they sign on to the DeGette bill. I have signed on to the bill of the gentlewoman from Colorado (Ms. DEGETTE). And though she may be a member of the minority party, she is right on how to address that issue.

The gentleman from Kentucky (Mr. WHITFIELD) has got a Republican version. But always we have to take the political cheap shot. We have always got to do that.

For once, even on a resolution, if it does not say enough, then it does not do that much damage. Can my colleagues not, at least, try to meet us halfway? Those of us that have met them halfway more times than they have ever come across our side of the aisle are standing here today and asking them, those of us that have crossed the aisle consistently, that on this resolution, all it is saying is, in July, let us see if the money is there and let us make the effort.

Mr. Speaker, I yield such time as she may consume to the gentlewoman from New Mexico (Mrs. WILSON).

Mrs. WILSON. Mr. Speaker, I know my colleagues wanted to do it today. So did I. And that is why I offered an amendment in the Committee on Rules.

The reason I was not ruled in order is probably the same reason my colleagues were not ruled in order is because we cannot spend money in this House that we do not yet have. But we all know in this room that we expect new estimates within a month.

It would have, I think, been irresponsible on our part to not move forward on prescription drugs and to keep this process moving forward to get a prescription drug plan. And I support that. But I would not want to have held that back to get a fix on more Medicare fixes this year and in the year starting in October just because we do not have the budget estimates yet. And that is the nature of this.

I have kind of taken this up as my personal cause on this side of the aisle. I think some of my colleagues sitting here know that I make it a pretty regular effort to do things in a bipartisan way, whether it is on low-power radio or Superfund or a whole variety of other things we are working on, Baca land in northern New Mexico, and quite a few things in the Committee on Commerce. That is just kind of who I am, and that is my style.

I commit to work with those of my colleagues who are concerned about Medicare reimbursement rates and the disparity in different parts of the country to try to make this work as soon as we have the budget estimates to do so. I give my colleagues my personal word on that.

Mr. TANNER. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I just say to my friend from California (Mr. BILBRAY), as I said at the outset of my remarks, we are going to support his resolution here. And there is nothing wrong with it.

It is just that when, at the end of this day, we had probably one of the most important Medicare bills in the history of the program here, this prescription drug benefit, and his leadership would not even give the Democrats an alternative.

Today, an hour ago, we tried to do this very thing this resolution does in a motion to recommit. Not one single vote for help. And so, when my colleague says they reach across the aisle more than we do, when their leadership does not even give us an alternative, reduces us to nothing more than a motion to recommit and we cannot get that, when we have a bill that does this, when we have an amendment that did this, after a while we begin to say, what is going on here? Do these people really want to do this?

We have the wherewithal to do it. It is called a bill. This resolution is fine, and we are going to support it, and we are going to reach across every time we can.

But I just tell my colleague, when we try to work legislatively and we are virtually shut out, as we were today, from any input at all and then after the fact, as the gentleman from Washington (Mr. MCDERMOTT) said, they have a resolution that says we are going to promptly do this, well, we could have promptly done it 2 weeks ago or tonight but we did not.

So I do not want to be partisan, either. I just say there is a way to do this called a bill and we are ready, willing, and able to do it. In fact, we would have done it an hour ago if we would have had some help.

Mr. Speaker, I yield back the balance of my time.

Mr. BILBRAY. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I would just like to say that I appreciate the support for this resolution. I just want to articulate that the gentleman is not the only one who gets frustrated the way sometimes this House is run. A lot of people were frustrated the way the House was run before the new majority took over.

Remember, I have got family that served with the gentleman that talked about the bad old days. So everybody gets frustrated with the leadership, even those of us on the majority side.

What we are asking as two individuals here and three individuals here that represent a lot of people out there that do not hold the Members responsible for party affiliation. When my colleagues look across the aisle, I hope they see the gentleman from California (Mr. BILBRAY), representative of San Diego, not just a Republican. And I think we need do more of that.

The gentlewoman from New Mexico (Mrs. WILSON) is probably the most sincere individual that could ever work on this issue, and I think that my colleagues recognize that she has worked hard with both sides of the aisle.

The gentleman from Alabama (Mr. BACHUS) has made his efforts. All we are asking is that here is a place we may disagree, we might have had disagreements today, but let us finish off the evening by at least saying this is something we can meet halfway and start building a future from now on rather than talking about animosity in the past.

Mr. Speaker, I yield back the balance of my time.

The SPEAKER pro tempore (Mr. PEASE). The question is on the motion offered by the gentleman from California (Mr. BILBRAY) that the House suspend the rules and agree to the resolution, H.Res. 535.

The question was taken.

Mr. BILBRAY. Mr. Speaker, on that I demand the yeas and nays.

The yeas and nays were ordered.

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX and the Chair's prior announcement, further proceedings on this motion will be postponed.

DRUG IMPORT FAIRNESS ACT OF 1999

Mr. BILBRAY. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 3240) to amend the Federal Food, Drug, and Cosmetic Act to clarify certain responsibilities of the Food and Drug Administration with respect to the importation of drugs into the United States.

The Clerk read as follows:

H.R. 3240

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Drug Import Fairness Act of 1999''.

SEC. 2. FINDINGS.

The Congress finds as follows:

(1) Pharmacists, patients, and other persons sometimes have reason to import into the United States drugs that have been approved by the Food and Drug Administration (''FDA'').

(2) There have been circumstances in which—

(A) a person seeking to import such a drug has received a notice from FDA that importing the drug violates or may violate the Federal Food, Drug, and Cosmetic Act; and

(B) the notice failed to inform the person of the reasons underlying the decision to send the notice.

(3) FDA should not send a warning notice regarding the importation of a drug without providing to the person involved a statement of the underlying reasons for the notice.

SEC. 3. CLARIFICATION OF CERTAIN RESPONSIBILITIES OF FOOD AND DRUG ADMINISTRATION WITH RESPECT TO IMPORTATION OF DRUGS INTO UNITED STATES.

Section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381) is amended by adding at the end the following subsection:

''(g)(1) With respect to a drug being imported or offered for import into the United States, the Secretary may not send a warning notice to a person (including a pharmacist or wholesale importer) unless the following conditions are met:

''(A) The notice specifies, as applicable to the importation of the drug, that the Secretary has made a determination that—

''(i) importation is in violation of section 801(a) because the drug is or appears to be adulterated, misbranded, or in violation of section 505;

''(ii) importation is in violation of section 801(a) because the drug is forbidden or restricted in sale in the country in which it was produced or from which it was exported;

''(iii) importation by any person other than the manufacturer of the drug is in violation of section 801(d); or

''(iv) importation is otherwise in violation of Federal law.

''(B) The notice does not specify any provision described in subparagraph (A) that is not applicable to the importation of the drug.

''(C) The notice states the reasons underlying such determination by the Secretary, including a brief application to the principal facts involved of the provision of law described in subparagraph (A) that is the basis of the determination by the Secretary.

''(2) The term 'warning notice', with respect to the importation of a drug, means a communication from the Secretary (written or otherwise) notifying a person, or clearly suggesting to the person, that importing the drug is, or appears to be, a violation of this Act.''.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from California (Mr. BILBRAY) and the gentleman from Ohio (Mr. BROWN) each will control 20 minutes.

The Chair recognizes the gentleman from California (Mr. BILBRAY).

Mr. BILBRAY. Mr. Speaker, I ask unanimous consent to yield the time for the purpose of management to the gentleman from Oklahoma (Mr. COBURN).

The SPEAKER pro tempore. Is there objection to the request of the gentleman from California?

There was no objection.

Mr. COBURN. Mr. Speaker, I yield 3 minutes to the gentleman from Minnesota (Mr. GUTKNECHT).

Mr. GUTKNECHT. Mr. Speaker, I thank the gentleman for yielding me the time.

Mr. Speaker, I am delighted that we are finally getting a chance to talk about this bill. We have had a lot of discussion today about the high cost of prescription drugs. I do not know if this chart was shown or a chart similar to it, but we have got a lot of charts and a lot of research has been done by a number of groups around the United States about the differences between what Americans pay for prescription drugs and what people around the rest of the world pay for exactly the same prescription drugs.

□ 2340

Let me give one example. My father takes a drug called coumadin. If one buys that drug in the United States, the price is $30, roughly $30.50 for a 30-day supply. If one buys that same drug made in the same plant under the same FDA approval in Europe, Switzerland, for example, you pay $2.85.

Now, Mr. Speaker, we have the North American Free Trade Agreement. We have passed a number of free trade agreements and somehow we always wind up on the short end of that stick.

Let me show another example. This is an example of a very commonly-prescribed drug called prilosec. If one buys it in Minneapolis, the average price for a 30-day supply is $99.95, but if one buys it in Winnipeg, Manitoba, if one happens to be vacationing and they have their prescription, they take it into a pharmaceutical shop and it can be bought for $50.88, but if one happens to be vacationing down in Mexico, in Guadalajara, Mexico, the same drug, made in the same plant, under the same FDA approval, can be bought for $17.50.

Mr. Speaker, this is really about basic fairness. If we are going to have the North American Free Trade Agreement, American consumers ought to be able to benefit from this. It is easy for us to blame the big pharmaceutical supply companies, the big manufacturers, but the truth of the matter is, one of the real culprits and one of the real reasons we can see these big differentials is our own Food and Drug Administration, because when consumers try to order these drugs or reorder drugs that they have bought at a pharmacy, whether it be in Guadalajara or Winnipeg or wherever, when they try to reimport, bring those drugs back in and reorder, they get a very threatening letter from our own FDA.

The unvarnished truth is, Mr. Speaker, our own FDA is defending this system. Our own FDA is standing between American consumers and lower drug prices.

So I have offered a bill. It is a relatively simple bill. Part of the problem is that right now the burden of proof is on the importer to prove that it is a legal drug in the United States, and that is very difficult for a senior citizen living in Minnesota or Montana or wherever.

What my bill basically says is the burden of proof is now going to be on the FDA. They must prove that those drugs are, in fact, illegal. Now, it is not the complete answer but it is a very important first step. If we can pass this here in the House, if we can get it passed in the Senate, if we can get it passed by the conference committee, we can begin the path to opening up our borders and having lower prescription drug prices for American consumers.

Mr. BROWN of Ohio. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I want to thank the gentleman from Minnesota (Mr. GUTKNECHT) for bringing attention to the fundamental issue underlying all of our efforts on prescription drugs. His efforts are admirable. Prescription drug prices are priced unreasonably, unjustifiably, outrageously high in the United States. That is the issue. Why are drug prices two times, three times, four times higher here than in other industrialized countries? Because the prescription drug industry can get away with it.

We do not negotiate prices. We do not demand that drug manufacturers reduce their prices to reflect the taxpayer-funded portion of research and development. We do not make use of the collective purchasing power of 39 million Medicare beneficiaries to demand reasonably priced drugs.

Two weeks ago I took a dozen seniors from northeast Ohio across the border to a Canadian pharmacy in Windsor, Ohio, where they paid one-half, one-third and in a couple of cases one-sixth of what it would have cost to purchase their prescriptions in Cleveland or Lorraine or Medina.

What these seniors were doing out of desperation was engaging in a practice called parallel importing. Current law prohibits reimportation of prescription drugs manufactured in the United States. FDA, however, permits exemptions for individuals who are purchasing a limited supply of an FDA-approved prescription drug for personal use.

The U.S. is the wealthiest nation in the world. Our tax dollars finance a significant portion of R&D underlying new prescription drugs. Our senior citizens should not have to leave the United States to get the medicines they need. It should never have reached this point.

Why do we tolerate it? We tolerate it because the prescription drug industry has a huge stake in the status quo and spends lavishly on television and in this institution to preserve it. They pour money into political campaigns. They pour money into front groups like Citizens for a Better Medicare. They pour money into advertising campaigns, campaigns touting the GOP's prescription drug coverage proposal, which this Congress in a partisan vote passed today, all of which undercuts the plan's credibility.

They try to scare Americans into believing that if we do not let drug manufacturers charge obscenely high prices that medical research and development will dry up, but drug companies could afford to spend $8.3 billion last year on marketing and advertising. Drug company profits outpace those of every other industry in this country by more than 5 percentage points.

Last year, Bristol-Myers-Squibb paid their CEO $146 million in salary and benefits.

The drug industry consistently leads every other industry in return on investment, in return on assets and return on equity. Thanks to huge tax breaks, the drug industry's effective tax rate is 65 percent lower than the average for other U.S. industries. Drug prices can come down in the United States without stifling research and development. Unfortunately, it does not matter whether we could take steps to make prescription drugs more affordable. The only thing that matters is whether we actually do take those steps, and if the Republicans' prescription drug coverage plan is any indication GOP leadership is not going to sneeze without asking the drug industry's permission.

That leaves American consumers who need affordable medicines with imperfect options like traveling to Canada to fill their prescriptions or to Mexico in

the southern part of the United States. That is what my colleague's amendment is about and I applaud him for that. It is intended to help pave the way for seniors to purchase their drugs across the border. Unfortunately, it does not fulfill that objective. It does not codify a senior's right to parallel import their prescription medications. The paperwork burden this amendment could create may force FDA to shift resources away from intercepting counterfeit or unsafe drugs.

The gentleman from Arkansas (Mr. BERRY), the gentlewoman from Missouri (Mrs. EMERSON) and the gentleman from Vermont (Mr. SANDERS) requested the right to offer an amendment during today's deliberations that would have explicitly enabled seniors to purchase their prescription drugs from countries where prices are reasonable, without compromising FDA's ability to protect consumers from counterfeit and unsafe medicines. The Republican leadership refused to permit consideration of that amendment.

Once again, the Republicans have created a Catch-22 that protects the drug industry at the expense of consumers.

Earlier, we were given a choice of voting for a smoke and mirrors prescription drug plan or voting for no plan at all. Now we are placed in a position of either, one, voting for an amendment that could compromise FDA's ability to protect consumers from counterfeit and unsafe medicines or, two, voting against an amendment that at least acknowledges the need to address prescription drug price discrimination and, most importantly, that asserts the right of consumers to fight back by getting their medicines outside the United States.

Again, I applaud the gentleman from Minnesota (Mr. GUTKNECHT) for his good work and for underscoring the need to do something about the drug industry's discriminatory pricing, but regretfully I must oppose this particular bill.

Mr. Speaker, I reserve the balance of my time.

Mr. COBURN. Mr. Speaker, I yield myself 30 seconds.

Mr. Speaker, just a couple of points on the points that the gentleman from Ohio (Mr. BROWN) made. We also are not allowed by the rule and by the powers that be with an ability to limit the direct consumer advertising that should be a part of this, that consumed $1.9 billion last year, will consume $3.8 billion this year and will consume $7.6 billion a year from now, all of which has no benefit for the American consumer except the American consumer is paying for it.

□ 2350

Mr. Speaker, I yield 2½ minutes to the gentleman from Florida (Mr. MILLER).

Mr. MILLER of Florida. Mr. Speaker, I thank the gentleman for yielding time to me.

I congratulate the gentleman from Minnesota (Mr. GUTKNECHT) for bringing this issue up. I have been an early cosponsor of his legislation.

My congressional district in Florida has more seniors than any district, or as many as any district in the country. It is a beautiful retirement area in southwest Florida.

At my town meetings, I have had two concerns expressed by seniors. One is, we need help with our prescription coverage. Our prescription costs are so much higher today than they were certainly in 1965 when Medicare came in. We need to do something about it.

This House for the first time in history finally passed legislation. Let us hope the Senate will act and we will get something to the President in the next few months. We really need to help the seniors.

The other issue is, why are drugs lower in Canada and elsewhere around the world? I do not know the answer to that. As the gentleman from Minnesota (Mr. GUTKNECHT) showed in his chart, we just look at prescription after prescription where this is a fraction of the cost in Europe, whether it is in England, Ireland, France, or if we go to Mexico, it is lower.

Why? I do not have an answer, but I do know how to solve the problem: Buy it where it is cheapest. If we can find a cheaper place to buy it, that is what the marketplace is all about. Let us let the market work. We should not have the government stand in the way to cause problems.

That is what this FDA is doing, just making it more difficult. There is no reason why we cannot go buy our drugs from Montreal or London or Belfast or Bombay or Mexico City. Why not allow the marketplace to work?

This is just a first step in the right direction. For my constituents, it is not going to be as convenient to go to Canada as for those of the gentleman from Minnesota (Mr. GUTKNECHT) or those of the gentleman from Vermont (Mr. SANDERS) over there, but we should be able to pick up an 800 number, a fax, or the Internet.

This is a global economy we are in. We have been opening up trade since I have been in Congress, whether it is the NAFTA bill back in 1993, then we had the GATT, and just a month or so ago we had opening more trade with China.

Why are not drugs available easily over the Internet? We should make that possible. Most drugs are manufactured outside the United States, anyway. The FDA certifies those laboratories where the drugs come from. It should not be that complicated to solve the problem.

I think our government is just too bureaucratic to solve the problem. I urge support for this bill, and I hope we can go further beyond this bill. I congratulate the gentleman from Minnesota (Mr. GUTKNECHT).

Mr. BROWN of Ohio. Mr. Speaker, I yield 2 minutes to the gentleman from Arkansas (Mr. BERRY), who has been a leader on this and an absolute warrior against outrageously high prescription drug prices.

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

Mr. BERRY. Mr. Speaker, I thank the gentleman for yielding time to me.

Mr. Speaker, I applaud the gentleman from Minnesota (Mr. GUTKNECHT) for his effort and his work addressing a very legitimate problem of Americans getting ripped off by drug manufacturers every time they visit their local pharmacy.

Undoubtedly, something is needed to rectify the injustice that has resulted in Americans paying more for FDA-approved products made in FDA-approved facilities than citizens of any other country in the world.

I have here two bottles. Both of them are Claritin, made by Schering Corporation. One of them is sold in North Dakota for $219 for 100 tablets. The same 100 tablets in Canada is $61. It is one of the safest drugs ever made by man. It is unbelievable how safe this product is. Yet, the American people get ripped off, pay four times what they ought to have to pay for this product just because of the laws of the country that protect the prescription drug manufacturers in this country.

The gentleman from Minnesota (Mr. GUTKNECHT) has approached this legislation with noble intentions and placed much effort into passing it. While I support his efforts, Congress should take a much more comprehensive approach in dealing with this situation.

Under the Food, Drug, and Cosmetic Act, the burden is on the importer to demonstrate that an imported drug is safe, effective, and approved by the FDA. That product was originally made in an FDA-approved facility. As long as FDA approval information is not required to follow drugs sold abroad, importation by anyone other than the manufacturer will be next to impossible.

There is also a great need to revisit a provision in the Food, Drug, and Cosmetic Act that protects American pharmaceutical companies at the expense of the consumers. This provision makes it illegal for anyone other than the manufacturer to reimport into the U.S. prescription medicine made by an American pharmaceutical manufacturer.

Mr. Speaker, I include for the RECORD a Dear Colleague letter concerning H.R. 1885.

The letter referred to is as follows:

SINCE 1994, DRUG MAKERS HAVE IMPORTED MORE FOREIGN-MADE DRUGS INTO THE U.S. THAN THEY HAVE EXPORTED!

ALLOWING PHARMACIES AND WHOLESALERS THE SAME AUTHORITY TO IMPORT SAFE, LOWER-PRICED, FDA APPROVED PRESCRIPTION DRUGS WOULD SAVE BILLIONS OF DOLLARS FOR PATIENTS AND AMERICAN BUSINESSES!!!

According to a recent analysis of global prescriptions drug pricing, the same prescription drugs an American citizen would spend $1.00 to purchase, would only cost $0.71

in Germany, $0.68 in Sweden, $0.65 in the United Kingdom, $0.64 in Canada, $0.57 in France, or $0.51 in Italy.

Economic experts agree that under a market system without regulatory or trade barriers, significant price differentials in prescription drugs would not be sustainable. Products would be bought from the lower-priced, foreign countries and then resold in the higher-priced country. Economic theory holds that as this process (known as arbitrage) occurs, prices in the lower-priced country would rise while prices in the higher-priced country would fall.

Under FDA regulations and the Food, Drug, and Cosmetic Act, only the manufacturers of a drug can import it into the United States. Drug makers have unfairly used this monopoly control over distribution in the United States to discriminate against American consumers.

By supporting H.R. 1885, The International Prescription Drug Parity Act, you can help level the playing field for American patients as well as businesses who are struggling to continue providing employees and retirees with quality, private sector coverage for prescription drugs.

H.R. 1885 amends the Food, Drug, and Cosmetic Act to allow American pharmacies and wholesalers to competitively purchase drugs abroad that were manufactured in FDA approved facilities, which have been safely stored and still meet FDA's standards, and pass significant savings down to consumers. Americans will benefit by being able to obtain needed prescription medicines on a more affordable basis. Under H.R. 1885, pharmacies and wholesalers importing drugs would still have to meet the same standards set by FDA, which allowed $12.8 billion worth of drugs to be imported into the U.S. by manufacturers in 1997.

Sincerely,

JO ANN EMERSON,
MARION BERRY,
BERNIE SANDERS,
Members of Congress.

(Table attachment).

PHARMACEUTICALS: U.S. SHIPMENTS, DOMESTIC EXPORTS, IMPORTS FOR CONSUMPTION, MERCHANDISE TRADE BALANCE, APPARENT CONSUMPTION, EXPORTS AS A PERCENT OF SHIPMENTS, AND IMPORTS AS A PERCENT OF CONSUMPTION, 1993–97

[Dollars in millions]

Year	Shipments	Exports	Imports	Trade balance	Apparent consumption	Exports as a percent of shipments (percent)	Imports as a percent of consumption (percent)
1993	$58,428	$7,222	$6,094	$1,128	$59,556	12.4	10.2
1994	60,811	7,565	6,966	599	61,410	12.4	11.3
1995	68,473	7,996	8,583	−587	67,886	11.7	12.6
1996	75,047	8,889	11,161	−2,272	72,775	11.8	15.3
1997	[1] 82,550	9,600	[1] 12,836	−3,236	79,314	11.6	16.2

[1] Estimated by U.S. International Trade Commission Staff.

Source: U.S. Department of Commerce.

Mr. Speaker, I include for the RECORD the text of the bipartisan amendment offered by the gentlewoman from Missouri (Mrs. EMERSON), myself, and the gentleman from Vermont (Mr. SANDERS), to the House Committee on Rules, which failed.

The amendment referred to is as follows:

Add at the end the following title:

TITLE IV—INTERNATIONAL PRICE COMPETITION REGARDING COVERED DRUGS

SEC. 401. FACILITATION OF IMPORTATION OF CERTAIN DRUGS APPROVED BY FOOD AND DRUG ADMINISTRATION.

(a) IN GENERAL.—Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.) is amended—

(1) in section 801(d)—

(A) by striking paragraphs (1) and (2); and

(B) by redesignating paragraphs (3) and (4) as paragraphs (1) and (2), respectively; and

(2) by inserting after section 801 the following section:

''IMPORTATION OF CERTAIN DRUGS

''SEC. 801A. (a) IN GENERAL.—After consultation with the United States Trade Representative (through the Office of International Relations under section 803), the Secretary shall promulgate regulations to carry out subsection (c) for the purpose of facilitating the importation into the United States of covered drugs (as defined in subsection (f)).

''(b) COMPLIANCE WITH REQUIREMENTS REGARDING SAFETY AND EFFECTIVENESS, ADULTERATION AND MISBRANDING, AND OTHER MATTERS.—With respect to the importation of covered drugs into the United States pursuant to this section, regulations under subsection (a) shall include such provisions as the Secretary determines to be appropriate (such as requiring tests or documents) to ensure that each of the requirements of this Act for the importation of drugs is met, including requirements with respect to—

''(1) the safety and effectiveness of the drugs;

''(2) good manufacturing practices and other provisions regarding the adulteration of the drugs;

''(3) the misbranding of the drugs; and

''(4) whether the drugs are forbidden or restricted in sale in the country in which they were produced or from which they were exported.

''(c) FACILITATION OF IMPORTATION.—If a covered drug is domestically approved and is manufactured in a State and then exported, or is domestically approved and is for commercial distribution manufactured in a foreign establishment registered under section 510, the manufacturer shall, as a condition of maintaining the domestic approval of the drug, comply with the following:

''(1) For each shipment of the drug that is manufactured in compliance with current good manufacturing practice and other standards under section 501, the manufacturer shall (without regard to whether the shipment is intended for importation into the United States) maintain a record that identifies the shipment and purchaser of the shipment and states the fact of such compliance.

''(2) For each such shipment, the manufacturer shall (without regard to whether the shipment is intended for importation into the United States) maintain a record that identifies the shipment and provides the labeling required for the drug pursuant to section 502 and pursuant to the application for domestic approval.

''(3) Upon the request of pharmacist, wholesaler, or other person who intends to import into the United States drugs from such shipment (and who meets applicable legal requirements to be an importer of covered drugs), the manufacturer shall provide to the person a copy of each of the records maintained under paragraphs (1) and (2) with respect to the shipment.

''(d) CERTAIN CRITERIA.—For the purpose of facilitating the importation into the United States of covered drugs, the Secretary shall through regulations under subsection (a) establish the following criteria:

''(1) Criteria regarding the records required in subsection (c) and the use of the records to demonstrate the domestic approval of the drugs and compliance of the drugs with sections 501 and 502.

''(2) Such criteria regarding the labeling of the drugs as the Secretary determines to be appropriate.

''(3) Criteria regarding the amount of charges that may be imposed by manufacturers of the drugs for maintaining and providing the records specified in paragraph (1). Any such charge may not exceed an amount reasonably calculated to reimburse the manufacturer involved for the costs of maintaining and providing the records.

''(4) Criteria regarding the information that may be required by manufacturers of covered drugs as a condition of providing the records.

''(5) Criteria regarding entities that may serve as agents of persons described in subsection (c)(3) or that otherwise may serve as intermediaries between such persons and manufacturers of covered drugs.

''(e) AUTHORITY TO REQUIRE REGISTRATIONS.—

''(1) IN GENERAL.—In promulgating regulations under subsection (a), the Secretary may provide that a person may not import a covered drug into the United States unless—

''(A) the person registers with the Secretary the name and places of business of the person; and

''(B) in the case of each factory or warehouse in a foreign country that held the covered drug prior to the drug being offered for importation into the United States (other than ones owned or operated by the manufacturer of the drug), the owner or operator of the factory or warehouse—

''(i) registers with the Secretary the name and places of business of the owner or operator; and

''(ii) agrees that the factory or warehouse is subject to inspection in accordance with section 704.

''(2) EXEMPTION FOR MANUFACTURER.—Paragraph (1) does not apply with respect to a covered drug that is domestically approved, manufactured in a State, exported, and then imported by the manufacturer of the drug.

''(f) DEFINITIONS.—For purposes of this section:

''(1) The term 'covered drug' means a drug that is described in section 503(b) or is composed wholly or partly of insulin.

''(2) The term 'domestically approved', with respect to a drug, means a drug for which an application is approved under section 505, or as applicable, under section 351 of the Public Health Service Act. The term 'domestic approval', with respect to a drug, means approval of an application for a drug under such a section.

''(3) The term 'pharmacist' means a person licensed by a State to practice pharmacy in the State, including the dispensing and selling of prescription drugs.

''(4) The term 'wholesaler' means a person licensed in the United States as a wholesaler or distributor of prescription drugs.''.

(b) CONFORMING AMENDMENT.—Section 801(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(d)) is amended in paragraph (2) (as redesignated by subsection (a)(1) of this section) by striking ''paragraph (3)'' each place such term appears and inserting ''paragraph (1)''.

MEMORANDUM

To:

From: Christopher J. Sroka, Economic Analyst, Resources, Science, and Industry Division, Congressional Research Service.

Subject: Summary of H.R. 1885, the International Prescription Drug Parity Act.

This memorandum responds to your request for a summary of the International Prescription Drug Parity Act (H.R. 1885). H.R. 1885 seeks to amend the Federal Food, Drug, and Cosmetic Act to facilitate the importation of prescription drugs into the United States.

It has been widely reported that prescription drug prices are lower in many foreign countries than in the United States. Two studies were conducted by the U.S. General Accounting Office in the early 1990s. One study examined prices in the U.S. relative to those charged in Canada, while the second study examined prices in the U.S. vis-a-vis the United Kingdom. The studies concluded that prices are typically higher in the U.S. than in Canada or the U.K. Complementing these empirical studies, there are many anecdotal accounts of American citizens traveling to Canada or Mexico to obtain their prescription drugs at a lower price. Differences between the prices charged in the U.S. and those charged in other countries have been attributed to various factors.

In theory, under a market system without regulatory or trade barriers, significant price differentials in prescription drugs would not be sustainable. Products would be bought from the lower-priced, foreign countries and then resold in the higher-priced country. Economic theory holds that as this process (known as arbitrage) occurs, prices in the lower-priced country would rise while prices in the higher-priced country would fall. Arbitrage would continue until, after taking into account differences in transportation costs, a uniform price would prevail in both countries.

Current federal law and Food and Drug Administration (FDA) policy prevents arbitrage in prescription drugs. All drugs sold in the U.S., including imported drugs, must have been manufactured in an FDA-approved facility. The FDA's policy is to assume that, unless the importer has proof to the contrary, imported drugs are not manufactured at FDA-approved facilities. Obtaining proof that a drug sold abroad was actually manufactured in an FDA-approved facility can be burdensome for the importer because the foreign seller of the drug might not have accurate documentation proving the drug's origin. Furthermore, the Prescription Drug Marketing Act of 1987 limits the reimportation of prescription drugs. Reimportation occurs when a drug manufactured in the U.S. is exported to another country and then imported back into the U.S. The prescription Drug Marketing Act of 1987 prohibits reimportation by an entity other than the original manufacturer of the drug. Thus, even if an importer could prove that the pharmaceutical it wishes to import was manufactured in an FDA-approved facility in the U.S., the reimportation would be illegal.

The intent of the FDA's importation policy and the Prescription Drug Marketing Act was not to prevent American consumers from obtaining drugs at lower prices. The purpose was to ensure the safety of prescription drugs for American consumers. At the time, the concern was that drugs imported into the U.S. may have been counterfeit copies of FDA-approved products. Counterfeit drugs could pose a serious health threat if they are not manufactured properly. Another concern was that, even if the drugs were not counterfeit, the proper storage and handling of legitimate products could not be guaranteed once they exited the U.S. Furthermore, drugs manufactured domestically but intended for export may be labeled for use in the country of destination. Thus, these drugs, if imported, might not meet the FDA's labeling requirements. Drugs not labeled in accordance to FDA regulations might pose additional health threats to American consumers.

H.R. 1885 seeks to remove the barrier to the importation of prescription drugs, while at the same time ensuring the safety of these drugs. The bill would strike the provisions of the Federal Food, Drug, and Cosmetic Act that were added by the Drug Marketing Act of 1987. Thus, entities other than the original manufacturer could reimport pharmaceuticals.

Furthermore, the bill would establish certain record-keeping requirements for pharmaceutical manufacturers. These requirements would apply to (1) all drugs manufactured in the U.S. and intended for export, and (2) all drugs manufactured in FDA-approved facilities in foreign countries. The record-keeping requirements would apply regardless of whether the drugs are intended for final sale in the U.S. Under the bill, pharmaceutical manufacturers would be required to keep records proving that each shipment of drugs was manufactured in an FDA-approved facility. Manufacturers would also be required to keep a record of the FDA-approved labeling for each shipment of drugs, regardless of its final destination. The bill would allow importers to obtain the manufacturing and labeling records from the pharmaceutical manufacturer. By obtaining these records, importers might be able to more easily prove that the drugs they wish to import are safe and comply with FDA regulations.

Mr. COBURN. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I would like to add to what the gentleman from Arkansas had to say. Mr. Speaker, $5.9 billion of Claritin were sold last year. There are four other drugs with similar chemical moieties that have been approved by the FDA. Guess what, they are all priced the same. Why is that? Because there is not price competition in the pharmaceutical industry.

Mr. Speaker, I yield 2 minutes to the gentleman from Michigan (Mr. HOEKSTRA).

Mr. HOEKSTRA. Mr. Speaker, I thank my colleague for yielding time to me. I also applaud my colleague, the gentleman from Minnesota (Mr. GUTKNECHT), for introducing this legislation and bringing it to the floor this evening.

Mr. Speaker, there is no doubt that U.S. consumers are paying a premium for their prescription drugs. It is wrong. U.S. consumers have no problem paying for the product that they consume. They have no problem paying for the research and development costs that the companies incur. They do not mind paying a fair return to the investor and the drug companies.

What they do object to is paying the profits and the research and development costs of our colleagues and our neighbors in Mexico, in Canada, in other parts of the world. We are subsidizing the consumption of prescription drugs in Canada, Mexico, and Europe. It is not fair to the American consumer, it is not fair to our American taxpayer.

What this bill does is it says that if our consumers find these drugs, prescription drugs, available at a lower price in Canada, Mexico, or somewhere else, these drugs, prescription drugs, will be made available to the American consumer. It is the fair thing and it is the right thing to do.

Mr. BROWN of Ohio. Mr. Speaker, I yield 5 minutes to the gentleman from Vermont (Mr. SANDERS), who has been very involved in fighting for parallel importation of prescription drugs.

Mr. SANDERS. Mr. Speaker, I very much thank my friend, the gentleman from Ohio, for yielding time to me.

I want to congratulate my colleague, the gentleman from Minnesota (Mr. GUTKNECHT), for introducing what I think is important legislation which raises some very, very fundamental issues.

I think that tonight's discussion in terms of prescription drugs is good, and I am delighted to hear it taking place in a nonpartisan way, progressives, conservatives, who are standing up for the American consumer.

I believe that I was the first Member of Congress to go across the border with constituents to purchase prescription drugs. I have made that trip twice. I made a trip a year ago to Canada. Like everyone else that we have heard tonight, my experience was that we went across the border and we were able to save Vermont constituents thousands and thousands of dollars.

The one particular drug that comes to my mind now is Tamoxifen, which is widely prescribed for breast cancer. Here we have women fighting for their lives, they go across the Canadian border and they purchase that product for one-tenth the price that they were paying in the United States.

It seems to me, and we have heard it all already, I must tell the Members, I have concerns about NAFTA and I voted against it; concerns about that aspect of the global economy.

The bottom line is, as the gentleman from Florida (Mr. MILLER) said a few moments ago, in every single product one can think of, whether it is a food product, whether it is shoes, whether it is apparel, there are massive amounts of trade taking place throughout the world. The question that the American people have to ask is why is it that there is an exception with prescription drugs.

Legislation that has been offered by the gentleman from Arkansas (Mr. BERRY) and the gentlewoman from Missouri (Mrs. EMERSON) and myself which now has 85 cosponsors is a very simple piece of legislation. It is a free trade piece of legislation.

What it says is exactly what the gentleman from Florida (Mr. MILLER) was talking about a moment ago. That is, if one is a prescription drug distributor, if they are a pharmacist, they should be able to go out and purchase anyplace in the world that they can FDA-safety-approved products at the best price that one can purchase it.

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And if the case is that one can go to Canada, the reason that Tamoxifen and all the other products are sold less expensively in Canada is that the pharmacists purchase the product for significantly lower amounts of money. Why is it that an American pharmacist has to pay 10 times more for a product than a Canadian or Mexican pharmacist?

Mr. Speaker, it seems that people who believe in the competitive, free enterprise system should support legislation which says that a prescription drug distributor, so long as the product that comes into the country is safe and that is easily done, that that businessperson has a right to purchase that product at the lowest price he or she can so that it can be sold to the American people at a lower price, so that we end the disgrace that that chart was showing us that Americans are paying by far more than the people of any other country for the same exact prescription drug.

Mr. Speaker, I think this particular piece of legislation is a small step forward, but it may open the door for further discussion. I hope tonight, and I mean this very sincerely, that in a nonpartisan way we can go forward. I think we are in basic agreement. The only rational objection that anyone can throw us is the fear of adulteration from abroad and so forth. That is easily addressed. If we can bring into this country pork and beef and lettuce and tomatoes from farms and ranches all over this continent, my God, we can regulate the importation of prescription drugs which are made in a relatively few factories.

I think that we are onto something big tonight, and I think if we continue to work together in developing the concept of reimportation, we can substantially lower the cost of prescription drugs in this country 30, 40, or 50 percent and not see the American consumer the laughing stock of the world by paying two, three, five times more for products than other people throughout this world.

So I see this discussion as a very, very important step forward. I congratulate the gentleman from Minnesota (Mr. Gutknecht) for bringing this piece of legislation to the floor; and I hope that after tomorrow, we will continue to meet and go forward and represent the American consumers and finally stand up to the pharmaceutical industry which is ripping our people off.

Mr. COBURN. Mr. Speaker, I yield 2½ minutes to the gentlewoman from Idaho (Mrs. CHENOWETH-HAGE).

Mrs. CHENOWETH-HAGE. Mr. Speaker, I thank the gentleman from Oklahoma for yielding me this time. It is very interesting, but since 1996, drug costs have increased by over 50 percent. But in yesterday's Wall Street Journal, the Wall Street Journal reported that the average cost of a prescription rose almost 10 percent in 1999.

Now, for those aged 70 and up, costs for prescriptions rose by 15 percent. Tell me, our senior citizens who are on fixed incomes, where are they going to get the extra 15 percent? From their heating bill? From their food? From the cost of their air conditioner? Where? And yet the drug companies are making massive profits off of the American consumer.

Prilosec here for instance, $109 here. But in Mexico, it is $17.64 for the same prescription. Something is dreadfully wrong.

The Canadian Government yesterday released a study showing that the Canadian consumers pay 56 percent less than Americans for patented medications.

Now, our drug companies are well supported by the American taxpayer. According to a 1993 report by the Office of Technology, in addition to general research and training support, there are 13 programs specifically targeted to fund pharmaceutical research and development. That same report noted, of all U.S. industries, innovation within the pharmaceutical industry is the most dependent upon academic research and the Federal funds that support it. Translate that to the taxpayers' dollars that already support it.

In fact, in 1997, Merck and Pfizer devoted only 11.2 percent of their revenue to research and development. Pfizer and Merck devoted 11.2 percent to research and development, while marketing costs consumed 30 percent. And that includes all the television ads that we are seeing now. So generally across the board for the drug companies, research and development is about 20 percent, marketing about 20 to 30 percent; but manufacturing is 5 to 25 percent. That is the level that other countries draw when they negotiate these contracts with American drug manufacturers.

Mr. Speaker, I highly support the bill offered by the gentleman from Minnesota.

Mr. BROWN of Ohio. Mr. Speaker, I yield 4 minutes to the gentleman from Michigan (Mr. DINGELL), who tried so hard to offer an alternative plan today, and was not allowed, on the prescription drug bill.

Mr. DINGELL. Mr. Speaker, I thank the distinguished gentleman from Ohio (Mr. BROWN) for making this time available to me.

I would love to support this bill. I think it is a wonderful thing. I am looking at the picture down there which tells how outrageously high drug prices are in this country. I commend the author of the legislation, and I hope that in some way this is helpful.

Mr. Speaker, I wish that we had considered these matters with a greater degree of care at a little earlier time when we were considering the legislation which related to what we are going to do to American citizens who are senior citizens who are desperately in need of fairer and more appropriate prices for prescription pharmaceuticals.

I think it is a great shame that this body did want to have a rule which permitted the proper consideration of a perfectly germane amendment which would have been offered by the gentleman from Arkansas (Mr. BERRY), the gentleman from Vermont (Mr. SANDERS), and the gentlewoman from Missouri (Mrs. EMERSON) on the other side of the aisle. I think that we would then have come up with an end package which would have afforded us a great deal more hope that, in fact, we were doing good for the American people in seeing to it that they got prescription pharmaceuticals at more fair and more competitive prices.

But, unfortunately, this curious rule has precluded us from considering a perfectly germane amendment which would have done that. We now find ourselves in the regrettable position of confronting the possibility that the easing of the law with regard to food and drug and cosmetics, which is going to be done here under this legislation, will in fact reduce the safety of the American consuming public.

I would like my colleagues to know that this Congress has worked very carefully to see to it that the American people got the greatest protection with regard to prescription pharmaceuticals. We did it by putting the burden upon the importers, putting the burden upon the manufacturers, so that at every stage the burden was on him who would release into the marketplace substances which have enormous capacity for doing good, but which also have intolerable and enormous capacity to do great hurt to the consuming public: to kill, to maim, to hurt, to blind, to poison, and, indeed, to sicken.

The practical result of this legislation the way it is done is going to be to facilitate the entry into this country of pharmaceutical products over which the Food and Drug Administration is going to lose much of its power to protect the American consuming public. And, in fact, the practical result of this legislation is going to be to increase the risk to the American public in order to afford competition for what we all know are, in fact, excessively highly priced prescription pharmaceuticals.

What we are doing here, and what history is going to tell us we have done, is that we have increased the risk

but afforded a very small increase in benefits in terms of competition and that the risk that we are increasing is going to be very, very large and that we are going to find that there will be some splendid scandal on the hands of those of us who vote for this legislation tonight.

Mr. Speaker, the result of that is going to be that we are going to be compelled at some time in the not-distant future, after we have seen what is going to occur under this legislation, to come back and address something which could have been handled better if the rule had permitted the consideration of the amendment which the gentleman from Arkansas (Mr. BERRY), the gentleman from Vermont (Mr. SANDERS), and the gentlewoman from Missouri (Mrs. EMERSON) would have offered to the people of this country and upon which we might have done a better job of legislating in the overall public interest.

Mr. Speaker, I regret what we are doing. We will be sorry.

Mr. Speaker, I rise in opposition to H.R. 3240, because, although it seems benign, it would hurt the enforcement of laws ensuring the safety and efficacy of imported drugs.

The Prescription Drug Marketing Act came into being after an investigation that revealed serious irregularities with respect to adulterated and counterfeit drugs from abroad. Recent investigations of Internet Web sites indicate there is still cause for concern. Significant quantities of prescription drugs from every source around the globe are entering this country on a daily basis through the U.S. mail. In fact, just last year the U.S. Customs agency had a more than 400 percent increase in the amount of pharmaceutical drugs they found being sent into this country from abroad. In many cases, these drugs arrive in unmarked plastic bags, with no indications of what they are, where they came from, or even how they should be taken. Are they real? Who knows? Are they adulterated? Who knows? Can they cause harm? Who knows? What we do know is that there was a problem with certain drug sources when we first looked into this matter more than decade ago, and there continues to be a problem today.

I do want to acknowledge the beneficial aspects of the bill before us. Lack of access to medically necessary prescription drugs is a real problem faced by millions of Americans. I command my colleague, Mr. GUTKNECHT, and all who will support him today, for recognizing that the price Americans pay for drugs is too high. But, first and foremost, the PDMA is a public health and safety law. We should therefore tread carefully before changing it. I am greatly concerned that the bill before us has not been the subject of hearings, or a thorough examination about why the Food and Drug Administration (FDA) sends warning letters to consumers that may be engaged in potentially risky behavior. This bill may make it very difficult for the FDA, as a practical matter, to provide thousands of consumers with a warning regarding what may be potentially risky behavior. I speak not only about the person that drives across to border to Mexico, but also to the numerous individuals now purchasing their drugs from one of hundreds of Internet sites that now exist.

I am open to a careful review and revision of PDMA for the purpose of creating a paradigm for drug importation that is safe for our consumers while facilitating access to the international market prices at which many commonly prescribed prescription drugs are available. But this bill, and this process, do not have my support.

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Mr. COBURN. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I would just like to make note of the fact that the wonderful Food and Drug Administration bureaucracy that we have seen built over the last 40 years, the average price to get a drug through that organization is $450 million, of which only $50 million is allocated for safety, $400 million for efficacy for a Food and Drug Administration to tell somebody where to put a bathroom in a plant, and bureaucratic overregulation.

So when we talk about how effective it is, it is important to know what portion of the costs are really on safety and that portion which is not associated with safety.

Mr. Speaker, I yield 3 minutes to the gentleman from Montana (Mr. HILL).

Mr. HILL of Montana. Mr. Speaker, I thank the gentleman from Oklahoma for yielding me the time, and I thank the gentleman from Minnesota (Mr. GUTKNECHT) for bringing this measure before the House. I am proud to be a sponsor of the bill and to stand here to support it.

We just spent I think about 12 hours debating Medicare reform and prescription drugs. Regardless of where my colleagues were on the final vote, I think that everybody in this House should be happy with the fact that the Congress has finally got on record that it is going to do something to try to help senior citizens with prescription drugs. I know that everybody here is hopeful that we can get a bill that the Senate can pass and the President can sign to do that.

But we have a big problem in this country, and that is the soaring cost of pharmaceutical drugs. The General Accounting Office estimated the bill we just passed will reduce the price of prescription drugs to seniors by 25 percent, perhaps as much as 39 percent. But I am concerned whether that will become a reality as a consequence of that bill. Drugs are going up at the rate of four times the rate of inflation. Last year, almost 10 percent, the price of pharmaceutical drugs went up.

The irony is that, in my State of Montana, people can go right across the border, and they can buy these same prescription drugs for 56 percent less in Canada. The reason is that the FDA, in essence, has created a barrier so that Montanans cannot purchase drugs. They cannot purchase their pharmacy needs in Canada.

Now, the irony of all this is that we have the North American Free Trade Agreement. We have below-cost, cheap cattle pouring across the border in Montana, over a million of them last year. We have below-cost wheat pouring across the Montana border taking away our markets. Cheap cattle and cheap grain come across the border, no problem at all.

As a matter of fact, I do not know if the Members of the House realize it, but cattle, swinging carcases, come into this country from Canada, and they have a USDA stamp on them that says that they are inspected and graded by the U.S. Department of Agriculture even though they are not because the NAFTA agreement says that they can do that.

Now, Montanans would like to have a little benefit from NAFTA. They would like to buy their medicines from Canada as well. The irony is that ag producers who are being forced to sell their products below cost are saying, buck it up. You cannot compete in this marketplace.

Yet, the FDA has, in essence, protected, created a protected market for one of the wealthiest industries in this country, in the world, in the pharmacy companies here in this country.

So what the Gutknecht bill basically says is, no, we are not going to do that anymore. We are going to try to induce competition by allowing people to buy their medications elsewhere.

The gentleman from Vermont (Mr. SANDERS) is absolutely correct. This does not just apply to retail. The bill of the gentleman from Minnesota (Mr. GUTKNECHT) basically applies only to retail trade and pharmaceutical drugs. It ought to apply to the wholesale as well so that our local pharmacists can buy from any distributor anywhere in the world.

Now, the gentleman from Michigan (Mr. DINGELL) raised a concern about the safety issue. But what we have to realize is that these are the exact same formulations that are licensed in the United States. They are produced in exactly the same plants as they are that come into the United States. They are in the same package.

I urge my colleagues to support this bill and also support the bill of the gentleman from Vermont (Mr. SANDERS).

Mr. BROWN of Ohio. Mr. Speaker, how much time is remaining on each side?

The SPEAKER pro tempore (Mr. PEASE). The gentleman from Ohio (Mr. BROWN) has 4½ minutes remaining. The gentleman from Oklahoma (Mr. COBURN) has 6 minutes remaining.

Mr. BROWN of Ohio. Mr. Speaker, I reserve the balance of my time.

Mr. COBURN. Mr. Speaker, I yield myself 2½ minutes.

Mr. Speakers, one of the ironic things about today's debate is the debate was about whose prescription drug bill would do the problem. We had a debate about the wrong problem. The problem is the lack of price competition in the pharmaceutical industry. For if prices were not rising, seniors would not be screaming, and we would not be addressing this issue at all, putting the risk of the Medicare program

and its viability in the future on the line.

It is interesting to note that we have a President that is screaming for a prescription drug bill, and his own Justice Department will not even answer letters requesting an investigation into the antitrust activities of the pharmaceutical industry.

It is interesting to note that politics has reigned supreme in the debate about pharmaceutical and Medicare drug benefit when, in fact, we can accomplish a limitation on advertising, we can accomplish setting in force of motion of the very administrative agencies that are already in place to assure the American people that we do not have monopolies and we do not have price gouging and we do not have price fixing.

It is to be noted that the FTC has already received two consent decrees from two large pharmaceuticals manufacturers, one of which was paying $60 million a year to another pharmaceutical company not to bring a drug to market, consequently costing American consumers for $250 million for that drug alone. That drug was a calcium channel blocker known as diltiazen.

Another one, Hytrin, used for prostatic hypertrophy and hypertension, same thing, $15 million a month paid to another pharmaceutical company so they will not bring a drug to market.

We have collusion, and we have lack of competition. Until we address that, we will not be good stewards of the Medicare program. We will not be good stewards, whatever drug benefit we offer.

The other point that I would make, as we have done in every other area of Medicare, because we have not been good stewards, we are going to cost shift. We are going to lower the prices. Under the Democrat plan or the Republican plan, the prices for Medicare seniors will go down. But that price, if we do not work on the industry, will cost shift to the private sector.

So we are going to raise taxes on everybody else, their cost of health care, to supplant the lack of the proper benefits in Medicare.

Mr. Speaker, I reserve the balance of my time.

Mr. BROWN of Ohio. Mr. Speaker, I yield 4¼ minutes to the gentleman from Pennsylvania (Mr. KLINK) who has worked hard for a prescription drug benefit for Medicare beneficiaries.

Mr. KLINK. Mr. Speaker, I would start off by thanking the gentleman from Ohio for yielding me the time, even though the hour is late, and I would like to compliment the gentleman from Minnesota (Mr. GUTKNECHT) for his bill.

However, I must rise in opposition to H.R. 3240 because, while it seems harmless, and I laud the goal in the end of making sure that we can get the most fair price for drugs for all of our senior citizens, in fact for all of our citizens, this bill may seem harmless, but it could very seriously undercut the Food and Drug Administration's ability to warn the public that they are importing something that may not, in fact, be real.

The gentleman from Montana (Mr. HILL) I will tell him I wished I had the same surety that he does that these drugs were made in the same factory. We have seen with a lot of the investigations that we have done that, in fact, we have seen adulterated products. We have seen products that are not what they purport to be.

My colleagues may not realize it, but the Internet has become the new frontier for international drug purchases. Anyone with a computer and a mouse can click on a site, and one does not even need prescriptions, one does not need a doctor's okay, one just gets the drugs, and who knows where they are shipped from.

One recent investigation that we had in the Committee on Commerce of Internet pharmaceutical sales shows that buying drugs on-line can really be the on-line equivalent of trick-or-treating on Halloween in a very dangerous neighborhood. The drugs are often shipped in unmarked packages. There are no indications of strength or quality, no way of knowing what the products are, no way of knowing where they came from, no way of knowing who handled them, where they were stored or even what is in them.

We have seen reports in the news of arrests that were made for smuggling in fake Viagra. We have seen accounts of arrests being made for selling fake Xenical that was made only from starch and a small amount of an anti-asthmatic drug. We have seen reports of fake ampicillin and AZT made from starch and anti-mold powder.

How prevalent are these bogus drugs? Well, the fact of the matter is we do not know. That is the frightening thing about all of this. Much of our investigation has focused on what the Federal Government is doing to protect consumers from unknowingly being harmed by something they import from one of these rogue sites.

Now, we have got to remember the Prescription Drug Marketing Act, which regulates the import of pharmaceutical products, was enacted in response to a lot of problems people had when they unknowingly imported drugs that were being adulterated or counterfeit drugs from abroad.

The gentleman, who had spoken earlier about the importation of food, one of the problems that he and I have both had with NAFTA and with GATT and with some of these other agreements is that we know that food has been brought into this country that was bad.

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We have seen strawberries in Michigan that have caused kids to get very sick. We have seen meat products that have come in that have caused people to get sick. We have seen vegetables and fruits that come in with DDT and other kinds of things sprayed on them that we could not get away with here. So we know that the safety of food has been a problem, and the safety of drugs has been a problem too.

I want to get where the author of this bill is trying to get, but I do not think this is the way to get there. We want to help the FDA be better. They are not perfect. The reality is that this piece of legislation, with virtual conveyor belts at every international airport coming in, with these drugs being shipped by the Internet, if it were just Canada, we could deal with that, because their system is very similar to ours. The problem is we are talking about Africa and Asia and South America and central America and all of these islands nations. These drugs are being set up and manufactured all over the place, and some are real, some are not. We do not know what we are getting into.

What the gentleman is doing here, we are putting unrealistic burdens on an FDA that we have found out in the Committee on Commerce that they cannot deal with the problem as it is now. They do not have enough people to deal with what is coming in now. And the communications between the FDA and Customs is horrible, and the public is at risk already.

We cannot make it more at risk. We all want to get senior citizens access to cheaper drugs. I have concerns about the potential unintended regulatory consequences of this bill. If this bill dealt only with imports from countries like Canada, we would not have a problem. I think we need to amend the Prescription Drug Marketing Act. I wish we that we had had hearings on this bill. I wish we had had a chance to talk more about it. I am not prepared tonight to gamble with the safety and efficacy of the drugs coming into this country.

Mr. BROWN of Ohio. Mr. Speaker, I have no further requests for time, and I yield back the balance of my time.

Mr. COBURN. Could I inquire of the Chair the time remaining.

The CHAIRMAN. The gentleman from Oklahoma (Mr. COBURN) has 3½ minutes remaining.

Mr. COBURN. Mr. Speaker, I yield 3½ minutes to the gentleman from Minnesota (Mr. GUTKNECHT).

Mr. GUTKNECHT. Mr. Speaker, first of all, I want to clarify something. Section 3 of our bill says including a pharmacist or wholesale importer. We want our local pharmacies to be able to set up correspondent relationships.

In terms of the whole issue of people getting bad drugs, I mean, the truth of the matter is, this is happening now; and the reason is because of these huge differentials. We have tried now for 2 years to work with the FDA to come up with a plan so that we can bring down these barriers to local pharmacists and HMOs.

Let me give an example. One of the HMOs in Minneapolis, they did a study on their own, and if they could buy their drugs from Winnipeg, if they could realize half of the savings that

they recognized in this study, they could save their subscribers $30 million a year. Now, they are already negotiating better deals with their drugs than the average consumer, certainly the average senior citizen can. So what we are talking about is opening up markets.

We want to work with the FDA, but for 2 years the FDA has basically refused to return our phone calls. Mr. Speaker, there is a crisis out there; but the crisis is price. I am not here tonight to beat up on the pharmaceutical companies. The truth of the matter is they are going to charge as much as they can. I mean, shame on the pharmaceutical companies, yes, for what they are charging; but shame on the FDA for letting them get away with it, and shame on us for not doing something about it.

Now, this bill is not perfect, and I understand that we should be going further; but I think that is as far as we can get this year, or at least in the next several weeks. As we go forward, perhaps in the Senate, perhaps in conference committee, sometime perhaps before we get it to the President's desk, maybe we can strengthen it this year. And if the FDA does not respond appropriately, I guarantee I will be back next year and we will be fighting for even stronger legislation. Because this idea that American consumers should pay $30.25 for Coumadin when consumers in Switzerland pay $2.85 for the same drug, that is simply wrong. And shame on us if we let that continue.

The time has come to send a very clear message to our own FDA that we are not going to allow them to stand between American consumers in the day and age of NAFTA, in the day and age of the Internet, and in the day and age of the information age. The game is over. We are not going to allow them to stand between American consumers, and particularly American seniors, and lower drug prices. The game is over.

This is the night when we begin the journey to bring lower prices to American consumers. When we allow markets to work, we will see lower prices for American consumers, and especially for American seniors.

The SPEAKER pro tempore (Mr. PEASE). The question is on the motion offered by the gentleman from California (Mr. BILBRAY) that the House suspend the rules and pass the bill, H.R. 3240.

The question was taken; and (two-thirds having voted in favor thereof) the rules were suspended and the bill was passed.

A motion to reconsider was laid on the table.

REPORT ON RESOLUTION WAIVING REQUIREMENT OF CLAUSE 6(a) OF RULE XIII WITH RESPECT TO SAME DAY CONSIDERATION OF CERTAIN RESOLUTIONS REPORTED BY THE RULES COMMITTEE

Mr. GOSS (during consideration of H.R. 3240), from the Committee on Rules, submitted a privileged report (Rept. No. 106–707) on the resolution (H. Res. 540) waiving a requirement of clause 6(a) of rule XIII with respect to consideration of certain resolutions reported from the Committee on Rules, which was referred to the House Calendar and ordered to be printed.

REPORT ON RESOLUTION PROVIDING FOR CONSIDERATION OF A CONCURRENT RESOLUTION FOR THE ADJOURNMENT OF THE HOUSE AND SENATE FOR THE INDEPENDENCE DAY DISTRICT WORK PERIOD

Mr. GOSS (during consideration of H.R. 3240), from the Committee on Rules, submitted a privileged report (Rept. No. 106–708) on the resolution (H. Res. 541) providing for consideration of a concurrent resolution providing for adjournment of the House and Senate for the Independence Day district work period, which was referred to the House Calendar and ordered to be printed.

REPORT ON RESOLUTION PROVIDING FOR CONSIDERATION OF H.R. 1304, QUALITY HEALTH-CARE COALITION ACT OF 2000

Mr. GOSS (during consideration of H.R. 3240), from the Committee on Rules, submitted a privileged report (Rept. No. 106–709) on the resolution (H. Res. 542) providing for consideration of the bill (H.R. 1304) to ensure and foster continued patient safety and quality of care by making the antitrust laws apply to negotiations between groups of health care professionals and health plans and health insurance issuers in the same manner as such laws apply to collective bargaining by labor organizations under the National Labor Relations Act, which was referred to the House Calendar and ordered to be printed.

LEAVE OF ABSENCE

By unanimous consent, leave of absence was granted to:

Mr. MARKEY (at the request of Mr. GEPHARDT) for today on account of family illness.

SPECIAL ORDERS GRANTED

By unanimous consent, permission to address the House, following the legislative program and any special orders heretofore entered, was granted to:

(The following Members (at the request of Mr. BROWN of Ohio) to revise and extend their remarks and include extraneous material:)

Mr. FILNER, for 5 minutes, today.

Ms. JACKSON-LEE of Texas, for 5 minutes, today.

ADJOURNMENT

Mr. COBURN. Mr. Speaker, I move that the House do now adjourn.

The motion was agreed to; accordingly (at 12 o'clock and 27 minutes a.m.), the House adjourned until today, Thursday, June 29, 2000, at 10 a.m.

EXECUTIVE COMMUNICATIONS, ETC.

Under clause 8 of rule XII, executive communications were taken from the Speaker's table and referred as follows:

8403. A letter from the Director, Office of Regulatory Management and Information, Environmental Protection Agency, transmitting the Agency's final rule—Prohexadione Calcium; Pesticide Tolerance [OPP–300998; FRL–6555–2] (RIN: 2070–AB78) received May 4, 2000, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Agriculture.

8404. A letter from the Secretary of the Air Force, transmitting notification that certain major defense acquisition programs have breached the unit cost by more than 15 percent, pursuant to 10 U.S.C. 2431(b)(3)(A); to the Committee on Armed Services.

8405. A letter from the Secretary of the Army, transmitting notification that a major defense acquisition program thresholds have been exceeded, pursuant to 10 U.S.C. 2431(b)(3)(A); to the Committee on Armed Services.

8406. A letter from the Assistant Secretary, Health Affairs, Department of Defense, transmitting the TRICARE Prime Remote Report to Congress January 2000; to the Committee on Armed Services.

8407. A letter from the Assistant Secretary, Health Affairs, Department of Defense, transmitting the report entitled, ''Report to the United States Congress Regarding Anthrax Vaccine and Adverse-Event Reporting''; to the Committee on Armed Services.

8408. A letter from the Assistant Secretary, Health Affairs, Department of Defense, transmitting a report to Congress on the Status of the Oxford House Pilot Project; to the Committee on Armed Services.

8409. A letter from the Assistant Secretary, Force Management Policy, Department of Defense, transmitting a plan to issue policy governing the pricing of tobacco products sold in military exchanges and commissary stores as exchange consignment items; to the Committee on Armed Services.

8410. A letter from the Assistant Secretary, Health Affairs, Department of Defense, transmitting a notice that the military treatment facility report for fiscal year 1999 is forth coming; to the Committee on Armed Services.

8411. A letter from the Comptroller, Department of Defense, transmitting a notice that the Department of the Navy is pursing a multiyear procurement (MYP) for the fiscal year 2000 through fiscal year 2004; to the Committee on Armed Services.

8412. A letter from the Secretary of the Navy, transmitting the report entitled, ''Multi-Technology Automated Reader Card Demonstration Program: Smart Cards in the Department of the Navy''; to the Committee on Armed Services.

8413. A letter from the Assistant Secretary for Legislative Affairs, Department of State, transmitting a copy of the determination and a memorandum of justification pursuant to Section 2(b)(6)(B) of the Export-Import