have occurred as a result of the use of unregulated ephedra; young athletes, young people, dying, suffering strokes, heart attacks, like Steve Bechler, because we voted in 1994 to say that safety did not count when it came to ephedra.

And with this bill tonight, its authors I know well-intentioned, angry at the price of drugs in America, angry at Canada because they impose price controls that take advantage of our citizens, angry at those trade laws that let it happen, they are asking us tonight to do exactly what we did in 1994, to vote for a bill that says safety does not matter when it comes to drugs, that safety does not really count; that we are going to repeal tonight, if they get their way, the language that is in the law that says that FDA must certify the safety of any drugs that are imported into this country; to take away the language that says FDA must do those things appropriate to ensure that the drug supply in this country is never compromised; that bogus, counterfeit, diluted, old, rotten drugs are not permitted into this country.

I voted wrong in 1994. I am not going to vote wrong tonight. I will never vote to compromise safety again in the use of drugs or products for our young people and our old people and our citizens.

Tonight we will learn about those rotten drugs that are coming into this country from Canada, yes, and from a lot of other countries, transhipped through Canada. We will have the smoking gun for tonight to show what is about to happen if we open the door to that awful problem.

I urge Members, vote against this bill.

Mr. DINGELL. Mr. Speaker, I yield myself 3½ minutes.

(Mr. DINGELL asked and was given permission to revise and extend his remarks.)

Mr. DINGELL. Mr. Speaker, this is a bad bill. On its face it would appear to be a good bill. It is not. It will allow this country to be flooded with unsafe, counterfeit drugs; drugs that will not do what they should; drugs that are unsafe; drugs that will kill the American people. I tell Members, it is a bad bill, and I ask them to remember the experiences that were reported by my colleague from Louisiana.

This bill would reduce the capacity of the Food and Drug Administration to protect our people from unsafe prescription pharmaceuticals, which will begin to flood the country if and when it is passed.

H.R. 2427 is a prescription for trouble. They open our borders. They provide millions of Americans with access to perhaps drugs which are cheaper, but drugs which are unsafe and which evade the responsibility and the ability of Food and Drug to protect the American people.

Mr. Speaker, do not take my word for that. Listen to what the health care professionals and regulators say.

The American Medical Association says, ''We believe H.R. 2427 would be so dangerous to patient safety that we must oppose it. This legislation would eliminate most of the important restrictions on reimportation of pharmaceuticals in current law and replace them with a system of unverifiable and unsafe provisions.''

The National Medical Association has said, ''This legislation would result in counterfeit, adulterated, and dangerous drugs entering the United States. We do not believe that H.R. 2427 should be enacted at the risk of jeopardizing patient safety.''

The American Osteopathic Association says, ''H.R. 2427, while increasing the possible number of drugs reimported into the United States, does nothing to ensure the safety and efficacy of these drugs. There is no bargain to be found for our patients who purchase drugs that are ineffective or contaminated.''

The Food and Drug Administration says, ''H.R. 2427 would authorize the importation of prescription drugs from foreign sources without adequate assurances that such products are safe and effective. H.R. 2427 creates a wide channel for large volumes of unapproved drugs and other products to enter the United States that are potentially injurious to public health and pose a threat to the security of our Nation's drug supply. The bill would do so by taking unprecedented steps that limit FDA's authority to assure the safety of prescription drug products to be used by American consumers.''

Mr. Speaker, this will enable foreign manufacturers to import into Canada for reimportation into the United States tons of counterfeit foreign drugs, drugs which are ineffective, over-age, unsafe, unregulated and improperly manufactured in ways which will offer threats to the United States, to our citizens and to the people who are looking to you to see to it that their food, drugs and cosmetics are safe.

Mr. Speaker, let us look at it. Foreigners are going to use this device to enter Canada to sell unsafe drugs to the American people. Do not deceive yourself to think that any one of those importers will be bound by any requirements of American law or that they will, in fact, sell those drugs at less price. They will simply sell them at U.S. market prices, and you are going to have on your hands the possibility that you have voted to injure, sicken, hurt or kill the American people by allowing the importation of unsafe drugs.

RECENT COUNTERFEITS

COUNTERFEIT LIPITOR

Lipitor, a cholesterol-lowering medicine, is used by 11 million Americans each year to help prevent serious heart disease. Last month, according to FDA, a large quantity of fake Lipitor entered the U.S. market. The product was imported to the U.S. and repackaged here, for sale to distributors and pharmacies. To date, FDA and Lipitor manufacturer Pfizer have recalled 200,000 bottles of this dangerous phony product.

FAKE AND MISLABELED ZERIT

Counterfeit Zerit, a medication to treat HIV infection, was first discovered in 1997. According to the real manufacturer, Bristol-Myers Squibb, this not only was not its authentic product, but the labels incorrectly told consumers they were taking 30 mg, when in fact the capsules inside the bottles allegedly contained 40 mg of the active ingredient. Patients were exposed both to a product of unknown origin and the dangerous possibility of an overdose.

PHONY CLARITHROMYCIN

This antibiotic, called Biaxin, is used to treat infections such as pneumonia, bronchitis, and ear infections—including infections in children. Recently, according to the drug's manufacturer, Abbott, counterfeit Biaxin, containing absolutely no active ingredient, has been found in Russia (where counterfeits make up 15 percent of the prescription drug market). Because the legal system in Russia makes pursuit and punishment of these counterfeiters difficult, these dangerous products remain available in Russia as well as for export to other lucrative markets like the U.S.

COUNTERFEIT NEURONTIN, ACCUPRIL, AND CELEBREX

Counterfeits of these Pfizer products—Neurontin, for seizures in children 3 and older and adults and for treating shingles pain in adults; Accurpril, for high blood pressure; and Celebrex, for treating debilitating arthritis pain—have recently been found in California, at a company called NuCare Pharmaceuticals. Laboratory analysis confirmed no active ingredient in any of the tablets, which actually were vitamins. Neither the origin of the bottles nor the disposition of the original medications is known.

FAKE ALLEGRA

Fexofenadine, an important active ingredient in products to treat allergies, is sold under the name Allegra in the U.S. Recently, security personnel of the product manufacturer, Aventis, ordered Allegra from an internet site purported to be based in the UK. The product shipped was one called Telfast, a fexofenadine product sold in other countries, but not approved by the U.S. FDA. Furthermore, a stick-on label indicated an expiration date of 1/03; the product actually had expired in 1/02. Finally, although the web site appeared to be promising products from a ''safe'' country in the UK, this product came not from the UK but from Vanuatu, an island off the coast of New Zealand well known for businesses trafficking in illegitimate prescription drugs destined for the U.S.

FAKE LOSEC

Losec (omeprazole), a treatment for ulcers and other gastric conditions, is sold in the U.S. as Prilosec. A generic version of Prilosec is also on the market in the U.S. Counterfeit Prilosec, according to its manufacturer AstraZeneca, was manufactured in an underground facility and distributed through an affiliated wholesaler. The counterfeiter boasted that the copies were sufficiently clever to avoid detection by the government and, in fact, only AstraZeneca had the technical information necessary to determine this product was a fake.

COUNTERFEIT MONOPRIL

Fakes of this high-blood-pressure medication were discovered earlier this year by the LA County Sheriff's Office. The counterfeit operation was uncovered after a local printing company contacted the sheriff to report a suspicious order for thousands of drug product labels. The product, vitamins substituted for the real pills, bottle caps, and seals were all counterfeit. Arrested individuals were owners of prescription drug diversion businesses in Canada, Europe, and Asia. Many other drugs found in the LA raid were

expired or fake, then repackaged, relabeled, and sold to American doctors and pharmacies.

COUNTERFEITS FROM INDIA

According to FDA, an American patient ordered product from an internet site promising ''Canadian drugs manufactured in the U.S.'' The drug he appears to have needed was a seizure medication called gabapentin. What he received was a knock-off from India, labeled ''Gabantin.'' What IS ''gabantin?'' Only the counterfeiter in India, and the so-called ''Canadian'' on-line pharmacy knows. The patient was the unwitting dupe.

COUNTERFEIT PROCRIT

Epoetin alpha, marketed as Procrit, treats anemia in patients with chronic kidney disease, HIV, and cancer. The first discovery of counterfeit Procrit was made in 2002; subsequent discoveries followed. The counterfeit, of unknown origin, has been found at two large wholesalers and a number of retail outlets. The counterfeit, some with 20 times less active ingredient than the real drug and some with no active ingredient but bacteria-contaminated water, appeared identical with the authentic product. Sophisticated anti-counterfeiting technology used on this product failed to challenge the ingenuity of the counterfeiters, who quickly learned to mimic it.

FAKE CRIXIVAN, PEPCIDINE, ZOROXIN, AND ZOCOR

According to Merck, the manufacturer of these products, substantial quantities of counterfeits were found in a police raid on a home in Bogota, Columbia. In addition to these products, the home possessed many other counterfeits. English language labeling suggested the final destination for many; unwary U.S. patients.

Mr. BROWN of Ohio. Mr. Speaker, I yield 2 minutes to the gentlewoman from Connecticut (Ms. DELAURO), who knows that the drug industry imports $15 billion worth of drugs into this country, but then claims that importation is unsafe in order to protect their profits.

Ms. DELAURO. Mr. Speaker, in my 13 years in Congress, no issue has made such a deep impression on my constituents than the rising price of prescription drugs. This is an issue for seniors, but high health care prices are eroding the living standards of middle-class families across this country. We all have a stake in driving drug prices down.

Last week, the Congress of the United States abrogated its responsibility to address the problem of soaring drug prices. It did worse than nothing, barring the government from negotiating lower prices for seniors.

We can strike a blow for lower prices with a simple step, giving ordinary Americans the choice they are taking on their own out of desperation. It should be legal to reimport drugs from some countries. This alone would save Americans $600 billion in the next decade, savings passed directly on to the consumer. We know that this is a safe option. In 2001, U.S. drug companies reimported $14.7 billion worth of brand name medications from their overseas plants.

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This legislation guarantees safety. It not only requires that drugs reimported from other countries are FDA-approved, but that the facilities they are manufactured in are rigorously inspected and approved by the FDA as well. Add to that the requirement that all prescription drugs use counterfeit-resistant packaging, which means every drug purchased here in the United States, reimported or otherwise, will be safer than the drugs that are available today.

The FDA's opposition is one more instance of a regulatory agency becoming captive of the industries they are supposed to regulate. There is no safety issue here. This bill would only allow the importation of FDA-approved drugs manufactured in FDA-approved facilities from 26 designated countries, clearly, a superior system to what we have today in the area of food and drug safety both.

The issue is not safety, I say to my colleagues. The issue is price. It is time that this Congress stop acting as a wholly owned subsidiary of the pharmaceutical companies and step up to its responsibility to help the consumers of this Nation.

I urge my colleagues to support this bill.

Mr. GUTKNECHT. Mr. Speaker, I just want to clarify real quickly that nothing in this bill deals with controlled substances like RU486 or morphine, and nothing in this bill would have anything to do with Ephedra.

Mr. Speaker, I am happy to yield 1½ minutes to the gentlewoman from Missouri (Mrs. EMERSON).

Mrs. EMERSON. Mr. Speaker, I want to thank the Speaker of the House for his graciousness in letting us bring this bill to the floor for debate tonight.

And speaking of the leadership in the House, I thought it would be important to all my colleagues for a little clarification. We hear talk about the FDA blasting the Gutknecht bill, saying that it is unsafe. I want my colleagues to know, and it is very important that they know, that in 2000 when we passed the reimportation language that is current statute, that language was written, that statute was written by our leadership, by a person who is now working at the White House, by me, and by the FDA.

My colleagues might remember it passed in the Agriculture appropriations act. The FDA chose the 26 countries where it felt it was safe to import from those countries, because our current drug manufacturers, U.S. manufacturers, are today manufacturing drugs in those facilities that are approved and inspected by the FDA.

It is very important that my colleagues know this. This is the underlying bill of Gutknecht. Plus, we have added extremely high-tech packaging, tamper-resistant, counterfeit-proof packaging. And this is in addition to the safety requirements, the chain of custody that the FDA has written in the underlying bill today.

Mr. TAUZIN. Mr. Speaker, I would point out that the packaging is held by a single company and the bill they have mandates a monopoly. We ought never do this in this country.

Mr. Speaker, I yield 1½ minutes to the gentleman from Florida (Mr. BILIRAKIS), the chairman of the Subcommittee on Health of the Committee on Energy and Commerce.

Mr. BILIRAKIS. Mr. Speaker, this dangerous bill is a legislative Trojan Horse that uses a promising veneer to hide dangerous realities.

I do not have the time to go into all of the reasons why I personally am opposing this legislation, but I want to remind my colleagues that a number of patient advocate organizations dedicated to the health and well-being of our constituents, including the ALS Association, the National Alliance for the Mentally Ill, and the Friends of Cancer Research, and this long list here, and so many others that will not fit on this chart, are joining me in my opposition tonight. They, they consider the issue safety. They consider the issue safety.

Also, the bill, in addition to the devastating impact on patient safety, would adversely affect the ability of our research-driven pharmaceutical and biotechnology industries to develop breakthrough cures for a myriad of devastating diseases.

Many of the solutions to high pharmaceutical prices have already been considered on this floor. They include a meaningful Medicare prescription drug benefit and Hatch-Waxman reforms to ensure quicker access to less costly generic drugs. We also need to find a way to reduce the number of Americans without health insurance. In fact, I recently introduced a bill that would attempt to do just that.

Mr. Speaker, this is a bad bill. It will do more harm than good. I urge my colleagues to do the responsible, the responsible and not the political thing, and that is to defeat H.R. 2427 tonight.

Mr. DINGELL. Mr. Speaker, I yield 1 minute to the distinguished gentleman from New York (Mr. TOWNS), my good friend.

Mr. TOWNS. Mr. Speaker, this is a bad bill. If we vote for this legislation tonight, we are kissing safety regulations good-bye and saying to patients, fend for yourselves in determining what drugs are safe. The FDA will have no oversight responsibility here.

I will admit that I am not qualified to determine what drugs are safe. It takes expertise to distinguish between counterfeit medicines and the genuine article. We rely on our government's health and safety officials like the Food and Drug Administration to keep unsafe drugs out of American medicine cabinets.

It is a mystery to me why anyone would vote for a bill that would prevent our health officials from doing their job. That just blows my mind. And it is a giant step in the wrong direction.

I ask all of my colleagues here tonight to vote against this bill because