MINUTES OF THE MEETING
OF THE
ASSEMBLY COMMITTEE ON COMMERCE AND LABOR
SUBCOMMITTEE ON SB 37

Seventy-Third Session
May 12, 2005

The Commerce and Labor Subcommittee on Senate Bill 37 was called to order at 1:40 p.m., on Thursday, May 12, 2005. Chairman Marcus Conklin presided in Room 3161 of the Legislative Building, Carson City, Nevada. Exhibit A is the Agenda. All exhibits are available and on file at the Research Library of the Legislative Counsel Bureau.

COMMITTEE MEMBERS PRESENT:

Mr. Marcus Conklin, Chairman
Mrs. Heidi S. Gansert

COMMITTEE MEMBERS ABSENT:

None

GUEST LEGISLATORS PRESENT:

Senator Valerie Wiener, Senatorial District No. 3, Clark County

STAFF MEMBERS PRESENT:

Brenda J. Erdoes, Legislative Counsel
Diane Thornton, Committee Policy Analyst
Kristen Roberts, Senior Deputy, Legislative Counsel
Vanessa Brown, Committee Attaché

OTHERS PRESENT:

Louis Ling, General Counsel, Nevada State Board of Pharmacy
David Goldwater, Investment Consultant, Caladon Health Solutions, Las Vegas, Nevada
Elizabeth A. Gallenagh, Associate Director, Regulatory Affairs, Healthcare Distribution Management Association, Arlington, Virginia
Daryl Capurro, Managing Director, Nevada Motor Transport Association

Chairman Conklin:
[Meeting called to order. Roll called.] We are here on the first revision of S.B. 37.

Senate Bill 37 (1st Reprint): Revises provisions governing wholesalers of prescription drugs. (BDR 54-13)

Chairman Conklin:
The Commerce and Labor Committee heard this bill on May 6. It's my intention to take new testimony, and if the parties have worked on amendments, Mrs. Gansert and I would like to look at those.

Senator Valerie Wiener, Clark County Senatorial District No. 3:
My sole intention with S.B. 37 is to provide legislative support for health and safety protections for the people of Nevada. I encourage your support of the bill that was presented with the modest amendment from the bankers (Exhibit B). This bill, with its legislative provisions, directly aligns with strong regulatory provisions that have been adopted by the Board of Pharmacy and approved by the Legislative Commissions' Regulatory Subcommittee last February. The health and safety protections are important for the people of our state. The major provisions in the bill are the pedigree requirements, background checks, bonding, and the penalties.

Knowing that we have 400 wholesalers who do business in our state and 38 wholesalers who are domiciled, it's my concern that I've only heard from one wholesaler who has any objections to the bill in its present form.

I urge you to pass S.B. 37 with the bankers' amendment (Exhibit B, Exhibit C) regarding lending; it is a substantial compromise that preserves the intent of S.B. 37. It maintains the integrity of the significant regulatory work that has already been accomplished regarding the consensus regulations that were developed and approved by our Legislative Commission. It also addresses the major concerns of S.B. 37. This will not undo the intent of the bill and it will not undo the intent of the regulatory scheme that is already in place.

This amendment (Exhibit C) deletes all sections of the bill except Section 6. Currently, Section 6 requires the State Board of Pharmacy to adopt regulations for the safe and efficient operation of wholesalers, the integrity and propriety of transactions involving the purchase and sale of prescription drugs by wholesalers, statements of prior sales that involve pedigree, and electronic pedigrees by January, 2007, if the technology is feasible. In addition to the

existing provisions in Section 6, it is amended in (Exhibit C) to require that the State Board of Pharmacy adopt regulations prescribing criminal penalties no higher than a Category C felony for failure to deliver or acquire pedigrees and for the destruction, alteration, forgery, or falsification of pedigrees.

[Senator Wiener, continued.] Section 6 will also be amended to authorize the State Board of Pharmacy to adopt regulations to address fingerprinting and criminal background checks for applications for licensure of wholesalers and other persons connected to them, and to address bonding requirements for licensed wholesalers up to a $100,000 bond. That becomes more of the enabling thing, whereas the first part was a requirement.

The proposed amendment (Exhibit C) also has an important accountability provision. It adds a transitory section to the bill that requires the State Board of Pharmacy to report back to the 74th Session of the Nevada Legislature. This report must explain the progress of the Board in adopting regulations and any recommendations for legislation as a result of any findings they may have during that regulatory process. This requirement ties the Board of Pharmacy back to the Legislature in a direct way and provides a necessary oversight. If they do bring regulations forward, we have another opportunity through the Legislative Commission and the Subcommittee on Regulations to review those regulations, and because there's a required report, they will be accountable for what they do based on this amendment (Exhibit C).

With the amendment (Exhibit C), we will allow interested parties, such as those who have come before the Committee, the time they need to address their concerns during the regulatory hearings. I strongly encourage anyone who has concerns or issues to participate vigorously in the regulatory process.

I would prefer you support S.B. 37 with the bankers' amendment (Exhibit B); however, in the spirit of compromise, I'm offering my amendment to the bill in hopes that we can move forward with the process through regulation. In this way, we can provide Nevadans with a critical and necessary health and safety protection that has been sought in S.B. 37.

Chairman Conklin:
Have you reviewed the HDMA [Healthcare Distribution Management Association] Model Act?

Senator Wiener:
S.B. 37 is modeled after the Model Act, as well as the National Board of Pharmacy Model Act. I took the key components and integrated them into S.B. 37.

Chairman Conklin:
There are four components to the HDMA Model Act, and the proposed amendment (Exhibit D) that came to the Committee during testimony is right on those four, and your bill goes significantly further than that. The Model Act tends to be a compromise to where an industry says we recognize we have a problem and here's where we think we can get to, and we're certainly willing to help. What took you beyond that Model Act to the provisions in S.B. 37?

Senator Wiener:
I did look seriously at the Florida act and in developing this amendment (Exhibit C) as a substitute by sending it to the Board of Pharmacy, those key components are addressed in terms of the bonding, the criminal background check, and they can develop regulations so the process will be open for important dialogue between the parties, which is difficult to do in the limited hearing process we have. I wanted to keep alive the concerns of the key points of the bonding, the radio frequency identification, which will be a national standard, and some of the penalties that are there if we have unhealthy wholesale practices. The key components of the Model Act are built into the recommendations we would send to the Pharmacy Board to develop the regulations over a period of time and report back to us so that dialogue can continue and we can establish the standards and practices we need in Nevada.

Chairman Conklin:
If the Committee has a particular issue in a section that is not in subsection 7, and instead of fixing it, we pass your amended version, what prevents the Board of Pharmacy from going ahead and enacting what it was that we didn't like about S.B. 37 in the first place?

Senator Wiener:
There's a check in place, and the intent is in my testimony and the bill. I'd have to ask counsel, because I'm not on the subcommittee to review the regulations. We only get the reports back, but the intent is a huge part of what is considered and whether or not we accept the regulations and the record is a big part of what is accepted or not accepted by that subcommittee. We're establishing the record of intent now.

Chairman Conklin:
Who reviews the regulations for the legislative body? Is it up to the legislator, or is there someone on LCB [Legislative Counsel Bureau] who reviews it?

Brenda Erdoes, Legislative Counsel:
The Legal Division does review each regulation, and we compare it to the statute to make sure it complies with it. We also look to see if it complies with

the legislative intent to the extent that the legislative intent portion is left more to the Legislative Commission than members of the Committee to review regulations. We do point out any concerns or problems that you might want to look at.

Senator Wiener:
The accountability component is built into the amendment (Exhibit C), where there's a mandatory report back as to the regulatory process, how they arrived where they did, and what they brought forward as regulations. Any recommendations for legislation is where they come forward and say, we need this in addition to what it is you asked us to work on. That's why, at the legislative level, we're tied beyond accepting the regulations and the next step through that mandatory report.

Assemblywoman Gansert:
I have the same concern. It's that "shall adopt regulations," and it gives some parameters, but it's pretty wide open, and in your transitory language there are still two years where they can do what they want to do. At that time we may say no, but they can enact something given this language. I'm concerned about not defining what it's going to be now.

Senator Wiener:
I hope the legislation gets through and will address some of those concerns that we've had in the past. That's what has been happening with a lot of agencies. They pass their regulations without any legislative input or consideration, but the bill I hope gets through won't allow that to happen. The legislation should manifest the intent of the Legislature and must have the approval of the Legislative Commission. Last year, 78 percent of the agencies got regulations through without legislative oversight, and this bill would prevent that from happening again. We legislators will have a place in approving or not approving the regulations because they can't go forward without legislative approval.

Assemblywoman Gansert:
My concern is the same because we haven't passed that legislation. That sounds ideal to do something like that, but right now that doesn't exist, and I'm concerned about allowing the adoption of regulations if we don't have that in place in the interim.

Senator Wiener:
Ms. Erdoes oversees a lot of that activity, and maybe she can provide assurances that the regulations won't go into place. The dream legislation is lingering right now.

Brenda Erdoes:
The Commission will review any regulation that the timing requires them to review and any regulation that any member of the Legislature asks to be reviewed. We hold those and they come to the Commission. There is some assurance that you can get this reviewed by the Commission, if that's your desire. If someone is watching for a regulation, my office will track that for you and let you know when it gets adopted.

Chairman Conklin:
If we pass this amendment (Exhibit C), which means we rejected the original bill, and a regulation comes back that looks similar to the bill we didn't pass, would it therefore be rejected and automatically sent to the Committee for review?

Brenda Erdoes:
Not unless you made a record to say, we don't like this bill and we're going to go with the regulation instead of it if you were going with a regulation to lessen the severity. Just going from a bill to a portion of the bill that would adopt regulations shouldn't have that in there.

Chairman Conklin:
I have your proposed amendment (Exhibit C), but it might be premature. There may be some things we can address within the bill. In Sections 6 and 7, there is a concern that while the FDA has said we intend to have a radio frequency identification (RFD), a legitimate fail-proof tracking system by 2007, but it's actually more years than that. The concern is that we have something written in statute that even if the FDA has something that's approved, it may be something that's not quite accurate, so we have people spending a lot of money buying a tracking system that doesn't quite solve the problem, and then having to do a new one two to four years down the road. There is a clause in here that the Board may move that date, but it might be worth using language that contains the criteria for our tracking device. When such a criteria is met upon Board approval with a certain amount of time that the Board can give for implementation, would that be language that would be...

Senator Wiener:
Knowing the realities of protecting integrity from manufacturer to purchaser, I know there are RFD systems in place. The Department of Defense has many materials that now go into pharmacy, as well as some of the major pharmaceutical chains in the country like Wal-Mart, CVS, and Rite-Aid. There is technology out there that's being utilized already in terms of tracking because those pharmacies are using it. I don't want to lose the fact that the tracking is

integral to protecting the integrity. I know there is some tracking already in place.

Louis Ling, General Counsel, Nevada State Board of Pharmacy:
As far as the January 1, 2001 deadline, the feds have stated it's not a mandatory deadline. They are holding that up as a goal. They said if you don't get there, we're going to make you get there, and states have taken the feds' lead and put that into their law. Every state that's done this has done the same thing in S.B. 37. They said if it's not feasible, we'll extend the time, and they recognize that this is going to solve so many of the problems the rest of S.B. 37 is trying to address. When we finally get electronic tracking, most of these problems are going to disappear.

S.B. 37 holds up the same basic idea of the feds, to hold it up as a goal and keep the manufacturer's and wholesaler's feet to the fire by having this date hanging over their heads. If they can't make it, we're all going to know it because everyone in the industry is going to watch this, including the Board of Pharmacy. We don't have any intention of requiring someone to do something that is impossible. We intend to make this happen as soon as they call. We're encouraged because we're seeing that the pilot projects are beginning to work. I don't know whether January 2007 is unrealistic, but I wouldn't want to take it out of the bill because then the Legislature is losing the power to order the manufacturers to fix it. If we adopt a looser standard, the only people who are going to take advantage of it are the manufacturers and wholesalers, which we don't want. We want everyone to know this is where we're headed.

Chairman Conklin:
If we could track this, many of our problems would go away. The problem is not the wholesaler. The wholesaler is a byproduct of the problem, which is the counterfeiter. That's the real problem, and it's a much harder problem to fix. There are some bad apples in every industry out there, so if we could fix that tracking, we'd do away with the counterfeiter problem. Unfortunately, I'm uncomfortable with setting a date in our statute. I'd rather just refer to federal statute and as they change theirs, ours would comply with that because many of the companies that are working on this, the manufacturers themselves, don't operate in our state. I don't know if they operate in our country anymore either. The federal government has a lot greater ability to force them to do it than we do.

Louis Ling:
I understand that, and I wish that were the real world. The feds passed the PDMA [Prescription Drug Marketing Act] in 1988. They have ducked passing paper pedigrees now. We're on the sixth duck. Every time it comes up, they

duck and don't pass it. Under the PDMA, Congress said, let's have some pedigree standards on a nationwide basis, and most people in the industry wish there was a national standard. But every time it comes up in the FDA hearings, they don't pass it. The reason why the states are where the innovation is coming from is because the federal government won't take care of this problem. The feds studied this for a year, and their final report came out with many recommendations, one of which set this target date of January 1, 2007. That had national input at the federal level. The feds have acknowledged, and the Board of Pharmacy is acknowledging, that as a hopeful date.

[Louis Ling, continued.] Wholesalers also want a good track and trade system. If we don't hold that goal out over their heads, we're going to see more stalling, and I don't want this to rest on the feds because they could drop the ball for another 10 years and we'd have to wait while the industry develops this sooner. We need to keep the industry pushing. This January date is great and we're in line now with our sister state to the west; they're going to have the same date. Florida is six months shorter than this. Indiana is also passing a bill similar to this. We'll see this date popping up all over the states, and as that happens, in order to comply with all the states, we're going to see innovation in the industry.

Only two things drive innovation: either the industry wants it, or regulators want it. In this case, it will actually help both, but we need to hold that goal up.

David Goldwater, Investment Consultant, Caladon Health Solutions, Las Vegas, Nevada:
Obviously the industry's frustration with the Board of Pharmacy and the regulatory board is the reason why we're before the Legislature. It's the only place where someone who is frustrated with the Executive Branch can go. In this case, you're eliminating the legislative check as legislators all over this building continue to get frustrated with the regulatory process of the Executive Branch boards and commissions. If you don't like the regulations that come out of that, pass better statutes. Regarding the January 7 date, are we moving forward with the substantive parameters of the proposed regulation, or are we moving forward with looking at the bill because the negotiations are in completely different contexts? [Submitted proposed amendment (Exhibit D).]

Chairman Conklin:
Her proposed amendment (Exhibit C) would be secondary. I would prefer to find something a little more concrete. We don't assume anything, but we put what we want in statute and we leave less of it to be filled and more of it to be enforced, instead of the opposite, where we lose control of the representation

of the people we're supposed to be serving. That's my intention, assuming we can find some common ground on the bill.

Senator Wiener:
My hope is to urge support of the bill as introduced with the bankers' amendment (Exhibit B). There isn't a lot of crossover between the proposed bill that I brought (Exhibit C), and his well-intended amendment (Exhibit D), which is a substitute for the bill. I wanted to bring an alternative (Exhibit C), not my first choice that would address the intent of the bill, but that would still leave the process open.

Chairman Conklin:
Have you met with Mr. Goldwater, or have you and Mr. Miller, Mr. Goldwater, and Mr. Ling all discussed the issues and concerns of the bill, or has the only dialogue been paper passage? If the only thing that's happened is paper passage, then I certainly understand where you're coming from. We haven't really begun to work out some of the details.

David Goldwater:
It's been paper passage, and to clarify what Senator Wiener said, the proposed amendment (Exhibit D) hopes to add to S.B. 37, not replace it. The proposed amendment wants to keep all of the good things in S.B. 37, clean up some of the language, and get rid of provisions that mandate that the Board pass broad regulations. The licensees here fear the Board. They're not stepping up because they're afraid of Board action. They want to be done with this issue. Mr. Ling and I had a phone conversation two days ago to begin negotiating on this, and Senator Wiener said she wanted to do it on her own.

Louis Ling:
When David and I talked, I was in an uncomfortable position because this is not our bill. This is the Senator's bill. While the Board of Pharmacy supports the aims of the bill and we've worked closely with the Senator in terms of giving her technical advice and assistance, I didn't want to negotiate away parts of her bill. I don't have that authority, but I would welcome the opportunity if the Senator wants a four-way conversation.

There are things in their proposed amendment (Exhibit D) that would be good additions to S.B. 37. The way the amendment was proposed to the full Committee, it cut everything beyond Section 6 out of Senator Wiener's bill. It cut off the whole back half of her bill and supplanted that with their amendments. That weakened the public protection portion of the bill, but adding some of their provisions to S.B. 37 is a good idea. Some of the HDMA model language you were talking about is in their amendments. Those additions to the

protections already in here would be good things. There is room to work around their amendments, but not if their amendment is going to gut half of her bill, because the back half of her bill is just as important as the front.

Chairman Conklin:
Senator Wiener, is there an opportunity here if we give you time to sit down with the other parties involved to see if you can come to an agreement? Mrs. Gansert and I are not experts on this and we haven't spent the amount of time that you have to research this bill. I fear that we will make decisions that are not as informed as the ones the parties who are involved will make in finding some common ground.

Senator Wiener:
I'll find a way to make this work. This bill is important policy, and we'll work toward the goal of the best interest of the people in Nevada.

Chairman Conklin:
I want to adjourn this meeting and reschedule for early next week and you can bring something back to us. It's my impression the Committee feels this issue is very important. There were many people on the Committee who felt like it almost criminalized a legitimate business sector, so we would like to see something that makes tougher protections for consumers and allows legitimate businesses to operate within the marketplace to deliver a necessity, which is to fill a shortage of supply and to provide a price advantage to consumers.

Assemblywoman Gansert:
I want you to have concrete regulations, because I'm troubled by enabling the Board to come up with the regulations without them being defined in this document (Exhibit C).

Senator Wiener:
I haven't gone this direction to tell them what they have to put in regulation would be put in statute. That would be my interpretation, and I would need a little help from counsel.

Assemblywoman Gansert:
It says the Board shall adopt regulations, and I want to know what those regulations are going to be.

Senator Wiener:
Okay. Would it be all right with the Subcommittee if, during our meeting with the other interested parties, we have our staff counsel there so we can work

out language? That would help us expedite a resolution. [Ms. Erdoes answered affirmatively.]

Elizabeth A. Gallenagh, Associate Director, Regulatory Affairs, Healthcare Distribution Management Association, Arlington, Virginia:
HDMA is the national organization representing full service wholesale distributors, health care companies that distribute primarily prescription drugs in a wide array of health care products throughout the country and in the state of Nevada.

This is an important issue for the state and for the rest of the country in terms of counterfeit drugs and stricter licensure requirements for wholesalers. Our bill promotes stronger penalties and licensure requirements from the outset, such as pre-licensure inspections, criminal backgrounds, and financial background checks, to make sure the bad actors don't get into the system. This really should be a fight against the counterfeiters, not legitimate businesses, and we appreciate that point. It is a criminal activity to counterfeit drugs and to knowingly traffic those products. We want to do everything we can to support the efforts of those who are trying to eliminate those channels.

We need to review the bill and the amendments further, and I'm encouraged by the fact that Mr. Goldwater and Senator Wiener will meet and come to some compromise. The provisions in the amendment offered by Mr. Miller and Mr. Goldwater (Exhibit D) come mostly from our HDMA recommended guidelines, which were meant to be best-business practices. They're voluntary guidelines outlining the due diligence that legitimate companies should do when dealing with other wholesalers and their trading partners to ensure they're not doing business with illegitimate companies.

We appreciate the work we've done with the Board. There's been contention in the state between local wholesalers and the Board, but there has been an effort made to work with the industry on the regulations that are currently in effect. Perhaps Mr. Goldwater, Senator Wiener, and the Committee might consider what Mrs. Gansert was talking about, having the regulations be more defined, and perhaps the way to address that is to set forth a formal committee or task force if that's the decision they come to in their proposal. It worked in terms of gathering Nevada representatives, PhRMA [Pharmaceutical Research and Manufacturers of America], NACDS [National Association of Chain Drug Stores], and HDMA to come up with something the industry can work with. It's not perfect for any side, but it was a compromise and it was a long process. I don't know that we want to throw all that good work away. The Board does need some help in getting criminal background checks, fingerprinting, and other good provisions in both of these proposals (Exhibit C) and (Exhibit D).

[Elizabeth Gallenagh, continued.] We're not in a position to oppose or approve of either proposal, because we like things that are in both of them. We have concern with the date because we don't believe that the industry will be ready. We appreciate the provision to extend that date, and perhaps there are factors that can be considered, or a reporting mechanism that can be carried out in terms of making sure the industry really does have widely available technology for the electronic pedigree to be implemented.

The spirit of both of the proposals (Exhibit C and Exhibit D) is what we're looking for, and hopefully they'll compromise.

Chairman Conklin:
Were you involved in the drafting of this bill? [Ms. Gallenagh answered in the negative.] Were you involved in the recently adopted regulations by the Pharmacy Board? [Ms. Gallenagh answered in the affirmative.] Were you referring to that as the compromise?

Elizabeth Gallenagh:
We would like to see something, if that's the way the Nevada Legislature decided to go in terms of giving the Board the additional tools they need and to make sure only legitimate players are in this business. The criminal background checks, the surety bond requirement, or a move towards an electronic pedigree, are necessary. They are all something HDMA supports. These proposals wouldn't replace the regulations that we worked on.

Chairman Conklin:
How familiar are you with Nevada law, including regulations and statutes, in this area?

Elizabeth Gallenagh:
I'm fairly familiar with them.

Chairman Conklin:
How do we rate in this area against the rest of the states in the nation?

Elizabeth Gallenagh:
You're probably one of the more strict states now, and that's a result of the legislation and regulations from the last couple of years. We have about 30 states right now that are working on legislation in this area. So you're ahead of the curve at this.

Assemblywoman Gansert:
In the original language of the bill, the bonding could be used for fines and licensures. There was a clause that it could be 60 days after any administrative proceeding against the licensee conducted pursuant to statute that they could take the $100,000 of the bond. Is that common in other states, or is it held in case there are fines that aren't paid for licensure?

Elizabeth Gallenagh:
Other states do consider, but I've seen that provision. Often an investigation might not happen until later in the career of the company. Should the company amid investigation go out of business or leave the state, by keeping the bond in place, it would give the Board the reach to give the company fines.

Assemblywoman Gansert:
When we talk about background checks and fingerprints, it seems that both bills have something to do with that. Do you have that for wholesalers who are just headquartered in a particular state, or if you import drugs from other states, do they also have to be fingerprinted and so forth?

Elizabeth Gallenagh:
Yes, we're seeing more states move in this direction because you're licensing both in-state and out-of-state companies. Some states rely on other boards for licensure information, but not every state had strict requirements and some of those are still in development, California, for example, requires non-resident wholesalers to submit fingerprints with their application. I commented in my letter to Senator Wiener (Exhibit E) on her original bill on the list of all employees, agents, guardians, and representatives. I understand the intent of it, but we do take the position that for the purposes of stronger licensure requirements and the background checks, quite often we think it's sufficient to require that information of officers, directors, and key shareholders, because those are the people you're going to want to reach in the event of a violation. We also thought the monthly reporting was onerous.

Assemblywoman Gansert:
What about site inspections? The Board needs to inspect every three years at least? [Ms. Gallenagh answered affirmatively.] For the pedigree, what about the Category C felony? Do you have felonies in other states if someone has tampered with a pedigree? [Ms. Gallenagh answered affirmatively.] Is that the same level of a felony?

Elizabeth Gallenagh:
I'm not sure what level because every state has different classes of felony crimes. I know Florida is the strictest in terms of the penalties. Something

beyond a misdemeanor is better than we've seen before the last couple of years.

Chairman Conklin:
Your company deals with wholesalers; there were some other issues discussed in the original testimony about secondary markets. Could you briefly explain to us wholesaler and secondary markets so we have a clear understanding?

Elizabeth Gallenagh:
They could be one and the same.

Chairman Conklin:
The folks you represent in HDMA are not secondary suppliers, unless by affiliation only, is that correct? [Ms. Gallenagh answered affirmatively.] Could you explain that to us?

Elizabeth Gallenagh:
There are two or more markets within the wholesale prescription distribution industry. HDMA represents primary full-line, full-service distributors who primarily purchase their products directly from the manufacturer and primarily distribute their product to pharmacies or other end-dispensing entities. Our secondary members are affiliated with us, and those companies are usually smaller and buying more of their product on the secondary market from other wholesalers, often selling to other wholesalers, sometimes buying from the manufacturer, and sometimes selling to the pharmacy. Often you hear about the "grey market," which borders on illegitimate, and that's where it's grey and we don't know what's going on. That's according to the most recent sources where reports of counterfeiting activity or other illegal activity carried out by criminals somehow enters the legitimate supply chain.

Chairman Conklin:
The secondary market is anytime you have multiple wholesalers involved in the chain of delivery? [Ms. Gallenagh answered affirmatively.] It has nothing to do with who you purchase the drug from, but the actual drug itself. [Ms. Gallenagh answered affirmatively.] It's just a different way to define how many folks this product is traveling through.

Elizabeth Gallenagh:
It usually involves many more transactions.

Assemblywoman Gansert:
We were talking about the bonds, and the organizations you represent are very large. A $100,000 bond is probably not that much, but do you have small organizations that still have to get $100,000 bonds?

Elizabeth Gallenagh:
Right now, Florida is the only state and California is starting to implement theirs. Those two states have bond requirements of $100,000 for all wholesalers. We want it to be one per company, if that would solve part of your problem. We do like the substitute language. There can also be another type of security, a designated account, or some other means for the Board to reach if a bond is not feasible. We would be supportive of that as well.

Chairman Conklin:
On Section 4, page 4, the $100,000 bond has to be executed by the principal plus the corporation? I noticed line 18 and it's more convoluted.

Elizabeth Gallenagh:
We would want it to be for each company, not multiple bonds.

Brenda Erdoes:
This is our standard bonding language in Nevada. It requires one bond.

Assemblywoman Gansert:
I'm thinking about a small wholesaler and whether it would be difficult to get fingerprints from some of the other wholesalers from which they purchase products. I don't want to create a lot of barriers to entry or for the continuing of business. Is that a difficult regulation to achieve?

Elizabeth Gallenagh:
It was my understanding the Board was getting the fingerprints from the wholesaler and the applicant was submitting the fingerprints.

Assemblywoman Gansert:
It was unclear to me who needed a licensure, whether it was just companies that were headquartered in Nevada or if it was companies who sell products to a wholesaler in Nevada, and who exactly would be required to produce the fingerprints and background checks.

Elizabeth Gallenagh:
How does this affect out-of-state? It was my understanding that all licensed wholesalers out-of-state or residents of Nevada would have to go through the same procedures.

Louis Ling:
The bill that was passed last session required anyone selling into Nevada to be licensed. Anyone buying from Nevada does not have to be licensed. If you're going to sell into Nevada, you have to get a license, which means you'll go through this fingerprinting and regular application process. The bill as it went through in the last session is working. We've been getting people who were selling into the state routinely who weren't licensed with us, who now are.

Elizabeth Gallenagh:
We have a technical issue in relation to the original bill regarding the authentication of the identifying statement. We want to make sure there is more flexibility. This is the provision in Section 6, subsection 4 (a) of the original bill. That requires an authentication signature for the pedigree or the identifying statement. We want to make sure it's clear that more than one or two individuals can serve that function. We don't want there to be a stop in business because the one person who authenticates pedigrees is not on the job that day. [Referred to Exhibit E]

Chairman Conklin:
If we had an adequate electronic system, there would be no need for the section involving the authentification of identifying statements?

Elizabeth Gallenagh:
That's correct, and it would depend on the parameters of that system. The way the system would work is you would be able to automatically identify the path of the drug and you read it using the appropriate technology. Therefore, you'd be able to authenticate that pedigree.

Chairwoman Conklin:
Thank you for your testimony. It's my intention to ask parties involved to get together and see if some work can be done on this to create a compromise. The Subcommittee will take up that compromise early next week.

Daryl Capurro, Managing Director, Nevada Motor Transport Association:
On behalf of UPS, FedEx, and others, our concerns are with the fingerprinting area that still appears in the proposed amendment (Exhibit C). Like the financial institutions, we're simply a conduit in which to deliver drugs. We have nothing to do with the sale, manufacture, or distribution. We'll ask that you consider an exemption, as in the Senator's amendment, for common carriers or other delivery services that deliver the drug at the direction of a manufacturer. Trying to get the fingerprints from the president and board of directors of UPS, and FedEx presents some serious problems.

Chairman Conklin:
Do you have anything in writing?

Daryl Capurro:
I have nothing in writing, but the language would be exempting, as you did the financial institutions in the proposed amendment (Exhibit B), common carriers or other delivery services.

Chairman Conklin:
Mr. Capurro has a concern that because his clients, UPS and FedEx, deliver and transport the drug from manufacturer to wholesaler and wholesaler to wholesaler, they will be wrapped up in the regulations on the fingerprinting issue, and a company like UPS with 10,000 employees would have an issue with that.

Senator Wiener:
I'd be happy to address that as we address the concern with the lenders that the bankers had.

Chairman Conklin:
Mr. Capurro, you might want to provide something in writing and please send it to me as well; we will forward it to staff. We'll leave it up to Senator Wiener to work it into her amendment.

Daryl Capurro:
I'd be happy to do so.

Chairman Conklin:
Please keep me apprised of the progress that you make so I can prepare staff for what we may or may not have before us next week.

Senator Wiener:
We'll meet directly following this meeting so we can collaborate.

Chairman Conklin:
The Subcommittee appreciates your efforts. Thank you very much. With that, we're adjourned [at 2:50 p.m.].

RESPECTFULLY SUBMITTED:

_____
James S. Cassimus
Transcribing Attaché

APPROVED BY:

_____
Assemblyman Marcus Conklin, Chairman

DATE: _____

EXHIBITS

Committee Name: Committee on Commerce and Labor

Date: May 12, 2005 **Time of Meeting: 1:40 p.m.**

Bill	Exhibit	Witness / Agency	Description
	A		Agenda
S.B. 37	**B**	Senator Valerie Wiener	Proposed amendment to S.B. 37 (R1)
S.B. 37	**C**	Senator Valerie Wiener	Proposed amendment to S.B. 37 (R1)
S.B. 37	**D**	David Goldwater, Investment Consultant, Caladon Health Solutions, Las Vegas, Nevada	Proposed amendment to S.B. 37 (R1)
S.B. 37	**E**	Elizabeth A. Gallenagh, Esq., Associate Director Regulatory Affairs, Healthcare Distribution Management Association	Letter to Senator Wiener