

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

**Seventy-third Session  
February 10, 2005**

The Senate Committee on Commerce and Labor was called to order by the Chair Randolph J. Townsend at 8:00 a.m. on Thursday, February 10, 2005, in Room 2135 of the Legislative Building, Carson City, Nevada. The meeting was videoconferenced to the Grant Sawyer State Office Building, Room 4412, 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 Tiffany  
Senator Joe Heck  
Senator Michael Schneider  
Senator Maggie Carlton  
Senator John Lee

**GUEST LEGISLATORS PRESENT:**

Senator Valerie Wiener, Clark County Senatorial District No. 3

**STAFF MEMBERS PRESENT:**

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

**OTHERS PRESENT:**

Fred L. Hillerby, Nevada State Board of Pharmacy  
Pat Coward, Pharmaceutical Research Manufacturers of America  
Liz MacMenamin, Retail Association of Nevada  
Robert Miller, Jr., President and CEO, Caladon Health Solutions

CHAIR TOWNSEND:

We will open the hearing on Senate Bill (S.B.) 37. Senator Wiener is here to speak to us about this bill.

**SENATE BILL 37**: Revises provisions governing wholesalers of prescription drugs. (BDR 54-13)

SENATOR VALERIE WIENER (Clark County Senatorial District No. 3):

I am speaking today on S.B. 37 which expands current regulations on pharmaceutical wholesalers and requires them to electronically track prior sales and prescription drugs. My interest in this bill begins with previous legislation during the 72nd Legislative Session dealing with the reissue of drugs that were uncontaminated in certain settings: State correction facilities, nursing homes, long-term care facilities, and mental health facilities and certain rural hospitals as requested. Strong components for tracking drugs provided integrity to make sure they remained uncontaminated, hermetically sealed and untouched by human hands. That particular legislation has saved the State millions of dollars. This interest and the awareness of legislative language adopted in Florida regarding wholesale markets caused me to ask for a bill draft request providing the same kind of tracking integrity and protection assurances to the people of our State. The bill before you ([Exhibit C](#)) responds to what is going on in the federal Food and Drug Administration (FDA). They have a standard effective in 2007 to require electronic tracking for the drugs we are talking about. The Department of Defense has utilized Radio Frequency Identification Devices (RFID) for quite some time and are integrating tracking into their prescription and pharmaceutical drugs.

The bill mirrors the National Association of Boards of Pharmacy (NABP) model rules for the licensure of wholesale distributors, and model rules for legislation developed by the Healthcare Distribution Management Association (HDMA), which is the national trade association for drug wholesalers. Like both of these models, S.B. 37 requires criminal background checks, a \$100,000 bond or other form of surety, stronger pedigree requirements for prescription drugs, stronger authorized distributor status, electronic pedigrees by January 1, 2007, and criminalizes certain harmful wholesaling conduct. The State Board of Pharmacy has developed a new set of consensus regulations, based on the recommendations from a committee represented by the pharmaceutical industry,

the general public, Nevada drug wholesalers, HDMA and other affected parties. This bill reflects the consensus recommendation.

SENATOR TIFFANY:

There have been reported cases in the media about tainted drug use and drug tampering in Florida. How would this bill impact that situation?

SENATOR WIENER:

We do have a Nevada example about drugs that were moved from place to place through resale after resale. I will ask Mr. Hillerby to address this question.

FRED L. HILLERBY (Nevada State Board of Pharmacy):

In response to Senator Tiffany's question, because of specific problems with tainted drugs and drug tampering, Florida began to look at the secondary wholesalers and found serious issues of accountability. They found the need for certain license requirements and the need to tighten up the shipping pedigree of drugs, to know where and to whom they have been shipped. This new screening process has already had an impact in Florida. We are hopeful these requirements will help in Nevada as well. This has been a national problem for some time.

I am here in support of Senator Wiener's bill, S.B. 37. It addresses an issue we have been working on since the last regular Legislative Session. As you will remember, we brought a bill, S.B. No. 425 of the 72nd Session, to begin to deal with these problems. The board has been developing the regulations to implement this bill. There are about 15 important and popular drugs that are being diluted and contaminated. Counterfeit wholesale drugs come from secondary wholesale markets. It has been difficult to get regulations in place. The board prepared the first draft of regulations. The Legislative Counsel Bureau (LCB) released their version of the draft. Reputable wholesalers, the State Board of Pharmacy and many other organizations had meetings all around the state and finally drafted and adopted LCB file No. R049-04 (Register of Administrative Regulations). Senator Wiener's bill actually goes further than originally requested in the previous bill, primarily in the areas of fingerprinting and bonding issues. Our board feels fingerprinting, bonding and other regulations outlined in S.B. 37 are a good next step for effective control in Nevada.

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SENATOR TIFFANY:

Will we talk about the regulatory intent before we pass the bill?

MR. HILLERBY:

I do not have the regulations here to discuss with you today. They were adopted by the board last month.

Senator TIFFANY:

I have seen doctor-to-doctor purchase of drugs. What do we do in that circumstance?

MR. HILLERBY:

I am not familiar with what is required for doctor-to-doctor drug sales to occur. I am not prepared today to answer your question, but I can get you the answer.

SENATOR TIFFANY:

This may fall under the jurisdiction of the Board of Medical Examiners, not the Board of Pharmacy. I do not want us to start regulating doctors, but is there any way of reporting these sales?

MR. HILLERBY:

I do not know. I will find out. We know it is possible for doctors to divert drugs. Whether counterfeit or not, we do not know, but clearly diversions do take place. We have a controlled substance tracking system that is a model for others around the country and has highlighted these kinds of issues for us. We work with the Board of Medical Examiners when we find these kinds of cases.

SENATOR TIFFANY:

I have found that fingerprinting holds up the licensing process for at least six months, whether it is real estate agents, massage therapists, or other agencies.

MR. HILLERBY:

There is the provision in Senator Wiener's bill for a temporary or provisional license so as not to hold up the license.

SENATOR CARLTON:

We need to look at all those people who are holding a provisional license. We do not know who they are. This is another area that needs a safeguard.

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SENATOR SCHNEIDER:

We are concerned about regulation of drugs and wholesalers in Nevada, but it appears that I can go to the Internet for many more drugs being offered on line. It looks like the wholesale market is moving to the Internet. We have no idea what is really being offered. No one can regulate it.

MR. HILLERBY:

It is a very difficult area. I congratulate Senator Wiener for coming forward two sessions ago with a bill on Internet sales. We do license Internet sales for many. We do not catch them all. The money involved with the sales of prescription drugs, legal and illegal, is enormous. We cannot ignore federal data. It clearly shows the opportunity for counterfeiting and degradation of drugs through the wholesale process is prevalent in our country.

SENATOR HECK:

Senator Wiener informed this Committee that there are 38 domiciled wholesalers in Nevada and another 400 outside the state. Of that number, do you know how many are not public corporations that would be affected by the surety bond?

MR. HILLERBY:

I do not, but I can find out for you.

CHAIR TOWNSEND:

Any other questions for Mr. Hillerby? How many wholesalers are currently licensed here?

MR. HILLERBY:

Of the 438 wholesalers licensed by our board, 38 of them are domestic and 400 are outside of the state, but do business with Nevada. We license only those who sell in Nevada.

CHAIR TOWNSEND:

Are they all treated the same whether domestic or out of state? Have all met the statutory requirements of the previous Legislative Sessions as well as the current regulations?

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MR. HILLERBY:

I cannot say, because the current regulations were just adopted by the State Board of Pharmacy and have yet to be reviewed and so are not technically in place.

CHAIR TOWNSEND:

Are we going to get copies of the regulations?

MR. HILLERBY:

Yes, LCB has them. I will see that you and the Committee get copies.

CHAIR TOWNSEND:

Senator Schneider's Internet question posed today is very important. How will we deal with that?

MR. HILLERBY:

I can not answer that, but I will find out. It is an enormous problem.

CHAIR TOWNSEND:

Is the bill perfect from the State Board of Pharmacy's perspective?

MR. HILLERBY:

We reviewed the bill. It is one we can support.

PAT COWARD (Pharmaceutical Research Manufacturers of America):

We spent time with Senator Wiener on this bill and support it. The most important thing from our point of view is the pedigree, enhancing the tracking of drugs, from the pallet to filling of the bottles. Anything that will improve the tracking and integrity of drugs is important to us.

SENATOR HARDY:

Is there anything more that needs to be addressed in this bill?

MR. COWARD:

We have no problem with the bill.

Liz MACMENAMIN (Retail Association of Nevada):

We worked hard with the Board of Pharmacy on the regulations; however, this language does not address some of the concerns we have regarding exemptions of pharmacies that may have distribution centers. We have had conversation with Senator Wiener and she has considered amendments because of our concerns. Originally the regulation exempted licensing publicly and privately held pharmacies that have distribution centers. It was intended to look at illegal wholesalers in the state operating counterfeit drug rings. Senator Wiener has agreed to look at an amendment to address this problem for retail pharmacies.

CHAIR TOWNSEND:

If the State Board of Pharmacy were to have accepted the regulation, you would have brought this concern there. Is the Board aware of the regulation flaw?

MS. MACMENAMIN:

Absolutely, yes sir.

CHAIR TOWNSEND:

Then why not address this in regulation?

MS. MACMENAMIN:

The National Association of Chain Drug Stores is looking at this. They were key to implementing the Florida legislation. This legislation does not address the issues of retail pharmacies.

CHAIR TOWNSEND:

Is the board amenable to changing this at the regulatory level?

MR. HILLERBY:

Yesterday was the first time we heard the LCB thought the retail pharmacy distribution centers would have to be licensed as wholesalers. If this is the case, we can go back and amend these regulations.

CHAIR TOWNSEND:

Mr. Powers, are you aware of this new-found point?

KEVIN POWERS (Committee Counsel):

I am not, Mr. Chair. I was not involved in drafting or reviewing of the regulation.

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CHAIR TOWNSEND:

We will get a copy of the regulation. How do we deal with the Internet drug problems?

MR. COWARD:

I would have no idea. Every day we get bombarded with e-mail and postal ads, and I just keep deleting them.

CHAIR TOWNSEND:

Has the Board of Pharmacy ever purchased these drugs and tested them for efficacy and legitimacy?

MR. HILLERBY:

There is no testing for legitimacy. I can go back to the board and ask that they prepare information for you regarding the Internet activities in which they have been involved, as it is an obvious concern. We then will bring to you an Internet presentation.

SENATOR HARDY:

As we get our own house in order at the state level, the push for control on these Internet issues will give those who practice illegally on the Internet a strong message. This will compel the federal government to act as well.

CHAIR TOWNSEND:

We have limited jurisdiction regarding drugs on the Internet. There needs to be an effective educational campaign, including all concerned agencies, informing the public, and building an understanding that there are no regulations on Internet drug purchases. This would be a joint effort from all agencies.

SENATOR CARLTON:

This could be a multilingual effort as well.

MR. HILLERBY:

It is an excellent idea to have an agency-wide educational campaign.



SENATOR HECK:

I have not had anything come back to me about the Internet. Many have bought from the Internet. Some drugs require a prescription to purchase.

ROBERT MILLER (President and CEO, Caladon Health Solutions):

I am a small wholesaler within the State. The fingerprinting requirement is overregulation in my opinion. The board is allowed to determine, at their own discretion, who will be fingerprinted. I have no problem with me or my company being fingerprinted. Some of my people will not like being fingerprinted because they are not the licensee.

SENATOR CARLTON:

This is not unusual. Everyone within the gaming industry has to be fingerprinted to work.

CHAIR TOWNSEND:

The State Gaming Control Board has the absolute authority to call anyone in on regulations violations.

MR. MILLER:

There are several issues regarding the bond. I am not sure where I would get this bond. I do not know if this bond even exists. I know Florida requires a bond.

CHAIR TOWNSEND:

Is this commensurate with bonds in other states? How did you come up with \$100,000, Mr. Hillerby?

MR. HILLERBY:

These are the new provisions from Senator Wiener's bill. We did not come up with a \$100,000 bond fee. Specifically, there are many surety providers for wholesalers who issue these kinds of bonds.

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SCOTT YOUNG (Committee Policy Analyst):  
Florida legislation requires a \$100,000 bond as well.

CHAIR TOWNSEND:  
Can any of this be done in the regulations?

MR. MILLER:  
Yes, part of this is done in the regulations.

MR. HILLERBY:  
Yes. Section 5 of the bill is verbatim. In section 6, most of the language regarding pedigree has been board regulation since 1993.

CHAIR TOWNSEND:  
Mr. Powers can you summarize in some manner for us what is in the regulations.

KEVIN POWERS:  
Yes, I can have this prepared for the Committee.

CHAIR TOWNSEND:  
Mr. Hillerby, is it fair to say that you do not have statutory authority with fingerprinting? Regarding the list of employees, in connection with the operation, do you not think you have authority to do this now?

MR. HILLERBY:  
That is correct, we do not.

CHAIR TOWNSEND:  
Section 4 has to do with bonding. Do you not have authority to deal with bonds?

MR. HILLERBY:  
We do not.

CHAIR TOWNSEND:  
You believe section 5 is pulled right out of the regulations.

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SENATOR HECK:

The statute intends to provide criminal penalty which is not in the regulations, and that is why it keeps coming up in the statute.

CHAIR TOWNSEND:

Part of section 6 is in the regulations. Regarding section 7, is any of it in the regulation? Is this the one regarding the pedigree?

Mr. Hillerby:

Yes sir.

CHAIR TOWNSEND:

Are you familiar with this section on pedigree and a tracking system by the military?

MR. HILLERBY:

When you receive the drug supply, an electronic identification stamp is issued. Tampering would be difficult.

CHAIR TOWNSEND:

How did you come up with a Class C felony? Is this from the Florida law?

MR. YOUNG:

Yes, Florida legislation.

MR. MILLER:

How would I authenticate a document provided to me by another wholesaler?

SENATOR CARLTON:

This is how the tracking identification system would help you.

MR. MILLER:

The Radio Frequency Identification Device (RFID) is not in place as yet. These are things that are out of my control.

SENATOR CARLTON:

We will need to compare this language to others. This is what the boards are after.

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CHAIR TOWNSEND:

I am assigning this bill to a subcommittee who will meet immediately after this meeting. Senator Carlton will chair and Senator Heck and Senator Tiffany will continue to hear dialogue.

The meeting is adjourned at 9:13 a.m.

RESPECTFULLY SUBMITTED:

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Shirley Parks,  
Committee Secretary

APPROVED BY:

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Senator Randolph J. Townsend, Chair

DATE: \_\_\_\_\_