Withdrawal/Redaction Sheet
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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. fax	Melinda Plaisier to Devora Adler re: Int'l Prescription Drug Parity Act (partial) (1 page)	10/20/1999	P6/b(6)

COLLECTION:
Clinton Presidential Records
Domestic Policy Council
Devorah Adler
OA/Box Number: 20465

FOLDER TITLE:
Drug Pricing

2012-0463-S
rc742

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.
PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).
RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

b(1) National security classified information [(b)(1) of the FOIA]
b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

Withdrawal/Redaction Marker
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Melinda K. Plaisier
Associate Commissioner
Office of Legislation
Food and Drug Administration
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facsimile transmittal

To:	Devora Adler	**Fax:**	(202) 456-5557
From:	Melinda Plaisier	**Date:**	10/20/99
Re:	Int'l Prescription Drug Parity Act	**Pages:**	9
CC:			

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Devora, as per our conversation, following are documents that should provide some background on this issue. I can explain further at our 1:30 call. Roger McClung from Rich Tarplin's staff at Dept. would like to be on the call, as the Secretary has a conference call scheduled for October 27, with many of the same Members on this issue. Could you please hook him in also? His number is [P6/(b)(6)] Thanks. [001]

As I briefly mentioned, we have been working on this issue for a very long time. Last year, Diane Thompson traveled to Minnesota at Senator Wellstone's request to meet with the Minnesota Seniors' Federation, and Dr. Henney did the same earlier this year. Senator Wellstone asked the Commissioner to review our personal importation policy (and enforcement discretion) for the possibility of expanding it, as a means to address senior's ability to legally bring in drugs from Canada that they can purchase at a lower cost.

The first document following is talking points that reflect the results of the Commissioner's examination of our enforcement discretion. The bottom line is that NAFTA, GATT, and the Prescription Drug Marketing Act (PDMA) prohibit us from expanding any personal importation enforcement discretion.

As I mentioned, there are many Members interested in this "drug pricing" issue, and there are at least two bills out intended to address this issue – H.R. 1885/S. 1191 "The International Prescription Drug Parity Act" (that amends the PDMA (Berry, Sanders, Dorgan, Wellstone); and S. 1462, Senator Jeffords bill .

The second document following is a side-by-side of the bills.

I also am sending a copy of a letter David Kessler sent to John Dingell, that appeared in the FDA Week in July. Is it a good discription of the history of PDMA, and concerns about amending it. Following that, is a n article in a SD newspaper about concerns with the Interational Drug Parity Act.

As I briefly mentioned, FDA is currently examining our personal importation policy – (not for public discussion). While we understand the motivation behind these bills, and certainly are concerned about how the price of drugs can ultimately affect the health of seniors, we have concerns about these bills. We urge the Administration to not take a position on these bills until we can more fully discuss them. Talk to you at 1:30.

Talking points -- Personal Importation Policy

- We appreciate your interest in FDA's policy regarding personal importation of prescription drugs. I assure you that we understand your constituents' concerns about the high cost of necessary medications and that we have fully considered a range of options.

- Current law prohibits the interstate shipment (including importation) of unapproved new drugs. Unapproved new drugs are any drugs, including foreign-made versions of drugs approved in the United States, that have not been manufactured in accordance with, and pursuant to FDA approval. Absent evidence that the specific drugs sought to be imported from a foreign country have been manufactured pursuant to an approved new drug application, in the manufacturing facility permitted under the application, such drugs would appear to be unapproved new drugs subject to FDA enforcement action.

- In addition, the Prescription Drug Marketing Act of 1987 provides that drugs manufactured in the U.S. and exported may be re-imported only by the original manufacturer, in order to reduce potential public health risks from the distribution of mislabeled, subpotent, counterfeit, or adulterated prescription drugs.

- Nevertheless, FDA recognizes that circumstances may exist where, for example, a person has begun treatment with an unapproved drug in a foreign country or suffers from a condition for which there exists no treatment approved by FDA. In such cases FDA's personal importation policy provides for the agency to exercise enforcement discretion and refrain from taking action against the illegal importation.

- In response to a request from Senator Wellstone, we agreed to do two things:

    - Reexamine the personal importation policy to determine whether we could permit a broader exercise of enforcement discretion, including economic considerations as a measure of product availability.

- Examine the possibility of regulatory action requiring labeling to bear indicia of manufacture under approved conditions.

- We aired these issues fully and concluded that:

  - A broader exercise of enforcement discretion with respect to Canadian products would violate GATT by treating the products of one nation more favorably than the products of others. If broader enforcement discretion were exercised equitably for the pharmaceutical products of all nations, we would be opening floodgates to unapproved unknown products.

  - Even in the event the product in question was the same chemical entity, composition varies from country to country. Allowing importation would contravene generic drug law, which requires premarket approval.

  - Enforcement discretion based upon economic criteria would be unenforceable. Neither Customs nor FDA could reliably determine an importer's economic status at a border crossing, much less when a shipment is by mail.

  - A labeling change to require indicia of manufacture under approved conditions theoretically could be done by rulemaking but would take years to implement because companies would want to exhaust existing label stock. Moreover, importers of such labeled products still would violate the PDMA prohibition on reimportation by other than the original manufacturer.

- We also discussed the workability of legislative changes:
  - amending PDMA to limit the reimportation prohibition to apply only to cases of suspected fraud, tampering, counterfeiting, or other product risk;
  - legislatively recognizing Canadian approvals (de facto creating a second category of generics);
  - creating a Medicare drug benefit.

- If you decide to proceed legislatively, we are available to provide technical assistance as appropriate.

H.R. 1885 : The International Prescription Drug Parity Act. (amends Prescription Drug Marketing Act)	**S.1191.** The International Prescription Drug Parity Act (amends Prescription Drug Marketing Act)	**S.1462.** (personal importation of prescription drugs from Canada)
Sponsor: Marion Berry (D-AR) **Co-sponsors**: Neil Abercrombie (D-HI), Thomas Allen (D-ME), Richard Baker (R-LA), John Baldacci (D-ME), Thomas Barrett (D-WI), Douglas Bereuter (R-NE), Leonard Boswell (D-IA), Sherrod Brown (D-OH), Peter DeFazio (D-OR), William Delahunt (D-MA), Jo Ann Emerson (R-MO), Earl Hilliard (D-AL), Maurice Hinchey (D-NY), Peter Hoekstra (R-MI), Darlene Hooley (D-OR), Asa Hutchinson (R-AR), Carolyn Kilpatrick, (D-MI), , Dennis Kucinich (D-OH), John Lewis (D-GA), William Luther (D-MN), Dana Rohrabacher (R-CA), Bernie Sanders (I-VT), Max Sandlin (D-TX), Ronnie Shows (D-MS), Louise Slaughter (D-NY), Pete Stark (D-CA), Ted Strickland (D-OH), Bruce Vento (D-MN), Anthony Weiner (D-NY).	**Sponsor:** Byron Dorgan (D-ND) **Co-sponsors**: Paul Wellstone (D-MN), Olympia Snowe(R-ME), Tim Johnson (D-SD)	**Sponsor**: James Jeffords (R-VT)

Purpose: To amend the Federal Food, Drug, and Cosmetic Act to provide for facilitating the importation in the United States of certain drugs that have been approved by FDA; creates an exception to the Prescription Drug Marketing Act for other than the original manufacturer to import approved drugs, subject to certain requirements (i.e. would permit pharmacists or groups of pharmacist to purchase approved drugs outside the US at lower prices, reimport them, and pass on savings to consumers).	**Purpose**: Identical to H.R. 1885.	**Purpose:** To amend the Federal Food, Drug, and Cosmetic Act to permit importation in personal baggage and through the mail order of certain covered products for personal use from Canada.
"**Covered drug**" means a drug described in section 503(b)(1), i.e. prescription drugs and insulin.	Same as H.R. 1885	**"Covered product"** means a prescription drug under section 503(b)(1).
Recordkeeping and labeling requirements: Regardless of whether drug is intended for importation into the United States, for each shipment of drug, manufacturer shall maintain a record that identifies the shipment of such drug; details how such shipment complies with current GMPs, and provides the labeling required pursuant to the NDA.	Same as H.R. 1885.	

Regulations: Secretary shall promulgate regulations setting forth: 1) criteria regarding records described above and use of records to showing compliance with sections 501 and 502 (i.e. that product not adulterated or misbranded); 2) criteria regarding labeling requirements; 3) criteria regarding amount of charges that may be imposed by drug manufacturers for maintaining and providing the records specified.	Same as H.R. 1885.	**Conditions:** 1. The intended use of the product is identified. 2. The product is not considered to represent a significant health risk, without any consideration given to the cost or availability in the US. 3. The importer affirms in writing that the product is for the personal use of the individual; seeks to import an amount appropriate for personal use (e.g. 3 month supply), provides the name and address of a health professional licensed to prescribe drugs in the US that is responsible for treatment with the product, or provides evidence that the product is for the continuation of a treatment begun in a foreign country, provides a detailed prescription of the product being imported, including the name, amount, and market value of the product, provides the time when and the place where the product was purchased, provides port of entry , provides name, address, and telephone number of importer, and provides any other information Secretary determines necessary.

		Consultation: Secretary shall consult with US Trade Representative and Commissioner of Customs regarding promulgation of regulations.
		Records: Secretary shall determine how above information shall be gathered and maintained.
		Study and Report: Secretary shall conduct study on imports permitted under this section and evaluate the safety and purity of products imported, and other patent and trade issues that may have an effect on the safety or availability of such products, not later than 5 years after enactment of this section.

legislation to repeal PDMA's prohibition on re-importing drugs. Furthermore, I believe that such a repeal or change in policy would re-create the substantial lic health risks PDMA was designed to eliminate," the letter says.

Dingell was the principle sponsor of PDMA in the House. Sources in his office did not return phone calls at press time (July 8) regarding the Kessler letter.

In the letter, Kessler cites the reasons for passage of PDMA from committee report language, including warnings about how diversion markets inhibit control over merchandise. "As a result, pharmaceuticals which have been mislabeled, misbranded, improperly stored or shipped, have exceeded their expiration dates, or are bald counterfeits, are injected into the national distribution system for ultimate sale to consumers," the letter says.

He also says that re-importation may be even more dangerous today than in 1986. "For example, with the rise of Internet pharmacies, the opportunities for illicit distribution of adulterated and counterfeit products have grown well beyond those available in prior years," Kessler says. He also said this would stretch FDA enforcement resources.

Kessler also suggests that prices to consumers would not generally be lowered and would go to middlemen if the law is changed.

Kessler Letter to Dingell on Drug Re-importation

The Honorable John D. Dingell
2328 Rayburn House Office Building
United States House of Representatives
Washington, DC 20515

Dear Representative Dingell:

You may recall that there has been a continuing controversy about the re-importation into the United States of prescription drugs manufactured here and exported abroad (so-called "American Goods Returned"). As you know the Prescription Drug Marketing Act of 1987 (the PDMA), P.L. 100-293 (Apr. 22, 1988), of which you were the principal sponsor in the House prohibits such reimportation. As the former FDA Commissioner who oversaw the implementation of many of the provisions of the PDMA, I wanted you to know of my concerns about this issue.

I believe the prohibition on re-importing exported drugs serves two critical public health purposes: (1) preventing the introduction into U.S. commerce of prescription drugs that may have been improperly stored, handled, and shipped overseas, and (2) reducing the opportunities for importation of counterfeit and unapproved prescription drugs. I know you will recall that the Energy and Commerce Committee described these purposes in its report accompanying the bill that became the PDMA.

Specifically, the existence and method of operation of a wholesale submarket, herein referred to as the "diversion market," prevents effective control over or even routine knowledge of the true sources of merchandise in a significant number of cases. As a result, pharmaceuticals which have been mislabeled, misbranded, improperly stored or shipped, have exceeded their expiration dates, or are bald counterfeits, are injected into the national distribution system for ultimate sale to consumers....

A significant volume of pharmaceuticals is being reimported to the United States as American Goods Returned. These goods present a health and safety risk to American consumers because they may have become subpotent or adulterated during foreign handling and shipping. The ready market for reimports has also been a catalyst for the perpetration of a continuing series of frauds against American manufacturers, and has provided the cover for the importation of counterfeit pharmaceuticals in several cases. Moreover, the hazards associated with reimports have forced the Food and Drug Administration and U.S. Customs Service to spend inspectional and other resources that are solely needed in other areas.

H.R. Rep. No. 76, 100th Cong., 1st Sess. 6-7 (1987).

In 1986, the Oversight and Investigations Subcommittee of the Energy and Commerce Committee, which you chaired, described the public health and safety concerns of allowing "American Goods Returned" as follows:

[T]he clear and present danger to the public health from reimported pharmaceuticals is the threat that subpotent, superpotent, impotent or even toxic substances labeled as U.S.-produced legend drugs will enter the distribution system. The foremost danger comes from so-called "generic" drugs produced in developing countries that do not provide product patent protection for pharmaceuticals.

Uncertain Returns: The Multimillion Dollar Market in Reimported Pharmaceuticals, 99th Cong., 2nd Sess. 23 (Comm. Print 99-GG 1986). One well-publicized example involved importation of more than one million counterfeit birth control pills, complete with counterfeit packaging and labeling, Id.; Dangerous Medicine: The Risk to American Consumers From Prescription Drug Diversion and Counterfeiting, 99th Cong., 2nd Sess. 22 (Comm. Print 99-Z 1986).

In my view, the dangers of allowing re-importation of prescription drugs may be even greater today that they were in 1986. For example, with the rise of Internet pharmacies, the opportunities for illicit distribution of adulterated and counterfeit products have grown well beyond those available in prior years. Repealing the prohibition on re-importation of drugs would remove one of the principal statutory tools for dealing with this growing issue.

I know one argument now being made for allowing re-importation is that this would make lower priced prescription drugs available to U.S. consumers. But, your Committee effectively rebutted that argument in 1986, in terms that seem to me to be equally applicable today.

Pharmaceuticals re-imported by diverters displace full price sales in the wholesale market. Moreover, prices to ultimate consumers are generally not lowered as a result of diversion. Rather, the profits go to the various middlemen, here and abroad, while consumers bear the risk.

Uncertain Returns, supra. at 32 (emphasis added). See also Dangerous Medicine, supra, at 25-26 ("there is little or no significant benefit to consumers from pharmaceutical reimportation, and there are obvious costs in terms of health and safety risks and the utilization of scarce FDA resources").

I know of no changed circumstances that require either a shift in FDA policy or the passage of legislation to repeal PDMA's prohibition on re-importing drugs. Furthermore, I believe that such a repeal or change in policy would re-create the substantial public health risks PDMA was designed to eliminate. I would welcome your analysis and comments on this matter.

Sincerely,

David A. Kessler, M.D.

Randall Rasmussen
Opinion page editor
Address: Box 460
Rapid City, SD 57709

Forum

Drug bill poses risks

By Dr. Jane Goyan
Dr. Goyan is dean of the University of California at San Francisco School of Pharmacy and a former commissioner of the Food and Drug Administration.

SAN FRANCISCO — It's not very often that we see legislation introduced into Congress that has the potential to lessen the consumer protections that we take for granted. But a bill that is now pending before the Congress, under the name "International Prescription Drug Parity Act" would have the potential to jeopardize the quality of our prescription drug supply and the health of American patients. One of the co-sponsors of this legislation is Sen. Tim Johnson, D-S.D.

The bill would permit pharmacists and drug wholesalers to buy prescription drugs outside the United States and sell them to unsuspecting patients. The intent of the legislation is to lower prices. After all, if a pharmacist or wholesaler can get a bargain overseas, why not?

The "why not" is obvious to me. First, the legislation is so poorly conceived that it does not even require that any savings realized by the pharmacist or wholesaler be passed along in some manner to the consumer. Thus, if this legislation is passed, it might primarily benefit only pharmacists and wholesalers.

However, that's not even the worst "why not." The worst case scenario is that this legislation would permit the importation into the U.S., and the sale to consumers, of prescription drugs that may have been shipped and stored under uncertain conditions, rendering them potentially subpotent or just plain ineffective.

As the dean of the University of California at San Francisco School of Pharmacy for 16 years and a former commissioner of Food and Drug Administration, I know that one of the guiding principles of the FDA is to take no chances with the quality of foods or medicines. Pharmaceuticals are very difficult to make. Drug companies must produce their products in facilities that are expensive to construct. They must follow very detailed manufacturing rules set forth by the FDA.

The FDA believes that such rules must be strictly enforced so as to assure the American public that they can count on the quality of every prescription drug they receive. To a remarkable degree, the FDA has succeeded and consequently, problems with prescription drug quality are very rare in the U.S.

In 1988, Congress passed the Prescription Drug Marketing Act, which dealt specifically with the issue of imports and exports of prescription drugs. The law prohibited the importation back into the U.S. of any drug that earlier had been exported, unless the drug remained at all times under the control of the original manufacturer.

The rationale behind this law was very clear. As Congress said in passing it: "These imports are a health and safety risk to American consumers because they may have become subpotent or adulterated during foreign handling and shipping." Congress went on to point out that prescription drugs are an easy target for adulterating or counterfeiting, which results in hazards to the consumer. Therefore, a sound import law is needed to protect us.

My successors at the FDA apparently share my concerns. FDA Commissioner Jane Henney recently stated that the agency has "public health concerns" about the bill. And Dr. Henney's immediate predecessor, Dr. David Kessler, wrote to Rep. John Dingell of the House Commerce Committee that passing this bill would create "substantial public health risks."

The legislation now pending before Congress would enable pharmacists and wholesalers to re-import drugs that had been previously shipped abroad. There is no provision in the legislation for assuring that the drugs were held under sanitary conditions or the right temperature. There is no provision for assuring that the drugs, since they are out of the original manufacturers' control, are not replaced by counterfeit products that look like the original. In short, there are no assurances that prescription drugs shipped around the world in this manner will remain of the high quality that we expect.

I respect the motivation of the members of Congress who support this legislation. They are reading, as am I, stories about high prescription drug prices and people who are unable to pay for drugs they need. But the solution to this problem lies in better insurance coverage for people who need prescription drugs, not in threatening the quality of medicines for all of us.

The "International Prescription Drug Parity Act" is simply the wrong answer to questions on how we should make the benefits of prescription medicines available to all patients.

cc: JENNINGS ✓
JOEL JOHNSON
USA JENNINGS
CHUCK BRAIN
C/O DAN
MCNICHOLAS
x55178

DEPARTMENT OF VETERANS AFFAIRS
Veterans Health Administration
Washington DC 20420

OCT 20 1999

In Reply Refer To:

The Honorable Thomas Allen
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Allen:

This letter is intended to provide clarification regarding the Administration's views on H.R. 664, which would extend discounts for pharmaceuticals to the Medicare population by requiring pharmaceutical manufacturers to provide discounts to retail pharmacies. As you know, the Federal government pays for pharmaceuticals that are purchased by a number of different agencies, including the Department of Health and Human Services (HHS), the Department of Defense (DOD), and the Department of Veterans Affairs (VA).

There are many ways to analyze the direct and indirect impacts of proposals such as those in H.R. 664, and the overall costs of such a proposal, if any, are unknown at this time. Our prior correspondence on this issue argued that H.R. 664 could have a negative impact on VA's ability to negotiate the lowest possible prices for drugs listed on the FSS, and other prices negotiated by VA, because drug manufacturers would be unwilling to continue to grant us discounts at prior levels. Others have argued that making drugs available to pharmacies at the lowest possible price would not undercut VA's ability to negotiate for the lowest price with drug manufacturers. The GAO has also concluded that the effect on schedule prices of opening up the FSS will "ultimately depend on the outcome of negotiations between VA and drug manufacturers. Because of the uncertainties related to these negotiations, it is not possible to predict how schedule drug prices would change. . . " (GAO/HEHS-97-60, June 1997).

We look forward to working with you and others in Congress on this issue.

Sincerely,

Thomas L. Garthwaite, M.D.
Acting Under Secretary for Health

CC: JENNINGS ✓
JOEL JOHNSON
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MONDISON
X55175

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Thomas L. Garthwaite, M.D.
Acting Under Secretary for Health

CC: JENNINGS ✓
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Veterans Health Administration
Washington DC 20420

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We look forward to working with you and others in Congress on this issue.

Sincerely,

Thomas L. Garthwaite, M.D.
Acting Under Secretary for Health

NATIONAL COMMUNITY
PHARMACISTS ASSOCIATION
(Formerly NARD)
205 Daingerfield Road
Alexandria, VA 22314

Date: 10/19

Pages including cover sheet: 4

TO: Chris Jennings

Phone:

Fax: 202 456 5557

FROM: *John M. Rector, Sr. VP*
Government Affairs and
General Counsel
NCPA (formerly NARD)

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If you have not received all pages, please contact
Shazia Noreen at (703) 838-2695

REMARKS: ☐ Urgent ☑ For your review ☐ Reply ASAP ☐ Please Comment

National
COMMUNITY
PHARMACISTS
Association

August 16, 1999

To: Editor
Rutland Daily Herald
P.O. Box 668
Rutland, VT 05702

Dear Editor:

I recently discussed with your writer Fred Bever the very serious concerns that pharmacists in Vermont and across the country have with Senator Jefford's bill "The Personal Use Prescription Drug Importation Act of 1999" (P.U.). We do agree with the Senator's diagnosis about the unfair pricing practices of U.S. drug makers and that such practices create "a serious health problem" for Americans, especially for the elderly with limited incomes.

N C P A

phone
703.683.8200

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703.683.3619

We also agree with the Senator's observation that when it comes to pricing for Americans and their pharmacies that drug makers have established a "platinum standard" and that we should be committed to "helping Vermonters and all Americans have access to the prescription drugs that they need at prices that they can afford."

We are, however, very troubled by the remedy that the Senator has provided in his "PU" bill. Rather than providing relief for American pharmacies and their consumers he is telling consumers, for example in Rutland not to patronize Beauchamps & O'Rourke, Inc. or the Rutland Pharmacy, but to drive to Canada and return with an unlimited supply of prescription drugs at prices below the platinum pricing standard that drug makers have established for American pharmacies. For those who can not regularly visit Canada the bill would allow them to buy through the mail, although they would initially have to see a Canadian physician. Additionally, FDA has already raised concerns about consumer safety being compromised under the "PU".

1898 1998

Not only does the proposed remedy significantly disadvantage the small businesses that we represent in Vermont and across the country, but it also attempts to deny consumers access to their highly trusted local pharmacist whose care and advise is essential to the appropriate use of prescription drugs.

There is a better way. It is the bipartisan "The International Prescription Drug Parity Act" introduced as S 1191 by Senator Jefford's colleagues Snowe (R-ME), Dorgan (D-ND) and Wellstone (D-Minn.) and in the House of Representatives as HR 1885 by Emerson (R-MD), Sanders (I-VT) and Berry (D-AR). This landmark legislation, which we have endorsed, is designed to permit the importation of prescription drugs by American pharmacies so long as the drugs meet Food & Drug Administration standards, including compliance with current good manufacturing practices. Such FDA-approved drugs are sold in Canada, the United Kingdom, and other countries for prices considerably lower than the best prices available to retailers in this country. We agree with Rep. Sanders that it "is a fair commonsense, free-market approach to lowering drug prices for constituents while benefiting small businesses."

The truth is that the community pharmacy marketplace has virtually all of the characteristics of a healthy competitive marketplace. It has a significant number of widely dispersed, diversely owned businesses that are readily available to consumers. These competitive businesses predictably have modest gross margins or markups and low profits. What these businesses do not have is access to fairly priced branded Rxs based on economies of scale. Drugmakers, through discriminatory pricing practices, are responsible for this unhealthy characteristic of the community pharmacy marketplace. This bipartisan bill is the proper remedy, the better solution.

Listen to what the key Republican House sponsor Rep. Jo Ann Emerson says about Americans crossing borders to get their prescription drugs: "Frankly, I think it's outrageous that Americans should have to resort to crossing borders to purchase their prescriptions. We should be able to buy our medications at reasonable prices from pharmacies in our own neighborhoods. That's why I am a lead cosponsor of legislation that will allow American pharmacists, wholesalers and distributors to take full advantage of the cheaper prescription drug prices in other countries to pass along the savings to American consumers."

Some may think that medicine alone saves lives. It does not unless used properly. Medicine when properly used, however, can save lives and improve both the duration and quality of life for patients and their families. Community pharmacists are especially trained to assist patients with the proper use of medication and to help them manage its proper use.

Pharmacy services can save lives, decrease morbidity, and lower health care costs. Pharmacists are an integral part of our country's health care team. Contrary to some perceptions, pharmacists do far more than simply dispense medicine. They can play an active role in the provisions of patient health care. Pharmacists can intervene before a

prescription is filled and before potentially injurious action is taken. They can identify potential adverse reactions a patient may have to their prescribed drugs. They can recognize errors in a prescription – whether it is an inappropriate or dangerous dose - or whether the prescribed drugs are incompatible.

In addition, pharmacists can play an important role counseling patients about prescribed medications, including providing special directions, precautions for preparation, potential side effects, drug allergy interactions, or consequences of long term use.

The International Prescription Drug Parity Act encourages and supports the role of pharmacists in our health care system and strengthens their ability to continue to provide critical services. The "PU" does not.

The community pharmacist of today is simultaneously a health care professional and a small businessperson. As owners, managers, and employees of independent pharmacies, our member's 30,000 pharmacies and their 75,000 pharmacists are committed to legislative and regulatory initiatives designed to protect the public; to provide independent pharmacy a level of playing field and a fair chance to compete; and to provide quality service to patients.

We hope that Senator Jeffords will reconsider the "PU" and support the bipartisan International Prescription Drug Parity Act that is pending before the Senate Committee that he chairs.

Sincerely,

John M Rector

John M. Rector
Senior Vice President of Govt. Affairs
and General Counsel
National Community Pharmacists Association

Fax

Name:	Chris Jennings
Organization:	Domestic Policy Council
Fax:	456-5557
From:	Karen Lightfoot and Phil Barnett
Date:	October 22, 1999
Subject:	Prescription Drug Study

As promised in our meeting yesterday, we are faxing some information on the prescription drug studies. The first piece is a confidential summary of the studies done to date and the national findings. The second is the study we wrote at the request of Rep. Karen Thurman which examines the differences between prices uninsured seniors pay in Florida with those of favored customers in the U.S. The third piece is the study we conducted for Rep. Wise, which examined the difference between the price uninsured seniors pay in the West Virginia and the price they would pay in Canada and Mexico.

We can produce either study -- domestic or international -- in a national format. Please let us know as quickly as possible if you would like us to produce one for the President. Many thanks.

- ~~CONFIDENTIAL~~ -

Investigation of Prescription Drug Price Discrimination

Minority Staff
Special Investigative Division
Committee on Government Reform
U.S. House of Representatives

The high cost of prescription drugs is a critical issue for senior citizens across the country. Seniors have the greatest need for prescription drugs, accounting for one-third of all prescription drug sales, but often live on fixed incomes and have no, or inadequate, prescription drug coverage. As a result of the high prescription drug prices, many senior citizens are forced to choose between buying food and paying for the medication they need.

The Prescription Drug Studies.

Last year at the request of Congressman Henry Waxman, the ranking Democrat of the Committee, the Government Reform Committee minority staff began an investigation of prescription drug prices to look at pharmaceutical company pricing practices and its impact on senior citizens without coverage. The initial study was completed in the 1st District of Maine and was quickly followed by studies in Texas and California.

To date, the Special Investigative Division has completed over 140 prescription drug pricing reports at the request of individual members of Congress. These studies have been conducted in 90 congressional districts across the country, from the most rural areas in North Dakota to the largest urban areas in California. The surveys have been conducted in 39 states,[1] whose citizens make up 86% of the U.S. population. To date, 90 of these studies have been released by the members.

The studies find that senior citizens in the United States who pay for their own prescription drug are charged, on average, 134 percent more, or over twice as much, for prescription drugs as the drug companies' favored customers. The studies have also found that American seniors must pay on average 85 percent more than consumers in Canada and 83 percent more than consumers in Mexico.

These price differentials are a form of price discrimination. In effect, the drug manufacturers are discriminating against seniors citizens by denying them access to prescription drugs at the low prices available to HMOs, insurance companies, and consumers in Canada and Mexico.

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[1] This includes the District of Columbia.

Domestic Price Discrimination Studies.

The first set of price discrimination reports examined the difference between the price charged to the drug companies' most favored customers, such as HMOs and the federal government, and the price charged to seniors who buy their own prescription drugs. This series investigated the pricing of the five brand name prescription drugs with the highest dollar sales to the elderly in 1997. These drugs are Prilosec, an ulcer and heartburn medication; Norvasc, a blood pressure medication; Zocor, a cholesterol-reducing medication; Zoloft, a medication used to treat depression; and Procardia XL, a heard medication. The results are based on a survey of retail prescription drug prices in chain and independently owned drug stores in congressional districts across the country.

To date, 99 congressional studies have been completed. For the top five drugs investigated in the studies, the average price differential was 134 percent. This means that senior citizens pay more than twice as much for these drugs than do the drug companies' most favored customers. In dollar terms, senior citizens must pay $27 to $98 more per prescription for these five drugs than favored customers. Table 1 summarizes these results.

Insert summary table.

For other popular medications, the price differential is even higher. For Synthroid, a commonly-used hormone treatment produced by Knoll Pharmaceuticals, preferred customers would pay only $1.75 for 100 pills while seniors would pay $29.12 for the same amount. This is a price differential of 1564%

International Price Discrimination.

The second set of studies compared the prices that seniors citizens who buy their own prescription drugs pay for prescription drugs with the prices that consumers who buy their own drugs must pay in Canada and Mexico. This study also focused on the five brand name drugs with the highest dollar sales to older Americans in 1997. To date, 42 international studies have been completed.

On average, the studies find that the prices that American senior citizens must pay are 85% higher than the prices that Canadian consumers pay and 830% higher than the prices that Mexican consumers pay. Table 2 summarizes these results.

Insert summary table

Other Findings.

The price differentials found in these reports are far higher for drugs than for other consumer items. Because preferred customers buy in bulk, some difference in retail and "favored customer" prices would be expected. But the reports found that average differential between the price received by favored customers and the price received by individual consumers for other consumer items such as rubber bands or paper towels is only 22% compared to the 134% price

differential for prescription drug.

The reports also found that pharmaceutical manufacturers, not drug stores, are responsible for the discriminatory prices that older Americans pay for prescription drugs. The studies found that pharmacies are responsible for less than one-fourth of the price differential between prices for favored customers and retail prices for seniors.

Taken together these studies indicate that drug manufacturers engage in a consistent pattern of price discrimination, resulting in prices for senior citizens who buy their own drugs that far exceed those pay by other purchasers in the United States and other countries.

These pricing practices victimize those who are least able to afford prescription drugs – senior citizens with no prescription drug coverage.

States in Which Drug Studies Have Been Conducted

Alabama
Arkansas
Arizona
California
Colorado
Connecticut
District of Columbia
Florida
Hawaii
Illinois
Indiana
Iowa
Kansas
Kentucky
Louisiana
Maine
Maryland
Massachusetts
Michigan
Minnesota
Mississippi
Missouri
Montana
N. Dakota
Nevada
New Mexico
New York
Ohio
Oregon
Pennsylvania
South Carolina
South Dakota
Tennessee
Texas
Vermont
Virginia
Washington
Wisconsin

Prescription Drug Pricing in the 5th Congressional District in Florida: Drug Companies Profit at the Expense of Older Americans

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Prepared for Rep. Karen L. Thurman

Minority Staff Report
Committee on Government Reform
U.S. House of Representatives

May 11, 1999

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EXECUTIVE SUMMARY

This staff report was prepared at the request of Rep. Karen L. Thurman of Florida. In Mrs. Thurman's district, as in many other congressional districts around the country, older Americans are increasingly concerned about the high prices that they pay for prescription drugs. Mrs. Thurman requested that the minority staff of the Committee on Government Reform investigate this issue. This report is the first report to quantify the extent of prescription drug price discrimination in Mrs. Thurman's district and its impacts on seniors.

Numerous studies have concluded that many older Americans pay high prices for prescription drugs and have a difficult time paying for the drugs they need. This study presents disturbing evidence about the cause of these high prices. The findings indicate that older Americans and others who pay for their own drugs are charged far more for their prescription drugs than are the drug companies' most favored customers, such as large insurance companies, health maintenance organizations, and the federal government. The findings show that a senior citizen in Mrs. Thurman's district paying for his or her own prescription drugs must pay, on average, more than twice as much for the drugs as the drug companies' favored customers. The study found that this is an unusually large price differential – more than five times greater than the average price differential for other consumer goods.

It appears that drug companies are engaged in a form of "discriminatory" pricing that victimizes those who are least able to afford it. Large corporate, governmental, and institutional customers with market power are able to buy their drugs at discounted prices. Drug companies then raise prices for sales to seniors and others who pay for drugs themselves to compensate for these discounts to the favored customers.

Older Americans are having an increasingly difficult time affording prescription drugs. By one estimate, more than one in eight older Americans has been forced to choose between buying food and buying medicine. Preventing the pharmaceutical industry's discriminatory pricing -- and thereby reducing the cost of prescription drugs for seniors and other individuals – will improve the health and financial well-being of millions of older Americans.

A. Methodology

This study investigates the pricing of the five brand name prescription drugs with the highest sales to the elderly. It estimates the differential between the price charged to the drug companies' most favored customers, such as large insurance companies, HMOs, and certain federal government purchasers, and the price charged to seniors. The results are based on a survey of retail prescription drug prices in chain and independently owned drug stores in Mrs. Thurman's congressional district in Florida. These prices are compared to the prices paid by the drug companies' most favored customers. For comparison purposes, the study also estimates the differential between prices for favored customers and retail prices for other consumer items.

B. Findings

The study finds that:

- **Older Americans pay inflated prices for commonly used drugs.** For the five drugs investigated in this study, the average price differential was 112% (Table 1). This means that senior citizens and other individuals who pay for their own drugs pay more than twice as much for these drugs than do the drug companies' most favored customers.

Table 1: Average Retail Prices for the Five Best-Selling Drugs for Older Americans in Mrs. Thurman's District Are More Than Twice as High as the Prices That Drug Companies Charge Their Most Favored Customers.

Prescription Drug	Manufacturer	Use	Prices For Favored Customers	Retail Prices For Seniors	Price Differential For Senior Citizens
Zocor	Merck	Cholesterol	$34.80	$103.19	197%
Prilosec	Astra/Merck	Ulcers	$59.10	$115.71	96%
Norvasc	Pfizer Inc.	High Blood Pressure	$59.71	$115.41	93%
Procardia XL	Pfizer Inc.	Heart Problems	$68.35	$129.45	89%
Zoloft	Pfizer, Inc.	Depression	$115.70	$216.44	87%
Average Price Differential					**112%**

- **For other popular drugs, the price differential is even higher.** This study also analyzed a number of other popular drugs used by older Americans, and in some cases found even higher price differentials (Table 2). The drug with the highest price differential was Synthroid, a commonly used hormone treatment manufactured by Knoll Pharmaceuticals. For this drug, the price differential for senior citizens in Mrs. Thurman's congressional district was 1,578%. An equivalent quantity of this drug would cost the manufacturers' favored customers only $1.75, but would cost the average senior citizen in Mrs. Thurman's district over $29.00. For Micronase, a diabetes treatment manufactured by Upjohn, an equivalent dose would cost the favored customers $10.05, while seniors in Mrs. Thurman's district are charged an average of $52.70. The price differential was 424%.

- **Price differentials are far higher for drugs than they are for other goods.** This study compared drug prices at the retail level to the prices that the pharmaceutical industry gives its most favored customers, such as large insurance companies, government buyers with negotiating power, and HMOs. Because these customers typically buy in bulk, some difference between retail prices and "favored customer" prices would be expected.

Table 2: Price Differentials for Some Drugs Are More Than 1,550%.

Prescription Drug	Manufacturer	Use	Prices for Favored Customers	Retail Prices for Seniors	Price Differential for Seniors
Synthroid	Knoll Pharmaceuticals	Hormone Treatment	$1.75	$29.36	1578%
Micronase	Upjohn	Diabetes	$10.05	$52.70	424%

The study found, however, that the differential was much higher for prescription drugs than it was for other consumer items. The study compared the price differential for prescription drugs to the price differentials on a selection of other consumer items. The average price differential for the five prescription drugs was 112%, while the price differential for other items was only 22%. Compared to manufacturers of other retail items, pharmaceutical manufacturers appear to be engaging in significant price discrimination against older Americans and other individual consumers.

- **Pharmaceutical manufacturers, not drug stores, appear to be responsible for the discriminatory prices that older Americans pay for prescription drugs.** In order to determine whether drug companies or retail pharmacies were responsible for the high prescription drug prices paid by seniors in Mrs. Thurman's congressional district, the study compared average wholesale prices that pharmacies pay for drugs to the prices at which the drugs are sold to consumers. This comparison revealed that the pharmacies in Mrs. Thurman's district appear to have relatively small markups between the prices at which they buy prescription drugs and the prices at which they sell them. The retail prices in Mrs. Thurman's district are actually below the published national Average Wholesale Price, which represents the manufacturers' suggested price to pharmacies. The differential between retail prices and a second indicator of pharmacy costs, the Wholesale Acquisition Cost, which represents the average price pharmacies actually pay for drugs, is only 19%. This indicates that it is drug company pricing policies that appear to account for the inflated prices charged to older Americans and other customers.

I. THE VULNERABILITY OF OLDER AMERICANS TO HIGH DRUG PRICES

This report focuses on a continuing, critical issue facing older Americans -- the cost of their prescription drugs. Numerous surveys and studies have concluded that many older Americans pay high costs for prescription drugs and are having a difficult time paying for the drugs they need. The cost of prescription drugs is particularly important for older Americans because they have more medical problems, and take more prescription drugs, than the average American. This situation is exacerbated by the fact that the Medicare program, the main source of health care coverage for the elderly, fails to cover the cost of most prescription drugs.

According to the National Institute on Aging, "as a group, older people tend to have more long-term illnesses -- such as arthritis, diabetes, high blood pressure, and heart disease -- than do younger people."[1] Other chronic diseases which disproportionately affect older Americans include depression and neurodegenerative diseases such as Alzheimer's disease, Lou Gehrig's disease, and Parkinson's disease.

The latest survey data indicate that 86% of Medicare beneficiaries are taking prescription drugs.[2] Moreover, older Americans spend almost three times as much of their income (21%) on health care than those under the age of 65 (8%).[3]

The average older American uses 18.5 prescriptions annually,[4] significantly more than the average under-65 population.[5] It is estimated that the elderly in the United States, who make up 12% of the population, use one-third of all prescription drugs.[6]

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[1] National Institute on Aging (NIA), *NIA Age Page* (1997) (online at www.nih.gov/nia/health/pub/medicine.htm).

[2] Health Affairs, *Prescription Drug Coverage, Utilization, and Spending Among Medicare Beneficiaries*, 237 (Jan./Feb. 1999).

[3] AARP Public Policy Institute and the Lewin Group, *Out of Pocket Health Spending By Medicare Beneficiaries Age 65 and Older: 1997 Projections* (Feb. 1997).

[4] *Prescription Drug Coverage, Utilization, and Spending Among Medicare Beneficiaries*, *supra* note 2, at 237.

[5] Senate Special Committee on Aging, *Developments In Aging: 1996*, 105th Cong., 1st Sess. 121 (1997) (S. Rpt. 36).

[6] Senate Special Committee On Aging, *Developments in Aging: 1993*, 103d Cong., 2d Sess. 35 (1994) (S. Rpt. 403).

Although the elderly have the greatest need for prescription drugs, they often have the most inadequate insurance coverage for the cost of these drugs. With the exception of drugs administered during inpatient hospital stays, Medicare generally does not cover prescription drugs. A recent study by federal researchers found that 35% of Medicare recipients do not have any insurance coverage for prescription drugs.[7] As a result, many older Americans -- a large percentage of whom live on a limited, fixed income -- are forced to pay the full, out-of-pocket expense of prescription drugs.

Although Medicare beneficiaries can purchase supplemental "Medigap" insurance privately, these policies are often prohibitively expensive or inadequate. Only three of the ten available plans offer any prescription drug coverage, and even the best available Medigap policy provides only a $3,000 drug benefit, while still leaving beneficiaries vulnerable to a high deductible and to paying at least half of their total drug costs.[8] Less than 10% of the Medicare population obtains prescription drug coverage from Medigap providers.[9] Moreover, while some Medicare managed care plans may offer optional prescription drug coverage, these plans serve only a small portion of the Medicare population, and have recently withdrawn coverage for over 400,000 seniors.[10]

Medicare beneficiaries without public or private prescription drug coverage are the group most at risk from high out-of-pocket prescription drug costs. According to the Senate Special Committee on Aging, this group includes those "who are not poor enough to receive Medicaid, do not have employer-based retiree prescription drug coverage, and cannot afford any other private prescription drug insurance plans."[11]

The high costs of prescription drugs, and the lack of insurance coverage, directly affect the health and welfare of older Americans. In 1993, 13% of older Americans surveyed reported

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[7] *Prescription Drug Coverage, Utilization, and Spending Among Medicare Beneficiaries*, *supra* note 2.

[8] *Id.* at 232.

[9] *Id.* at 235.

[10] *Clinton Plans to Intervene as HMOs Exit Medicare*, New York Times, A1 (Oct. 8, 1998).

[11] *Developments In Aging: 1996*, *supra* note 5, at 122.

that they were forced to choose between buying food and buying medicine.[12] By another estimate, five million older Americans are forced to make this difficult choice.[13]

II. ARE DRUG COMPANIES EXPLOITING THE VULNERABILITY OF OLDER AMERICANS?

Rep. Karen L. Thurman of Florida asked the minority staff of the Committee on Government Reform to investigate whether pharmaceutical manufacturers are taking advantage of older Americans through price discrimination, and, if so, whether this is part of the explanation for the high drug prices being paid by older Americans in her congressional district. This report presents the results of this investigation.

Industry analysts have recognized that price discrimination occurs in the prescription drug market. According to a recent Standard & Poor's report on the pharmaceutical industry, "[d]rugmakers have historically raised prices to private customers to compensate for the discounts they grant to managed care customers. This practice is known as 'cost shifting.'"[14] Under this practice, "drugs sold to wholesale distributors and pharmacy chains for the individual physician/patient are marked at the higher end of the scale."[15]

Although industry analyses acknowledge that price discrimination occurs, they have not estimated its degree or impact. This report, prepared at Mrs. Thurman's request, is the first attempt to quantify the extent of price discrimination and its impact on senior citizens in Florida's 5th Congressional District.

The study design and methodology used to test whether drug companies are discriminating against older Americans in their pricing are described in part III. The results of the study are described in part IV. These results show that drug manufacturers appear to be engaged in substantial price discrimination against older Americans and other individuals who must pay for their own prescription drugs. The consequences of the manufacturers' pricing policies are discussed in part V.

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[12] Families USA Foundation, *Worthless Promises: Drug Companies Keep Boosting Prices*, 6 (Mar. 1995).

[13] Senate Special Committee on Aging, *A Status Report -- Accessibility and Affordability of Prescription Drugs For Older Americans*, 102d Cong., 2d Sess. 2 (1992) (S. Rpt. 100).

[14] Herman Saftlas, Standard & Poor's, *Healthcare: Pharmaceuticals*, Industry Surveys, 19-20 (Dec. 18, 1997).

[15] *Id.* at 19.

III. METHODOLOGY

A. Selection of Drugs for this Survey

This survey is based primarily on a selection of the five patented, nongeneric drugs with the highest annual sales to older Americans in 1997. The list was obtained from the Pennsylvania Pharmaceutical Assistance Contract for the Elderly (PACE). The PACE program is the largest outpatient prescription drug program for older Americans in the United States for which claims data is available, and is used in this study, as well as by several other analysts, as a proxy database for prescription drug usage by all older Americans. In 1997, over 250,000 persons were enrolled in the program, which provided over $100 million of assistance in filling over 2.8 million prescriptions.[16]

B. Determination of Average Retail Drug Prices for Seniors

In order to determine the prices that senior citizens are paying for prescription drugs in Mrs. Thurman's congressional district, the minority staff and the staff of Mrs. Thurman's congressional office conducted a survey of twelve drug stores -- including both independent and chain stores. Mrs. Thurman represents the 5th Congressional District on the western coast of Florida, which includes the cities of Gainesville, Inverness, and New Port Richey. The location of the stores is shown in Appendix D.

C. Determination of Prices for Drug Companies' Most Favored Customers

Drug pricing is complicated and drug companies closely guard their pricing strategies. For example, drug companies require HMOs to sign confidentiality agreements before offering them pricing discounts. The best publicly available indicator of the prices drug companies charge their most favored customers is the prices the companies charge the federal government.

The federal government pays for prescription drugs through several different programs. One important program is the Federal Supply Schedule (FSS), which is a price catalogue containing goods available for purchase by federal agencies. Drug prices on the FSS are negotiated by the Department of Veterans Affairs (VA) and often approximate the prices that the drug companies charge their most favored non-federal customers. According to the U.S. General Accounting Office, "[u]nder GSA procurement regulations, VA contract officers are required to seek an FSS price that represents the same discount off a drug's list price that the manufacturer

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[16] Pharmaceutical Assistance Contract for the Elderly ("PACE"), Pennsylvania Department of Aging, *Annual Report to the Pennsylvania General Assembly January 1 - December 31, 1997* (Apr. 1998).

offers its most-favored nonfederal customer under comparable terms and conditions."[17] To obtain additional price discounts available to the private sector, the VA has established at least two additional negotiated-price programs: (1) a VA formulary that operates similarly to the formularies established by well-managed HMOs,[18] and (2) a Blanket Price Agreement (BPA) program, under which the VA commits to purchasing minimum quantities of particular prescription drugs. Yet another program through which the federal government obtains prescription drugs is section 340(b) of the Public Health Service Act, which entitles four agencies (the VA, the Indian Health Service, the Department of Defense, and the Public Health Service) to purchase drugs at a maximum price of 24% below the manufacturer's average nonfederal price.

This analysis uses the lowest price paid by the federal government as a proxy for the prices paid by drug companies most favored customers.[19] All prices were updated in February 1999 to reflect current pricing.

D. Determination of Prices Paid by Pharmacies

The survey also looked at two other pricing indicators: (1) the Average Wholesale Price (AWP) and (2) the Wholesale Acquisition Cost (WAC). These two prices provide an indicator of the extent of markups that are attributable to the pharmacy (in contrast to those that are due to the drug manufacturer). The AWP represents the price that manufacturers suggest that wholesalers charge retail pharmacies; the WAC represents the actual average price that wholesalers charge pharmacies. Both AWP and WAC were obtained from the Medispan database and were updated on March 1, 1999, to reflect current pricing.

E. Determination of Drug Dosages

When comparing prices, the study used the same criteria (dosage, form, and package size) used by the GAO in its 1992 report, *Prescription Drugs: Companies Typically Charge More in the United States Than In Canada*. For drugs that were not included in the GAO report, the study used the dosage, form, and package size common in the years 1994 through 1997, as indicated in the *Drug Topics Red Book*.

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[17] U.S. General Accounting Office, *Drug Prices: Effects of Opening Federal Supply Schedule for Pharmaceuticals Are Uncertain* 6 (June 1997) (emphasis added).

[18] For a detailed description of the Department of Veterans Affairs Formulary program, see the National Formulary Content Page, online at www.dppm.med.va.gov/newsite/national.htm.

[19] For Norvasc, Prilosec, Procardia XL, Micronase, and Synthroid, the Federal Supply Schedule price was used as the indicator of best price. For Zocor the VA's formulary price was used as the indicator of best price. For Zoloft, the VA's Blanket Pricing Agreement price was used as the indicator of best price.

F. Comparison of Price Differentials for Other Retail Items

In order to determine whether the differential between the most favored customer prices and retail prices for drugs commonly used by older Americans is unusually large, the study compared the prescription drug price differentials to price differentials on other consumer products. To make this comparison, a list of consumer items other than drugs available through the FSS was assembled. FSS prices were then compared with the retail prices at which the items could be bought at a large national chain.[20]

IV. DRUG COMPANIES CHARGE OLDER AMERICANS DISCRIMINATORY PRICES

A. Discrimination in Drug Pricing

In the case of the five drugs with the highest sales to seniors, the average price differential between the price that would be paid by a senior citizen in Mrs. Thurman's congressional district and the price that would be paid by the drug companies' most favored customers was 112% (Table 1). The study thus showed that the average price that older Americans and other individual consumers in Mrs. Thurman's district pay for these drugs is more than double the price paid by the drug companies' favored customers, such as large insurance companies and HMOs.

For individual drugs, the price differential was even higher. Among the five best selling drugs, the highest price differential was 197% for Zocor, a cholesterol treatment manufactured by Merck. For other popular drugs, the study found even greater price differentials. The drug with the highest price differential was Synthroid, a commonly used hormone treatment manufactured by Knoll Pharmaceuticals. For this drug, the price differential for senior citizens in Mrs. Thurman's district was over 1,550%. An equivalent quantity of this drug would cost the most favored customers only $1.75, but would cost the average senior citizen in Mrs. Thurman's congressional district $29.36. For Micronase, a diabetes treatment manufactured by Upjohn, the price differential was 424% (Figure 1). Every drug looked at in this study had a large price differential. Among the five highest selling drugs, three (Zocor, Prilosec, and Norvasc) had price differentials that equaled or exceeded 90%. The lowest price difference was still high -- 87%, for Zoloft.

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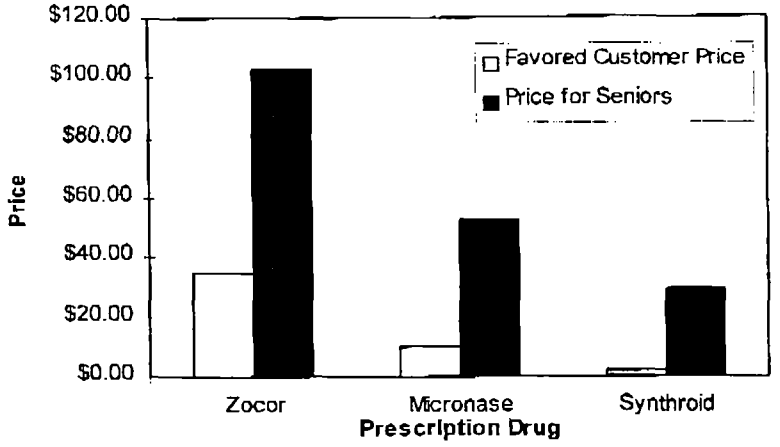
[20] The items used were paper towels, envelopes, rubber bands, toilet paper, pencils, Rolodexes, tape dispensers, waste baskets, correction fluid, post-it notes, paper clips, and scissors.

Figure 1: Older Americans in Mrs. Thurman's District Pay Inflated Prices for Prescription Drugs.



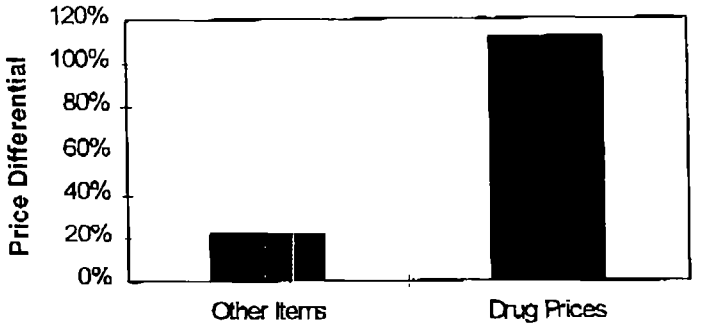
B. Comparison with Other Consumer Goods

The study also analyzed whether the large differentials in prescription drug pricing could be attributed to a volume effect. The drug companies' most favored customers, such as large insurance companies and HMOs, typically buy large volumes of drugs. Thus, it could be expected that there would be differences between the prices charged the most favored customers and retail prices. The study found, however, that the differentials in prescription drug prices were much greater than the differentials in prices for other consumer goods. The study found that, in the case of other consumer goods, the average difference between retail prices and the prices charged most favored customers, such as large corporations and institutions, was only 22%. The average price differential in the case of prescription drugs was more than five times larger than the average price differential for other consumer goods (Figure 2). This indicates that a volume effect is unlikely to explain the large differential in prescription drug pricing.

C. Drug Company Versus Pharmacy Responsibility

The study also sought to determine whether drug companies or retail pharmacies are responsible for the high prices being paid by older Americans. To do this, the study compared the average wholesale prices that pharmacies pay for drugs to the prices at which the drugs are sold to consumers. This comparison revealed that pharmacies appear to have relatively small markups between the prices at which they buy prescription drugs and the prices at which they

Figure 2: Price Differentials on Drugs Commonly Used by Older Americans Are Far Higher Than Differentials for Other Consumer Goods.

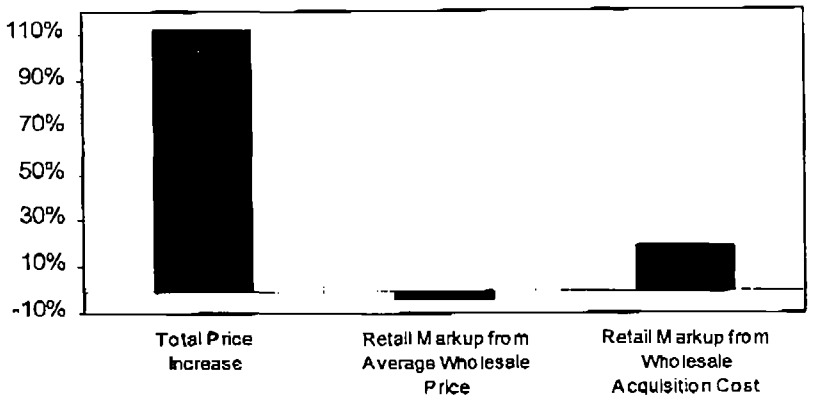


sell them. The study found that the average retail price for the five best-selling prescription drugs was actually lower than the published Average Wholesale Price, and only 19% above the pharmacies' Wholesale Acquisition Cost (Figure 3). This finding indicates that it is drug company pricing policies, not retail markups, that account for the inflated prices charged to older Americans and other individual customers. These findings are consistent with other experts who have concluded that because of the competitive nature of the pharmacy business at the retail level, there is a relatively small profit margin for retail pharmacists.[21]

The study found few significant differences in retail prices between pharmacies in different parts of Mrs. Thurman's district. Moreover, although there were variations in prices between chain and independent pharmacies, these differences were in general not systematic.

[21] National Association of Chain Drug Stores, *Did You Know . . .* (pamphlet) (citing financial data assembled by Keller Bruner & Company, P.C., Certified Public Accountants 1995).

Figure 3: Drug Companies, Not Retail Pharmacies, Are Responsible for High Prescription Drug Costs



V. DRUG MANUFACTURER PROFITABILITY

There are two conflicting consequences of the current drug industry pricing practices. Although these pricing practices have allowed the drug industry to grow and amass large profits, they have also imposed severe financial hardship on older Americans and others who buy their own drugs.

Drug industry pricing strategies have boosted the industry's profitability to extraordinary levels. The annual profits of the top ten drug companies is nearly $20 billion.[22] Moreover, the drug companies make unusually high profits compared to other companies. The average manufacturer of branded consumer goods, such as Proctor & Gamble or Colgate-Palmolive, has an operating profit margin of 10.5%. Drug manufacturers, however, have an operating profit margin of 28.7% -- nearly three times greater (Figure 4).[23]

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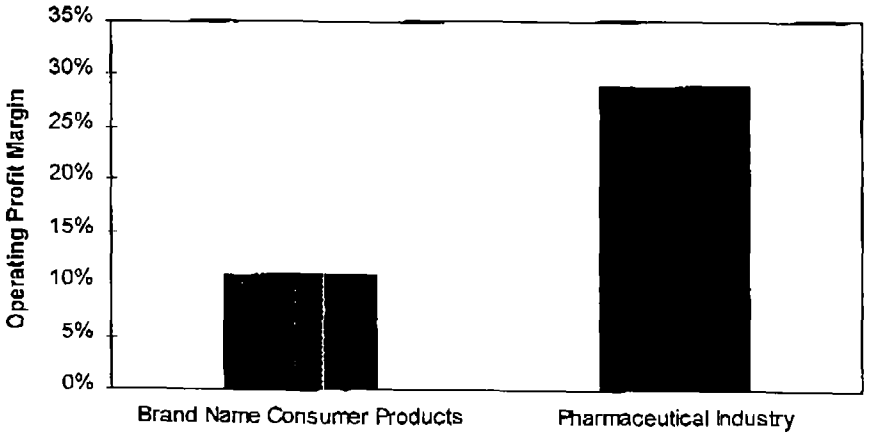
[22] Fortune, *1998 Fortune 500 Industry List* (1998) (Online at www.pathfinder.com/fortune500/indlist.html).

[23] Paul J. Much, Houlihan Lokey Howard & Zukin, *Expert Analysis of Profitability* (Feb. 1998).

These high profits appear to be directly linked to the pricing strategies observed in this study. For instance, Merck, the country's largest pharmaceutical manufacturer, had an increase in profits of 15% to 18% in the second quarter of 1998. According to industry analysts, Merck's increased profits were due in large part to sales of Zocor,[24] which is sold in Mrs. Thurman's district at a price differential of 197%. Zocor itself accounts for 6% of Merck's revenues.[25]

Overall, profits for the major drug manufacturers are expected to grow by about 20% in 1998, compared to 5% to 10% for other companies on the Standard & Poors Index. The drug manufacturers' profits are expected to grow by up to an additional 25% in 1999.[26] According to one analyst, "the prospects for the pharmaceutical industry are as bright as they've even been."[27]

Figure 4: The Pharmaceutical Industry's Profit Margins Are Larger Than Those for Other Companies.



[24] USA Today, *Drugmakers Have Healthy Outlook* (July 20, 1998).

[25] IMS America, *Top 200 Drugs of 1997* (1998) (Online at www.pharmacytimes.com/top200.html).

[26] *Drugmakers Have Healthy Outlook, supra* note 24.

[27] *Id.*

Appendix A

The Five Top Selling Patented, Nongeneric Drugs for Seniors Ranked by 1997 Total Dollar Sales

Rank	Drug	Manufacturer	Indication
1.	Prilosec	Astra/Merck	Ulcer
2.	Norvasc	Pfizer, Inc.	High Blood Pressure
3.	Zocor	Merck	Cholesterol reduction
4.	Zoloft	Pfizer, Inc.	Depression
5.	Procardia XL	Pfizer, Inc.	Heart Problems

Source: Pharmaceutical Assistance Contract for the Elderly ("PACE"), Pennsylvania Department of Aging, *Annual Report to the Pennsylvania General Assembly: January 1 - December 31, 1997* (Apr. 1998).

Appendix B

Information on Prescription Drugs Analyzed in This Study

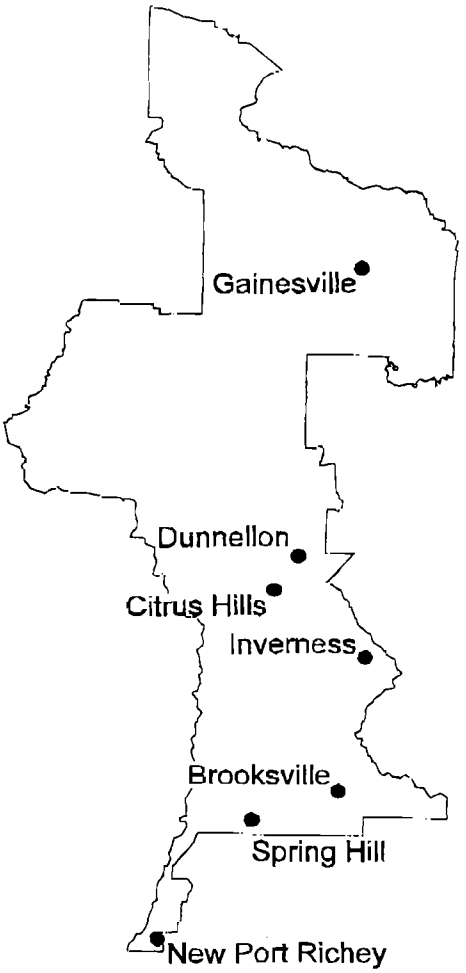
			Prices (Dollars)				
Brand Name Drug	Dosage and Form	Indication	Favored Customer Price	Wholesale Acquisition Cost	Average Wholesale Price	Average Retail Price	Price Differential (Average Retail Price vs. Favored Customer Price)
Zocor	5 mg, 60 tablets	Cholesterol reducer	$34.80	$85.47	$106.84	$103.19	197%
Prilosec	20 mg, 30 cap.	Ulcer	$59.10	$96.74	$120.93	$115.71	96%
Norvasc	5 mg. 90 tablets	High Blood Pressure	$59.71	$95.33	$119.16	$115.41	93%
Procardia XL	30 mg, 100 tab.	Heart Problems	$68.35	$110.69	$138.36	$129.45	89%
Zoloft	50 mg, 100 tab.	Depression	$115.70	$181.71	$227.14	$216.44	87%
Average Price Differential							**112%**

Appendix C

Price Comparisons For Non-Prescription Drug Items

Item	FSS Price	Retail Price	Differential
Binder Clip, small, 1 box	$0.49	$0.49	0%
Rubber Bands, 1 lb.	$2.57	$2.67	4%
Toilet Paper, 96 Rolls	$44.74	$47.98	7%
Rolodex, 500 Card	$13.24	$14.29	8%
Tape Dispenser	$1.44	$1.69	17%
Wastebasket, Plastic, 13 qt.	$2.95	$3.49	18%
Scissors	$10.88	$12.99	19%
Pencils, #2, 20-pack	$1.03	$1.26	22%
Paper Towels, 30 Rolls	$22.94	$29.98	31%
Post-It Notes	$2.08	$2.89	39%
Envelopes, 500, White, 20 lb. weight	$6.45	$9.49	47%
Correction Fluid, 18 ml., dozen.	$6.66	$9.99	50%
Average Price Differential			**22%**

Appendix D:
Prescription Drug Pricing Survey Locations in Florida's 5th Congressional District



Geography and Map Division, Library of Congress, May 1999 G-1999-53-LMC

Prescription Drug Pricing in West Virginia: An International Price Comparison

Prepared for Rep. Robert E. Wise, Jr.

Minority Staff Report
Committee on Government Reform and Oversight
U.S. House of Representatives

July 14, 1999

Table of Contents

EXECUTIVE SUMMARY

This report, which was prepared at the request of Rep. Robert E. Wise, Jr., compares prescription drug prices in the 2nd Congressional District of West Virginia with drug prices in Canada and Mexico. The report finds that senior citizens and other consumers in West Virginia who lack insurance coverage for prescription drugs must pay far more for prescription drugs than consumers in Canada and Mexico. These price differentials are a form of price discrimination. In effect, the drug manufacturers are discriminating against senior citizens in West Virginia by denying them access to prescription drugs at the low prices available to consumers in Canada and Mexico.

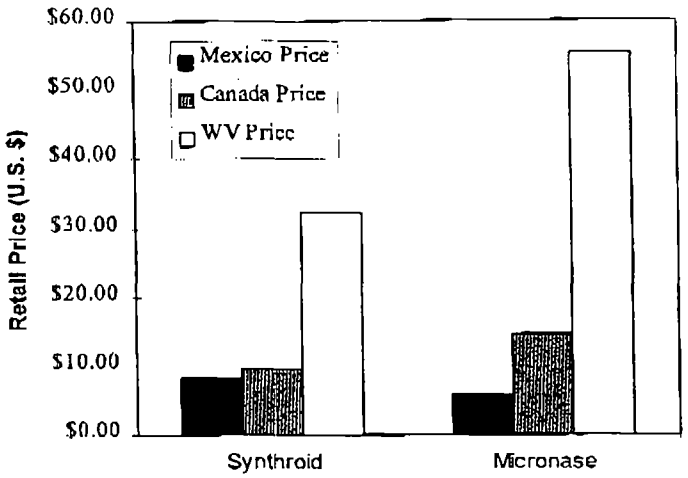
This study investigates the pricing of the five brand name prescription drugs with the highest 1997 dollar sales to the elderly in the United States. The study compares the prices that senior citizens who buy their own prescription drugs must pay for these drugs in West Virginia with the prices that consumers who buy their own drugs must pay for the same drugs in Canada or Mexico. The study finds that the average prices that senior citizens in West Virginia must pay for prescription drugs are approximately twice the prices that Canadian and Mexican consumers are charged. Compared to Canadian consumers, West Virginia senior citizens must pay 99% more for these drugs; compared to Mexican consumers, West Virginia senior citizens must pay 94% more (Table 1).

Table 1: West Virginia Seniors Pay Significantly Higher Retail Prices for Prescription Drugs Than Consumers in Canada or Mexico.

Prescription Drug	U.S. Dosage and Form	Canadian Retail Price	Mexican Retail Price	West Virginia Retail Price	Canada-West Virginia Price Differential	Mexico-West Virginia Price Differential
Zocor	5 mg, 60 tablets	$46.14	$63.15	$114.48	148%	81%
Prilosec	20 mg, 30 cap.	$54.87	$39.47	$127.34	132%	223%
Procardia XL	30 mg, 100 tablets	$75.68	$86.89	$138.43	89%	86%
Zoloft	50 mg, 100 tablets	$129.65	$131.79	$245.00	83%	59%
Norvasc	5 mg, 90 tablets	$90.67	$107.09	$130.46	44%	22%
Average Differential					**99%**	**94%**

In the case of two additional drugs considered in the study, Synthroid and Micronase, West Virginia senior citizens were forced to pay at least three times, and in one case more than nine times, the prices charged to Canadian or Mexican consumers (Figure 1).

Figure 1: Price Differentials for Two Popular Drugs



This is the second congressional report on drug price discrimination requested by Rep. Wise. The first report showed that senior citizens in West Virginia are forced to pay substantially more for their prescription drugs than are the drug companies' favored domestic customers, such as large insurance companies, large HMOs, and the federal government.[1] This report shows that senior citizens in West Virginia are also forced to pay far more for their prescription drugs than are consumers in other countries. Taken together, the two studies indicate that senior citizens and other U.S. consumers who buy their own drugs are at the bottom of a complex drug pricing hierarchy. As a result, they are forced to pay more for their prescription drugs than both favored institutional buyers in the United States and individual consumers in other countries.

[1] Minority Staff Report of the House Committee on Government Reform, *Prescription Drug Pricing in West Virginia: Drug Companies Profit at the Expense of Older Americans* (June 1999).

I. INTRODUCTION

In the United States, drug manufacturers are allowed to discriminate in drug pricing. As one industry analysis commented, "[d]rugmakers have historically raised prices to private customers to compensate for the discounts they grant to managed care customers. This practice is known as 'cost shifting.'"[2] Under this practice, "drugs sold to wholesale distributors and pharmacy chains for the individual physician/patient are marked at the higher end of the scale."[3]

The extent of this price discrimination in West Virginia has been documented in a report released by Rep. Robert E. Wise, Jr.[4] This report found that senior citizens and others in West Virginia who lack insurance coverage for prescription drugs pay approximately twice as much for their prescription drugs as the drugs companies' most favored customers, such as large insurance companies, large HMOs, and the federal government. Rep. Wise's study also found that this discriminatory pricing imposes severe hardships on senior citizens, many of whom are on fixed incomes and must choose between purchasing their prescribed medications and paying for other necessities such as food.

The governments of Canada and Mexico do not allow drug manufacturers to engage in price discrimination. In Canada, approximately 35% of prescription drugs are paid for by the government for beneficiaries of government health care programs.[5] In Mexico, 30% of prescription drugs are paid for by the government under similar circumstances.[6] The rest of the population in these two countries must either buy their own drugs or obtain prescription drug insurance coverage. To prevent the drug companies from charging individual consumers excessive prices, both the Canadian and Mexican governments regulate prices for patented prescription drugs.[7] Drug manufacturers do not have to sell their products in Canada or Mexico,

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[2] Herman Saftlas, Standard & Poor's, *Healthcare: Pharmaceuticals*, Industry Surveys 19-20 (December 18, 1997).

[3] *Id.* at 19.

[4] *Prescription Drug Pricing in West Virginia: Drug Companies Profit at the Expense of Older Americans*, *supra* note 1.

[5] Health Canada, *National Health Expenditures in Canada 1975-1996: Fact Sheets*, 12 (June 1997).

[6] National Economic Research Associates, *Financing Health Care: The Health Care System in Mexico*, 78 (August 1998).

[7] Congressional Research Service, *Prescription Drug Price Comparisons: The United States, Canada, and Mexico* (January 1998).

but if they do, they cannot sell their drugs at prices above the maximum prices established by the government.

This report is the first effort to compare retail prices that senior citizens in West Virginia must pay for prescription drugs with the prices at which the same drugs are available in Canada and Mexico.[8] It finds that senior citizens in West Virginia who lack prescription drug benefits must pay far more for prescription drugs than consumers in Canada and Mexico. The drug companies thus appear to engage in two distinct forms of price discrimination: (1) as documented in Rep. Wise's first report, the drug companies are forcing senior citizens in West Virginia to pay more for prescription drugs than more favored U.S. customers, and (2) as documented in this report, the drug companies are forcing senior citizens in West Virginia to pay more for prescription drugs than consumers in more favored countries.

II. METHODOLOGY

A. Selection of Drugs for This Survey

This survey is based primarily on a selection of the five patented, nongeneric drugs with the highest annual sales to older Americans in 1997. The list was obtained from the Pennsylvania Pharmaceutical Assistance Contract for the Elderly (PACE). The PACE program is the largest out-patient prescription drug program for older Americans in the United States for which claims data is available. It is used in this study, as well as by several other analysts, as a proxy database for prescription drug usage by all older Americans. In 1997, over 250,000 persons were enrolled in the program, which provided over $100 million of assistance in filling over 2.8 million prescriptions.[9]

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[8] In a 1992 study, *Prescription Drugs: Companies Typically Charge More in the United States Than in Canada*, the U.S. General Accounting Office compared producer prices for prescription drugs in Canada and the United States. This study did not include information on retail prices. In a 1998 study, *International Comparison of Prices For Antidepressant and Antipsychotic Drugs*, Public Citizen compared wholesale prices for newly developed antipsychotic and antidepressant drugs. This study also did not compare retail prices paid by consumers, but instead looked at pharmacy acquisition costs. The study also only looked at a small class of drugs. A recent Canadian study, the Patented Medicine Prices Review Board's *Tenth Annual Report*, compared manufacturer's prices for a wide selection of drugs, but contained no information on specific drugs. None of these studies included information on prices in West Virginia.

[9] Pharmaceutical Assistance Contract for the Elderly ("PACE"), Pennsylvania Department of Aging, *Annual Report to the Pennsylvania General Assembly* (January 1 - December 31, 1997).

In addition to the top five drugs for seniors, this study also analyzed two additional prescription drugs, Synthroid and Micronase. These popular prescription drugs were included in the study because the earlier analysis indicated that there is substantial discrimination in the pricing of these drugs.

B. Determination of Average Retail Drug Prices in West Virginia

In order to determine the prices that senior citizens are paying for prescription drugs in West Virginia, the minority staff and the staff of Mr. Wise's congressional office conducted a survey of nine drug stores, including both independent and chain stores. Mr. Wise represents the 2nd Congressional District in West Virginia, which runs from the Ohio River to the Eastern Panhandle and includes the cities of Charleston and Martinsburg.

C. Determination of Average Retail Drug Prices in Canada and Mexico

Retail prices for prescription drugs in Canada and Mexico were determined via a survey of four pharmacies in Canada and two pharmacies in Mexico. In Canada, pharmacies were surveyed in three provinces: Ontario, British Columbia, and Nova Scotia. In Mexico, pharmacies were surveyed near the eastern border of Mexico and the United States. No significant price differences were observed between prices at different pharmacies in Canada; similarly, no significant price differences were observed at the different pharmacies in Mexico.

Prices from Canadian pharmacies were determined in Canadian dollars, and prices from Mexican pharmacies were determined in pesos. All prices were converted to U.S. dollars using commercially available exchange rates.

D. Selection of Drug Dosage and Form

In comparing drug prices, the study generally used the same drug dosage, form, and package size used by the U.S. General Accounting Office in its 1992 report, *Prescription Drugs: Companies Typically Charge More in the United States Than in Canada.* For drugs that were not included in the GAO report, the study used the dosage, form, and package size common in the years 1994 through 1997, as indicated in the *Drug Topics Red Book.*[10]

All prescription drugs surveyed in this report were available in Canada in the same dosage and form as in the United States. In Mexico, several drugs were not available in the same dosage and form. In these cases, prices of equivalent quantities were used for the comparison. For example, in the United States the drug Zocor is commonly available in containers containing five mg. tablets, while in Mexico Zocor is available only in containers containing ten mg. tablets. To compare Zocor prices, this report compared the cost of 60 five mg. tablets of Zocor in the

[10] Medical Economics Company, Inc., *Drug Topics Red Book* (1997).

United States with the cost of 30 ten mg. tablets in Mexico. Several drugs are also sold under different names in Mexico. The Mexican equivalents of U.S. brand names were determined using the 44th edition of the *Diccionario de Especialdades Farmaceuticas* (1998).

III. FINDINGS

A. Senior Citizens in West Virginia Pay More for Prescription Drugs Than Consumers in Canada

Consumers in Canada obtain prescription drugs in one of two primary ways. Approximately 35% of the prescription drugs sold in Canada are paid for by the provincial governments on behalf of senior citizens, low-income individuals, and other beneficiaries of government health care programs. The rest of the population in Canada must either buy their own drugs or obtain prescription drug insurance coverage.

The regulatory system in Canada protects individual consumers who buy their own drugs from price discrimination.[11] The Patent Medicine Prices Review Board (PMPRB), established under the Ministry of Health by a 1987 law, regulates the maximum prices at which manufacturers can sell patented medicines.[12] If the Board finds that the price of a patented drug is excessive, it may order the manufacturer to lower the price, and may also take measures to offset any revenues it has received from the excess pricing.[13] Pharmacy dispensing fees for individual retail customers are not controlled by the government. Each pharmacy sets its usual and customary dispensing fee and must register this fee with provincial authorities.[14]

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[11] Patented Medicine Prices Review Board, *Tenth Annual Report for the Year Ended December 31, 1997* (1998) (online at www.atreide.net/PMPRB).

[12] The PMPRB establishes a set of guidelines to determine if manufacturers' prices are excessive. Under these guidelines, the prices of new drugs must not exceed the maximum price of other drugs that treat the same disease. For "breakthrough" drugs, introductory prices must not exceed the median of the prices of the drugs in other industrialized countries. Subsequent price increases are limited to changes in the Consumer Price Index.

[13] These may include further reductions in the price of the drug, reductions in the price of another of the manufacturer's drugs, or additional payments directly to the Canadian government.

[14] These fees are generally only a small part of the overall prescription drug prices. In Ontario, for example, pharmacies are currently charging usual and customary dispensing fees ranging from $1.25 to $12.00. Ontario Drug Benefit Formulary Program, *ODB Facts: Dispensing Fees* (June 1998) (dispensing fees converted to U.S. dollars).

This study indicates that the Canadian system produces prescription drug prices that are substantially lower in Canada than in the United States. Average retail prices for the top five drugs for seniors were 99% higher in the United States than in Canada (Table 1). For all five drugs, retail prices were higher in the United States. For two drugs, Zocor and Prilosec, the U.S. prices were more than twice as high as the Canadian prices. The highest price differential among the top five drugs was 148%, for Zocor, a cholesterol medication manufactured by Merck.

For other drugs, price differentials were even higher. Synthroid is a hormone treatment manufactured by Knoll Pharmaceuticals. For this prescription drug, senior citizens in West Virginia pay an average retail price of $32.11, while consumers in Canada pay only $9.80 -- a price differential of 228%. Similarly, for Micronase, a diabetes drug manufactured by Upjohn, West Virginia senior citizens pay prices that are 276% higher than Canadian consumers.

This finding is broadly consistent with the findings of other analyses. In 1992, GAO looked at the prices that drug companies charge wholesalers for 121 prescription drugs and found that these prices were, on average, 32% higher in the U.S. than in Canada. According to GAO, "government regulations and reimbursement practices contribute to lower average drug prices in Canada. In setting prices, manufacturers of patented drugs must conform to Canadian federal regulations that review prices for newly released drugs and restrain price increases for existing drugs."[15]

Similarly, in 1998, Canada's Patented Medicine Prices Review Board performed a comprehensive review of prices in Canada, the U.S., and six European countries.[16] The Board found that prescription drug prices in the U.S. were 36% higher than prices in Canada and that prices were even lower in other industrialized countries. Prices in the United States were 168% higher than prices in Italy, 155% higher than prices in France, 94% higher than prices in the United Kingdom, 86% higher than prices in Sweden, 60% higher than prices in Germany, and 45% higher than prices in Switzerland. The United States had the highest prices among the eight industrialized nations that were part of the survey.

GAO also investigated whether the price differential it observed was attributable to differences in the costs of production and distribution. GAO found that drug costs -- such as research and development -- are not allocated to specific countries, and the costs of production

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[15] U.S. General Accounting Office, *Prescription Drugs: Companies Typically Charge More in the United States Than in Canada*, 2-3 (September 1992) (GAO-HRD-92-110).

[16] *Tenth Annual Report for the Year Ended December 31, 1997*, *supra* note 11, at 18.

and distribution make up only a small share of the cost of any drug. The study concluded that "production and distribution costs cannot be a major source of price differentials."[17]

B. Senior Citizens in West Virginia Pay More for Prescription Drugs Than Consumers in Mexico

As in Canada, consumers in Mexico also obtain prescription drugs in one of two primary ways. Approximately 30% of the prescription drugs sold in Mexico are purchased by the government and provided to eligible citizens at a significant discount through the social security system.[18] The rest of the population in Mexico must either buy their own drugs or obtain prescription drug insurance coverage.

The regulatory system in Mexico, like the system in Canada, protects individual consumers who buy their own drugs from price discrimination. Drug prices and rates of price increases in Mexico are controlled by the Ministry of Commerce and Economic Development (known by its Spanish acronym, Secofi) under the Pact For Economic Stability and Growth.[19] Under the Mexican law, manufacturers and the government engage in negotiations to determine the nationwide maximum prices for prescription drugs.[20] Pharmaceutical products are prepackaged and stamped with the maximum sales price, guaranteeing consistent prices throughout the country.

This study indicates that the Mexican system produces prescription drug prices that are substantially lower in Mexico than in the United States. Average retail prices for the top five drugs for seniors were 94% higher in the United States than in Mexico (Table 1). For all five drugs, retail prices were higher in the United States. The highest price differential among the top five drugs was 223%, for Prilosec, an ulcer medication manufactured by Astra/Merck.

For other drugs, price differentials were even higher. In the case of Micronase, senior citizens in West Virginia pay an average retail price of $55.19, while consumers in Mexico pay

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[17] *Prescription Drugs: Companies Typically Charge More in the United States Than in Canada, supra* note 15, at 14.

[18] *Financing Health Care: The Health Care System in Mexico, supra* note 6.

[19] Jeanne Grant, *Headaches for Pharmaceuticals*, Business Mexico, 8f (August, 1991).

[20] The final negotiated price is based on a number of factors, including the purchasing power of the Mexican population, the availability of generic substitutes or other drugs that treat similar diseases, and other economic factors, such as the manufacturers' cost to produce the product.

only $5.81 -- a price differential of 849%. Similarly, in the case of Synthroid, West Virginia senior citizens pay prices that are 286% higher than Mexican consumers.

These findings are consistent with those of other experts. While there have been few direct comparisons of prices in the United States and Mexico, the Congressional Research Service has found that differences in the regulatory systems between the two countries result in the large price differentials. CRS concluded that "of greater importance in explaining price differentials in drug prices in Mexico and the United States is the fact that price controls and government procurement policies are in place in Mexico, and have been for some time."[21]

[21] *Prescription Drug Price Comparisons: The United States, Canada, and Mexico*, *supra* note 3.

Congress of the United States

Washington, DC 20515

SUMMARY OF THE INTERNATIONAL PRESCRIPTION DRUG PARITY ACT, H.R. 1885

Offered by Congressmen Bernard Sanders (I-VT), Marion Berry (D-AR) and Jo Ann Emerson (R-MO)

WHAT DOES THE BILL DO?

It addresses the absurd situation by which American consumers are paying substantially higher prices for their prescription drugs than are the citizens of Canada, Mexico and other countries. The International Prescription Drug Parity Act amends the Food, Drug, and Cosmetic Act to allow American distributors and pharmacists to reimport prescription drugs into the United States as long as the drugs meet strict safety standards. Pharmacists and distributors will be able to purchase drugs at lower prices and then pass the huge savings along to American consumers.

WHY IS THE BILL NEEDED?

Under federal law, it is technically illegal for individuals to go to Mexico, Canada or any other country with low-priced prescription drugs and bring them back into the United States. Nonetheless, tens of thousands of Americans currently cross the Mexican or Canadian borders and buy their drugs in those countries' pharmacies. The United States Customs Service has exercised discretion on a per case basis to allow individuals to bring small amounts of prescription drugs across the border for personal use.

This bill enables all Americans, regardless of where they live, to take advantage of the lower costs of prescription drugs in foreign countries. It is consistent with the "free market" competitive philosophy in the global economy. It is pro-business in that it allows American pharmacies and distributors to become competitive with foreign businesses that now can purchase prescription drugs at far lower prices from the pharmaceutical companies.

Under current federal law, pharmaceutical companies are the only ones allowed to reimport drugs made in the United States back into this country. The drugs are made in our country, shipped to Canada or Mexico or England, and sold by pharmacists and distributors in those countries. But if an American pharmacist or distributor wants to purchase these American-made drugs at the much-lower prices and pass the savings along to their customers, they are prohibited by law from doing so. We need to amend current federal law to allow pharmacists and distributors to buy drugs that are made in the United States and shipped to Canada or other countries. This is a common-sense thing to do. It is pro-business, pro-consumer and pro-American.

WHAT IS THE PRICE DIFFERENCE BETWEEN DRUGS SOLD IN THE U.S. AND OTHER COUNTRIES?

The Government Reform Committee minority staff has issued a series of reports detailing how much less expensive the 10 drugs most commonly used by seniors are in Canada and Mexico than the United States. In Vermont, these drugs cost 81 percent more than in Canada and 112 percent more than in Mexico. In Arkansas, drugs cost 72 percent more than in Canada and 103 percent more than in Mexico. This trend is consistent throughout the country.

In fact, the following chart shows how much more seniors in the United States pay for their drugs than seniors in other nations:

Country	Price
United States	$1.00
Germany	$0.71
Sweden	$0.68
United Kingdom	$0.65
Canada	$0.64
France	$0.57
Italy	$0.51

The same drug that costs a senior in the United States $1.00 costs a senior in Canada only 64 cents. Drug companies are forcing American seniors to subsidize the lower prices of their drugs sold in other countries. This is wrong and unfair to Americans and must be changed.

Table 1: Vermont Seniors Pay Significantly Higher Retail Prices for Prescription Drugs Than Consumers in Canada or Mexico.

Prescription Drug	U.S. Dosage and Form	Canadian Retail Price	Mexican Retail Price	Vermont Retail Price	Canada-Vermont Price Differential	Mexico-Vermont Price Differential
Zocor	5 mg, 60 tablets	$43.97	$47.29	$109.43	149%	131%
Ticlid	250 mg, 60 tablets	$52.35	$39.61	$122.07	133%	208%
Prilosec	20 mg, 30 cap.	$53.51	$29.46	$116.38	117%	295%
Relafen	500 mg, 100 tablets	$59.55	$49.26	$120.27	102%	144%
Procardia XL	30 mg, 100 tablets	$72.82	$87.78	$134.36	85%	53%
Zoloft	50 mg, 100 tablets	$124.41	$155.52	$226.50	82%	46%
Vasotec	10 mg, 100 tablets	$73.42	$57.03	$109.19	49%	91%
Norvasc	5 mg, 90 tablets	$87.71	$88.08	$117.82	34%	34%
Fosamax	10 mg, 30 tablets	$45.01	$51.33	$57.62	28%	12%
Cardizem CD	240 mg, 90 tablets	$142.70	$88.14	$179.69	26%	104%
Average Differential					**81%**	**112%**

U.S. Senator Ron Wyden

FAX TRANSMISSION

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News Advisory . . .

U.S. Senators Ron Wyden & Olympia Snowe

FOR IMMEDIATE RELEASE
September 24, 1999

Contacts: **Lisa Finkel** (Wyden), 202/224-5244
Dave Lackey (Snowe), 202/224-5344

WYDEN, SNOWE TO LAUNCH GRASSROOTS CAMPAIGN FOR PRESCRIPTION DRUG COVERAGE

Senators Take to the Senate Floor to Urge Seniors to Send in Their Bills

Washington, DC – U.S. Senators Ron Wyden (D-Ore.) and Olympia Snowe (R-Me.) will address the U.S. Senate to launch their grassroots campaign for prescription drug coverage on Tuesday, September 28.

Snowe and Wyden are the authors of the Seniors Prescription Insurance Coverage Equity (SPICE) Act -- the *only* bipartisan bill to provide prescription drug benefits to all Medicare recipients.

Wyden and Snowe, who earlier this year won 54 votes in the Senate for a budget amendment to direct tobacco tax revenues toward a prescription drug benefit, will discuss their legislation and urge seniors to send copies of their prescription drug bills to their Senators to draw attention to the cause.

Wyden and Snowe's remarks will be broadcast on C-SPAN 2. The coordinates are Sat Com C-4; Transponder 19.

WHO:	**U.S. Senator Ron Wyden (D-Ore.)** **U.S. Senator Olympia Snowe (R-Maine)**
WHAT:	**Sens. to Launch Grassroots Prescription Drug Coverage Campaign** **Bipartisan Duo to Urge Seniors to Send in Their Bills**
WHEN:	**Tuesday, September 28, 1999**
TIME:	**TBD** *(All times are subject to changes in the legislative schedule.)*
WHERE:	**Senate Floor, The Capitol**

###

Wyden and I have been united in the belief that we owe it to seniors to develop the best and most practical solution. SPICE represents a straightforward, comprehensive, and responsible approach that should appeal to anyone who agrees that seniors need coverage of prescription drugs.

"Cynics are asking, 'Can the country afford to cover prescription drugs?'. I believe we can't afford not to. It's not pie-in-the-sky, but a reasonable idea that actually provides coverage for needy seniors through a delivery system that's senior-friendly and uses marketplace competition and consumer choice to hold down costs," Wyden said.

Snowe and Wyden said that their approach offers an "affordable, realistic" approach to covering prescription drug costs, and said they would rely for funding on the 55 cent increase in tobacco taxes, and acceleration of a 15-cent increase already in law, as proposed in President Clinton's budget. A special reserve fund for prescription drugs, created during Senate consideration of the Fiscal 2000 Budget Resolution through an amendment offered by Snowe and Wyden, will provide a portion of the $505 billion from the non-Social Security on-budget surplus if necessary, they said. The budget reserve fund is triggered if the Senate Finance Committee reports legislation significantly extending the solvency of the Medicare program.

Under the Snowe-Wyden SPICE Act, beneficiaries will choose among comprehensive coverage options for their prescription drug needs under guidelines set and approved by an independent board. The board will establish a model plan, and a cap on out-of-pocket spending for prescription drug expenses, and beneficiaries will be responsible for a co-pay and annual deductibles. The benefit will be administered by an independent agency, reporting to the Secretary of Health and Human Services.

# # #

SENIOR PRESCRIPTION INSURANCE COVERAGE EQUITY (SPICE) ACT

Senators Olympia Snowe and Ron Wyden

Eligibility: All seniors who are eligible for Medicare Parts A and B will be eligible for a SPICE drug plan. Seniors will choose from competing benefit plans, which will pay for prescription drug costs with varying deductibles and copays. In this way, seniors may choose the plan that best fits their needs.

Financial Assistance: Seniors earning below 150 percent of the poverty level (currently $12,075/ single, $16275/couple) will pay no premiums for prescription drug insurance plan of their choice. For those earning between 150 percent of poverty and 175 percent ($14088/single, $18988/couple) will have their premium assistance phased down from 100 percent to 25 percent. All other seniors will have 25 percent of their premiums subsidized. The policies will all meet a threshold standard developed by the SPICE

Plan Options: The SPICE Board would work with the National Association of Insurance Commissioners to develop the threshold drug benefit using the FEHBP program and large group market plans as a guide. Plans would then compete to offer plans at either the threshold level or better so seniors could have a choice of plans. NAIC will also make recommendations to the SPICE Board concerning offering a drug plus other benefits policy through SPICE.

In addition, beneficiaries in Medicare +Choice plans that charge premiums for a drug benefit would receive some assistance.

Administration: The program would be administered by the SPICE Board that would be separate from the Health Care Financing Administration, but report to the Secretary of HHS. The Board would provide information, make sure consumers have choice of plans, and report to Congress concerning the funding and benefit design adequacy for seniors health care needs.

Plans would have to be approved at the state level just like current medigap policies is currently, and by the SPICE Board. Consumer protections that apply to medigap would apply to these plans.

An open annual enrollment would be available so seniors could change plans or get coverage should their Medicare+choice plan or private prescription drug plan terminate.

Financing: SPICE will be funding through the on-Budget, non-Social Security surplus and a 55 cent tobacco tax increase and acceleration of a 15 cent increase in tobacco taxes already in law.

Seniors Prescription Insurance Coverage Equity Act

Senator Olympia Snowe/ Senator Ron Wyden

The SPICE Act creates a voluntary supplemental drug insurance policy that all Medicare eligible individuals can purchase. These policies will be guaranteed issue -- no one can be turned down. SPICE eligibility will begin when Medicare eligibility begins. There will be a penalty for late entry, just as there is for those who make a late entry into the Medicare Part B program. The penalty fee for late entry will be waived if the late entry is based on the loss of prior drug coverage from a Medicare + Choice plan or a retiree group health plan.

All seniors will receive some premium support assistance on a sliding scale based on income. Every senior will receive at least 25% premium support. Those below 150% of the federal poverty line will receive 100% premium support. A sliding scale will phase down the premium support from 100% to 25% for those between 150% and 175% of the federal poverty line.

The federal premium support will be used to allow seniors to purchase SPICE policies from private providers, similar to the Medigap program. The policies will all meet a threshold standard developed by the SPICE Board, which includes consumers, state insurance commissioners, and insurance representatives, and will be designed with seniors needs in mind. Medicare+Choice and group health plans which provide drug coverage for Medicare eligible individuals will be able to receive the actuarial value of the drug benefit if their plans meet or exceed the SPICE Board threshold benefit plan.

Seniors will be given a choice of plans. This will ensure competition and help keep the costs down and will allow seniors to chose the plan that best meets there needs. To provide an idea of the types of choices, plans may offer coverage for different drugs (formularies), copays, deductibles, and caps. The SPICE Board will disseminate information about these choices, much like the Federal Employee Benefit Health Program (FEHBP) does.

Funding sources for the benefit will come from the on-budget surplus, which the Congressional Budget Office (CBO) estimates show to be $505 billion after the $792 billion tax cut legislation that is currently in conference. Additional funding may come from implementing the President's FY2000 budget proposal to raise the tobacco tax by 55 cents per pack in addition to enacting the 15 cent tobacco increase already in law one year earlier than originally planned.

[pS10222]

Mr. WYDEN. Mr. President, today Senator SNOWE and I are introducing legislation to provide seniors with insurance coverage for prescription drugs. This legislation, the Seniors Prescription Insurance Coverage Equity Act, SPICE, is the only bipartisan, market-based approach to provide seniors with choice and access to coverage that is actually paid for. It will give seniors the same kind of coverage that their member of Congress has.

The key issue for seniors around our nation, when it comes to the issue of prescription drugs, is affordability. Our proposal will assure that each and every senior who voluntarily chooses to enroll in a SPICE plan will have the bargaining power of HMOs and of the large insurers whose job it is to get the best price they can. At least 13 million seniors have no prescription drug coverage at all. Those seniors get penalized twice: they have to pay all their costs, and they pay more because they can't get the negotiated rate that the insurers and HMOs can. This bill will level the playing field for those seniors giving them affordability and access.

We know the kinds of drugs that are coming on the market now can help save lives, better the health status of an older person and, in many instances, save dollars because seniors taking their prescription drugs as they are told to by their doctor will prevent costly hospitalizations and the progression of disease. If we were to create Medicare today from scratch, there would be no questions about including prescription drug coverage. If we want to assure that Medicare beneficiaries stay healthy longer we must provide prescription drug coverage. If we want to be thoughtful, prudent purchasers of health care, we must find a way to assure seniors access to the drugs.

I believe the Snowe-Wyden proposal is that thoughtful, prudent and reasonable way. It assures a variety of options for coverage, and it assures that we bring real dollars to the table to pay for the program. There is no smoke and mirrors, no IOUs or other budget gimmicks in this plan.

The Snowe-Wyden proposal will be funded by funding from the non-Social Security on-budget surplus and a 55-cent increase in the tobacco tax. During this body's deliberations of the budget resolution, an amendment that Sen. SNOWE and I offered received 54 votes, including 12 Republican votes to do just this-fund a prescription drug benefit for seniors with an increase in the tobacco tax.

The SPICE legislation creates a senior-oriented program using the Federal Employees Benefit Program (FEHBP) as a model to provide benefits that

include prescription drugs and other non-Medicare covered benefits. This benefit would be open to every beneficiary and be voluntary. However, if the senior elected coverage later rather when they were first eligible, the individual would pay incrementally more the longer he or she waited to choose a comprehensive coverage option.

The individual senior would be able to select from an array of drug policies and Medicare+Choice plans with prescription drugs coverage. This would be voluntary. No senior would have to change what their current coverage is if they do not choose to do so. All plans would be offered by private sector companies. For beneficiaries under 150 percent of the poverty level-$12,075 for a single senior and $16,275 for a couple, the federal government would pay the entire premium. For those between 150 percent and 175 percent of the federal poverty level, the amount the federal government would pay phases down from 100 percent of premium to 25 percent of the premium amount. For beneficiaries at 175 percent of poverty and over, the federal government would pay 25 percent of the premium amount.

Our SPICE benefit will be administered by a new Board that would be separate from the Health Care Financing Administration but report to the Secretary of Health and Human Services. The Board would approve plan designs and premium submissions, approve and distribute consumer education materials, develop enrollment procedures and make recommendations concerning additional funding, further ability to pay mechanisms and other steps needed to assure continuing availability of comprehensive coverage as seniors' health needs change over time.

Many of us would prefer to do an overhaul of Medicare and modernize it to include benefits like prescription drugs. However, the thirteen million Medicare beneficiaries who need coverage and the millions who have coverage that does not truly help them, need a way to get meaningful coverage today. This proposal will do that.

Source: Government Printing Office

CC: JENNINGS ✓
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WILSON
X55173

DEPARTMENT OF VETERANS AFFAIRS
Veterans Health Administration
Washington DC 20420

OCT 20 1999

In Reply Refer To:

The Honorable Thomas Allen
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Allen:

This letter is intended to provide clarification regarding the Administration's views on H.R. 664, which would extend discounts for pharmaceuticals to the Medicare population by requiring pharmaceutical manufacturers to provide discounts to retail pharmacies. As you know, the Federal government pays for pharmaceuticals that are purchased by a number of different agencies, including the Department of Health and Human Services (HHS), the Department of Defense (DOD), and the Department of Veterans Affairs (VA).

There are many ways to analyze the direct and indirect impacts of proposals such as those in H.R. 664, and the overall costs of such a proposal, if any, are unknown at this time. Our prior correspondence on this issue argued that H.R. 664 could have a negative impact on VA's ability to negotiate the lowest possible prices for drugs listed on the FSS, and other prices negotiated by VA, because drug manufacturers would be unwilling to continue to grant us discounts at prior levels. Others have argued that making drugs available to pharmacies at the lowest possible price would not undercut VA's ability to negotiate for the lowest price with drug manufacturers. The GAO has also concluded that the effect on schedule prices of opening up the FSS will "ultimately depend on the outcome of negotiations between VA and drug manufacturers. Because of the uncertainties related to these negotiations, it is not possible to predict how schedule drug prices would change. . . " (GAO/HEHS-97-60, June 1997).

We look forward to working with you and others in Congress on this issue.

Sincerely,

Thomas L. Garthwaite, M.D.
Acting Under Secretary for Health