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

Seventy-third Session
February 10, 2005

The subcommittee of the Senate Committee on Commerce and Labor was called to order by Chair Maggie Carlton at 9:17 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:

Chair Maggie Carlton
Senator Sandra Tiffany
Senator Joe Heck

STAFF MEMBERS PRESENT:
Scott Young, Committee Policy Analyst
Kevin Powers, Committee Counsel
Lynn Hendricks, Committee Secretary
Jane Tetherton, Committee Secretary

OTHERS PRESENT:

Fred L. Hillerby, Nevada State Board of Pharmacy
Lance Packer, Legend Pharmaceutical Incorporated.
Robert E. Miller, Jr., President, Chief Executive Officer, Caladon Health Solutions
Liz MacMenamin, Retail Association of Nevada

CHAIR CARLTON:
We will now work as a subcommittee on Senate Bill (S.B.) 37. We need to address any unanswered questions and come to some type of resolution. In eliminating a couple of sections in S.B. 37, how would that affect the other sections with regard to new penalties? Does that take those particular sections out of the penalty phase?

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

KEVIN POWERS (Committee Counsel):

> Thank you Senator Carlton ... . The point made by Senator Heck earlier in the Committee meeting was very accurate. This bill creates an entire statutory scheme, and in particular, the scheme involves what is being commonly referred to as the pedigree. Some of these criminal penalties are based largely around activity surrounding the pedigree, which is essentially the electronic record of the transaction between the wholesalers. So those criminal penalties would be affected by removing certain provisions of this bill. However, this is not the only approach that could be taken in order to add or enhance criminal penalties. What could be done is a section that directs the board of pharmacy to adopt regulations relating to the pedigree and then make a violation of those regulations a Category C felony; that is possible as well .... . You can restructure the statutory scheme and still preserve the criminal penalties.

CHAIR CARLTON:

The concern I have is that we are allowing the State Board of Pharmacy to create something that could be a criminal offense. The responsibility lies with us to make those decisions and lay our guidelines for the Board.

KEVIN POWERS:

> I will say that it is not necessarily unusual; most violations of the Regulatory Board, chapters in *Nevada Revised Statutes* Title 54, are at the very least misdemeanors. The types of violations that rise to felonies, there are a few in Title 54 as well, so having a criminal penalty for violation of a regulatory board's regulation is not out of the norm.

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

Pedigrees have been around for years in paper form. We have been talking to Senator Wiener about this bill regarding new federal requirements to have an electronic pedigree called Radio Frequency Identification Device (RFID).

I am referring to section 7 of the bill regarding the requirement for a pedigree. Some of the language was adopted by the Board in 1993 but did not have the felony penalty. The Board expects a distributor to understand those obligations since it has been in the regulations for some years now.

CHAIR CARLTON:
We have been doing this since 1993, just in a paper process rather than an electronic process? Have we had many difficulties doing it in the form of a paper trail?

MR. HILLERBY:
Clearly there can be problems with a paper process, such as the paper being destroyed in shipping. The electronic process will be required on all boxes being shipped, which will help the tracking situation.

CHAIR CARLTON:
What are the penalties now with relation to the paper pedigree, in comparison to these penalties?

LANCE PACKER (Legend Pharmaceutical Incorporated):
My understanding of the regulations and statutes is that I will be fined if I do not process the pedigree paperwork properly. We as secondary wholesalers have to pedigree everything, whereas the larger wholesalers are not abiding by these same regulations.

The Pharmaceutical Drug Manufacturers Association (PDMA) has something similar that states if you have a longstanding relationship with a manufacturer, they do not have to supply a paper trail. This law is already in place in the state and federal regulations. If I sell something outside of Nevada, it falls under the PDMA, according to my legal counsel.

CHAIR CARLTON:
I am confused on what you just stated. Please explain in layman's terms.

MR. PACKER:
There are loopholes in the PDMA. Senate Bill 37 does not make you adhere to the pedigree process every single time.

CHAIR CARLTON:
What do you suppose is the reason for that?

MR. PACKER:
The PDMA states if you have an ongoing working relationship with that manufacturer, it means you are an authorized distributor for that manufacturer. You are not required to document the paper trail.

CHAIR CARLTON:
Is this something that has been around for a while? Is it because large corporations have more accountability than smaller corporations? Where do you think that rationale came from?

MR. PACKER:
I believe the PDMA has been in existence since 1987. The Board adopted a lot of the PDMA regulations for the purpose of identifying drugs. It is unfair that the pedigree process is always enforced upon secondary distributors but never upon the primary distributors, such as McKesson Pharmacy Systems.

CHAIR CARLTON:
This is a debate we had last session. I do not want to debate the same things over again.

MR. PACKER:
I understand, but there is a loophole.

CHAIR CARLTON:
We will compare that to the Florida law, because a lot of the things we are discussing may be directly related.

ROBERT E. MILLER (President, Chief Executive Officer, Caladon Health Solutions):
The pedigree when it was originally designed in the Prescription Drug Act (PDA) in 1987 was for the purposes of recalling drugs that were not legitimate; it was not used as a tracking device. Because of counterfeiting issues, the pedigree is being used to verify the authenticity of a drug. This can create problems; as Mr. Hillerby said, the paper can be forged. The pharmacy industry responded to what happened in Florida. The Healthcare Distribution Management Association (HDMA) is a health care distribution management association, of which I am a member. They wanted to demonstrate to the regulators who were dealing with

the Federal Drug Administration (FDA) that the industry could police itself. The state of Florida overreacted and passed statutes similar to what you see today. In response to that the HDMA produced these guidelines. I will provide a copy of guidelines to all Senators. The guidelines are neither statutory nor regulatory, but voluntary. I cannot do business in the pharmaceutical distribution industry unless I adopt these guidelines. The vendors and customers require that I adhere to the HDMA guidelines. In my opinion, S.B. 37 in some cases is redundant.

CHAIR CARLTON:
I disagree. Associations are to promote and protect members who are in their industry and boards are there to protect the public. The HDMA guidelines may not be the same guidelines that we to use to protect our constituents with relation to prescription drugs.

MR. HILLERBY:
Much of the language in section 6 was modeled after the HDMA guidelines regarding prescription drugs. This bill does take it a step further in that it is no longer a voluntary situation. There are records that have to be maintained which would be under the pedigree process.

SENATOR TIFFANY:
Is the focus on what we are trying to change here related to felonies, fingerprinting and registration?

MR. MILLER:
No, there are more changes. Section 6, subsection 1 of this bill states:

> An ongoing relationship between a wholesaler and a manufacturer is established by: (a) A written franchise, license or other agreement between the wholesaler and manufacturer to distribute prescription drugs; (b) The presence of the wholesaler on a list of distributors with which the manufacturer does business, created by the manufacturer and located on a publicly accessible Web site maintained by the manufacturer … .

How can we ask manufacturers to create a Web site that is publicly accessible with a list of their customers? Also with respect to the written franchise license or other agreement, I buy direct from several manufacturers with whom I have no written agreement.

SENATOR TIFFANY:
That can lead to exclusivities and lack of competition.

CHAIR CARLTON:
Does section 6 come from the association guidelines?

MR. HILLERBY:
Yes, it was discussed during the regulatory process. Most of section 6 is verbatim from regulations that the Board passed in January 2005.

KEVIN POWERS:

> Section 6 and section 7 work in conjunction with each other. Section 6 is not establishing requirements, it is just establishing conditions if, in section 7, the wholesaler would not have to use the pedigree for that particular transaction. In section 7, you have to use the pedigree for a certain transaction, unless you meet the conditions in section 6. The wholesaler does not have to meet the conditions in section 6, it is not establishing additional conditions. It only establishes requirements if they want to be exempt for certain transactions from the pedigree requirements of section 7.
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> To follow up on Senator Tiffany's question, these are not establishing requirements for operating a business. Any wholesaler can continue to operate as they do. If however, they do not meet the requirements of section 6, they need to follow the pedigree requirements in section 7.

MR. MILLER:
Why not establish the pedigree rules for every transaction? With regard to section 6, subsection 1, paragraph (c):

> The existence of the purchase by the wholesaler of at least 5,000 sales units of prescription drugs from the manufacturer within the 12 months immediately preceding the transaction for which the wholesaler claims to have an ongoing relationship ... .

There are some manufacturers I purchase from on an annual basis with whom I do not come anywhere near the 5,000 units. The reason the HDMA supported this guideline is because it is largely funded by the primary wholesalers, who

can easily comply. Under these rules, I can no longer claim to be an authorized distributor for maybe 50 of the manufacturers from whom I purchase on an annual basis.

KEVIN POWERS:
"All that would mean, as I follow the language of the bill, is that you would then have to do the pedigree process. It does not prevent you from engaging in business with the manufacturer."

MR. MILLER:
No, I am not suggesting that. What I am suggesting is that a pedigree be required for every transaction in which you do not directly purchase a drug from a manufacturer. I purchase from a major wholesaler, McKesson Pharmacy Systems, and if McKesson does not provide the pedigree initially, I would be guilty of a Category C felony for not being able to authenticate a pedigree.

CHAIR CARLTON:
Where do they get their product?

MR. MILLER:
Generally from the manufacturer. The major wholesalers in the United States probably account for 85 percent of products that move through the chain of distribution. McKesson probably purchases 90 percent directly from the manufacturer.

CHAIR CARLTON:
Can I assume there are very strict regulations at the manufacturing level? In the first step, where a company purchases from the manufacturer, employers are not required to follow the pedigree process. In the second step, where the wholesalers are involved, there are concerns about the legitimacy and the efficiency of the drugs. Is that correct to assume?

MR. MILLER:
Yes.

SENATOR HECK:
I appreciate the intent of S.B. 37. It is very important that we try to safeguard the health and welfare of our citizens regarding counterfeit drugs. I have four concerns with the bill as it is currently written. The first is a matter of

significant interest. I think it is somewhat nebulous for the Board to determine who in the company has a significant interest and is required to go through this process. Can that be better defined?

MR. HILLERBY:
Some businesses have been placed in relatives' names and the operations have continued to be conducted by known felons who knew they could not get a license. A concern might be problems with the fingerprinting of persons involved in the operation of the business. The language from the Florida law could probably be tightened.

MR. MILLER:
I am not sure how the fingerprint rules would fix the problem of felons working in the drug distribution business. I do not see how this change can eliminate felons from the business.

CHAIR CARLTON:
Through the investigative process it is possible a problem would be found and a statute would allow the Board to go forward with the investigation. You have to trust the Board to do the things they need to do to protect the public.

MR. PACKER:
As the wholesaler, we want to protect the consumer, but this bill just does not do it. We already have an application process that covers much of the bill. We cannot trust the Board as litigation is currently ongoing.

CHAIR CARLTON:
We will not disparage other people. We need to work together. If you have any disagreements with the Board, it should be handled at the court house.

MR. PACKER:
The Board is being sued for abuse of power.

CHAIR CARLTON:
So I guess the mechanism works.

MR. PACKER:
We want to protect the public, too. That is why Florida did what they did. We just feel these new regulations do not address everything.

SENATOR HECK:
One issue is with the requirement that the wholesaler has to submit a change of employee list within 15 days after they hire or fire someone, whether or not that person has significant influence in the pedigree process such as someone working on the warehouse floor. If they need to submit that every 15 days, that may be somewhat cumbersome.

The impact of the surety bond on the smaller wholesalers is another issue. The intent is to guarantee payment of fines that may be accessed by the Board. Have we had a problem where fines have been assessed and not paid?

Finally, there is the issue of the unintentional or inadvertent inclusion of generic drug manufacturers who deal directly with the wholesalers or retailers. With regard to the pedigree, perhaps this does not go into effect until the first resale of the drug. In this situation, the issue is not worrying about maintaining a pedigree from the manufacturer to the McKesson wholesaler. Upon the first resale the pedigree needs to be maintained. I would like to see that information, if you can provide it.

SENATOR TIFFANY:
There are two parts in the bill that should be examined. The matter of whom in a company exercises significance influence is one part and the bond security issue is the other part.

CHAIR CARLTON:
We will compare those to the Florida law and the association guidelines.

MR. PACKER:
With regard to the pedigree process, it might end up back with the wholesaler who does not pedigree anything. That is where I think the paper trail will end. I do not know how you will correct the pedigree problem until the electronic process is in effect.

MR. HILLERBY:
Some of the information we have been discussing is already in the regulations. The Board would be happy to provide any information you need.

LIZ MACMENAMIN (Retail Association of Nevada):
Are we going to look at drafting a solution to bring the retail industry under the same guidelines?

CHAIR CARLTON:
Yes.

MR. HILLERBY:
It is the same with the generic manufacturers who deal directly with the retailers.

CHAIR CARLTON:
Yes, I agree. If there are no other questions, this meeting is adjourned at 10:07 a.m.

RESPECTFULLY SUBMITTED:

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Jane Tetherton,
Committee Secretary

APPROVED BY:

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Senator Maggie Carlton, Chair

DATE:_____