

**MINUTES OF THE
SENATE COMMITTEE ON COMMERCE AND LABOR**

**Seventy-third Session
May 12, 2005**

The Senate Committee on Commerce and Labor was called to order by Chair Randolph J. Townsend at 8:02 a.m. on Thursday, May 12, 2005, in Room 2135 of the Legislative Building, Carson City, Nevada. The meeting was videoconferenced to the Grant Sawyer State Office Building, Room 4406, 555 East Washington Avenue, Las Vegas, Nevada. [Exhibit A](#) is the Agenda. [Exhibit B](#) is the Attendance Roster. All exhibits are available and on file at the Research Library of the Legislative Counsel Bureau.

COMMITTEE MEMBERS PRESENT:

Senator Randolph J. Townsend, Chair
Senator Warren B. Hardy II, Vice Chair
Senator Sandra J. Tiffany
Senator Joe Heck
Senator Michael Schneider
Senator Maggie Carlton
Senator John Lee

GUEST LEGISLATORS PRESENT:

Assemblywoman Barbara E. Buckley, Assembly District No. 8
Assemblyman Bob McCleary, Assembly District No. 11

STAFF MEMBERS PRESENT:

Kevin Powers, Committee Counsel
Scott Young, Committee Policy Analyst
Shirley Parks, Committee Secretary

OTHERS PRESENT:

Michael Tanchek, Labor Commissioner, Office of Labor Commissioner,
Department of Business and Industry
David Kersh, Carpenters/Contractors Cooperation Committee, Incorporated
Christina Dugan, Las Vegas Chamber of Commerce
Fred L. Hillerby, Washoe County Regional Transportation Commission

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John (Jack) E. Jeffrey, Southern Nevada Building and Construction Trades
Raymond Bacon, Nevada Manufacturers Association
Cal Ludeman, Commissioner, Office of Commissioner, Department of Employee
Relations, State of Minnesota
John Ellerton, M.D.
Scott Watts, Nevada Alliance for Retired Americans
Marian Conrad
Charlie Cox, President, United Auto Workers Local 2162
Xahis Castro
Roberta (Bobbie) Gang, Nevada Women's Lobby
Barry Gold, American Association of Retired Persons Nevada
Robert A. Desruisseaux, Northern Nevada Center for Independent Living
James Brown
William J. Birkmann, Communications Workers of America
Keith W. Macdonald, Executive Secretary, State Board of Pharmacy
Richard Miller, United Federation of Teachers Retiree Chapter of the American
Federation of Teachers of Nevada
Chris Ward, President, Ward Health Strategies
Liz MacMenamin, Retail Association of Nevada
Marc Kealey, Chief Executive Officer, Ontario Pharmacists' Association
Tom Wood, Pharmaceutical Research and Manufacturers of America
Diane Darvey, National Association of Chain Drug Stores
Matthew Van Hook, Pharmaceutical Research Manufacturers of America
Joe Tyler, National Alliance for the Mentally Ill of Nevada

CHAIR TOWNSEND:

The hearing on Assembly Bill (A.B.) 340 and A.B. 384 is postponed to another time. The hearing on A.B. 44 is now open.

[ASSEMBLY BILL 340 \(1st Reprint\)](#): Revises provisions relating to certain short-term, high interest loans. (BDR 52-126)

[ASSEMBLY BILL 384 \(1st Reprint\)](#): Makes various changes relating to certain short-term, high-interest loans. (BDR 52-806)

[ASSEMBLY BILL 44 \(1st Reprint\)](#): Revises provisions governing payment of overtime to certain employees. (BDR 53-761)

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ASSEMBLYMAN BOB MCCLEARY (Assembly District No. 11):

This bill gives the labor commissioner jurisdiction for enforcement over all labor laws for the State of Nevada. Presently, if a worker is on the job and has a conflict with an employer, the worker would have to go to the United States Department of Labor. This can be time consuming and it might be two years before a decision is made. The labor commissioner would have jurisdiction and be able to intervene and act much sooner on behalf of the worker. I understand there is an amendment to this bill that will be offered.

MICHAEL TANCHEK (Labor Commissioner, Office of Labor Commissioner, Department of Business and Industry):

I have worked with the Legislative Counsel Bureau (LCB) in the development of language on A.B. 44. The concept is that the labor commissioner would now have jurisdiction on the daily overtime for people who make more than one and one-half times the minimum wage. The bill as it was originally presented extended the daily overtime to everyone in the state. I filed a fiscal note with the bill. That portion of the bill has been removed. If the minimum wage were to go higher, the daily overtime threshold would move up with it. I do not know the impact this will have as far as enforcement is concerned.

DAVID KERSH (Carpenters/Contractors Cooperation Committee, Incorporated):

We worked very hard with all the interested parties to develop language making the daily overtime, after eight hours of work, applicable to everyone. We are in support of A.B. 44. I have distributed a handout with an informational chart that explains the changes proposed in the bill ([Exhibit C](#)). Basically, the law remains the same "overtime after 40-hours-a-week" law. The only change, and it is an important one, is where a worker can go to file a claim if he or she has been deprived of overtime compensation. This bill will streamline the process.

CHAIR TOWNSEND:

Commissioner, will you be able to accommodate this extra workload with your current structure?

MR. TANCHEK:

We can; there will be some adjustments. We may bring as many as a quarter of the work force into the daily overtime provision.

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CHAIR TOWNSEND:

Assemblyman McCleary, as sponsor of the bill, will need to make sure the commissioner's offices will not have a backlog of work. There should not be any surprises for the staff.

CHRISTINA DUGAN (Las Vegas Chamber of Commerce):

The bill in its current form is one we can support. We wanted the Committee to know this for the record.

FRED L. HILLERBY (Washoe County Regional Transportation Commission):

We support the bill. It makes good sense to involve the labor commissioner with the enforcement issues. We have a proposed amendment to the bill concerning flexible work hours ([Exhibit D](#)). This amendment proposes to have Nevada mirror the federal law. Basically, it states overtime pay is for the employee who works more than a 40-hour scheduled week of work. Those who work flexible hours and work more than the weekly scheduled 40 hours will receive overtime pay for the extra hours worked.

SENATOR CARLTON:

Were you speaking for the Washoe County Regional Transportation Commission with this proposal? There are public-safety employees who have provisions that allow peace officers and firefighters to work flexible hours. Are you saying that this template would be a model for everyone?

MR. HILLERBY:

Yes. Basically, this concept mirrors the federal law.

JOHN (JACK) E. JEFFREY (Southern Nevada Building and Construction Trades):

Originally this was a contentious bill. There have been extensive negotiations. I have worked with the bill's sponsor and the various interested groups. Nothing has been changed in the existing law except who would enforce it. The law states that if an employee makes less than one and one-half times the minimum wage, the worker is entitled to overtime after eight hours. This has not been changed. Labor and management agreed the labor commissioner would be the entity to enforce the law. I support the bill as it stands. I do not agree with the amendment that is proposed by Mr. Hillerby.

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RAYMOND BACON (Nevada Manufacturers Association):

We can accept Mr. Hillerby's proposal, but we offer up the following thoughts for process. The amendment might be applied later and made effective if and when the minimum wage changes. The current number of people affected by this proposal is small. The number of affected workers becomes larger and will change every year with the rise in minimum wage.

CHAIR TOWNSEND:

With a whole new group of people coming forward because of minimum wage raises, this concept would need to be discussed with the labor commissioner as we do not want to create a problem where he would have to consider a fiscal note. Additional personnel might be needed.

ASSEMBLYMAN MCCLEARY:

It is a possibility another person would need to be hired. It is not a great sacrifice to have local control. I oppose the amendment. Employers can take advantage of the employee with a flexible 40-hour work week. This bill has been drafted to protect all workers against abuses.

CHAIR TOWNSEND:

The hearing on A.B. 44 is closed and we will open the hearing on A.B. 195.

ASSEMBLY BILL 195 (1st Reprint): Makes various changes concerning purchasing prescription drugs from Canadian pharmacies and regulation of certain pharmacies located outside Nevada. (BDR 54-875)

ASSEMBLYWOMAN BARBARA E. BUCKLEY (Assembly District No. 8):

Joining me this morning is Cal Ludeman, Commissioner of Employee Relations and chair of the Governor's Cabinet on Health for the state of Minnesota. Minnesota has implemented the measures contained in A.B. 195. Dr. John Ellerton, who has a current physician's license in Canada, will bring a medical perspective to the presentation.

CHAIR TOWNSEND:

Dr. Ellerton is well known in Nevada. He has testified before this Committee in the past.

ASSEMBLYWOMAN BUCKLEY:

I will provide some background on this bill, which is essentially a consumer-protection measure. The high cost of prescription drugs is an ongoing problem we all face. In 2003, Americans spent more than \$163 billion in retail pharmacies. Nevadans spent more than \$930 million. Nationally, the average price of retail prescriptions in 2003 was \$52.97, a 6.7-percent increase from the prior year. Paying for these drugs that are prescribed by a physician can be difficult for those who are without insurance or are underinsured. Nevada has the highest rate for the uninsured in the nation with 19 percent of the population having no insurance in 2003. Seniors under the new Medicare bill will have to pay 100 percent of their medication costs when the costs go up to \$2,520 but do not rise to catastrophic levels. Federal and state officials of all political persuasions are working to find effective solutions to bring down the cost of prescription drugs to reasonable levels for the average citizen and yet not hurt the nation's vital pharmaceutical industry. Citizens are struggling daily to pay for their prescription drugs in addition to their other necessities of life. Solving this problem may ultimately take months, even years. Legislation is pending in the U.S. Congress on this issue. In the meantime, people must find a way today to pay for their prescription drugs. Some have turned to the Internet and the foreign markets to buy less-expensive drugs. Some Americans, particularly seniors, have made bus trips to Canada specifically for the purpose of buying their prescription medications. Recently, the executive director of the Canadian International Pharmacy Association estimated that the Canadian industry is now serving approximately 1.8 million Americans.

I have distributed packets with information about this issue ([Exhibit E](#)) and ([Exhibit F](#)). In the packets are statistics about Nevadans purchasing medications from Canada through the Internet. There is a chart in your packet that gives a price comparison of the most frequently used drugs. Based on these prices, we can understand the dilemma. Those people who turn blindly to the Internet for prescription drugs may find there are safety issues, because they are ordering from Canada but in reality are ordering from Sri Lanka, China, India and South America or some other foreign country. Here are some of the concerns that have been identified by the counsel and state government and summarized by a report made in 2004. Regarding quality assurance, the products cannot be verified as safe. Counterfeit drugs can be ineffective or significantly diluted and present a health risk to consumers. Untested substances that have not been approved by foreign drug manufacturers have not been evaluated and could be dangerous to the consumer. Labeling and language issues are usually associated

with drugs intended for non-English-speaking markets. They may conceal side effects and instructions for dosage amounts. Web sites often may imply a link to Canada, but they are not. Internet sales that require the credit card numbers could become an identity-theft problem. The consumer may never know from where the drugs originated. These safety concerns do not exist when a person purchases prescription medication from a licensed pharmacy in Canada, selling prescription drugs approved either by Canada Health or the federal Food and Drug Administration (FDA). To protect the Nevada consumer is the major goal of A.B. 195.

Five other states have paved the way for their citizens to safely purchase drugs from Canada. Procedures are in place with proper forms, a list of included medications and comparative prices on drugs. Canadian pharmacies have been approved, not licensed, but meet the state standards for safety. Several states provide official links to Canadian pharmacies. Many local governments, cities and counties are providing mail-order programs for their employees. This is what A.B. 195 proposes to do. First, the role of the State Board of Pharmacy allows licensing of pharmacies in foreign countries. The Board would license these pharmacies just as they do in Nevada. There would be applications, visits, inspections and quality assurance to ensure the same standards that are being utilized today. The bill provides that Canadian pharmacies that give mail-order service to a Nevada resident shall not sell, distribute, or furnish any of the following items to the resident: controlled substances, prescription drugs that have not been approved by the FDA or the Canadian government, a generic prescription drug that has not been approved by the FDA or the Canadian government, a prescription drug for which the FDA has withdrawn or suspended its approval, or a quantity that includes more drugs than the prescribed three-month basis. The second measure of the bill is the role of the Office for Consumer Health Assistance. This office was established by the 1999 Legislature to provide assistance to the consumer with health issues. A.B. 195 naturally extends the duties of this office to require it to establish and maintain a Web site. This would include information concerning purchases of prescription drugs from state-licensed Canadian pharmacies and links to the Web sites of these pharmacies. People are currently ordering these drugs from Canada through the "personal use" exemption under the federal ban on drug imports. The exemption provides that citizens with a valid prescription can import a 90-day supply of prescription drugs into the United States for personal use. The FDA has not shut down the Web sites in other states or the program operated in a much more direct way to actually provide state or local employees with

prescription drugs. The FDA has actually stated they have no intention of shutting down these programs. The states providing these services do provide legal disclosures so that the consumer makes informed decisions when choosing to order prescriptions through the Internet. I would suggest that Nevada follow the state of Minnesota's disclosure statement as a model, because it gives the consumer all the information needed, the pros and cons. This is a clear statement and it allows Nevada citizens to make informed decisions. Some have said the Canadian government may close its doors to our prescription drug orders. As long as they are accepting these orders and it remains an option, we cannot legislate on the possibility of what might be done in the future by a foreign government. We can take steps today to make sure that our citizens can afford the drugs they need and take advantage of this opportunity, making sure that these prescription drugs are safe. This issue is addressed in A.B. 195. The bill thoroughly covers consumer protection.

SENATOR TIFFANY:

The Office for Consumer Health Assistance will set up and maintain the Web sites. Will there be a fiscal note involved with this new responsibility? Creating a Web site will require personnel. Has this been discussed?

ASSEMBLYWOMAN BUCKLEY:

Yes. This fiscal note has been brought to the attention of the State Board of Pharmacy and with the Office for Consumer Health Assistance. Those who seek licensing will need to pay a fee. Based on the fee, they will be able to absorb any costs along with establishing the program. The hardest work will be done by the State Board of Pharmacy. They have to process the application and ensure our safety standards are met. Adding a link on the Web site will be easy. Existing staff will absorb this function.

SENATOR TIFFANY:

There will be a financial impact. How comfortable will the finance people be with this new fee? Who will monitor this process? Who will receive reports and issue penalties?

ASSEMBLYWOMAN BUCKLEY:

The State Board of Pharmacy will have this responsibility. They will treat Canadian pharmacies the same as any other pharmacy. If they have concerns, they will do surprise inspections, require documents and look at computer

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systems. They will look at prescription-drug pedigrees. Whatever existing standards they have in place will apply.

SENATOR TIFFANY:

How would these requirements be implemented? The bill was not specific in some areas of concern.

ASSEMBLYWOMAN BUCKLEY:

It was not necessary to include all the concerns, because if we require Canadian pharmacies to be licensed, then all of our licensing statutes would apply. They will be held to the same standard as any pharmacy in Nevada such as being subject to reviews, penalties and whatever the reports may reveal.

SENATOR TIFFANY:

Our pharmacies are here. We can have easier access to inspections and other information. How will we do this in Canada?

ASSEMBLYWOMAN BUCKLEY:

The existing law allows us to license pharmacies in foreign countries. It was passed by the Legislature in 2003. The Board will only exercise the authority of a license if they are sure the Canadian pharmacies will be in compliance with our laws and that it is safe for the public.

SENATOR TIFFANY:

This bill addresses everyone with a need for inexpensive medications, but seniors need to maintain their prescription drugs. Will they be able to use the Internet and be comfortable using a credit card to pay for their drugs? Some of these people do not have a computer.

ASSEMBLYWOMAN BUCKLEY:

Mr. Ludeman will speak about the Internet issues. Senior centers do have computers, and there is assistance available for people to receive help with their orders. Once they are licensed, these Canadian pharmacies do offer "800 numbers"; it will be easy to order by phone.

SENATOR TIFFANY:

Who would we contact to find out what is happening at the federal level?

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ASSEMBLYWOMAN BUCKLEY:

Mr. Ludeman is here to answer some of these questions.

CHAIR TOWNSEND:

Regarding page 4, in the existing state programs, I would assume Mr. Ludeman will address the contracting issue. I would like more information on whether it is state or county employees who are in a prescription program. With regard to A.B. 195, at the bottom of page 3, subsection 4, section 2, "The Board shall notify the Office for Consumer Health Assistance ... and recommend that the Office for Consumer Health Assistance include each such pharmacy" Will the Office for Consumer Health Assistance determine whether someone who is licensed will be on the Internet? How did you choose this language?

ASSEMBLYWOMAN BUCKLEY:

This language was chosen for me by the Legal Division, LCB. I believe they have indicated the Board of Pharmacy would license and recommend or provide the names to the Office for Consumer Health Assistance.

CHAIR TOWNSEND:

It is not a large issue, but I just happened to pick up on this language. There are many people who are interested in this issue. Some are not insured and others are insured. How will this work for the person who is partially insured? Will this bill work in practice for these people?

ASSEMBLYWOMAN BUCKLEY:

These Canadian pharmacies do not take insurance. The consumer will look at the prices of the prescription drug and make a decision whether to buy the drug from Canada without using the insurance, because it costs less.

CAL LUDEMAN (Commissioner, Office of Commissioner, Department of Employee Relations, State of Minnesota):

I will explain what Minnesota has been doing with Canadian prescription drugs the last year and a half. This is a topic of concern for all health-care consumers. The cost of medicine remains one of the fastest growing cost-drivers of health-care and health-insurance costs. It is important to remain realistic in the marketplace and understand the reason for the high demand of pharmaceuticals. Manufacturers have successfully marketed and supplied a wide variety of drugs which Americans want. Lifesaving drugs, health maintenance drugs and "feel good" drugs are all in high demand. Unfortunately, consumers as individuals are

not as able to combat the high prices for prescription drugs sold in the United States as they are with other commodities. So, we have rising costs and rising demand for these drugs and the inability of the consumer to do much about it.

Minnesota has been able to do something others have not. We have challenged the system. We are proud of what we have accomplished for the citizens of Minnesota. We hope all American consumers can find access to more affordable prescription drugs. In the fall of 2003, Minnesota began a three-phase program to help control the high costs of prescription drugs. The first phase was to develop a Web site for Minnesotans to purchase prescription drugs through Canadian pharmacies. The second phase was a Web site for state employees and their dependents to purchase prescription drugs from Canada. The third phase was to work with the U.S. Department of Health and Human Services and other federal officials to remove barriers to ordering prescription drugs from Canada. Before this action was taken, hundreds of busloads of Minnesotans were traveling to Canada to purchase prescription drugs. We knew the imported drug costs were less than those purchased in the United States. We did not know if they were safe and effective. The Governor of Minnesota, Tim Pawlenty, directed the various state commissioners to establish a method to purchase prescription drugs from Canada ensuring that the drugs dispensed would be appropriate, safe and meet United States standards. In order to accomplish this task, the Department of Health and Human Services staff went to Canada and personally inspected the Canadian pharmacies. The inspection included reviewing the quality of the facilities, the source of the medications and the licensing. Once the inspections were completed, we created a Web site. The Web site is based on staff expertise and information gathered from the Canadian pharmacy inspections. The Web site allows Minnesotans access to lower cost prescription drugs and ensures all users are receiving the prescription as written by their doctor. At its launch, Minnesotans could access 829 prescription drugs. Not all drugs available in the United States are available on this Web site. The Web site is designed to be user-friendly and informative. It allows the comparison of prices and then permits the purchaser to mail their order to the Canadian pharmacy. As of last week, over 12,000 orders have been placed. There is great interest in this program.

The second phase of Governor Pawlenty's initiative addresses medication costs for 120,000 state employees and their eligible dependents. It is my job to negotiate contracts with 48,000 state employees and their dependents and provide benefit packages for the employees. There is a Web site specifically for

the employees with 52 drug options. Eight of these options are the most-used, name-brand prescription drugs in America. These medications selected for the Web site were designed to maximize savings for the state and its employees. There are many advantages to this program and a huge savings for the state. These savings help contain health-care costs. Continuing, ongoing inspections of the Canadian pharmacies that are on the Web site ensure quality and safety. This program is designed to empower the individuals to take control of their health care and some of the health-care costs and make informed decisions.

The third phase of this initiative, to work at the federal level to remove the barriers for purchasing prescription drugs from Canada, is well under way. We are taking a series of steps to accomplish this goal. We are urging legislative leaders to pass comprehensive legislation allowing the purchase of prescription drugs from Canadian pharmacies. In addition, the FDA has asked us to work with the national association of the boards of pharmacy to ensure the Canadian pharmacies providing prescription drugs through our program meet United States standards. We have agreed to do this. Former FDA Commissioner, David Kessler, stated before the United States Senate that importation should be legalized for safety reasons. We are importing now, and we cannot have a system that would jeopardize public health. Congress has the responsibility to fix the problem. The American public will be much safer with a regulated system than one with uncontrollable risks.

SENATOR TIFFANY:

Is this program you have described for state employees only?

MR. LUDEMAN:

I have described two programs. The general Web site is for the public, sanctioned by the state, and another program is the state-employee Web site.

SENATOR TIFFANY:

Did you do a state pilot program first?

MR. LUDEMAN:

No. We did not use the state employees as guinea pigs.

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SENATOR TIFFANY:

The public came first and then the state program came next. It really was a three-phase plan. Was the credit card use online a problem with the senior population?

MR. LUDEMAN:

We have an organization in Minnesota named the Senior Federation. They have a large Web site and they have agreed to sit down with seniors at a kiosk-type arrangement and help them work through the transactional parts of this procedure. It is important to note this is not the "grand silver bullet" to all related prescription drugs. Seniors do not need to order all their prescription drugs from Canada. We only offer the process for individuals. State employees are able to use the computer and place orders easily.

SENATOR TIFFANY:

There are federal importation laws; how do you work around this? There is a 90-day prescription drug limit on each order. Some people have a lifelong drug they need to take. Is there a way they will have access to larger amounts of their medications? Please explain this.

MR. LUDEMAN:

There is a 90-day limit on all prescription drugs. This provision is nonnegotiable. It can be a lifelong drug, but it is parceled out every 90 days.

SENATOR TIFFANY:

Do the individuals go back to the doctor each time they need to renew their prescription after the 90 days?

MR. LUDEMAN:

They do not go back to the doctor, but there is a reorder through the pharmacy. The doctor may give a year's supply prescription, but it would be filled continuously every 90 days with our plan. This is how we do business.

SENATOR TIFFANY:

Can you tell us what is happening with Congress? With five states actively purchasing prescription drugs from Canada, there has to be some dialogue concerning this issue.

MR. LUDEMAN:

We are still in negotiations with the FDA, and there are four very competitive bills related to this issue. There has been no final action from Congress or a bill signed by the President. The FDA cannot change anything regarding policy until Congress acts. They have the personal-use provision which is being practiced now and covers these orders to Canada.

SENATOR TIFFANY:

Have any of these states had any problems with the FDA or any shutdown of operations?

MR. LUDEMAN:

The only problem we have had was a postal confiscation at one of our borders. It was an inconvenience only. There was no problem for the Canadian pharmacy to simply repackage and send out the order again.

SENATOR HECK:

Do you have demographic data on the Web site use by senior citizens, non-senior citizens, insured and uninsured?

MR. LUDEMAN:

There is claims data available and yes, it is a considerably high number of seniors. We do not know if they are insured or uninsured. This is not a question that would be asked on the Web site.

SENATOR HECK:

Are the health insurers accepting this? Do they pay for these purchases from Canada or are people purchasing strictly on their own and foregoing their insurance company?

MR. LUDEMAN:

The savings are so significant that it is not a co-payment issue for most participants. Many self insurers are able to make these purchases with a waiver of the co-payment.

SENATOR HECK:

There is a controversy on the FDA personal importation policy. It does not change the law of the *United States Code*. As I understand the FDA importation policy, it is their personnel guidance, strictly issued to the individuals whom

they may encounter whose medication has been personally imported, whether by airport or by mail. There are specific criteria currently listed in their policy. I am curious when you set up your plan in Minnesota if you received a letter of interpretation to the contrary, because the FDA policy reads, "it is up to the discretion of the FDA inspector whether to allow the material to pass." The discretion is based on a person's serious condition for which effective treatment may not be available. There is to be no known commercialization or promotion to people in the United States. Would the Web site be considered commercialization?

MR. LUDEMAN:

There is no such letter, but the practice does indicate some cooperation. The conversations we have had with our top officials are all about the practice and enforcement methods that the FDA would be using. Their practice is more in conformity with today's reality.

SENATOR HECK:

You did not receive any word from the FDA that would countermand their policy.

MR. LUDEMAN:

In the beginning, our advice from the FDA was to not do this. There was a contentious time. This has been worked out. Remember, there were busloads of Minnesotans going to Canada long before we began this Web site.

ASSEMBLYWOMAN BUCKLEY:

Is this legal? Here is the link to the FDA. On the next to last page of [Exhibit E](#), it states:

The U.S. Food and Drug Administration (FDA) maintains that: Reimporting into the United States prescription drugs originally manufactured in the United States is a violation of the Food, Drug and Cosmetic Act and importing medications made in other countries violates the Food, Drug, and Cosmetic Act if the medicine is not approved by the FDA or if it does not meet all FDA approval requirements. However, to our knowledge the U.S. government has not stopped individual United States residents from buying small amounts of prescription drugs for their own personal use, or that of a family member, and the FDA has made

statements to the media that they do not plan to interfere with such small individual purchases. It basically says that FDA staff can choose not to stop shipments that might violate federal law, under these circumstances: 1) the appropriate use is identified, is not for the purpose of a serious condition, and the product is not considered dangerous; or 2) the medication is for a serious condition and is not available in the United States; the medication is not promoted to U.S. residents; the FDA does not consider the medication to pose an unreasonable risk; and the person buying the medication verifies that the medication is for personal use, and provides the name and address of his/her United States doctor or can show that the medication is necessary to continue treatment.

This information is available to the consumer and they make the choice.

SENATOR HECK:

Are you aware of any medication shipments ordered from the Web site that have been interdicted through the mail prior to reaching the intended consumer? The shipment would be pulled by customs or the FDA and would not be processed. Should this happen, do you have a mechanism in place to give the consumer recourse?

MR. LUDEMAN:

Yes. This has happened on occasion. It was a customs interdiction. We simply called the pharmacy and they reissued the order as quickly as possible at no cost.

CHAIR TOWNSEND:

Are there any other questions or comments on this bill? I want to know more about the public-employee portion of the bill. I do not want the focus to shift, but I would like to look at the three-phase plan Minnesota has in place. The public-employee plan has been in place for one year. Should Nevada get a phase-two plan, similar to the Minnesota plan, into the mix soon so it can be approached next Session? As you know, our program continues to be one of the larger challenges, because we do not know how to deal with it.

ASSEMBLYWOMAN BUCKLEY:

I agree we need to look at the public-employee piece of the Minnesota plan next Session. This is a leap for some people, and they are not sure this is the right

thing to do. They are hesitant about this idea. For A.B. 195, I chose to highlight only the public Web site. I made the provisions the strongest possible safety measures with licensing rather than approval. I did not add the state-employee piece although many are interested in it, because it will save the employee and the State money. Minnesota has several phases to the plan and even has it structured so their employees may choose whether or not they want to purchase prescription drugs from Canada.

CHAIR TOWNSEND:

We need to look for more ways to be efficient. The public health and pay issues are a separate component from these other parts of the bill. Minnesota has saved the state \$1.4 million since beginning this plan one year ago.

MR. LUDEMAN:

Yes. This fall we will have new calculations on the savings. We offer other health plans. Some of the health plans are co-payment and others are co-owned or contracted. I negotiate the contracts with the health plans for the next calendar year's insurance benefits. Negotiations are going much better this year because of the savings with prescription drugs.

CHAIR TOWNSEND;

Mr. Ludeman, keep us abreast of your progress. I have not been on the Web site. Can you tell us, Assemblywoman Buckley, are you satisfied it is user-friendly?

ASSEMBLYWOMAN BUCKLEY:

I am impressed with the Minnesota Web site. I like the approach the state has taken in terms of working with the federal government. There is cooperation to make importation become legal, safe and acceptable. The design of the Web site is easy to follow, easy to use and easy to read. There are disclosures for the pros and cons to enable the consumer to make their own decision. Yes, I have looked at the Web site, and it is quite good.

CHAIR TOWNSEND:

There could be many definitions of user-friendly. How would we design a Web site? Could we use the Minnesota Web site as a model?

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ASSEMBLYWOMAN BUCKLEY:

Many times we do find useable material from other states. We can take someone's successful work and from it modify and develop our own Web site. Our State Board of Pharmacy would need to be involved in the process. They would need to be comfortable with the disclosures and the language. Senior groups could have valuable input.

SENATOR TIFFANY:

Mr. Ludeman, I believe I heard you say the FDA advised you not to do this. Is this illegal?

MR. LUDEMAN:

No, we do not believe so. As the governor began to develop a plan, more information was forthcoming on the FDA policy for the personal-use exemption. It was evolving more clearly as the months passed. We are not the purchaser. We are not the wholesaler and we have no prescription drugs to market. We are making the information available with full disclosure. The consumer makes all the choices.

SENATOR TIFFANY:

You cannot answer me black and white, that this is illegal. Does the federal government or the FDA consider this illegal?

MR. LUDEMAN:

Is this illegal? With the policy definition for personal use that the FDA has in place, I think the governor of our state would say no; it is not illegal.

SENATOR TIFFANY:

This is a difficult issue. Are we saying, ask forgiveness instead of permission?

MR. LUDEMAN:

It is debatable. The FDA is waiting for instruction from Congress. They must say this in such a way as to not put their regulatory role at risk while they wait.

SENATOR CARLTON:

This discussion has clarified that this is a consumer-driven issue. They have decided to find ways to purchase less-expensive prescription drugs. The FDA may say they have concerns, but consumers all over the country have decided to take steps for their own health care. It is up to the Legislature to build in

safeguards so consumers have protection. We can respond to them by ensuring safe and effective drugs through this bill.

SENATOR SCHNEIDER:

This bill addresses Canadian pharmacies. Have the pharmacies in Mexico been considered for possible purchases of prescription drugs? We are six hours from the Mexican border and there are almost two million Nevadans who would benefit from the closer border.

ASSEMBLYWOMAN BUCKLEY:

I did investigate this possibility. Mexico and Ireland were both considered. There was discussion on how many drugs are manufactured in Ireland, and we did factor in Ireland. Their safety standards are identical. We heard from some consumers that we should consider a few different countries to ensure the supplies might be more readily available. I chose Canada for several reasons. The General Accounting Office (GAO) report, [Exhibit E](#), was so clear that there have been no concerns with the safety standards or effectiveness of the Canadian pharmacies or their prescription drugs. The pharmaceutical industry and their promotional people will give a negative look at these same standards. They try to confuse the consumer about the legitimately licensed Canadian pharmacies by using photos entirely out of context from other countries. I did not want the Canadian results to become diluted. There has been enough concern about this bill that I decided to not expand the issues to other countries. I have tried to simplify the process. The GAO report was a significant help with this decision.

SENATOR HECK:

Mr. Ludeman, I am intrigued with your program. How did you decide on the particular drugs you have offered on the public Web site?

MR. LUDEMAN:

The pharmacy professional in the Minnesota Department of Human Services took into consideration the assurance of safety. It is the unique and costly drugs that make the safety issues higher. With the more popular drugs, the safety issues go down. They have been used successfully over a period of time. Our state employee Web site is all about economics.

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SENATOR HECK:

Do you allow drugs that are solely approved by a Canadian equivalent or are the drugs being purchased FDA approved?

MR. LUDEMAN,

There are a few exceptions. This was done by executive order and not legislated. There are no refrigerated drugs and we made sure they were FDA-approved drugs. We wanted as many drugs as possible on the market but with a high degree of safety.

SENATOR HECK:

The drugs being imported through the Web site meet the intent of *United States Code* Title 21 and are therefore legal including the labeling requirements. These are FDA-approved drugs. The labeling requirements match the code requirements.

MR. LUDEMAN:

That is correct. They do not require any special handling or refrigeration. There are other standards.

SENATOR TIFFANY:

This is fascinating information. A worldwide marketing system is the direction of the future. Remember when we first began the Senior Rx Program or the Nevada CheckUp Program? We began with small steps in order to get the enrollment up. Mr. Ludeman, did not your program begin with about 15,000 orders? What is the population of Minnesota?

MR. LUDEMAN:

Yes. This is correct. Our population is about five million.

SENATOR TIFFANY:

Minnesota has a larger population than I thought. It is about two and a half times the population of Nevada. These orders, given the state population, are not massive orders.

MR. LUDEMAN:

We actually call it a modest approach to facilitate as much as we can for the consumer to make choices. Twelve thousand out of five million is not a huge number. The numbers are not important but, rather that the program exists and

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is growing. By word-of-mouth is the best way we have increased the Web site usage.

SENATOR TIFFANY:

This is not a panacea by any means. It is a modest "baby step."

MR. LUDEMAN:

This is correct.

SENATOR TIFFANY:

It is costly to implement the program. Would the travel expenses be the highest expense?

MR. LUDEMAN:

Travel time was the expense. We did the development of the Web sites internally with our staff. The cost of travel with the board of pharmacy inspectors, regulators and adjustors was the most expensive implementation cost.

JOHN ELLERTON, M.D.:

I am a physician practicing in Las Vegas and I am licensed in Canada as well. I support A.B. 195 wholeheartedly. A large number of my patients purchase their medications from Canada and from Mexico. This bill helps to ensure the safety of these drugs. I have personally identified one Canadian pharmacy and the patients are receiving drugs from several others that are highly reliable. The received orders are FDA-approved and properly labeled drugs. One of the pharmacies I have used requires a Canadian-licensed physician to send a written prescription for the patient to the pharmacy. The drugs are then dispensed. This is not the reason I keep my license in Ontario, Canada. It has become useful because I can write the prescriptions and it fulfills a pharmacy requirement. This is an issue of safety. It is optional and a consumer choice. These are brand-name prescription drugs. The costs are much less than the pharmacies in the United States. These consumer choices may put pressure on pharmacies to lower drug prices. Physicians are part of the process because of the prescriptions they must write so their patients may place their orders. We can no longer be bystanders of these rising costs. We are to be responsible for the patients' care. I am most impressed with the Minnesota Web site.

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MR. LUDEMAN:

Our staff will be available to address any questions that you may have through the Web site or by phone.

SCOTT WATTS (Nevada Alliance for Retired Americans):

We are a nonprofit, nonpartisan organization with approximately 16,000 members in 18 affiliated chapters. You have a copy of my text ([Exhibit G](#)). Seniors need relief now. Prescription-drug costs are the number one concern for our seniors. The issue crosses all party lines. It is a nonpartisan issue. It affects the young and the old in Nevada. For this reason, we would urge the Senate to pass this bill and get it to the Governor for his signature.

MARIAN CONRAD:

I am a retired teacher. I taught for 31 years in Washoe County. I do have a good health plan that includes a prescription-drug plan through the Washoe County School District. A number of changes have occurred in the plan. This last year there was a great increase in the co-payment. Because of the health problems that I have, I am now paying over \$300 a month for prescription drugs. The American consumer is charged the highest prices in the world for their prescription drugs, more than any other industrialized nation. The cost comparisons are unbelievable. We are not being treated fairly. A large number of seniors, individual retirees on fixed incomes, face increasing costs for their medications. Seniors often pay for the medications instead of food or other necessities. This bill would be a great help because it provides a choice to save on the costs of prescription drugs.

CHARLIE COX (President, United Auto Workers Local 2162):

I am in support of A.B. 195. I want to bring a different perspective to this issue. I know this issue is geared toward the senior citizen, but here is another thought. As part of the collective-bargaining process, unions negotiate formulary agreements with drug companies. Most of our American companies are at a complete negotiation disadvantage over the foreign competition. In Canada, we are at a \$12.90 per hour disadvantage because of the cost differences with Medicare, Medicaid costs and medical benefits. The prescription drugs are rising at about 11 to 12 percent a year and they are killing us at the bargaining table. It is difficult to negotiate a lesser wage in order to keep the current medical benefits. As an example, when pricing automobiles, the price of a Japanese automobile will include a \$400 fee which will pay for the workers' medical-benefit plan. When you purchase a Cadillac, \$2,800 is included in the

price to cover the workers' medical plan. There are other issues within the medical plan concerning prescription drugs with which an employee must deal. One last point on medical costs, the steel that my company purchases for the manufacture of all their 160,000 automobile units costs less than the medical benefits for our employees.

XAHIS CASTRO:

I am here to support A.B. 195. I am close to retirement age. My insurance has been excellent through my employer. I know the challenge that I am about to face with my medication costs. I have a number of conditions for which I will need prescription drugs. With my current insurance I have a co-payment of \$40 a month for one of my prescriptions. When I retire and I am on Medicare, I will have to pay \$120 a month for one prescription. It is ridiculous that we seniors have to face these huge price increases, when these same drugs are available at an affordable price in Canada. I will be living on a fixed income and have to make the choice to purchase my medication or the necessities of life. Prescription drugs from Canada will help give us a better quality of life.

ROBERTA (BOBBIE) GANG (Nevada Women's Lobby):

We have heard from several of our members and they are already ordering prescription drugs from Canada. We believe this bill will make them a more discerning consumer. I have provided a handout with testimonials ([Exhibit H](#)) from three of our members. All three testimonials tell us Canadian drugs are saving a third to a half of the price of the same drug in the United States. The savings are significant. Two of these women work through their doctors. The doctor writes a prescription and it is faxed to the Canadian pharmacy where it is filled and processed. The doctor is directly involved many times.

BARRY GOLD (American Association of Retired Persons Nevada):

There is a great concern by Nevada citizens for the high cost of prescription drugs. As I have highlighted in the handout ([Exhibit I](#)), we will all need to work together to find the best decisions for health care. The use of technology will provide information and an access to certain services. Mail-order pharmaceuticals in a three-month supply have proven to be a cost-effective means for many. Other states are implementing ways to reduce costs. We must all work together to find alternative purchasing processes. This is one of the ways to send a message to the large drug companies.

ROBERT A. DESRUISSEAU (Northern Nevada Center for Independent Living):

I urge your support of A.B. 195. Individuals with disabilities struggle on a daily basis with this issue of medication, especially maintenance drugs. I want to point out who this will impact. It is not just low-income people but even those with higher incomes. The prescription drugs are costly for all. I have three prescriptions that are not filled because of cost. I am underinsured. I have to make sacrifices in my life necessities to ensure I will be able to purchase my prescription drugs. At this point in time, I have no other choice but to purchase my medications from Canada. This bill provides assurance to all Nevadans who are uninsured or underinsured that licensed Canadian pharmacies will be safe and effective.

JAMES BROWN:

I am here to urge the Committee to support A.B. 195. There are many seniors who need to have affordable medications. Nevadans should not have to choose between life necessities and medications.

WILLIAM J. BIRKMANN (Communications Workers of America):

I want to encourage your support of A.B. 195. There are people who have a prescription-drug insurance plan who find the co-payment for their medication purchase is higher than some medication costs in the large discount stores. An insurance plan is not always a guarantee that you will pay less for prescription drugs.

CHAIR TOWNSEND:

Mr. Macdonald, the bill we have in front of us will call for a great deal of assistance from the State Board of Pharmacy. The Committee has questions with regard to your role, the Board's role and your staff's role. Would you please give us some insight as to how you would proceed under this bill?

KEITH W. MACDONALD (Executive Secretary, State Board of Pharmacy):

We are quite interested in the bill to the extent that we will need to coordinate with the registrars, or if you will, the colleges of pharmacy in Canada. The provinces have a different view of their health regulation and we will need to coordinate with them and with some of the states that are already involved in this activity. We stand ready to protect the consumers' health and to ensure the mandates in the bill are met. Specifically, we will provide assurance that all drugs are FDA-approved and/or Health Canada-approved drugs. We do not have a plan developed as yet, but this is our goal and we can accomplish it.

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RICHARD MILLER (United Federation of Teachers Retiree Chapter of the American Federation of Teachers of Nevada):

I am here to urge your support of A.B. 195. By authorizing certain Canadian pharmacies licensed in Nevada to provide prescription drugs through mail order and requiring the Office for Consumer Health Assistance to establish and maintain an Internet Web site to provide information to consumers purchasing prescription drugs for specific Canadian pharmacies licensed in this State, you will empower our seniors to seek out competitive prices for their drugs. Seniors are searching for affordable drugs; they are seeking out competitive prices for their medications. Americans are already ordering their medications from Canada. Other states have provided their residents with Internet access to state-approved Canadian pharmacies through their Web sites. This bill is a "win-win" for all concerned, since it will save taxpayer dollars by requiring the state to buy prescription drugs from Canada for prisons and state services. I have faxed a complete testimony to the Committee ([Exhibit J](#)).

VICE CHAIR HARDY:

Chair Townsend indicated he would like to have the opposition have some time to respond, beginning with Chris Ward.

CHRIS WARD (President, Ward Health Strategies):

I have prepared a PowerPoint presentation. The hard copy is being distributed for your files ([Exhibit K](#)). It is appropriate to disclose my interest in this issue and my bias. I spent a number of years in the Ontario Legislature. My bias is related to prescription-drug access and public policy. Our company has an expertise in the health-policy field on behalf of a variety of clients. This would include health industries, pharmaceutical companies and the Ministry of Health with the Canadian government. We are at this time conducting a major review of the health profession's regulation on behalf of the government. Nonprofit organizations are involved as well. I have a strong personal bias and a belief that no one should suffer from financial devastation because of a catastrophic illness. In Canada, there is no prescription-drug benefit. Each province has found ways to shield their people from high drug costs.

SENATOR CARLTON:

I would like to know who sponsored your trip to Nevada?

MR. WARD:

The Legislature sponsored my trip.

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SENATOR CARLTON:

How many legislatures have you testified before?

MR. WARD:

At different times in the past 5 years over a wide variety of issues, I would say 30 times. That includes both houses of Congress.

SENATOR CARLTON:

Can you disclose any of the other professional relationships you have with any of the other pharmaceutical companies?

MR. WARD:

I have no relationship with any pharmaceutical companies. I have done consultation work for the Pharmaceutical Research and Manufacturers of America (PhRMA). I want to stress that, whenever required, I register with the federal government, because I feel strongly that disclosure is important.

This issue is much broader than you may have perceived. Canada has concerns with this issue. We do not consider this drug importation, but instead, drug exportation. Canadian seniors, patient groups, pharmacy associations and physician associations all met in Ottawa to release a national poll. The poll expressed 85 percent of Canadians want to ban the sales of Canadian drugs to the United States. There are a number of reasons, not the least of which is the integrity of their health-care system, the appropriateness of supply and issues related to safety. Importation of drugs from a foreign country puts consumers at risk if the importation supply chain invades the regulatory safeguards that are in place. Importation means the United States consumer waives their rights to federal laws. All Web sites have a waiver that must be signed by the consumer. This waiver protects the Canadian pharmacy from liabilities that may arise with the imported drugs. There are many safety issues to be addressed. Most importantly, there is no certainty of supply. The reality is that Canada simply cannot be America's drug store. There is empathy for this issue, but it would be better to look at the systemic reasons for the higher health-care costs in America and find ways to address the needs of seniors and other vulnerable people. Importation will take away the motivation and incentives to find a solution to the problem.

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LIZ MACMENAMIN (Retail Association of Nevada):

I am here today representing 700 community pharmacies and 31,000 employees. Beside me is Marc Kealey, Chief Executive Officer, Ontario Pharmacists' Association. He will speak to the Canadian pharmacies concerns.

MARC KEALEY (Chief Executive Officer, Ontario Pharmacists' Association):

We are the largest pharmacy association in Canada. We have 10,000 members representing 2,860 pharmacies in our great province. Ontario, Canada, is 13 million strong and we are the largest province in Canada. I have copies of my speaking notes in a handout that has been distributed to you ([Exhibit L](#)). I wholeheartedly endorse what Chris Ward has told you. He is being realistic with the Committee that caution is important as A.B. 195 is considered. I have communicated by letter with all the governors of states bordering Canada. I received one letter in return from Maine. This issue has had only minimal attention in Canada, because they do not understand what you are trying to do. When the reality is understood that the United States consumer is purchasing large quantities of Canadian prescription drugs, it will look like a hostile act on Canada's part to then refuse to allow the importation of drugs to America. We recently initiated a poll of 650 Canadians and 83 percent of these people were concerned with the impact and the unintended consequence of what this legislation will do to the availability of Canadian drugs. I am opposed to this bill.

TOM WOOD (Pharmaceutical Research and Manufacturers of America):

One of our guest panelists has a flight delay and cannot be here until a later time. His expertise is valuable. Is there a way we can reconvene to hear his legal interpretation on the issue?

VICE CHAIR HARDY:

We are scheduled for Senate floor time now. Committee, we will discuss and decide when to reconvene this meeting. Chair Townsend will make an announcement on the floor. This meeting of the Senate Committee on Commerce and Labor is recessed at 10:59 a.m.

CHAIR TOWNSEND:

We will now reconvene the Senate Committee on Commerce and Labor at 12:10 p.m. The Committee will hear testimony from someone who was expected earlier but had a travel delay. We will open the hearing on A.B. 195.

DIANE DARVEY (National Association of Chain Drug Stores):

We support, as an association, access to low-cost prescription drugs. Due to the federal laws and serious concerns about patient safety, we do not support the personal importation of drugs. The importation of drugs is illegal according to federal law. We believe this is clear. Current federal law permits only manufacturers to import prescription drugs, including drugs that are produced in the United States and exported to a foreign country. We do not believe what is illegal can be made legal under state laws. We have a safe system in our country, and going outside the system even for good motives does not warrant violating federal law or subjecting consumers to safety risks. There is a risk to the consumer who receives drugs from all different sources. An accurate record cannot be kept and there is a risk of drug interactions and other safety issues.

Changing the law needs to be done through proper channels. There are other means to obtain safe drugs for the consumers of this state. There are a number of programs offered by drug manufacturers giving patients assistance with drug prices. The less-expensive generic drugs are available. Many consumers in our states are helped by the drugstore pharmacy with information on low-cost prescription drugs. There are Web sites that direct patients to assistance programs for prescription-drug plans. There are other alternatives informing the consumer of low-cost drugs. The pharmacies in the United States will be competing in an unfair market against the Canadian pharmacies that have no concern with compliances. Our pharmacies must comply with business-license requirements and regulations that incur many costs.

CHAIR TOWNSEND:

Would you give me some insight? Is "chain drugstore" a correct term to use? We have a chain drugstore on every corner. Is this true of Canada? Do they have chain drugstores?

MS. DARVEY:

The "chain drugstore" is a correct term. I am not sure. I am not entirely aware of the business relationships that may exist with drugstores in the United States and Canadian drugstores. Canada does not have any national chain drugstores.

CHAIR TOWNSEND:

I was curious that a pharmacy here may have a corresponding relationship with a Canadian pharmacy. I wanted to explore the corporate view with this possible relationship. They could give insight to both sides of the issue.

Ms. DARVEY:

They could only give a perspective that reflects federal law. They recognize that it is currently illegal under federal law to import prescription drugs. They would not be able to engage in this issue.

CHAIR TOWNSEND:

This seems to be the main problem that everyone has a different interpretation of the federal law. We have had many different versions of the federal law regarding prescription drugs today.

Ms. DARVEY:

Let me sort it out for you. It is confusing. I will make it as simple as possible. Basically, there are two ways to import, personally or commercially. Personal importation is the bus trip to Canada. Some are now subscribing to the Internet personal importation. In a letter I recently received, the FDA has said:

There has been some confusion about whether the FDA personal-importation policy changes the law with respect to personal imports of pharmaceuticals. This confusion is reflected in your letter. Personal importation policy is used to guide the agency's enforcement discretion with respect to imports by individuals of drugs for their personal use. Under certain defined circumstances as a matter of enforcement discretion, the FDA allows consumers to import otherwise illegal drugs. Under this policy, the FDA permits individuals and their physicians to bring into the United States small quantities of drugs sold abroad for a patient's treatment of a serious condition for which effective treatment may not be available domestically. This approach has been applied to products that do not present an unreasonable risk and for which there is no known commercialization and promotion to persons residing in the United States. A patient seeking to import such a product must also provide the name of the licensed physician in the United States responsible for his or her treatment with the unapproved drug product. However, this policy is not

intended to allow importation of foreign versions of drugs that are approved in the United States, particularly when the foreign drugs are being commercialized to United States citizens.

MS. DARVEY:

Moreover, the policy simply describes the agency's enforcement priorities. It does not change the law, and it does not give a license to persons to import or export illegal drugs into the United States. The FDA is very clear on personal importation. They have chosen not to enforce the law, but this does not make it legal. States entering into any agreements with Canadian pharmacies are in contradiction of the law.

SENATOR SCHNEIDER:

Why do you think they do not choose to enforce it?

MS. DARVEY:

I believe it is a political situation. That would be my short answer to this. It may also be a manpower issue. This would be my understanding. There was a law passed in Congress two years ago that would have allowed, I believe, commercial importation but could only become effective if the Secretary of Health and Human Services would have agreed to guarantee the safety of the drugs. There was no agreement. The law is not in effect.

SENATOR LEE:

The federal law has not been enforced in Minnesota. It has not proven they are enforcing federal law. There is civil disobedience with this issue, but the FDA is silent with no enforcement. I am here to gain knowledge on the issue, but it seems the proponents have done a good job of promoting the issue for importation of prescription drugs.

MS. DARVEY:

If your question is why has the FDA been silent in terms of enforcement actions and will this determine what they are doing as quasi-legal? Is this one way to state the problem?

SENATOR LEE:

It would be better than the civil-disobedient attitude taking place in these states. I think we need a broader explanation on the lack of federal action with this issue.

MS. DARVEY:

My understanding is that the FDA has chosen to use their enforcement discretion. They have had action in some instances against entities that import drugs. Our next speaker plans to address this question.

VICE CHAIR HARDY:

Matthew Van Hook needs to speak next, because he is on a tight time schedule for a flight.

MATTHEW VAN HOOK (Pharmaceutical Research and Manufacturers of America):

I have written testimony ([Exhibit M](#)). I am with a law firm in Washington, D.C., and my specialty is working with FDA issues as well as biological issues. I am familiar with the Food, Drug, and Cosmetic Act and the mechanisms that were established to assure that the drug supply is safe. I will address that part of the issue, how drugs are reviewed and approved. In earlier testimony, it was suggested that this issue is a gray area. It really is not gray at all. It is a comprehensive federal system. When a drug is approved by the FDA as being safe and effective, it includes detailed specifications about where it will be manufactured, how it will be handled, how it will be distributed from the manufacturer to the pharmacies, how it will be labeled, how it should be used and requirements for prescribing the drug in the United States. All this is geared to the patient so they may receive all the benefits and to ensure the drug is safe and effective, not adulterated or counterfeit. There is a pedigree requirement. I emphasize this, because when you purchase drugs outside the United States you walk outside the safety web. This legislation that you are considering has no real consumer protection. It gives direction to your Board of Pharmacy, but how they go about taking care of the safety issues could be difficult. Also, included in the legislation is the prospect of licensing Canadian pharmacies. No state has fulfilled this requirement. One state has been grappling with how they could ever implement the licensing provision and protect patients. The FDA is facing these practicality problems. This is the reason for the FDA-enforcement discretion. No one has found a way to make the Internet safe as yet. These states that have Web sites also have disclosure and waivers on that same Web site. What can be good about saying "buyer beware" as part of the ordering process. Individuals may purchase prescription drugs on the Internet as a personal exemption, but to have a state become involved is a whole different matter. I have a packet of material ([Exhibit N](#)) in which I underscored some of the actual Web sites that are riddled with waivers and disclaimers from participating states. I would urge you to be aware of any disclaimers, because

you will need them. There is serious potential liability for Nevada. There could be negligence claims, potential tort claims, breach of warranty claims and people are going to believe the State of Nevada is supporting this site. Nevada has taken great steps to make sure the drugs that reach the pharmacy are safe. In Canada, there are no safeguards to protect drug pedigrees. They certainly do not have the safety net that Nevada has in place.

SENATOR CARLTON:

People are doing this now. The consumer is doing this in person or by the Internet. Our concern is that they may not really know when they are on the Internet if the Canadian flag or the Pakistani flag is on the Web page. In order to protect the people of Nevada, we are looking at A.B. 195. We are saying our Board will get involved and make recommendations to the people of Nevada through the Web site. This is a step forward, not a step back. We know this is already happening in other states.

MR. VAN HOOK:

The concern I have is Nevada would step into the shoes of the FDA and say we are going to guarantee the citizens of the State that these drugs are safe. It would not comply with FDA requirements. These may not even be FDA-approved drugs. I do not see any mechanism here to identify one or more pharmacies as approved by Nevada.

SENATOR CARLTON:

I do not think our Board of Pharmacy would ever try to fill the shoes of the FDA. There are two different tasks here. The Board is here to license pharmacies to protect the public. It would be their task and through their regulation to treat those Canadian pharmacies the same way they treat any licensed pharmacy. We are mandated by law to treat everyone equally. They are not taking on the FDA responsibility.

MR. VAN HOOK:

My concern is the Board of Pharmacy will take it for granted that these drugs are safe just as they would any drug in the United States. The problem is that the Canadian regulations and requirements on prescription drugs may not be of the same standard. You cannot piggyback onto the Canadian system, this is illegal under federal law.

SENATOR CARLTON:

We will have to disagree, because I do not read it that way in this legislation.

SENATOR HECK:

I have three issues that I want to question. Two are very important to me. You spoke directly of pedigree and potential liability. I have a concern over the pedigree of any drug brought into the United States for a resident in Nevada. I had the impression that if our Board is licensing the Canadian pharmacies, they would then have to meet all of our criteria in order to be licensed. Part of the criteria is to show the pedigree. If it does not exist and the pharmacy cannot show the pedigree, then I would assume they would not receive a license.

MR. VAN HOOK:

This is why I strongly urge you, if you decide to move forward with this bill, to look at the details. There are misunderstandings of terminology.

SENATOR HECK:

We are going to license these pharmacies. They will have to meet our requirements for licensure. They then would have to show the drug pedigree if our Board were to go to Canada and ask. If they could not show the pedigree, they would not be licensed.

MR. VAN HOOK:

This will require a tremendous resource commitment from this Board and the State.

SENATOR HECK:

You raised the potential for liability to the State, because we license these pharmacies or give an imprimatur of approval. If the pharmacy down the street, which is licensed by the State, issued a bad drug or a counterfeit drug they were not aware of got into the system, would the State have the same liability or is the liability on the pharmacy?

MR. VAN HOOK:

Under those circumstances, clearly, the liability would be with the pharmacy where it occurred. It would be an unprecedented situation if a state were to license a foreign pharmacy.

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SENATOR HECK:

A license is a license no matter where it is issued. We have already licensed pharmacies in other states within the United States. I want to get an understanding of the liability issue. Why would the liability be on the State?

MR. VAN HOOK:

In my view, you are stepping outside the bounds of a very closed regulatory system in this country and stepping outside those regulatory bounds. I view it as an ultra-hazardous activity.

SENATOR HECK:

It would be more hazardous to use a pharmacy outside the country. I have one last question. The issue of importation not meeting United States laws and FDA approval is addressed in another letter that was posted on the FDA Web site. The writer states that it is highly unlikely that a foreign pharmacy would be able to meet all of our requirements. If it were possible for a foreign market to meet all the regulations and requirements of prescription drugs to satisfy the United States standards, what would be the issue then?

MR. VAN HOOK:

That is why you are absolutely right that it is theoretically possible, but highly unlikely that this will happen.

SENATOR SCHNEIDER:

I may be confused. We heard this morning that many drugs are manufactured in Europe. These are FDA-approved drugs. These same drugs are being sent to Canada or Mexico or other countries. They are purchased by Nevada citizens. There are checks and balances within the system. The Canadian pharmacies are operating with concern for the best drugs for their citizens. Anyone licensed in this country has to follow the regulations of the licensing boards. We are struggling with the licensing issues. Are you saying the Canadian government is being irresponsible by not regulating those pharmacies?

MR. VAN HOOK:

The Canadian government has made it clear on the record their concerns are not for American citizens and no, they do not care about the safety of Nevada citizens. One thing to remember is that these drugs are passed off from one place to the other and there needs to be continued standards of safety. Not all drugs are FDA approved when manufactured. How do we know which drugs

will be safe during shipments? Packaging and labeling and how they are shipped needs to be FDA approved as well as the prescription drugs. I have seen the illegal side of this issue and there is much that can go wrong within these circumstances. When we begin to talk about international gaps it gets even more difficult to manage.

SENATOR TIFFANY:

You are an attorney. Do you specialize in these issues?

MR. VAN HOOK:

Yes. Our law firm specializes in FDA drug-related and biotech issues. I am the lawyer who is called on for these issues because of my past experience.

SENATOR TIFFANY:

I have been told, in Canada the reason the drugs are less expensive is because the Canadian government told the manufacturer if they do not deal with Canada at this price level, they will not honor the manufacturer's patents and will have Canadian manufacturers supply their prescription drugs. Is this true? One other item came to my attention. Canada agreed not to have more drugs available than could supply their own country. Is this true?

MR. VAN HOOK:

In terms of the first question, it is true. It is a price-controlled country. One of the challenges in dealing with pharmaceuticals is to remember that research is costly. Many times the attempts to develop a new drug will end with no results. It takes a great deal of money and time to bring a finished new medical product to market. Canada's price control suppresses the opportunity for research and development of new drug products.

SENATOR TIFFANY:

My question is do you know if it is true, to keep costs lower, Canada stated they would violate the patents and manufacture their own prescriptions? The second question has to do with Canadian purchases of only enough prescription drugs for their country's needs.

MR. VAN HOOK:

I have no answer for the second question. I am not sure of Canadian policy.

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SENATOR TIFFANY:

If it is true that Canada has only enough drugs to supply their country, then Canada will be unable to meet the demand for prescription drugs from other countries.

MR. WOOD:

I want to add something concerning Web sites. There is a Web site that is full of information with 140 companies with 260 programs that are available and accessible. I would highly recommend an Internet search for any of these Web sites. There are many patient programs available. Most likely, the Internet will give the best overview for assistance to the consumer.

SENATOR CARLTON:

How many people will actually use a Web site?

MR. WOOD:

One particular Web site is a Nevada version of the PhRMA Web site and the hard number is a fraction under 3,000 people. The PhRMA is now developing a national Web site that will be a tremendous help for the consumer.

SENATOR CARLTON:

I will follow up with them as to how the Web site is utilized.

JOE TYLER (National Alliance for the Mentally Ill of Nevada):

My personal prescription-drug use must be totally safe and effective. Prescription drugs must be safe as well as effective. I am opposed to this bill because there are no safeguards.

ASSEMBLYWOMAN BUCKLEY:

Licensing and state standards are in place and will be met. If we can license the pharmacies and make sure the quality is the same as Nevada and get our citizens prescription drugs at one-third the cost, then it is the right thing to do.

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VICE CHAIR HARDY:

Having no other business, the meeting of the Senate Committee on Commerce and Labor is adjourned at 1:01 p.m.

RESPECTFULLY SUBMITTED:

Shirley Parks,
Committee Secretary

APPROVED BY:

Senator Randolph J. Townsend, Chair

DATE: _____