2003-04 SESSION COMMITTEE HEARING RECORDS

Committee Name:

Senate Committee on Health, Children, Families, Aging and Long Term Care

(SC-HCFALTC)

Sample:

Record of Comm. Proceedings … RCP

- 03hrAC-EdR_RCP_pt01a
- 03hrAC-EdR_RCP_pt01b
- 03hrAC-EdR_RCP_pt02

- Appointments … Appt
- **

- Clearinghouse Rules … CRule
- **

- Committee Hearings … CH
- **

- Committee Reports … CR
- **

- Executive Sessions … ES
- **

- Hearing Records … HR
- 03hr_sjr0046_pt04

NO DATE

- Miscellaneous … Misc
- **

- Record of Comm. Proceedings … RCP
- **

2003 SENATE JOINT RESOLUTION 46

reducing supply to Canada other Co's too many do get around.

October 15, 2003 – Introduced by Senators ROBSON, BRESKE, CARPENTER, CHVALA, DECKER, ERPENBACH, LASSA and RISSER, cosponsored by Representatives SERATTI, BERCEAU, HINES, HUBER, LOTHIAN, MOLEPSKE, POCAN, TURNER, ZEPNICK, TAYLOR and MILLER. Referred to Committee on Health, Children, Families, Aging and Long Term Care.

reacting to issues

People just going there getting on line

Relating to: strongly urging Congress and the Administration to enact the Pharmaceutical Market Access Act or similar legislation allowing individuals and pharmacies in the United States to import and re–import prescription medications purchased in other countries that have regulatory safeguards for the manufacture and distribution of drugs comparable to regulatory safeguards in the United States.

look at safety standards w/o medical intermediary

Whereas, the practice of medicine has undergone a shift toward more utilization of outpatient prescription medications for patients who in previous years would have been hospitalized; and

Whereas, expenses for outpatient prescribed medicines increased from $72.3 billion in 1997, or 13 percent of total medical expenses, to $103 billion in 2000, 16 percent of total medical expenses; and

Whereas, between 1990 and 2001, prescription drug spending in the United States grew by about 12 percent per year; and

Not Pharmacist involved

1 Whereas, Americans pay drug prices that are 30 to 300 percent higher than
2 prices paid for the same drugs in European and other industrialized nations, and
3 Canadian drug prices are on average 68 percent lower than American prices; and
4 Whereas, individuals, from young adults to senior citizens, without
5 prescription drug coverage pay the highest prices for prescription drugs and
6 frequently leave their prescriptions unfilled, compromising their health and leading
7 to more costly medical intervention; and
8 Whereas, the estimated cost of prescription drug benefits for participants in
9 state employee health insurance plans is $125 million annually and the cost of
10 prescription medications purchased for Wisconsin prison inmates is $12 million
11 annually; and
12 Whereas, if the medications in those 2 programs were purchased at the
13 Canadian prices, the savings to Wisconsin taxpayers would be $83 million; and
14 Whereas, taxpayers and individuals with no or inadequate health insurance
15 need relief from the high cost of prescription drugs; and
16 Whereas, Congress twice has passed legislation to allow American pharmacists
17 and drug wholesalers to import FDA–approved drugs from other countries, but the
18 U.S. department of health and human services has declined to implement a drug
19 import program; and
20 Whereas, as part of Medicare legislation being developed in Congress, the U.S.
21 house of representatives passed the Pharmaceutical Market Access Act, which
22 requires the federal food and drug administration, within 180 days of enactment, to
23 design and implement a system to grant individuals, pharmacists, and wholesalers
24 in America the ability to import FDA–approved drugs from FDA–approved
25 manufacturing facilities in 26 industrialized nations; and

1 Whereas, this provision would also require imported medicine to be shipped in
2 antitampering and anticounterfeiting packaging; now, therefore, be it
3 ***Resolved by the senate, the assembly concurring, That*** the Wisconsin
4 legislature strongly urges Congress and the Administration to enact the
5 Pharmaceutical Market Access Act or similar legislation allowing individuals and
6 pharmacies in the United States to import and re–import prescription medications
7 purchased in other countries that have regulatory safeguards for the manufacture
8 and distribution of drugs comparable to regulatory safeguards in the United States;
9 and, be it further
10 ***Resolved, That*** the Wisconsin legislature urges Congress and the
11 Administration to develop long–term solutions to bring down the price of
12 prescription medications so that we do not have to rely on imports; and, be it further
13 ***Resolved, That*** the senate chief clerk provide a copy of this joint resolution to
14 the President of the United States, to the secretary of the U.S. department of health
15 and human services, and to all members of the congressional delegation from
16 Wisconsin.
17 **(END)**

PHARMACY
SOCIETY OF
WISCONSIN

"Leading Our Profession in a Changing Health Care Environment"

Testimony before the Senate Committee on Health, Children, Families and Long Term Care On Senate Joint Resolution 46

Tom Engels, Vice President of Public Affairs
Pharmacy Society of Wisconsin

The Pharmacy Society of Wisconsin represents over 2000 pharmacists and pharmacy practices that all adhere to strict rules and regulations. Everyday pharmacists hear from their patients, especially the elderly, about the rising cost of prescription drugs. That is why PSW supports publicly funded and administered programs like SeniorCare, Medicaid, BadgerCare and the Health Insurance Risk Sharing Plan.

However, the resolution before you today puts in the spot light an issue that has become a political hot potato. Before we even discuss the concerns with the issue of prescription drug importation, I believe it is beneficial to lay some groundwork by acknowledging that it is illegal, in almost every case, to import or facilitate the importation of prescription drugs from other countries. Senate Joint Resolution 46 urges federal action to change the law in order to allow for the importation of prescription drugs.

Any effort to import drugs from Canada or any other nation must be done in a cautious manner. Cynics may scoff at the notion that drugs coming from countries like Canada are not safe, in fact one person in a recent Senate debate commented, "Show me the dead Canadians." The Pharmacy Society of Wisconsin never wants to come before this committee with a report of dead Wisconsin citizens due to imported medications.

We recommend that Senate Joint Resolution 46 include language that acknowledges the importation of prescription drugs is currently illegal. Requesting changes to current law is an appropriate approach to this issue but supporting or encouraging the violation of the law is not and the Wisconsin legislature should state that upfront.

For almost 100 years American citizens have been able to receive their prescription medications from a secure system that is the envy of the world. It is paramount that we maintain a safe and secure prescription drug distribution system in the United States. An open system of importation would greatly compromise that safety net.

PSW supports the concept, outlined in the resolution that would allow for licensed pharmacies to import prescription medications that have been certified as safe by the Food and Drug Administration or ones that have been maintained in such a secure system. However, widespread importation by individuals creates the potential for tampering and counterfeiting. It also eliminates the interaction between consumers and pharmacists. It is a practice that PSW does not support nor advocate.

3 1 - 90 age - 68/40
2 - and state WI Cun Sup
3 -

701 Heartland Trail
Madison, WI 53717
tele 608.827.9200
fax 608.827.9292
info@pswi.org
www.pswi.org

How importation should operate

Pharmacists are well aware of the rising cost of prescription drugs and the difference in prices charged by pharmaceutical manufacturers for the same drug sold in different countries. There are sometimes even vastly different prices charged to different purchasers of the same drug in this country. Frankly, instead of urging for action to allow for the importation of prescription drugs, we should petition congress to address the pricing inequities associated with prescription drugs in this country and abroad.

The resolution before the members of this committee today should also be clarified and some of the facts presented in the body of the resolution corrected.

For example:

1. IMS, the leading drug data company, reported prescription sales for out patient prescription drugs to be nearly $150 billion in 2000 (not $103 billion). That is approximately 11% of the overall health care spending not the 16% referenced in SJR 46. (In fact, IMS reported yesterday that outpatient pharmaceutical sales exceeded $216 billion last year and had a growth of 11.3% over the prior year.)

2. Drug prices in Canada are not, on average, 68% less than U.S. prices. Generic drugs actually cost more, on average, in Canada than in the United States. Brand name drugs are clearly less expensive in Canada, due to the government's system of price controls, but the 68% figure is not verified.

3. It is inaccurate to suggest that Wisconsin would save $83 million by accessing Canadian prices. This figure was apparently determined by simply multiplying the projected 68% discount times the current spending of the state programs referenced in the resolution. This level of savings is neither accurate nor possible, even if importation was allowed, and therefore it is misleading to the public.

However, with that all said, The Pharmacy Society of Wisconsin would support this resolution if it were amended in the following manner:

1. The factual items included in the resolution are corroborated or corrected.

2. Personal importation is not advocated and importation was only recommended through the current U.S. distribution system safely and securely.

3. The resolution is revised to acknowledge that prescription drug importation is currently illegal and potentially unsafe because it occurs outside the U.S. health care system.

4. The resolution is revised to acknowledge and emphasize the important services provided by Wisconsin pharmacists to Wisconsin consumers.

Thank you for this opportunity. I would be pleased to respond to your questions.

escription Drug and Modernization Act
The Bad, The Ugly

ouse of Representatives
approve H.R. 1, the
rug and modernization
te voted 54 to 44 to
on November 25. The
of Representatives split
r republicans voting for
e four democrats voting
tors Feingold and Kohl

ates a prescription drug
(Part D) and establishes
m to replace the current
t C). The prescription
06, is voluntary and ben-
premium after enrolling.
ld have access to a drug
on their drug purchases

es payments based on a
One area of major differ-
the so-called "premium
whereby the original
n would be required to
are Advantage program.
es a 6-year Comparative
ch the concept of premi-
in a limited number of
MSAs). The conference
ilization fund to create
nto and remain in the

CONTINUED ON PAGE 2

Highlights

The Good:

- Very low-income older persons with low assets will receive significant help with the cost of Rx drugs.
- Persons with extremely high Rx drug costs will receive catastrophic coverage.
- Everyone is assured that a prescription drug plan will be available and will have a choice of enrolling in a prescription drug plan only while remaining in the regular Medicare program.
- Expansion of Medicare benefits.
- Increased payments to health care providers in Wisconsin.

The Bad:

- A major $2,850 gap in coverage where beneficiaries receive no assistance with the cost of drugs.
- Asset - testing for very low-income persons.
- Means - testing for higher income persons starting at $80,000.
- A cap on general revenue spending for Medicare.
- A provision forcing Medicare to compete with subsidized private insurance plans ("Comparative Cost Adjustment" program).
- A very modest Rx drug benefit for most older people.
- Not effective until 2006
- Medicaid recipients are likely to have less access to the full range of drugs covered by Medicaid and fewer protections against higher costs.
- A transitional drug discount card that will provide little help in 2004 and 2005.

The Ugly:

- Prohibition against purchasing Medigap insurance to cover gaps in drug coverage (e.g. the doughnut hole).
- Does not legalize free trade with Canada and other countries for people who want to shop around for better prices for their drugs.
- The creation of health savings accounts to provide tax breaks for the wealthy.
- Total capitulation to drug companies who will be able to sell more higher priced drugs while pocketing millions (possibly billions) of dollars in money that used to support Medicaid and other low-income program.
- Indexing premiums, deductibles, benefit limit, and coverage gap to the increase in the cost of drugs without doing anything to contain the cost of drugs.

I am writing you in regards to your support of importation of Canadian drugs, in an effort to cut costs for state employees. So you know who I am, I went to high shool with your son, Marc, and spoke with you at the cancer relay for life in Clinton, WI. I am a family physician at Mercy Clinic East. I loudly applaud your efforts in the above matter. I am tired of the monopolization of the drug industry by the brand-name pharmaceutical industry, and their padding of politician pockets. This recent Medicare reform package was a joke. I just wanted to provide you with some ammunition, as there has been a couple recent articles in regards to this issue. The first was in the Annals of Pharmacotherapy. 2003 Oct; 37(10): 1403-1408, which found when serious drug safety problems were identified in a timely manner after US approval, the products were not subsequently approved in Canada. Canada has longer approval times, and thus allows for observation of actual market experience. Another article appeared in the Medical Letter, December 8, 2003, which found that most Canadian drugs came from manufacturers in the US, and that the Canadian drug-approval process is very similar to that here. To say that Canadian drugs are unsafe, is undeniably false! My only concern would be the selling of counterfeit drugs by unregulated dealers. I'm proud you and Governor Doyle have taken a stand against the greedy drug companies. Health care costs will be a major problem in the future, as our population ages, and our resources become limited. I'd like to see nationalized healthcare, for the benefit of all, and yet to the detriment of physician salaries and HMO profits. Even a state-wide plan would have great attractiveness. Keep up the great work, and if I can be of any further assistance, let me know.

Paul Mannino, MD
10235 East Waite Road
Clinton, WI 53525
608-676-2471
e-mail--micwil@inwve.com

To the senators and representatives relating to 2003 Senate Joint Resolution 46

Thank you for this priveledge to speak in favor of this resolution

My name is Loren J Close-I live in rural Edgerton-I am 82 years old and I do not take any kind of medication. I am fortunate that my good health does not subject me to the cruelity that the drug compaanies inflict on the inflicted.

In 1972 I was appointed by Gov. Lucey to be the first Ex. Secty. Of the Wisconsin Board on Aging---so, I am very cognizant of the problems that the poor elderly have in the battle to exist juggling the budget to eat under a roof and to get the drugs that they must have to see the tomorrow's sunshine---I have a dust covered file of some of their dilemmas of having to make bad decisions---such as splitting pills so they do a little good---or eating dog food so that theyhave drugs-so they can feel good enough to eat dog food---many of the stories are heart wrentching! It just is not fair!!!

It is not only not fair--it borders on --if not genicide--then genicides first cousin-, in essense the drug companies say--"Give me your money-then we will save your life--lots of money---if you cannot pay--well, this is America--the land of the greedy--home of the discompassionate!"

Legislators, ask yourself--Why is it that when the price of gasoline jumps up a nickel there is a congressional stir to call for an investigation onprice-gouging???Yet, nothing ever gets to first base to halt the insane prices that Americans must pay for drugs???Is this lack of attention an oversight in congress or is that DRUG-CASH COW---AN OFF- THE -TABLE- SACRED COW-?---either way it does nothing for the ailing public:DC needs to establish people oriented empathy!

The drug companies claim that they need all that loot for research and development---WRONG they spend more for advertising than for R &D you must know that they lie to you---

The present congress is stratosphere-high on free trade---OH YES, EXCEPT FOR DRUG TRADE WITH CANADA-----If cheap labor is good for Walmart--then why isn't cheap drugs good for my poor ailing aunt ??-----Congressional integrity is on the line!!!

We all know that Tommy Thompson would never allow American drug producer to send drugs to our cousins in Canada if they were not up to acceptable standards----so, no lies about that issue!A scarce hand full of you are old enough to really know about our whiskey prohibition law that sank like a rock---The hogs in our" back 40" got pretty tippsy on eating the mash from the neighbors still---a big operation---a Capone operation!

So, just saying no to affordable drugs will also sink like a rock--we are too close to Canada---and bless our creative American minds , we are too good at "do-it-yourself" to allow an edict from distant DC curb our desperate needs----and the result is that the big losers will be the local pharmacies---The truth is that the only way to keep Canada- Direct out of the equation is to include the local pharmacies----say at a price that gets drugs to those in need for --say, 10% over Canadian prices.

I truly believe that you will act on this Joint Resolution because---it is the right thing to do!

Thanks you for your kind patience!!

Distributed by:

Judy Robson

Wisconsin State Senator

State Capitol: P.O. Box 7882, Madison, WI 53707-7882
Telephone: (608) 266-2253
District Address: 2411 East Ridge Road, Beloit, WI 53511
Toll-free 1-800-334-1468 • E-Mail: sen.robson@legis.state.wi.us

BERNARD & JACKIE KRAKAU
2725 HYACINTH AVE.
JANESVILLE, WI 53545

I would like to have this legislation enacted at the earliest possible date.
Bernard Krakau

2003 – 2004 LEGISLATURE

LRB–3402/1
PJD:kmg:ch

2003 SENATE JOINT RESOLUTION 46

October 15, 2003 – Introduced by Senators ROBSON, BRESKE, CARPENTER, CHVALA, DECKER, ERPENBACH, LASSA and RISSER, cosponsored by Representatives SERATTI, BERCEAU, HINES, HUBER, LOTHIAN, MOLEPSKE, POCAN, TURNER, ZEPNICK, TAYLOR and MILLER. Referred to Committee on Health, Children, Families, Aging and Long Term Care.

Senator Robson,

As a nurse, I am very concerned about the costs of medication in the US. When working in acute care and rehabilitation, I saw the problems that occurred when persons who could not afford their medications either stopped taking them or cut the dose down or maybe took it every other day or so. These medical problems often caused expensive hospitalizations, sometimes with severe consequences such as a stroke, leaving the client dependent on others or the system to care for them. This is a very expensive outcome of inability to obtain medication.

Since my retirement from paid employment, I volunteer in a local free health clinic. I see the needs there growing continuously as more and more people are unemployed, lose benefits for various reasons (perhaps the death of spouse) and those on fixed incomes or with low paying jobs whose buying power is constantly being eroded. We are able to get some people meds thru the drug company assistance programs but this takes a great deal of time for the patients and the volunteer staff-every company requires different information and the paperwork usually has to be resubmitted every 90 days. One volunteer spends many hours on the phone to drug companies following up on these requests.

As a senior, I am very lucky to have good company sponsored insurance thru my husband, however at the annual retirement informational session, we were encouraged to contact our federal legislators to vote for the medicare bill because "they had paid into it for so long it's about time they got some benefit" ie they could lower our benefits if the bill went thru. I am very disappointed in the federal legislation, especially the part about not negotiating the costs of medications. That is absolutely ridiculous, we negotiate the price of anything that we can, our homes, cars, look for the best prices in telephone service, sales on household goods, clothing and even food. Are our legislators so out of touch with the average American.

The bottom line is I urge the Wisconsin Legislature to pass Senate Joint Resolution 46.
Sincerely

Karen A Bernard RN, MS
2605 Cedar Pointe Drive
Janesville, WI 53546-5453
email papab@ticon.net

Senator Robson:

Given the short timeline, I will e-mail my testimony to you, urging you to do what you can to put pressure on Congress to pass the Pharmaceutical Marketing Access Act.

I have been a pastor for the past 21 years, and in that time I have always ministered to the needy in society. For the past two years, the Food Pantry in the church, where I served has experienced a doubling of the demand. Those who hand out groceries, keep track of why people come for assistance. These records make it strikingly clear that people increasingly turn to food pantries because they are forced to choose between eating and filling their prescriptions. Churches can provide free food, but not free medicine, so they turn to us, to avoid having to make this life-threatening decision. These are not the chronically destitute who already go without, but increasingly the elderly on pensions, workers whose health benefits won't cover prescriptions, those with chronic health conditions such as diabetes or high blood pressure.

It would not only be an act of mercy, but also serve the cause of justice, if the current unfair trade restrictions were lifted, thus also helping to lift the unfair burdens born by those who are only seeking to keep body and soul together.

If there is any way I can be of further assistance in this regard, please let me know.

Sincerely,
The Rev. Carol Wickersham
612 High St.
Clinton, WI 53525
(608)676-4583

Dear Senator Robson:

I will not be able to attend the hearing on Senate Joint Resolution 46, but wish to register my wholehearted support for this legislation. I hope the Pharmaceutical Marketing Access Act will pass the U.S. Senate, or some other bill which would limit the cost of drugs, such as the Canadian Government has.

Something drastic needs to be done to help cut the cost of prescription drugs. Now some of the drug companies are threatening to cut off supplies to pharmacies in Canada who re-sell to U.S. citizens, and this should also be addressed with some form of punitive damages to those profiteering companies.

Thanks for all your attention and help in this matter, and also in your efforts to keep jobs in Wisconsin, rather than out sourcing them.

Best regards,

Jerry & Nancy Ladwig
2424 Shopiere Rd
Beloit, Wi 535ll

Dear Sen. Robson,

Due to the short notice regarding tomorrows meeting, we will not be able to attend the scheduled meeting.

We in the U.S. have the best health care system in the world and it is inaccessible for many due to the high cost.
We would like to suggest that the Government should negotiate with the drug companies for prescription drugs at an affordable price for all people. We also need some kind of affordable insurance. Self-employed are caught in the cracks with no place to turn, the rich and those employed by others are probably o.k. Those who retire at age 62 are out on a limb and nobody seems to care.

Yes, we do need affordable health care and affordable prescription medications in this country.

I am a 63 year old woman who went on Social Security at the age of 62. My health care premium at present nearly exceeds my social security each month. The amount of the premium is $15.00 less than what I receive each month. Then, add on $25.00 for each of four prescriptions and you can see I am a little short. (Just for routine health care!)

I have a sister-in-law who is disabled and receives Social Security and other benefits which takes her $100.00 over the limit. Otherwise her medications would be covered. Her medications are necessary for her very life to continue. They are suffering a real hardship.

I have a daughter and her family who live in Florida. At present they have no insurance and are unable to attain such due to the fact that their 4 yr. old child was born with acid reflux and he is "uninsurable". This acid reflux condition has been resolved, but the insurance companies still will not cover this child.

Help!

Sandra and Bill Hein
3544 S. Murray Rd.
Janesville, Wisconsin
53548-92251

Dear Senator Robson,

Please help to pass this Pharmaceutical marketing access act. I've been taking Lipitor (which is manufactured in Ireland) according to the label. 3 months supply mail-order for $25. Well, I just got laid off from my job & this same pill will be $110 a month at Walmart's pharmacy. So when my present dosage is gone, I'm not taking any-more, I'm going to change my diet instead!

Thank you,

Carol Aimers

Mrs. Carol Aimers
1753 Cranston Rd.
Beloit, WI 53511-2557

PHARMACY
SOCIETY OF
WISCONSIN

"Leading Our Profession in a Changing Health Care Environment"

Testimony before the Senate Committee on Health, Children, Families and Long Term Care On Senate Joint Resolution 46

Tom Engels, Vice President of Public Affairs
Pharmacy Society of Wisconsin

The Pharmacy Society of Wisconsin represents over 2000 pharmacists and pharmacy practices that all adhere to strict rules and regulations. Everyday pharmacists hear from their patients, especially the elderly, about the rising cost of prescription drugs. That is why PSW supports publicly funded and administered programs like SeniorCare, Medicaid, BadgerCare and the Health Insurance Risk Sharing Plan.

However, the resolution before you today puts in the spot light an issue that has become a political hot potato. Before we even discuss the concerns with the issue of prescription drug importation, I believe it is beneficial to lay some groundwork by acknowledging that it is illegal, in almost every case, to import or facilitate the importation of prescription drugs from other countries. Senate Joint Resolution 46 urges federal action to change the law in order to allow for the importation of prescription drugs.

Any effort to import drugs from Canada or any other nation must be done in a cautious manner. Cynics may scoff at the notion that drugs coming from countries like Canada are not safe, in fact one person in a recent Senate debate commented, "Show me the dead Canadians." The Pharmacy Society of Wisconsin never wants to come before this committee with a report of dead Wisconsin citizens due to imported medications.

We recommend that Senate Joint Resolution 46 include language that acknowledges the importation of prescription drugs is currently illegal. Requesting changes to current law is an appropriate approach to this issue but supporting or encouraging the violation of the law is not and the Wisconsin legislature should state that upfront.

For almost 100 years American citizens have been able to receive their prescription medications from a secure system that is the envy of the world. It is paramount that we maintain a safe and secure prescription drug distribution system in the United States. An open system of importation would greatly compromise that safety net.

PSW supports the concept, outlined in the resolution that would allow for licensed pharmacies to import prescription medications that have been certified as safe by the Food and Drug Administration or ones that have been maintained in such a secure system. However, widespread importation by individuals creates the potential for tampering and counterfeiting. It also eliminates the interaction between consumers and pharmacists. It is a practice that PSW does not support nor advocate.

701 Heartland Trail
Madison, WI 53717
tele 608.827.9200
fax 608.827.9292
info@pswi.org
www.pswi.org

Pharmacists are well aware of the rising cost of prescription drugs and the difference in prices charged by pharmaceutical manufacturers for the same drug sold in different countries. There are sometimes even vastly different prices charged to different purchasers of the same drug in this country. Frankly, instead of urging for action to allow for the importation of prescription drugs, we should petition congress to address the pricing inequities associated with prescription drugs in this country and abroad.

The resolution before the members of this committee today should also be clarified and some of the facts presented in the body of the resolution corrected.

For example:

1. IMS, the leading drug data company, reported prescription sales for out patient prescription drugs to be nearly $150 billion in 2000 (not $103 billion). That is approximately 11% of the overall health care spending not the 16% referenced in SJR 46. (In fact, IMS reported yesterday that outpatient pharmaceutical sales exceeded $216 billion last year and had a growth of 11.3% over the prior year.)

2. Drug prices in Canada are not, on average, 68% less than U.S. prices. Generic drugs actually cost more, on average, in Canada than in the United States. Brand name drugs are clearly less expensive in Canada, due to the government's system of price controls, but the 68% figure is not verified.

3. It is inaccurate to suggest that Wisconsin would save $83 million by accessing Canadian prices. This figure was apparently determined by simply multiplying the projected 68% discount times the current spending of the state programs referenced in the resolution. This level of savings is neither accurate nor possible, even if importation was allowed, and therefore it is misleading to the public.

However, with that all said, The Pharmacy Society of Wisconsin would support this resolution if it were amended in the following manner:

1. The factual items included in the resolution are corroborated or corrected.

2. Personal importation is not advocated and importation was only recommended through the current U.S. distribution system safely and securely.

3. The resolution is revised to acknowledge that prescription drug importation is currently illegal and potentially unsafe because it occurs outside the U.S. health care system.

4. The resolution is revised to acknowledge and emphasize the important services provided by Wisconsin pharmacists to Wisconsin consumers.

Thank you for this opportunity. I would be pleased to respond to your questions.

escription Drug and Modernization A
The Bad, The Ugly

ouse of Representatives
approve H.R. 1, the
rug and modernization
te voted 54 to 44 to
on November 25. The
of Representatives split
r republicans voting for
four democrats voting
tors Feingold and Kohl

ates a prescription drug
(Part D) and establishes
m to replace the current
t C). The prescription
06, is voluntary and ben-
premium after enrolling.
ld have access to a drug
on their drug purchases

es payments based on a
One area of major differ-
the so-called "premium
whereby the original
n would be required to
are Advantage program.
es a 6-year Comparative
ch the concept of premi-
in a limited number of
MSAs). The conference
ilization fund to create
nto and remain in the

CONTINUED ON PAGE 2

Highlights

The Good:

- Very low-income older persons with low assets will receive significant help the cost of Rx drugs.
- Persons with extremely high Rx drug costs will receive catastrophic coverag
- Everyone is assured that a prescription drug plan will be available and will h choice of enrolling in a prescription drug plan only while remaining in the lar Medicare program.
- Expansion of Medicare benefits.
- Increased payments to health care providers in Wisconsin.

The Bad:

- A major $2,850 gap in coverage where beneficiaries receive no assistance wi cost of drugs.
- Asset - testing for very low-income persons.
- Means - testing for higher income persons starting at $80,000.
- A cap on general revenue spending for Medicare.
- A provision forcing Medicare to compete with subsidized private insurance ("Comparative Cost Adjustment" program).
- A very modest Rx drug benefit for most older people.
- Not effective until 2006
- Medicaid recipients are likely to have less access to the full range of drugs co by Medicaid and fewer protections against higher costs.
- A transitional drug discount card that will provide little help in 2004 and 2

The Ugly:

- Prohibition against purchasing Medigap insurance to cover gaps in drug co (e.g. the doughnut hole).
- Does not legalize free trade with Canada and other countries for people who to shop around for better prices for their drugs.
- The creation of health savings accounts to provide tax breaks for the wealt
- Total capitulation to drug companies who will be able to sell more higher drugs while pocketing millions (possibly billions) of dollars in money that u support Medicaid and other low-income program.
- Indexing premiums, deductibles, benefit limit, and coverage gap to the in in the cost of drugs without doing anything to contain the cost of drugs.

To the senators and representatives relating to 2003 Senate Joint Resolution 46

Thank you for this priveledge to speak in favor of this resolution

My name is Loren J Close-I live in rural Edgerton-I am 82 years old and I do not take any kind of medication. I am fortunate that my good health does not subject me to the cruelity that the drug compaanies inflict on the inflicted.

In 1972 I was appointed by Gov. Lucey to be the first Ex. Secty. Of the Wisconsin Board on Aging---so, I am very cognizant of the problems that the poor elderly have in the battle to exist juggling the budget to eat under a roof and to get the drugs that they must have to see the tomorrow's sunshine---I have a dust covered file of some of their dilemmas of having to make bad decisions---such as splitting pills so they do a little good---or eating dog food so that theyhave drugs-so they can feel good enough to eat dog food---many of the stories are heart wrentching! It just is not fair!!!

It is not only not fair--it borders on --if not genicide--then genicides first cousin-, in essense the drug companies say--"Give me your money-then we will save your life--lots of money---if you cannot pay--well, this is America--the land of the greedy--home of the discompassionate!"

Legislators, ask yourself--Why is it that when the price of gasoline jumps up a nickel there is a congressional stir to call for an investigation onprice-gouging???Yet, nothing ever gets to first base to halt the insane prices that Americans must pay for drugs???Is this lack of attention an oversight in congress or is that DRUG-CASH COW---AN OFF- THE -TABLE- SACRED COW-?---either way it does nothing for the ailing public:DC needs to establish people oriented empathy!

The drug companies claim that they need all that loot for research and development---WRONG they spend more for advertising than for R &D you must know that they lie to you---

The present congress is stratosphere-high on free trade---OH YES, EXCEPT FOR DRUG TRADE WITH CANADA-----If cheap labor is good for Walmart--then why isn't cheap drugs good for my poor ailing aunt ??-----Congressional integrity is on the line!!!

We all know that Tommy Thompson would never allow American drug producer to send drugs to our cousins in Canada if they were not up to acceptable standards----so, no lies about that issue!A scarce hand full of you are old enough to really know about our whiskey prohibition law that sank like a rock---The hogs in our" back 40" got pretty tippsy on eating the mash from the neighbors still---a big operation---a Capone operation!

So, just saying no to affordable drugs will also sink like a rock--we are too close to Canada---and bless our creative American minds , we are too good at "do-it-yourself" to allow an edict from distant DC curb our desperate needs----and the result is that the big losers will be the local pharmacies---The truth is that the only way to keep Canada- Direct out of the equation is to include the local pharmacies----say at a price that gets drugs to those in need for --say, 10% over Canadian prices.

I truly believe that you will act on this Joint Resolution because---it is the right thing to do!

Thanks you for your kind patience!!

Who is the guy with the silver tie in the front row - he looks familiar! ?!

Tom Moore
use to work for
Petrek
he works in
Rep's office

Ok - that's the
first time I've
heard Ron
Brown lose
his temper!

You
me too.

Senate Joint Resolution 46

Relates to strongly urging Congress and the Administration to enact the Pharmaceutical Market Access Act or similar legislation allowing individuals and pharmacies in the United States to import and re-import prescription medications purchased in other countries **that have regulatory safeguards for the manufacture and distribution of drugs comparable to regulatory safeguards in the United States.**

- It is very likely that representatives from the pharmaceutical companies, pharmacists and pharmacist examining board will be testifying.
- I would not be surprised if older adults also testified.
- **I think it is important to remember that this is a resolution, not a proposal to allow for re-importation. Passage of this bill does not change current law as it relates to re-importation.**

Certify Safety
licensed in WI
AT Minnesota VS Am
Pharmacies
High degree of control
unsafe/ineffectiveness

SJR
46

Prepared winter '03

FEDERAL DRUG ADMINISTRATION

General

- Under the Food Drug &Cosmetic Act (FD&C), the interstate shipment of any prescription drug that lacks required FDA approval is **illegal**. Interstate shipment includes importation--bringing drugs from a foreign country into the United States.
- Drugs sold in the United States also must have proper labeling that conforms with the FDA's requirements, and must be made in accordance with good manufacturing practices.
- Drugs can only be manufactured at plants registered with the agency, whether those facilities are domestic or foreign. If a foreign firm is listed as a manufacturer or supplier of a drug's ingredient on a new drug application, the FDA generally travels to that site to inspect it.
- After the FDA approves a drug, manufacturers still are subject to FDA inspections and must continue to comply with good manufacturing practices.

Re-importation

- The FD&C Act also states that prescription drugs made in the United States and exported to a foreign country can only be re-imported by the drug's original manufacturer. Even when original manufacturers re-import drugs, the drugs must be real, properly handled, and relabeled for sale in the United States if necessary.
- The Medicine Equity and Drug Safety Act (MEDS), enacted in 2000, would have allowed prescription drugs manufactured in the United States and exported to certain foreign countries to be re-imported from those countries for sale to American consumers.
- Supporters of the bill hoped that lower drug pricing in other countries would be passed along to consumers. But Health and Human Services Secretary Tommy G. Thompson responded by saying that, while he believed strongly in access to affordable drugs, he could not implement the act because it would sacrifice public safety by opening up the closed distribution system in the United States.
- Though the law was enacted in 2000, before the bill can take effect, one provision requires that the HHS secretary determine whether adequate safety could be maintained and whether costs could be reduced

significantly. Both Thompson and his predecessor, Donna Shalala, concluded that these conditions could not be guaranteed.

"Once an FDA-approved prescription drug is exported for sale in another country, it is no longer subject to U.S. requirements and it can no longer be monitored by U.S. regulators," Thompson wrote in a letter to Sen. James Jeffords (I-Vt.), one of the bill's sponsors. "In addition, it may not have the U.S.-approved labeling. Instead it may have labeling for the country to which it is exported."

Guidance on Personal Use

- Although importing unapproved prescription drugs is illegal, the FDA's guidance on importing prescription drugs for personal use recognizes that there may be circumstances in which the FDA can exercise discretion to not take action against the illegal importation.
- The guidance allows individuals with serious conditions, such as a rare form of cancer, to get treatments that are legally available in foreign countries but are not approved in the United States.

The current policy is not a law or a regulation, but serves as guidance for FDA personnel. The importation of certain unapproved prescription medication for personal use may be allowed in some circumstances if all of these factors apply:

- If the intended use is for a serious condition for which effective treatment may not be available domestically.
- If the product is not considered to represent an unreasonable risk.
- If the individual seeking to import the drug affirms in writing that it is for the patient's own use and provides the name and address of the U.S.-licensed doctor responsible for his or her treatment with the drug or provides evidence that the drug is for continuation of a treatment begun in a foreign country.
- If the product is for personal use and is a three-month supply or less and not for resale. Larger amounts would lend themselves to commercialization.
- If there is no known commercialization or promotion to U.S. residents by those involved in distribution of the product.

"While we can appreciate the cost issue, saving money on prescription drugs isn't one of the circumstances," says the FDA's McCallion. "The guidance doesn't condone the use of buying foreign-made versions of drugs available in the United States, even if they are sold

Enforcement

- To date, the FDA has focused its enforcement resources on those who commercialize the practice of importing drugs into the US from abroad.
- The FDA generally has not seized drugs from those who have taken buses across the border and then brought foreign drugs back into the US for their own personal use. Instead, the FDA has attempted to educate such citizens about the safety risks associated with consuming foreign drugs.
- FDA retains the authority to bring an enforcement action in any case in which a provision of the Food, Drug and Cosmetic Act has been violated.

WISCONSIN

Canada Drug Service

- Canada Drug Service, operated by someone who is not a pharmacist, is a storefront operation that has recently opened in Wauwatosa. There are also locations in Green Bay, Sheboygan and Racine. According to the Pharmacy Society of WI., the owner plans to open 12 more stores in WI.
- According to the MJS, Canada Drug Service operates in the following manner:

  Customers drop off their prescriptions at the store in Wauwatosa. The prescriptions are then forwarded to physicians in Canada. The Canadian physicians then refer the prescriptions to pharmacies in British Columbia. Then, within two weeks, prescriptions are sent by mail to customers' homes in the U.S.

2/2/04 JH asked Tom Engles for status. Yes, DRL still investigating.

- 9-18-03: The Pharmacy Society of WI sent a letter to the DRL WI Pharmacy Examining Board requesting that the Board investigate Canada Drug Service's conduct and pursue appropriate enforcement action.
- 9-18-03: The PSW also asked that the Pharmacy Examining Board (PEB) immediately open an investigation on the Premium Discount Pharmaceutical Services and a website operated by the Coalition of Wisconsin Aging Groups. PSW requested the PEB to make a similar request of the WI Attorney General.
- 10-31-03: The Illinois Professional Regulation Department ordered Canada Drug Service to take "drug" out of its name. Only a licensed pharmacy can use "drug" or "pharmacy" in its name or advertising.

Rx Depot (not in WI but could relevant to Canada Drug Service)

- The President of Rx Depot is Carl Moore. He runs more than 85 stores in states such as California, Texas, Florida and Oklahoma.
- 9-11-03: The U.S. Justice Department filed suit against Rx Depot. The government is seeking an injunction to close the stores run by Rx Depot.
- James Scaban, a drug law specialist at Heller Herman in Washington said in a USA Today article, "To win an injunction, the Justice Department will have to show that allowing Rx Depot to stay in business could cause "irreparable harm" and is not in the public interest."
- 11-6-03: Federal Judge Claire Eagan of the 10th Circuit Federal Court ruled against Rx Depot. This decision is to effectively shut down physical storefronts in the U.S.

Governor

- 11-4-03: The Governor, DHFS Secretary Helene Nelsen and Corrections Secretary Matt Frank met with David Mackay, who represents a coalition of 6 Canadian pharmacies that are prepared to serve the United States.
- 10-29-03: The Governor announced that he and key administration officials will meet with officials from Canadian pharmacies in Madison next week to explore the possibility of buying lower price prescription drugs from Canada.

FDA and Pharmacy Society of Wisconsin

- 11-3-03: The following people held a press conference in opposition to purchasing drugs from Canada: Christopher Decker (PSW), Corey Hoze (Regional Director for the Department of Health and Human Services), Thomas McGinnis, RPh, (Director of Pharmacy Affairs in the Office of Policy at the FDA) and Susan Sutter (Chairman of the Pharmacy Examining Board for the State of WI).
- Thomas McGinnis: "*The safeguards we have established are there for a reason: they protect the safety of our drug supply and the health of consumers." The FDA recently reviewed 1,153 prescription drugs at four different international mail facilities and we found 88% of the drugs were not FDA approved."*

Pharmaceutical Examining Board

- At its October 14th meeting the Board discussed the issue of purchasing drugs from Canada. The Board voted to take the following actions:
  - Communicate with the entire Legislature authoritative information on this subject to foster a greater understanding of both the legal and safety issues;
  - Request the Attorney General investigate the legality of these storefront operations under the Wisconsin law;
  - Ask the Secretary of the Department of Regulation and Licensing to make the pending cases related to this issue a top priority for the Division of Enforcement to complete.

Resolution

- Senator Robson has introduced Senate Joint Resolution 46. This resolution strongly urges Congress and the Administration to enact the Pharmaceutical Market Act or similar legislation allowing individuals and pharmacies to the United States to import and re-import prescription medications purchased in other countries that have regulatory safeguards for the manufacture and distribution of drugs comparable to regulatory safeguards in the United States.
- 10-15-03: This Resolution was referred to the Senate Committee on Health, Children, Families, Aging and Long Term Care.

CONGRESS

Pharmaceutical Market Access Act of 2003

- 6-11-03: H.R. 2427 was introduced. This bill amends the Federal Food, Drug and Cosmetic Act to direct the Secretary of Health and Human Services to promulgate regulations allowing qualifying individuals to import covered products.
- 7-25-03: Bill passed 243-186 and was referred to the Senate Committee on Health, Education, Labor and Pensions.

Medicare

- The House and the Senate have passed legislation to add a prescription drug benefit to Medicare. Both plans create a benefit costing about $400 billion over the next ten years.

Key elements of the House and Senate plans:

  - Both the Senate and House plans will offer a pharmacy discount card beginning in 2004 with a paid benefit starting in 2006. The plans, however, differ on deductible levels and out of pocket expenses.

- Both plans include language to address the reporting by PBM's of rebate amounts, pharmacy discounts and other price concessions received by the PBM (transparency provisions). However, it is not clear what access the public will have to this information.
- Only the House version requires beneficiaries to obtain services from a pharmacy and not from a mail order house. The Senate version seems to allow for the establishment of a mail order pharmacy system to be offered only by the PBM.
- Both plans contain provisions that preempt states that have "any willing pharmacy" laws or PBM regulation. That includes Wisconsin's Pharmacy Open Panel Law.
- Both plans have provisions related to medication therapy management services to be provided by pharmacists, but it appears the PBM would select the pharmacist to provide the service, not the patient.

OTHER STATES

Minnesota

- 10-16-03: Governor Tim Pawlenty announced a plan to help Minnesotans import U.S. manufactured drugs from Canadian pharmacies. Minnesota is believed to be the first state in the nation to pursue imports as a method for lowering prescription drugs.
- The five step prescription drug plan would include:

  - A Web site at which any Minnesotan could buy prescription drugs from approved Canadian pharmacies negotiated by the state.
  - Identify foreign-made, FDA approved prescription drugs and negotiate with a wholesaler or broker to import the state.
  - Provide financial incentives to state employees as a way to encourage them to buy their medications online.
  - Encourage U.S. Health and Human Services Sec. Tommy Thompson to eliminate barriers to importing prescription drugs.
  - Convene a Gov.'s summit on prescription drugs by the end of the year.

Illinois

- Illinois Gov. Blagojevich has asked the federal government to allow Illinois to explore a plan to import approved medications from Canada.
- The Gov. also has an online petition urging Congress and the FDA to allow Americans to purchase drugs from Canada.

Iowa

- Gov. Vilsack has put a link on his website to sign onto Illinois Gov. Blagojevich's petition. Gov. Vilsack supports purchasing drugs from Canada.
- 9-24-03: The Governor announced that he plans to seek lower-priced medications from Canada for state employees. He has asked aides to draft plans for state health insurance programs to buy medicines from Canadian suppliers.

CONCERNS

- Importing drugs from Canada is illegal (under the Food, Drug and Cosmetic Act). Anyone violating this Act would be subject to liability under that statute, regardless of whether the importation was otherwise sanctioned by the state.
- There are no pharmacy services provided.
- There are no safety mechanisms in place to ensure the consumer is receiving the prescription medication prescribed by the person's physician (i.e. correct drug, dosage).
- No regulations in place to ensure the medication has been stored or shipped properly (puts consumer of drug at risk).
- According to Susan Sutter of the Pharmacy Examining Board, a person would not have legal recourse if they unknowingly received the wrong medication or were given medication that had been tampered with.
- Not all of the drugs provided from Canada meet FDA standards or have been approved by the Canadian equivalent (Health Canada's Health Products and Food Branch).
- Drugs coming to the United States from Canada may be coming from some other country and simply passing through Canada. The drugs could also be counterfeit, contaminated, or subpotent, among other things.
- A pharmacist would be penalized by the Pharmacy Examining Board for purchasing drugs from Canada and then selling them to his/her customers. Yet, the state is allowing individuals without any pharmaceutical experience to purchase and dispense prescription medication.