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

The Senator from Mississippi.

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

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

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

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

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

I urge the Senate to again support this amendment.

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

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

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

FROM CHINA TO PANAMA, A TRAIL OF POISONED MEDICINE

(By Walt Bogdanich and Jake Hooker)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CHEATING THE SYSTEM

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

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

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

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

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

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

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

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

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

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

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

A MYSTERIOUS ILLNESS

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

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

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

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

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

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

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

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

A MAJOR CLUE

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

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

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

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

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

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

A SUSPECT FACTORY

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

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

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

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

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

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

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

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

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

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

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

A COUNTERFEITER'S CONFESSION

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

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

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

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

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

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

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

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

ALL IN A NAME

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

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

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

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

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

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

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

The PRESIDING OFFICER. The Senator is correct.

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

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

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

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

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

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

The PRESIDING OFFICER. Is there a sufficient second?

There appears to be a sufficient second.

The clerk will call the roll.

The legislative clerk called the roll.

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

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

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

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

[Rollcall Vote No. 151 Leg.]

YEAS—49

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

NAYS—40

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

NOT VOTING—11

Allard	Ensign	Obama
Biden	Inhofe	Reed
Brownback	Johnson	Tester
Dodd	McCain	

The amendment (No. 1010) was agreed to.

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

The motion to lay on the table was agreed to.

The PRESIDING OFFICER. The Senator from Massachusetts.

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

The PRESIDING OFFICER. That request has been granted.

AMENDMENT NO. 990

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

Who yields time?

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

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

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

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

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

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

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

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

The motion to lay on the table was agreed to.

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

The PRESIDING OFFICER. Is there objection?

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

The PRESIDING OFFICER. Objection is heard.

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

Who yields time?

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

The PRESIDING OFFICER. The Senate will be in order.

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

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

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

The PRESIDING OFFICER. Could we please have order.

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

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

The PRESIDING OFFICER. Who yields time?

The Senator from North Dakota is recognized.

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

The PRESIDING OFFICER. The Senator from Wyoming is recognized.

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

CLOTURE MOTION

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

The assistant legislative clerk read as follows:

CLOTURE MOTION

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

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

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

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

The yeas and nays are mandatory under the rule.

The clerk will call the roll.

The legislative clerk called the roll.

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

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

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

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

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

[Rollcall Vote No. 152 Leg.]

YEAS—82

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

NAYS—8

Casey	Grassley	Vitter
DeMint	Sanders	Webb
Dorgan	Snowe	

NOT VOTING—10

Allard	Ensign	Obama
Biden	Inhofe	Tester
Brownback	Johnson	
Dodd	McCain	

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

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

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

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

The PRESIDING OFFICER. The Senator from Tennessee is recognized.

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

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

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

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

ENGLISH: OUR NATIONAL LANGUAGE

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

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

We conduct Senate debates in English.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

According to an article that appeared today in USA Today:

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

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

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

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

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

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

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

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

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

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

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

[From USA Today, May 7, 2007]

ENGLISH-ONLY WORKPLACES SPARK LAWSUITS

(By Stephanie Armour)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The PRESIDING OFFICER. The Senator from Iowa.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Mr. HARKIN. I will yield.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

I yield the floor.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

I yield the floor.

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

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

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

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

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

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

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

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

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

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

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

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

I yield the floor.

The PRESIDING OFFICER. The Senator from New Hampshire.

AMENDMENT NO. 993

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

I yield the floor.

The PRESIDING OFFICER. The Senator from Ohio is recognized.

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

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

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

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

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

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

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

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

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

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

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

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

BIOEQUIVALENCE STANDARDS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

AUTHORIZED GENERICS

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

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

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

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

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

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

AMENDMENT NO. 1042

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Sincerely,

MICHAEL D. MAVES, *MD, MBA.*

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

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

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

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

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

Sincerely,

JOHN A. STROSNIDER, *DO, President.*

MORNING BUSINESS

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

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

ADDITIONAL STATEMENTS

REMEMBERING HAWAII'S DON HO

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

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