MINUTES OF THE MEETING OF THE ASSEMBLY COMMITTEE ON COMMERCE AND LABOR

Seventy-Third Session May 6, 2005

The Committee on Commerce and Labor was called to order at 12:07 p.m., on Friday, May 6, 2005. Chairwoman Barbara Buckley presided in Room 4100 of the Legislative Building, Carson City, Nevada, and, via simultaneous videoconference, in Room 4401 of the Grant Sawyer State Office Building, Las Vegas, 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:

Ms. Barbara Buckley, Chairwoman

Mr. John Oceguera, Vice Chairman

Ms. Francis Allen

Mr. Bernie Anderson

Mr. Marcus Conklin

Mrs. Heidi S. Gansert

Ms. Chris Giunchigliani

Mr. Lynn Hettrick

Ms. Kathy McClain

Mr. David Parks

Mr. Richard Perkins

Mr. Bob Seale

Mr. Rod Sherer

COMMITTEE MEMBERS ABSENT:

Mr. Morse Arberry Jr. (excused)

GUEST LEGISLATORS PRESENT:

Senator Bernice Mathews, Washoe County Senatorial District No. 1 Senator Valerie Wiener, Clark County Senatorial District No. 3 Senator Maurice Washington, Washoe County Senatorial District No. 2

STAFF MEMBERS PRESENT:

Brenda J. Erdoes, Legislative Counsel Diane Thornton, Committee Policy Analyst Vanessa Brown, Committee Attaché

OTHERS PRESENT:

Buffy Gail Martin, Government Relations Director, American Cancer Society of Nevada, Reno, Nevada

Sunil Sharma, M.D., Chief, Gastrointestinal Oncology Program; Chief, Phase I Program, Nevada Cancer Institute, Las Vegas, Nevada

Heather Murren, President and CEO, Nevada Cancer Institute, Las Vegas, Nevada

Dianne Buckley, Nevada State Co-Chairperson, Advocates Alliance for Action, National Patient Advocate Foundation, Carson City, Nevada

Phillip Nowak, Chief of Business Lines, Division of Health Care Financing Policy, Nevada Department of Human Resources

Nancy Howard, Assistant Director, Nevada League of Cities and Municipalities

Carol Tidd, Commissioner, Financial Institutions Division, Nevada Department of Business and Industry

Bill Uffelman, President and CEO, Nevada Bankers Association

Danny Weddle, Legislative Advocate, representing Nevada Collectors
Association

Rod Barbash, Nevada Collectors Association

Marel Giolito, President, Nevada Collectors Association

Louis Ling, General Counsel, Nevada State Board of Pharmacy

Keith McDonald, Executive Secretary, Nevada State Board of Pharmacy

David Goldwater, Investment Consultant, Caladon Health Solutions, Las Vegas, Nevada

Robb Miller, President and CEO, Caladon Health Solutions, Las Vegas, Nevada

Janine Hansen, President, Nevada Eagle Forum

Vice Chairman Oceguera:

[Meeting called to order. Roll called.] I'll open the hearing on <u>S.B. 29</u>.

Senate Bill 29 (1st Reprint): Requires policies of health insurance to provide coverage for certain treatments for cancer. (BDR 57-265)

Senator Bernice Mathews, Washoe County Senatorial District No. 1:

S.B. 29 is a phase one clinical trial that is added to the other phase of clinical trials in a bill that passed before. The bill specifically deals with phase I clinical trials. It was brought by the American Cancer Society.

Buffy Gail Martin, Government Relations Director, American Cancer Society, Reno, Nevada:

I support <u>S.B. 29</u>. Nationally, more than 1.2 million new cancer cases are expected to be diagnosed this year. We can expect to lose 555,000 people in 2005 to this deadly disease. In Nevada, 10,300 new cancer cases will be diagnosed in 2005, and we can expect to lose about 4,300 people to cancer this year. We can no longer ignore the opportunities and the hope that cancer clinical trials provide cancer patients and their families. Cancer is a disease that affects the whole person, family, and our society. Only by exercising every treatment possibility can we curb the rates of cancer incidence and death. This bill could dramatically change the lives of cancer patients in our state. Each year, our nation invests more than \$15.5 billion dollars in biomedical research.

One of the most important ways we can advance and increase cancer treatment knowledge is through clinical trials. Clinical trials offer unique opportunities for testing the viability of certain cancer treatments, while at the same time providing opportunities for improved quality of life and survivorship. The American Cancer Society is in full support of <u>S.B. 29</u>, which would increase clinical trial access for Nevadans, and with increased participation, we can find a cure.

<u>S.B. 29</u> is a timely bill. The Nevada Cancer Institute, located in southern Nevada and in northern Nevada, has opened its doors. This state-of-the-art, comprehensive cancer care center will allow for all Nevadans to have access to highly specialized care and greater hope. The Nevada Cancer Institute will also conduct phase I cancer clinical trials.

It is vital that insurance companies operating in Nevada cover cancer clinical trials to ensure our citizens will be able to access the benefits of the Nevada Cancer Institute. S.B. 29 could eliminate the need for cancer patients to leave our state for treatment. Two years ago, this Body passed a law ensuring access to phases II, III, and IV cancer clinical trials, and I assure you cancer patients in our state are grateful for that law. It is now time for our state to join the ranks of 19 other states and the federal government to ensure access to phase I cancer clinical trials.

About 4 percent of adult cancer patients are enrolled in clinical trials, and the number of participants for phase I is very low; approximately 15 to 40 people

participate in a phase I cancer clinical trial. Since we are talking about a very small number of individuals enrolled in phase I trials, the cost effect of these trials is quite small. Studies conducted by the American Association of Cancer Institutes, the Mayo Clinic, and Kaiser Permanente compare the cost of patients enrolled in clinical trials and those receiving standard cancer therapy. The total mean direct medical charges for patients enrolled in cancer clinical trials were less than charges for those receiving standard treatment, so clinical trials offer not only hope, but overall they save money.

[Buffy Martin, continued.] All clinical trials are voluntary, and the patient signs legally binding consent forms releasing any claim of negligence against the facility providing the treatment. In other states where health plan liability has been argued, legal opinions conclude the mere act of providing payment for clinical trials does not make the health plan liable for any possible negligence arising from the trial. As lawmakers, you make decisions everyday that impact Nevadans, and rarely do you have the opportunity to provide such hope and support to those whose lives have been affected by cancer. S.B. 29 would do just that. It would provide hope, new treatment, and perhaps even a cure for cancer. On behalf of the American Cancer Society and our 6,000 statewide volunteers, we urge you to support S.B. 29. [Submitted Exhibit B]

Assemblyman Hettrick:

You said 19 states do this now? [Ms. Martin answered affirmatively.] Would we be unique on the West Coast?

Buffy Martin:

We would not be unique on the West Coast. It's across the board.

Assemblyman Hettrick:

You said the federal government permits this as well? [Ms. Martin answered affirmatively.]

Senator Mathews:

I have not needed a clinical trial, but I'm a 20-year survivor in September.

Sunil Sharma, M.D., Chief, Gastrointestinal Oncology Program; Chief, Phase I Program, Nevada Cancer Institute, Las Vegas, Nevada:

I'm in charge of developing a new drug and development of the experimental therapeutics program at the Nevada Cancer Institute. Everyone on the Committee has a unique opportunity to support cancer research with no incremental cost. New cancer medications are developed in various formats in the laboratory, but the hope they provide to cancer patients comes from their clinical testing. The only way to attract newer therapies for Nevadans is to

guarantee patients who are participating and having access to the normal drugs required for cancer care are covered by the insurance companies in Nevada.

[Sunil Sharma, continued.] We're asking for coverage for usual care. If the patient is undergoing any kind of research procedure, the insurance company will not be responsible for any payment. All patients who are enrolled in clinical trials or are otherwise healthy have to meet significant health criteria, have to sign legally binding consents, and in the event they are not participating in the clinical trial, their usual care would be covered by the insurance company. If the insurance coverage is not available for the clinical trial for their usual customary care, they will be excluded from the trial because they cannot participate.

In order to build a cancer research program in Nevada that everyone can use as a resource and can be proud of, we definitely need to show our support and we urge you, as lawmakers, to help us with this effort. In your folder (Exhibit C), we provided certain articles that indicate most of these clinical trials are extremely safe. They offer a lot of hope and do not incur any incremental costs for the health care system.

Heather Murren, President and CEO, Nevada Cancer Institute, Las Vegas, Nevada:

It's important to the Nevada Cancer Institute that we pass <u>S.B. 29</u>. We are the official cancer center for Nevada, created two and a half years ago. Our role in the community is to carry out research about cancer to hopefully work towards a cure for that disease, and also, through that research to bring cutting-edge types of equipment, treatment, and novel therapeutics to the people of our state. We also provide education, support, outreach, and prevention activities. We've done a good job collectively to be able to bring this effort forward over the last two and a half years.

We are a fairly young cancer center compared to others around the nation. We began with a \$50 million loan, and we've raised \$50 million privately to fund this effort. We are 85 days away from opening a 140,000-square-foot, state-of-the-art cancer research center, and we've brought in people like Dr. Sharma, who comes from Novartis Pharmaceuticals Corporation, and our director from the University of Chicago Cancer Research Center. We're attracting the best and brightest people from around the nation. It's important to be able to carry out phase I clinical trials because we know we have excellent community oncologists here, but what is missing is a more advanced research effort. To be able to provide all of the patients here in Nevada with a continuum of care if a standard therapy doesn't work for them, or if they'd qualify for something that may be better, we offer opportunities here so people don't have to leave the state to seek them. Close to 25 percent of our cancer patients do

leave the state to be treated somewhere else, and we hope to decrease those numbers over time.

[Heather Murren, continued.] A large phase I program would include about 100 patients, so it's a small program where the standard of care would be given anyway, meaning there's no incremental cost, and it sends an important message to the community. We compete as other cancer centers do for grants from donors, from foundations, from the medical community and to bring companies in to work with us. One way we can send a message to them that our state cares a lot about the work we do is through the passage of <u>S.B. 29</u>. We hope you will support this bill.

Dianne Buckley, Nevada State Co-Chairperson, Advocates Alliance for Action, National Patient Advocate Foundation, Carson City, Nevada:

[Read from Exhibit D.] The National Patient Advocate Foundation (NPAF) endorses S.B. 29 regarding health insurance policies to cover clinical trials and studies. However, we urge the Committee to revise the language that limits the study or trials to the state of By limiting the insurance coverage to just Nevada, it creates the potential for access to trial issues because all diagnoses may not be offered in the state of Nevada. Our medical community cannot yet compete with the University of California, San Francisco, or University of California, Davis, on occasion. The medical community here still does not have more resources than the Nevada system does. This is why patients are still referred to California in many cases. The bill as written only allows for clinical trials in the state of Nevada. If changed, this could create access to clinical trials or studies for patients who need to leave the state to enter the NIH [National Institutes of Health] sponsored trials for their specific diagnoses.

We urge this Committee to look at this language carefully and allow for coverage for those patients who don't qualify for clinical trials in Nevada. Please don't deny patients access to health care because the clinical trial isn't available in Nevada for their specific need. Please make sure the language also includes cancer patients currently receiving Medicare and Medicaid. It is necessary that all have access to care. The longer the patient is ill, the longer the patient is in the system.

Vice Chairman Oceguera:

In your letter (<u>Exhibit D</u>), you've outlined your question on this, but do you have those amendments in written form?

Dianne Buckley:

No, we have it written as it's outlined in the letter (Exhibit D).

Vice Chairman Oceguera:

I'll direct you to Ms. Thornton if you have specific concerns with the language of the bill.

Assemblyman Anderson:

Your suggested amendment is well intended, and I want to make sure that people who are not in southern Nevada, where the Cancer Institute is, might have greater access. I know those facilities in northern and southern California tend to be located close to major research hospitals. I'm concerned that this diminishes the opportunity of resources for the development of the southern Nevada facility because those people may have a confidence level with going to more established programs, rather than recognizing the uniqueness of the program we're trying to start in Nevada. I want to make sure people get the treatment they need, and I also want the development of the southern Nevada facility, which is the state facility.

Dianne Buckley:

The National Patient Advocate Foundation in Washington, D.C., strongly supports this bill, and it's absolutely necessary in Nevada. Melanoma is a lethal disease, and currently patients are being treated at the University of California, San Francisco, where the melanoma center is located. I don't want to confuse anyone on my testimony, but once this bill goes through, if their specific cancer need can't be taken care of in Nevada, they shouldn't be penalized because they live in Nevada and they may be able to get that treatment anywhere else.

Assemblyman Anderson:

The bill is of enough importance that we may want to take it as the first step. If we don't achieve your suggested amendment, you wouldn't want to endanger the bill?

Dianne Buckley:

No, absolutely not.

Phillip Nowak, Chief of Business Lines, Division of Health Care Financing Policy, Nevada Department of Human Resources:

We request that there be clarifying language added to the bill in the context of our Nevada State plan for Medicaid, and our Medicaid policy, which does not permit participation in clinical trials due to the exclusion of the federal matching funds in such circumstances. This already applies to the Medicaid membership

that is not enrolled in managed care. The bill does not make clear that this would also be the case for Medicaid and Nevada Check Up members who are enrolled in managed care. The language (Exhibit E) clarifies that members in either program who are enrolled in managed care only as it relates to the Medicaid aspects would not be required to participate in the clinical trials.

Assemblyman Anderson:

That would probably disqualify those senior citizens who nominally are on the Medicaid area from participating in any of these kinds of programs because that would be the only insurance available to them, in terms of medical help, unless they did it on their own nickel.

Phillip Nowak:

The senior citizen population within Medicaid is not enrolled in managed care; there is no managed care coverage. Your statement is correct as it stands, and the issue before us wouldn't be part of this bill. Whether they have coverage through Medicare potential would be a separate matter. As it relates to Medicaid, the current policy would not permit clinical trial participation.

Assemblyman Anderson:

It would hit the senior population more substantially than the other population as a whole, who might be in managed care programs?

Phillip Nowak:

The matter of whether senior citizens who are Medicaid recipients can participate is irrespective of managed care, which is not a factor in Nevada. Medicaid recipients, non-managed care under current Medicaid policy in Nevada, would not be able to participate unless they have other coverage.

Assemblyman Hettrick:

Would you disagree if we amended the bill to say that we would participate, but it would be up to the insured to make up the 50 percent match that the feds wouldn't pay? That way, the insured would not lose 100 percent of coverage.

Phillip Nowak:

Our only concern from the standpoint of representing state's interests is they're not a burden that is not funded to the extent that there is a policy that would enable a recipient through other means or coverages, to participate. We would have no opposition or position.

Assemblyman Hettrick:

If we amended the language to say they could participate, but they would have to make up the 50 percent or the match normally provided by the federal government, you wouldn't have an objection to that?

Phillip Nowak:

From a fiscal standpoint, no. That's a policy decision.

Assemblyman Hettrick:

The fiscal issue is the issue and our job will do the policy. We need to make sure there is not a problem. This idea is not to run off somebody who has coverage through Medicaid and make them pay 100 percent of this. If the feds want to make up the difference, at least it would give them the opportunity.

Nancy Howard, Assistant Director, Nevada League of Cities and Municipalities:

We are neutral on this bill. Our only concern is it's a broadening of a mandated benefit and will in effect increase health care premiums for everyone. That's our only concern. Whenever we see a mandated benefit, we try hard to keep health care costs down. Health care premium costs have skyrocketed and people can't afford it. The benefits of this bill are good, but it is going to increase health care premiums.

Assemblyman Hettrick:

If you're receiving care you normally would have received anyway, but then go into a clinical trial, the way it works now is the insurance companies cut it off. They are saying they want the insurance company to continue paying the exact same cost of care they were paying before, but allow this person to be in the trial. I don't see how that increases cost. The person could have chosen not to go on the trial, or they may die or get sicker, and the insurance company would pay even more. I don't see continuing on with the continuum of care beyond what the trial would do; I don't see how that would cost any more money.

Nancy Howard:

I understand that, and I'm not an insurance expert; however, if they're not paying for something that they now will, they will factor that into the health care premium. It may only be \$1 a month to the increase in a premium, but there will be an increase in premium. I don't know how much, and it may be very insignificant, but there should be something there.

Assemblywoman Buckley:

We appreciate that, but we also realize if we could find a cure for cancer, all of our health care and insurance costs will go down.

Vice Chairman Oceguera:

We'll close the hearing on S.B. 29.

Chairwoman Buckley:

We'll open the hearing on S.B. 431.

<u>Senate Bill 431 (1st Reprint):</u> Makes various changes to provisions governing financial institutions and related business entities. (BDR 55-361)

Carol Tidd, Commissioner, Financial Institutions Division, Nevada Department of Business and Industry:

I've been the Commissioner for almost 18 months, and we've been trying to address several issues across all the licensees we work with. S.B. 431 gets common language across all of our chapters of NRS [Nevada Revised Statutes]. One key issue is getting the fining capability of up to \$10,000 for violations. Right now, it ranges from \$500 to \$1,000. I'm following the model of one of my peers in the Mortgage Lending Division, and \$10,000 gets people's attention, which is consistent across the bill. We're putting consistent time limits on how long it takes to get a business open to go through the approval process. We're eliminating some issues we've had with confusingly similar names for new licensees. We're setting some standardized licensing rules and reconciling some bonding issues. Several of our licensees require bonding. We're doing a lot of work on something that is important to Chairwoman Buckley: the payday lenders. In NRS Chapter 604, one of the key issues is making them licensees instead of registrants. There are several other chapters we're addressing that are various cleanup items and consistent with different chapters of NRS.

Chairwoman Buckley:

In working on the payday loan bill, I was approached by some of the licensed payday lenders about a potential amendment with regard to the unlicensed lenders. Their pitch is that the fine going up from \$500 to \$10,000 is good and gives you more clout, but they do not feel that this is harsh enough. The companies are saving more than \$10,000 in unpaid taxes, payroll taxes, licensing fees, audit fees, and even if they get caught, they're eligible for licensing again. They would like to propose a \$50,000 fine for unlicensed loan sharking, all contracts null and void, higher civil remedies for customers of loan sharks, a misdemeanor, and no eligibility for future privileged licenses. Maybe that's a little harsh. Certainly, we have to make it consistent across NRS for other unlicensed activities, but the point they're making is you shouldn't get away with getting a license after the fact. If we were able to find some

additional penalties that are consistent among other NRS chapters, would that be agreeable to you if we amended that? [Ms. Tidd answered affirmatively.]

[Chairwoman Buckley, continued.] I don't see any more questions. Thank you very much for your testimony. On the issue of the fees, my conversation with the Governor's Office revealed that they're currently reviewing that with the Commissioner, and perhaps where it's broadening but not a new fee, they still might support that. The Commissioner will let us know.

Bill Uffelman, President and CEO, Nevada Bankers Association:

We worked with the Commissioner on the bill and we endorse the amendment to Section 5 of the bill (<u>Exhibit F</u>) on page 2, lines 33 to 36, which effectively strikes that language, because many banks have foreign nationals who are on boards of directors, and the holding company may not be a U.S. domestic holding company. With respect to the potential doubling of the fees, we've also talked to the Commissioner on that issue.

Chairwoman Buckley:

That's going to be worked on a bit.

Danny Weddle, Legislative Advocate, representing Nevada Collectors Association:

We support <u>S.B. 431</u> with the amendment past April 25, and the two amendments ($\underbrace{\text{Exhibit F}}$) done by the Attorney General's Office.

Rod Barbash, Nevada Collectors Association:

We are in agreement with the proposed amendments ($\underbrace{Exhibit F}$), and we hope you pass this bill.

Chairwoman Buckley:

We'll now move to Las Vegas.

Marel Giolito, President, Nevada Collectors Association:

We wholeheartedly support the amendments (<u>Exhibit F</u>) to <u>S.B. 431</u> as they apply to NRS 649. It's a good step in the right direction, and we hope you take positive action.

Carol Tidd:

NRS Chapter 671, the money transmitters section, went through the myriad changes we made; this is common language we had applied to all of our chapters. This had been missed in a couple of the prior versions, so the first grouping is that. The next section of the amendment (<u>Exhibit F</u>) is getting information to do the background checks for licensing and doing investigation

either as part of a complaint or as part of our normal examination process. There are gaps in some of the language in various chapters, so this is a cleanup on that.

[Carol Tidd, continued.] The next four sections were for changing the language in a prior amendment to remove restrictions for those depository institutions for all the depositories that are insured by an outside agency, National Credit Union Administration, America Insurers Insurance, or the Federal Deposit Insurance Corporation (FDIC). We do extensive background checks jointly with those groups, so there were restrictions with the language that we don't need to have in there because we do take care of those through our background check process.

On the last page (Exhibit F), there are several references that are removing language about the 21 years of age limit and the citizen of the United States. Those only apply to the depositories. There is also removal of language that deals with collection agencies for continuing education for qualified managers. We have dropped that. The last section is fine tuning of the collection agency bonding requirements.

Chairwoman Buckley:

On page 2 (Exhibit F), subsection 1 (c), any person who you have reasonable cause to believe is violating, or about to violate, whether or not they claim to be within the authority or beyond the scope of this chapter, it's a question for the Committee as to whether that's too broad and how that mirrors whatever existing regulatory authority an agency has over unlicensed activities, which I assume is the intent of that paragraph. Do you have any comments on that question?

Carol Tidd:

We took that out of one of our other chapters of NRS, I don't have a specific reference for you but I can get that for you. I don't think it was completely new language, but I'm not sure what chapter it came from.

Chairwoman Buckley:

We'll have Brenda check into that and make sure it's consistent with our other chapters. Thank you for your testimony. With that, I'll close the hearing on S.B. 431, and I'll open the hearing on S.B. 37.

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

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

I urge your support for <u>S.B. 37</u>, which both expands current law regulating pharmaceutical wholesalers and requires pharmaceutical wholesalers to electronically track prior sales of prescription drugs.

For those of my colleagues who participated in the 72nd Legislative Session, my bill allowed for one re-issuance of prescription drugs if the unused drugs were uncontaminated. The re-issuance, in certain settings, was carefully tracked to ensure the integrity of the re-issued drugs. This involved only one re-issuance of unused drugs in state corrections facilities, long-term care facilities, nursing homes, mental health facilities, and for long-term hospital patients in rural hospitals. This legislation was passed and has the potential to save Nevada millions of dollars.

With my concerns about protecting unused drugs throughout the re-issue process, I became concerned about the protection of other drugs in the normal chain of distribution for our citizens.

Two years ago, I learned about Governor Jeb Bush's aggressive efforts in Florida to protect the integrity of drugs from the point of manufacture to retail sale. I asked for a bill draft request to ensure that Nevada offered important statutory protections for our citizens, people who purchase prescription drugs with full faith that their prescription drugs are real and uncontaminated.

<u>S.B. 37</u> is the end product of this effort and represents my intentions to ensure essential protections to the prescription drug consumers in our state. <u>S.B. 37</u> allows our state to remain a national leader in developing increased accountability for pharmaceutical wholesalers. Currently, Florida and California have substantial laws in place, and 11 other states are considering legislation similar to S.B. 37.

This legislation responds to Food and Drug Administration policy, effective in January 2007, which will require all prescription drugs to be subject to an electronic pedigree tracking system. In fact, the Department of Defense has utilized a Radio Frequency Identification (RFID) system for years and is adapting this tracking system to its pharmaceutical products. Also, major drug store chains in our country, such as Wal-Mart, Rite Aid, and CVS, are already utilizing the RFID tracking system.

<u>S.B. 37</u> expands on current laws affecting pharmaceutical wholesalers. This bill mirrors the National Association of Boards of Pharmacy Model Rules for the Licensure of Wholesale Distributors. It also mirrors the model rules for legislation

developed by the Healthcare Distribution Management Association (HDMA), the national trade association for drug wholesalers.

[Senator Weiner, continued.] Like both of these national associations, <u>S.B. 37</u> requires criminal background checks of applicants for wholesale prescription drug distribution licenses. It requires a \$100,000 bond or other form of surety which, pursuant to this bill, our Pharmacy Board may reduce, after 5 years, to as little as \$5,000. It strengthens pedigree requirements—which is the tracking to ensure the integrity of the drug—for prescription drugs, by requiring a wholesaler to prepare, deliver, acquire, and maintain a statement of prior sales pursuant to regulations adopted by the Board.

This bill strengthens authorized distributor status. It requires electronic pedigrees by what the federal standards will be on January 1, 2007. It criminalizes certain harmful wholesaling conduct. S.B. 37 provides for a Category C felony under certain circumstances in Section 7 and Section 8 of the bill.

Currently, Nevada has 38 pharmaceutical wholesalers who are domiciled in Nevada and are licensed by the Board of Pharmacy to do business here. Around 400 wholesalers, though located elsewhere, are licensed to do business in Nevada. Our state has experienced its own problems with unlawful wholesaling practices. I would defer to Louis Ling, representing the State Pharmacy Board, to explain this in greater detail.

The first amendment (Exhibit G), requested by Bill Uffelman of the Nevada Bankers Association, addresses references to "lender" in Section 2 and Section 3 of the bill. It was not my intent when preparing this legislation to include regulated banking institutions in this reference.

The second amendment (Exhibit H) was offered to me by former Assemblyman David Goldwater on behalf of Robb Miller and his company, Caladon. I greatly appreciate Mr. Goldwater's efforts to work with me on S.B. 37. However, after carefully reviewing his proposed amendment, I want to express my concerns about this amendment's content and potential impact on the public, and also state that I do not support it.

The amendment (Exhibit H) is six pages of new language and deletes Sections 4 through Section 13. The amendment offered by Mr. Goldwater strikes three of the four basic components of S.B. 37. The amendment completely removes the \$100,000 bond requirement, which is critical in assisting the Pharmacy Board with relevant investigations. The amendment completely removes the electronic pedigree requirement, which is necessary to ensure the integrity of the

prescription drug from manufacturer to pharmacist. The amendment completely removes the criminal penalties, which are necessary for holding wholesalers accountable, especially those who might put the consuming public at risk with counterfeit drugs.

[Senator Weiner, continued.] In addition to these deletions, the amendment (Exhibit H) also modifies the fingerprinting requirement by narrowing who must give fingerprints, how often the wholesaler must report to the Board, and which wholesalers will even be subject to the fingerprinting requirement. In effect, this amendment would completely undo the current regulatory scheme, parts of which took several months to develop through a strong collaborative effort. These consensus regulations were based on recommendations from a committee comprising representatives from the pharmaceutical industry, the general public, Nevada drug wholesalers, HDMA, and other affected parties. regulations These comprehensive were approved by the Legislative Commission's Regulatory Subcommittee on February 28.

You will find language in the amendment (Exhibit H) that seeks to replace these regulations starting with Section 7, subsection 2, through Section 10. Other regulations that would be undone by this amendment have been in place since their legislative approval in 1992 and 2001. The amendment also seeks to redefine key concepts. Section 7 (Exhibit H) changes when a pedigree is required and who qualifies as an authorized distributor. Section 8 (Exhibit H) changes from whom a wholesaler may make purchases. Section 9 (Exhibit H) changes what qualifies as a bona fide transaction. Section 10 (Exhibit H) changes when and how a wholesaler must produce routine records upon request from the Board.

One of my greatest concerns is how this amendment weakens protections for the public, which was, and is, the primary reason I introduced $\underline{S.B.\ 37}$. Once I learned about what Governor Bush was doing in Florida to protect that state's citizens, I got to work on a similar plan for Nevada. Counterfeit drugs are increasingly profitable and more commonplace than ever before. My intent remains constant: to protect Nevadans from the dangers of unscrupulous wholesalers and practices that can lead not only to serious health consequences, but also to death. This is why I offered $\underline{S.B.\ 37}$ as a strong consumer protection bill.

Much of the language of this amendment has already been proposed to the Pharmacy Board and was rejected in 2002. Later, in the 2003 Legislative Session, similar language was proposed through the subcommittee process, and that, too, was not accepted. However, none of the language of the amendment

was offered during the nine-month-long regulatory hearings process in which the Board engaged throughout 2004.

[Senator Weiner, continued.] <u>S.B. 37</u> was processed and amended through subcommittee and committee work in the Senate. The first reprint (<u>Exhibit G</u>) before you reflects the substantial effort of my colleagues in the Senate. The amendatory language (<u>Exhibit H</u>) offered to you today was not included in the first reprint (<u>Exhibit G</u>). I want to stress that the six-page amendment (<u>Exhibit H</u>) will virtually undo both the regulatory work of the Pharmacy Board and the statutory work of the Senate.

S.B. 37 addresses an important health and consumer protection issue in Nevada. The federal government has laid out its standards for prescription drug protections. National associations have established their model language and standards regarding pharmaceutical wholesalers. Nevada's Pharmacy Board has developed rigid regulations that mirror these federal government and national association standards to address the need for crucial consumer protections. We, as Nevada legislators, have a responsibility and opportunity to adopt critical and necessary statutory protections for our citizens. With statutory protections, we can help ensure the safety that our citizens both demand and deserve in their pharmaceutical purchases. It is for these reasons that I urge you to support S.B. 37.

Louis Ling, General Counsel, Nevada State Board of Pharmacy:

We reviewed <u>S.B. 37</u> in its existing form and have unanimously endorsed the bill. This bill reinforces industry norms amongst good wholesalers who are practicing already within these industry norms. That's why you're not seeing any opposition to this bill from the major wholesalers. You have a letter from the HDMA (<u>Exhibit I</u>) that was written two days ago. They raise a couple of small concerns with the bill, and say,

In particular, we thank you for including several of the measures we recommend in our model legislation, such as criminal background checks for applicants, a requirement for applicants to obtain a surety bond or other security, recognition of the industry's movement toward an electronic pedigree solution, and increased penalties (Exhibit I).

The HDMA is saying they support the four pillars of Senator Wiener's bill. We have prepared a packet (Exhibit J). In the last couple of weeks, events have occurred nationally that show how important this bill is and how important it is to keep Nevada on the front of the issue of regulating wholesale distribution of drugs.

[Louis Ling, continued.] Elliot Spitzer, the Attorney General of New York, has just executed subpoenas against the three major wholesalers as well as a number of secondary wholesalers in New York. He's investigating the relationship between the major wholesalers and the secondary source industry and how counterfeit drugs have managed to get into the nation's drug supply. On February 28, the FDA [Food and Drug Administration] indicted seven secondary source wholesalers. In the back of the book (Exhibit J), there are five pages of that document. The secondary source wholesalers were engaged in the kinds of behavior that S.B. 37 is intended to address, and the FDA felt compelled to notify the public of the 80 pharmacies involved in this that bought these drugs out of the secondary source market. On the last two pages of the book (Exhibit J), there are 27 drugs that were affected by this indictment and may have been compromised. They're asking for a voluntary recall from these pharmacies, warning patients that the drugs they receive from these pharmacies may be compromised. Most of these pharmacies were in California and New York.

The book *Dangerous Doses* (Exhibit J) was written by a Rhodes scholar, Katherine Eban, who spent two and a half years researching this industry and how counterfeits have gotten into the nation's drug supply. In chapter 24 (Exhibit J) is Nevada's experience with counterfeit drugs. She attended the Board of Pharmacy's hearing regarding this case. We just argued this case on judicial review yesterday in front of Judge [Valerie] Adair in Las Vegas. She also has three sheets in the front of this packet (Exhibit J) showing you the drugs that have already gotten into the U.S. drug supply that have been counterfeited, what the counterfeits were, what happened, and she has also included a fact sheet (Exhibit J) of the problems with tainted medicine in America and how the secondary source wholesale market has been instrumental in getting these counterfeit drugs into the hands of patients in the United States.

In two weeks, the Nevada Board of Pharmacy will be receiving the Fred Mahaffey Award at the National Association of Boards of Pharmacy meeting, which is awarded to the state board of pharmacy who is doing the most in the country to protect the public. We're being recognized for our efforts in regulating the secondary source wholesale market and our efforts in enforcing the present laws. We are one of the lead states in the country right now in dealing with bad wholesaling and the dangers it presents to the public. We've been writing these regulations since 2001, and we spent last year writing a new set of regulations to strengthen our position and that was approved as the Senator raised on February 28.

[Louis Ling, continued.] Two days ago I received a call from a man who was going to make a presentation to the Board of Pharmacy from the company Acerity (Exhibit J). Acerity has developed a software solution that will implement the RFID track-and-trace technology so you could track a drug all the way from the manufacturer to the pharmacy via computer systems. They're going to present this software solution to the Board of Pharmacy in three weeks. We're excited to know that software is there and the hardware exists. The major component that must occur is we need to get the manufacturers to start putting these tags on the bottles. The component of S.B. 37 that has the January 1, 2007, date to get the electronic pedigree system in place is critical to this bill. Electronic track and trace is the single best way to protect the public from counterfeits and other things, and if we can keep the manufacturers' and the industry's feet to the fire on this with states like us, California, Florida, and the FDA putting these timelines in place, we can keep this thing moving and maybe we will get our RFID in place in the next couple years.

On the last page of the book (Exhibit J), we are very excited that one of the big three wholesalers, Cardinal Health, just announced in the Wall Street Journal yesterday that they aren't going to buy drugs out of the secondary source market anymore. If the other two wholesalers follow suit, much of what's in S.B. 37 will not be necessary because as the secondary source wholesale market has been supplying drugs to the major wholesalers, if they all refuse to buy from a secondary source industry, we couldn't be more excited because it keeps the possibility of counterfeit from entering into our pharmacies in Nevada very low and minimizes harm. Those are all things that are coalescing right now and within the last couple of weeks have proven the necessity of S.B. 37. This bill reinforces industry norms; it will allow us in Nevada to have tools which are explained in Dangerous Doses (Exhibit J).

In Florida they can do this to law enforcement, so they can arrest the people who are doing this and this book is all about how that works and how hard a few dedicated men in Florida have been working to crack down on this industry. In Nevada, if you were to commit the same kinds of crimes in this book, you would walk away with nothing. S.B. 37 provides no tools whatsoever, from a law enforcement basis, to reach this kind of conduct. Again, to reinforce what Senator Wiener said, we have been provided a copy of the amendment from Mr. Goldwater (Exhibit H), and that amendment would not only remove three of the four pillars of her bill, but it would also gut the last four years' worth of work the Board of Pharmacy has been engaged in, and it's a shame the language that shows up in Mr. Goldwater's amendments (Exhibit H) was not presented to the Board. We've had seven meetings over the course of nine months to set these recent regulations that were just passed by this Body, and this language never showed up.

Chairwoman Buckley:

I find this information really fascinating. Let's get to the heart of it. I'm sure everyone wants to ensure the safety of our drug supply, and this Committee supports anything we can do to make sure that happens. Let's go to the bill and talk about how it does that and whether there are any portions of it that overreach the goal of trying to keep everyone safe. Let's do this section by section and then open it up for questions so we have a good understanding of it. The first part of the bill is the fingerprint part?

Louis Ling:

Presently, the Board of Pharmacy does not have the authority to gather fingerprinting. *Dangerous Doses* and our own personal cases in Nevada highlight that people who have been convicted felons in either illicit drugs like cocaine or other trafficking, or convicted in the trafficking of pharmaceuticals, can get licenses almost anywhere right now. Florida put in the fingerprinting requirements, but we don't have that authority right now, and we'd love to be able to do that. Right now, we run a background check as best we can using publicly available databases, but it's time consuming and not nearly as accurate or comprehensive as a fingerprint check would be.

Chairwoman Buckley:

The proposal on fingerprints is in Section 2, natural person, the person partnership, each partner, corporation, each officer and director of the corporation, sole proprietorship, and then in addition you get a list of every employee, consultant, guardian, and then you can require fingerprints of them. That seems really broad, and I don't care what the regulations are because the Legislature can do what it wants to do. It would seem like the buck stops at the top. If they're a corrupt company, you yank their license and throw them in jail. Why do that to every employee and consultant? What if it's a consultant on human resources? Give the Committee some information on that.

Keith McDonald, Executive Secretary, Nevada State Board of Pharmacy:

We've had many people apply for licenses by submitting their children or other individuals as the principals of the business, when indeed they're the ones operating the entire activity behind the scenes. They call themselves consultants or administrators, and they put persons up in the business who have nothing to do with it as a front. In the business we call that person a strawman, which is the reason for the extent of the bill. We didn't recommend those numbers of individuals to be fingerprinted, but that's what Florida did, and consequently Senator Wiener included it.

Chairwoman Buckley:

Of all the wholesalers doing business in Nevada, whether licensed here or out of state doing business here, how many concern you? How many do you have questions about?

Keith McDonald:

In Nevada, we have about 38 and around 400 are licensed to do business in the state. There's approximately half a dozen or less who are people more interested in buying and selling drugs amongst themselves and other people. The national wholesalers who are here, MERCK, PFIZER, and Henry SCHEIN, and others are not here today to object because they don't find this to be a problem.

Chairwoman Buckley:

Is there an easier way to get at the 6 than to make 400 good companies have to update every employee, consultant, independent contractor, every month? Is there any more surgical way to get at those folks who are hurting our drug supply?

Keith McDonald:

The Board of Pharmacy would have no problem if it was reported quarterly. Those we're interested in are small in number, but we also had another concept at one time that was not introduced in this bill. If they're publicly traded companies licensed with the SEC [Securities and Exchange Commission], they wouldn't be required to follow those particular portions of the bill. Someone suggested that was unfair, so it's in as is.

Assemblyman Conklin:

In Section 1, subsection 1, I wonder if we're violating some due process here because it appears we're criminalizing every business that does this. Although there might be some bad apples out there, they probably aren't all that way. My question relates to lines 8 and 9. Are we submitting these fingerprints to the Central Repository for matching or for submission into the system? There's a significant difference because that system is designed for criminals, people who have committed crimes, not for anyone who submits fingerprints for business licenses. I've done it several times for business licenses in my industry, so it's not the fingerprint that's the issue, it's the way that it's treated and the way the businessperson is treated based on what you do with that fingerprint. I'm curious what your intent is with that particular language.

Louis Ling:

This is not our bill, so our intent is not an issue here. Our understanding of what Senator Wiener is trying to do is that we would be able to check the criminal

backgrounds of the principals, and these concepts were borrowed from gaming, where the same intent is to keep out of gaming and buying and selling drugs. Certain people would not otherwise be honest on their applications potentially. For example, with the last person who applied to us for a wholesaler license, I could only find information from the publicly available resources, and they had lied to us. They said they didn't have a criminal background, and we found they did. The fingerprint check is actually fair to the applicants because it's a standard process, and everyone does it; I had to be fingerprinted to become a lawyer. You're going to get all of the data.

Assemblyman Conklin:

I understand that it's used, but I want to make sure it's used to check and not that we are submitting these for future cross-reference checks, as we do for criminals. That's how we populate the database in the first place, and it doesn't read that way.

Chairwoman Buckley:

Maybe if you limit it to any individual either operating the company or substantially participating in the operation of the company, rather than every consultant, to get at what you're trying to get at. If someone is using a strawman, then you could get to them, but otherwise you couldn't.

Assemblyman Conklin:

There's language littered through the bill that reads "exercise significant influence over the operation of the applicant or over the operation of the wholesaler, or over operation..." I've never come across that language before and it strikes me as incredibly broad. I'm wondering if there's a definition out there somewhere. What is the intent of that language? It's in Section 2, subsection 2; subsection 4; Section 3, subsection 2; and in Section 3, subsection 3.

Chairwoman Buckley:

We'll check with our legal counsel.

Louis Ling:

That language was borrowed from gaming because that's where gaming gets their concept of anyone who might be in control. Anytime you put a laundry list on, they look at the laundry list and give them a title that's not on the list. What you're really looking to do here is find who owns the business and is really running it, because oftentimes in this industry we get on the applications names of people who know nothing about what they're doing except that they were put up to have their name on the application. That's what we're trying to get at here. It's not the intention of Senator Wiener to give this Board the authority to

ask for fingerprints from everyone. The Board of Pharmacy wouldn't be benefiting from that. All we're looking to do is find who really is going to run this business and find out about that person.

Chairwoman Buckley:

Let's move to Section 3. There are probably the same kinds of questions and concerns as to how we get at strawmen but not unduly hurt the rest. Let's move on to Section 4.

Louis Ling:

On Section 3, the Board of Pharmacy gets lists like this on an annual basis from our pharmacies. We inspect the pharmacies and pull the list of all their employees. Then pharmacies are required to tell us within 10 days whenever pharmacists leave their employment or hire on so that we know who is where. That might be a provision you could parallel here if this is going to get some technical amendments.

Chairwoman Buckley:

Are there any questions on the bonding amount? How does that relate to other bonds that are used, for example, with pharmacies in Nevada? How does that compare?

Louis Ling:

I did a search across all of the Title 54 Boards to see what kind of bonding requirements are out there—the \$100,000 bond, or anything in that range from \$50,000 to \$100,000, almost always seems to turn on either fiscal trust, or in this case, trusting people with lifesaving drugs. The \$100,000 bond is on the high end, but that's why the bill allows that bill to be knocked back to \$5,000 if the person in business has been operating well in the state for five years, at the Board's discretion. That \$100,000 bond came from Florida's legislation, where Senator Wiener got her inspiration for this bill. It has worked in Florida very well, and we keep in touch with the Florida regulators.

Chairwoman Buckley:

Let's move on to Section 5, the statement of prior sales. Is that to track one drug's life from manufacturer to final point?

Louis Ling:

The idea is to have a transparent drug handling system so that regulators can track a drug all the way from the manufacturer to the pharmacy. Everywhere that drug stops all the way along needs to get added to this document. We call it pedigree. The pedigree is intended to create that transparency, and eventually that will be electronic, which is one of the key features of this bill, so that it will

eventually be impossible to forge or make fraudulent. One of the biggest problems in this industry right now, as detailed in *Dangerous Doses* (Exhibit J) and in our cases, has been fraudulent pedigrees, people who make things up, stick it on a piece of paper, and you have to check it all out.

Chairwoman Buckley:

Is this the best way to do it? Couldn't they just make up where they got it from?

Louis Ling:

No, this is tracking federal legislation from the PDMA [Prescription Drug Marketing Act] originally. The feds have never fully implemented this at the federal level, so they've left it to the states to do this. In Nevada, we've been a lead state on this. Our wholesalers have had to provide pedigrees since 1992, so this is the industry norm.

Assemblyman Conklin:

I've read the chapter of the book (Exhibit J), so I recognize there is a problem here. What bothers me a little bit, and maybe you have a solution to this, what we're doing here is tracking and regulating to a certain level the wholesaler, when we're talking about a bad drug, a contraband drug that's been manufactured somewhere else. Who's handling that section? It seems that we'd be dealing with that first because if we could stop the source of a bad drug, a significant portion of this problem would be resolved.

Keith McDonald:

The problem is that drug counterfeiters aren't identifying themselves, and they're very hard to find because they've used every kind of printing and relabeling device and using products one-tenth of the strength with a false label. It's manufactured so that even the keen eye of a person who handles these drugs all the time can't identify it. The persons who have done that and put them into a marketplace, only through the secondary source drug market, have entered counterfeit drugs into the system of the United States. That's the only place they've entered into. Manufacturers aren't making counterfeits. The regular wholesalers who sell downstream to pharmacies aren't making counterfeit drugs. The secondary source market is the only place where these drugs enter. You can't find the counterfeiters, because the first person who bought them knew they were committing a criminal act and they aren't going to identify them.

Louis Ling:

Our experience with the counterfeiting case, which is documented in the book $(\underline{\text{Exhibit J}})$, shows what's wrong with the paper system. The representations

made to the Nevada wholesaler from the Florida wholesaler were that the Florida wholesaler, through the pedigree, represented that he bought the drug from a manufacturer. He's not going to tell you he bought it from a counterfeiter, so he made up a phony piece of paper saying he bought this drug from the manufacturer and sold it to the Nevada wholesaler, making that false representation.

Assemblyman Conklin:

In some other areas of criminal law, we attempt to minimize the criminal impact of the actual act itself, purchasing from a counterfeiter in an effort to capture the counterfeiter. It would appear that here we're doing just the opposite. We're not caring about the counterfeiter, we're penalizing the source who may or may not know he purchased from a counterfeiter, but because there's a possibility there, he is not going to admit to it. Did you explore that option at all?

Louis Ling:

As we've seen in the four cases we've prosecuted, when you're dealing with a counterfeiter, someone who is making phony paperwork, a reasonable businessman looking at the circumstances wouldn't buy from that situation. The testimony was clear that you could only get this drug for a certain price. When the drug shows up on these phony pedigrees, it's literally half that price. If I offered to sell you a Rolex watch for \$100, you'd know one of two things: either it's not a Rolex watch, or I stole it. That's the way this industry works, and we all have to trust these wholesalers. All of our drugs pass through their hands. We all are forced to trust them, and we also have to put a commensurate obligation in responsibility on them because they're the ones who can protect our drug supply, not us. I can't watch every possible sale, so I have to trust them, which means they have to protect their supply lines by knowing who they're buying from, and when the price is too good to be true, it really is. That's not a hard judgment to make. We don't have any other way to police the system. We have to police the paperwork after the fact; that's all we can do.

Keith McDonald:

There's one other problem that's very serious. We're a state agency and we can't cross state lines, and invariably these drugs cross state lines for that very purpose.

Louis Ling:

S.B. 37 in its present form is going to keep us out on the front of the national curve here. There are 14 other states that will possibly join us, and soon the states will fix this problem. The amendments proposed by Mr. Goldwater (Exhibit H) will knock us back five years and all of the innovation and hard work

the Board of Pharmacy has put into this issue will be thrown away. We urge you not to consider those amendments.

Bill Uffelman, President and CEO, Nevada Bankers Association:

The one page amendment (Exhibit G) that removes banks from the list of people who potentially could be fingerprinted under Section 2, subsection 2 of the reprinted bill, was put in by Senator Wiener. She didn't intend to capture those who were already regulated in the fingerprinting business. We appreciate her effort to remove us from the bill.

David Goldwater, Investment Consultant, Caladon Health Solutions, Las Vegas, Nevada:

As a member and chair of this Committee, I got involved in this issue, and over the interim I was contacted to meet with the secondary pharmaceutical wholesalers. We were involved in the 72nd Legislative Session that allowed the Board to create some regulations. The Board used their power to regulate a small portion of an industry out of business. The essential policy question before the Body is, do you or do you not want to have secondary wholesalers involved in the distribution of drugs? You want to regulate or get them out because there are counterfeiters and bad actors who do act poorly, and if we get that portion of the business out, then retailers can deal directly with manufacturers or with the larger primary wholesalers, which might be better for the consumers in Nevada. That might be a policy question you want to decide on. On the other side, there is a viable secondary wholesale market. As a policymaker, I made the decision that a secondary wholesaler was a good thing because it was a consumer protection or regulatory partner that would exist. There are plenty of other avenues for counterfeit drugs to get into the nation's drug supply.

We passed this bill, and the Board continued to regulate the secondary wholesalers. Mr. Ling's and Mr. McDonald's conduct regarding pharmaceutical wholesalers has been so egregious that they have been sued personally in federal court for attempting to put these guys out of business. They have had injunctions placed upon them and have motions pending. The State and the industry have spent hundreds of thousands of dollars litigating what is essentially two rogue agents of the State operating to put someone out of business. What they did is the equivalent of the Executive Secretary of the Ethics Commission, rather than bringing a good case through the system for you, starting to go out to your constituents and say, I'm from the Ethics Commission and you're a bad representative. That's the type of conduct they've engaged in against these secondary wholesalers, and a case is pending in federal court.

[David Goldwater, continued.] In State court, in the items throughout this book (Exhibit J), there was a preliminary ruling, and the \$1.4 million worth of fines the Board levied are gone, not legitimate, nor worthwhile. The license revocation is not justified. Mr. Ling is quoted (Exhibit J) as saying, "The lawsuit alleging that Ling and McDonald aimed to drive all secondary wholesalers from Nevada has proof, having told their lawyer he would 'continue to piss in your client's soup until they get out of Dodge'." We have a policy question: which are wholesalers or not wholesalers? That policy question isn't to be decided by the Executive Branch or the Board of Pharmacy, but by you, the elected members of the Legislature. If you decide you don't want wholesalers, I support you; get all the secondary wholesalers out. If you decide you want wholesalers, and the State wants a regulatory partner and someone to help protect consumers, then we need to pass statutes that create a statutory and regulatory framework that's workable for these guys to stay in business.

Chairwoman Buckley:

Let's shift to the bill now.

David Goldwater:

Before you is a proposed mock-up amendment to <u>S.B. 37</u> (<u>Exhibit H</u>). I support <u>S.B. 37</u>, and we're here to help promote a regulatory environment that's worthwhile.

Robb Miller, President and CEO, Caladon Health Solutions, Las Vegas, Nevada:

I am a drug wholesaler. I sell primarily to mail-service pharmacies, big chains, and local surgery centers. I purchase 95 percent of my products directly from the manufacturer or from one of the three major wholesalers. I'm a self-funded company, so I use other wholesale partners to reach mail-service pharmacies and the big chains because they demand longer terms than what I can afford to extend. That's why I've been tagged with being a secondary wholesaler, because I'm not a primary wholesaler, so I don't ship my entire product directly to the dispenser. I may work through another wholesaler to reach certain customers.

Chairwoman Buckley:

Can you discuss your views on our conversation about trying to do more fingerprinting of those who have a substantial position with the company?

Robb Miller:

I support fingerprinting. I've been fingerprinted to obtain licenses in other states, and it's an excellent attempt to find out who is in charge. Regarding the existing process, Mr. Ling said someone applied for a license and had lied to them about having a criminal background, so at some level the existing system does work.

We do support fingerprints for the applicants. Strawmen have been an issue in the past, but fingerprinting all of these other individuals is beyond what's necessary, as you alluded to.

[Robb Miller, continued.] We definitely support the electronic pedigree. This issue with the current pedigree is that it can be forged very easily because it's merely a piece of paper. The amendment I put forth, until the radio identifier issue, would definitely solve the counterfeit problem, but until that technology is adopted by the manufacturers, there needs to be a way to certify that a pedigree is accurate. I think the amendment (Exhibit K), in Section 7, puts upon me that I must research who I'm doing business with and document those things in a fashion that the Board of Pharmacy can't at this point. One of the challenges that Mr. Ling and Mr. McDonald have had in enforcing things in the past is reaching across state lines, asking a regulatory agency in another state to look into a person, and maybe they don't have the resources. My compromise proposal forces me as the wholesaler to go out and gather a lot of information on whoever I'm doing business with, if they are a wholesaler, and gives the Board the ability to reach across state lines in a fashion they wouldn't if I didn't exist. I have to gather and certify that the information I'm receiving is real for anyone I'm doing business with. I also have to inspect their facilities. Mr. Ling and Mr. McDonald could not fly to California and inspect someone else's facility. I can be forced to do that and I can keep those documents for their inspection at any time. In Section 4, 1(d), no state requires a wholesaler to receive a product liability insurance policy of \$1 million.

Section 6 refers to site inspection documents. Part 4 of Section 6 requires I get a signed contract with another wholesaler saying they're going to comply with the law, and if they don't, or there's any kind of material change, I can't do business with them.

Assemblyman Anderson:

My concern relates to the background check of the wholesaler you're going to deal with. In terms of good business practice, are you not aware of the reputation of the wholesaler you would be buying from?

Robb Miller:

I am; however, there are those who have existed in my industry who do not do that. This would require that.

Assemblyman Anderson:

Would that not be a good thing to do to make sure everyone plays by the same set of rules? Because the consumer is relying upon the local pharmacist who I buy from, who bought from you, he's relying upon your integrity, right?

Robb Miller:

Absolutely. That's why we're proposing this.

Assemblyman Anderson:

Does S.B. 37 do that initially?

Robb Miller:

It does, but in an arduous way that's very difficult for me to comply.

Assemblyman Anderson:

Because you'd have to physically go there?

Robb Miller:

No, I'm actually proposing that I'd have to physically go there. Counterfeits have only entered the marketplace through unregulated secondary wholesalers. The way the counterfeiters are able to get their drugs into the normal supply chain is by lying on these pedigree forms. They move the drug around through three or four different entities, washing the pedigrees so the pedigree is legitimate at some point; it's not just made up. My proposal requires I verify that pedigree in a way that the Board of Pharmacy can't because they would have to reach across state lines. Although I only buy about 5 percent of the products I sell from other wholesalers, I do go and visit people, and I have a long-term business relationship with them. I do my due diligence, and some don't. This proposal (Exhibit K) is something I'm already compliant with. It's a codification of the HDMA guidelines and was brought up by Mr. Ling and Senator Wiener. The HDMA has been in support of a lot of these things. I drafted a lot of this amendment (Exhibit K) from the HDMA guidelines, which were voluntary and were developed by the largest trade association. I'm already complying with those and they're a fair compromise so why don't we codify those now?

Chairwoman Buckley:

I'm going to put this into a subcommittee and allow a few people to sort through it. The bill probably would be supported in some measure, but perhaps it can be worked out a little more. I'll ask Assemblyman Conklin to chair it and Assemblywoman Gansert to serve on it. I'll close the public hearing on $\underline{S.B. 37}$.

On <u>S.B. 80</u>, I have a proposed amendment on that bill. If the Committee wouldn't mind doing a motion to reconsider, I could replace it on work session with the amendment.

ASSEMBLYMAN PARKS MOVED TO RECONSIDER SENATE BILL 80.

ASSEMBLYMAN CONKLIN SECONDED THE MOTION.

THE MOTION CARRIED. (Assemblyman Arberry and Assemblywoman McClain were not present for the vote.)

Chairwoman Buckley:

We'll now turn to our Work Session Document (<u>Exhibit L</u>). Let's start with S.B. 3.

Senate Bill 3 (1st Reprint): Revises certain provisions relating to regulation of public utilities. (BDR 58-656)

Diane Thornton, Committee Policy Analyst:

<u>S.B. 3</u> increases the maximum amount of civil penalties that the State may impose for violating any regulation of the Public Utilities Commission of Nevada conformity with the federal Natural Gas Pipeline Safety Act of 1968 as amended, and for violating a federal regulation adopted pursuant to that Act. The maximum penalty is increased from \$10,000 per day for each violation to \$100,000 per day, and from \$500,000 for any related series of violations to \$1 million.

Additionally, <u>S.B. 3</u> provides that certain sections of the NRS addressing aspects of railroad regulation are suspended as long as they are preempted by federal laws. If federal laws are subsequently repealed, the State provisions will again be enforceable. Testifying on behalf of the bill was the Public Utilities Commission of Nevada. There were no amendments and no opposition to the bill.

Assemblyman Anderson:

I've had an opportunity to meet with people from Public Utilities Commission (PUC) and the railroad inspection section, and while I remain concerned about the general operations and the railroad safety inspection programs that are in place, I believe the PUC is making a good-faith effort to try to carry out that. I believe they will need additional help in the future to carry out some of the attempts. I remain concerned about the preemptive nature of interstate commerce and how the railroads often hide behind the preemptive nature of that business, but I'm willing to support the bill as it's presented here.

ASSEMBLYMAN ANDERSON MOVED TO DO PASS SENATE BILL 3.

ASSEMBLYMAN PARKS SECONDED THE MOTION.

THE MOTION CARRIED. (Assemblyman Arberry and Assemblywoman McClain were not present for the vote.)

Chairwoman Buckley:

We'll open the hearing on S.B. 240.

Senate Bill 240 (1st Reprint): Enacts provisions relating to health benefit plans that have high deductibles and are in compliance with certain federal requirements for establishing health savings accounts. (BDR 57-47)

Senator Maurice Washington, Washoe County Senatorial District No. 2:

S.B. 240 would allow health insurance companies in Nevada to offer a policy to allow people to establish health savings accounts (HSA) as referred to under the federal law. HSAs were established in federal law in December of 2003. They are tax-free accounts designed to help individuals save and pay for health care expenses. The money in HSAs can be spent on qualified medical expenses like prescription drugs, medical care and services, diagnostic devices, as well as some non-prescription drugs for things such as eye care, dental care, and other items of services. The money in HSAs can also be used to pay premiums for qualified long-term insurance or for COBRAs [Consolidated Omnibus Budget Reconciliation Act], or other health insurance used during the period of unemployment. HSAs must be established in conjunction with high deductibles from health insurance policies that have an annual coverage deductible of at least \$1,000 for individuals and \$2,000 for families. Health plans may cover preventative care before the deductible is spent. A combination of health savings accounts may be made by either employers or the individuals and may be carried over from year to year.

In 2005, the annual contributions can be up to \$2,650 for an individual or \$5,250 for families. When an individual makes contributions and takes above-the-line deductions up to \$2,600 on the federal income tax, and a family takes a deduction up to \$5,150, although similar measures have already been passed, such as medical savings accounts, there is a difference between HSAs.

They're less restrictive, they're broader, and the rules are more open so the eligibility can be expanded. They provide tax breaks and they have a low annual deductible.

[Senator Washington, continued.] In 2004, 26 states considered health-savings-related legislation. Most of these encouraged or defined HSAs to conform to state and federal law. These states include Colorado, Connecticut, Florida, Louisiana, and Maryland. Several other states have pending legislation besides Nevada.

In conclusion, health savings accounts help the individual and the family and those employers who may not be able to afford full coverage for their employees.

Chairwoman Buckley:

When we had another bill on health savings accounts that was introduced by Assemblyman Hettrick, I spoke to a couple of the health insurers about it, and they told me they were already offering HSA products. If they are, then why do we need the bill?

Senator Washington:

In Nevada they haven't really offered them. They're available because of the federal law, but this bill actually comports with the federal law. The problem is, you have to work with the banking and financial institutions to set up these accounts. It's available, but no one is actually taking advantage of it.

Chairwoman Buckley:

I think Sierra told me they were offering them, so I'm curious about that.

Senator Washington:

It could be true.

Assemblywoman Gansert:

We're complying with the federal law, but this bill actually puts it under our Insurance Commissioner as far as getting a license for it versus just federal.

Chairwoman Buckley:

Brenda, could you confirm for us that's the case? It probably would make sense to make sure it's in our statutes and under the jurisdiction of our Insurance Commissioner. [Ms. Erdoes answered affirmatively.] Thank you very much for your testimony.

Janine Hansen, President, Nevada Eagle Forum:

Eagle Forum has nationally supported medical savings accounts and health savings accounts since before 1996, so I have a strong philosophical commitment to this, but I have a personal commitment as well. This offers individuals and families medical freedom of choice, which is important. When my son was on a mission in Pennsylvania, he became very ill and ended up in the hospital. He ended up coming home and I took him to our regular physician under our insurance. He said he wanted to put him on Paxil. I said, my son is very ill, he's not depressed, and if he is depressed it's because he's ill, and we will not do that. I took him to my other physician who is not only an M.D., but does many other alternative and natural medicines. He tested my son and found out he had salmonella, Hepatitis A, and a genetically engineered food poisoning. It took 6 months for my son to get better, but through the help of an alternative M.D., he was able to do that. My doctor doesn't take regular insurance, so we paid out of pocket very much money.

This bill provides the means of getting the things under health insurance that I'm interested in. It's important to offer people health insurance they can deduct from their income tax and they can have access to the kind of meaningful health care that includes medical free choice. It helps to lower the costs of health care, which we're all interested in, because when you're spending money that's in your account, you may ask the question, how much does this procedure cost, is it necessary, and what are my alternatives? When I go to my doctor, because none of it's under insurance, he always gives me cost alternatives, which are important in helping to lower the cost of insurance.

It allows for rollovers from year to year, so if you don't use all of your money, you can still have access to that and you're not penalized at the end of the year. If you have an emergency later on, it allows you to access that money. I'm excited this opportunity is coming to Nevada. It will help people like me who want to have access to more choices in health care, and it can help to reform the entire health care system for the benefit of consumers.

Chairwoman Buckley:

We'll get the clarification of the legal effect. I don't see a problem with the bill. With that, we'll close the public hearing on <u>S.B. 240</u>, and we'll go back to our Work Session Document (<u>Exhibit L</u>). We'll now go to <u>S.B. 226</u>.

Senate Bill 226 (2nd Reprint): Makes various changes to provisions governing payment of certain workers' compensation claims. (BDR 53-891)

Diane Thornton, Committee Policy Analyst:

The bill is sponsored by Senator Carlton and was heard on May 4, 2005. The bill limits the amount a health care provider may collect from an injured worker to no more than the amount the provider would have received had the claim been approved upon appeal. This limitation applies to all providers of health care except hospitals. The bill also requires the entity found responsible for payment of a workers' compensation claim to reimburse an injured worker or health or casualty insurer that paid for treatment or other services on behalf of the injured worker. The bill allows an injured worker or insurer to recover from a health care provider any amount paid in excess of the amount the provider was entitled to under the Nevada Medical Fee Schedule or the provider's agreement with the insurer. The bill does not apply to treatment or other services provided by a provider of health care to an injured worker before July 1, 2005. There was one amendment proposed that would essentially include hospitals as a health care provider and amend Section 2, page 3, by deleting lines 31 and 32 and inserting the language "The provisions of subsection 1 apply only to the treatment or other services," and it also deletes lines 38 through 41 on page 3.

ASSEMBLYWOMAN GIUNCHIGLIANI MOVED TO AMEND AND DO PASS SENATE BILL 226.

ASSEMBLYMAN OCEGUERA SECONDED THE MOTION.

THE MOTION CARRIED. (Assemblyman Arberry and Assemblywoman McClain were not present for the vote.

Assemblyman Anderson:

On a previous Work Session Document, we looked at <u>S.B. 152</u>, and you held it because of some questions that I had with the physical therapists. The physical therapists have spoken with me about the background and training of the assistants, and my reservations have been satisfied. I wanted to see if you were planning it for a future work session.

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We were waiting for your questions to be answered, so now that they are, we'll put it on the next work session. Thanks for that. With that, we're adjourned [at 2:12 p.m.]

	RESPECTFULLY SUBMITTED:	
	James S. Cassimus Transcribing Attaché	
APPROVED BY:		
Assemblywoman Barbara Buckley, Chairwoman	_	
DATE:	_	

EXHIBITS

Committee Name: Committee on Commerce and Labor

Date: May 6, 2005 Time of Meeting: 12:07 p.m.

Bill	Exhibit	Witness / Agency	Description	
	Α	Commerce and Labor Committee	Agenda	
29	В	Buffy Gail Martin, Government Relations Director, American Cancer Society, Reno, Nevada	Winning the War on Cancer Depends on Increases Access to Clinical Trials	
29	С	Sunil Sharma, M.D., Board Certified in Medical Oncology; Chief, Gastrointestinal Oncology Program; Chief, Phase I Program, Nevada Cancer Institute, Las Vegas, Nevada	Developing a common understanding about need for phase one trials in Nevada	
29	D	Dianne Buckley, Nevada State Co- Chairperson Advocates Alliance for Action, National Patient Advocate Foundation, Carson City, Nevada	Letter with amendment to S.B. 29	
29	E	Phillip Nowak, Chief of Business Lines, Nevada Department of Human Resources, Division of Health Care Financing Policy	Nevada State Division of Health Care Financing and Policy.	
431	F	Carol Tidd, Commissioner, Financial Institutions Division, Nevada Department of Business and Industry	Financial Institutions Division proposed amendments to S.B. 431.	
37	G	Senator Valerie Wiener	Proposed amendment to S.B. 37 first reprint	
37	Н	David Goldwater, Investment Consultant, Caladon Health Solutions, Las Vegas, Nevada	Proposed amendment to S.B. 37, mock-up	
37	1	Senator Valerie Wiener	Letter to Senator Wiener from Ms. Gallenagh,	

			Esquire
37	J	Louis Ling, General Counsel, Nevada State Board of Pharmacy	Documents Accompanying Testimony to S.B. 37
37	K	Robb Miller, President and CEO, Caladon Health Solutions, Las Vegas, Nevada	Compromise proposal for S.B. 37.
	L	Diane Thornton, Committee Policy Analyst	Work Session Document