ALASKA STATE LEGISLATURE
HOUSE LABOR AND COMMERCE STANDING COMMITTEE
April 7, 2017
3:17 p.m.

MEMBERS PRESENT

Representative Sam Kito, Chair
Representative Adam Wool, Vice Chair
Representative Andy Josephson
Representative Louise Stutes
Representative Chris Birch
Representative Gary Knopp
Representative Colleen Sullivan-Leonard

MEMBERS ABSENT

Representative Mike Chenault (alternate)
Representative Bryce Edgmon (alternate)

COMMITTEE CALENDAR

HOUSE BILL NO. 9
"An Act relating to the Board of Pharmacy; relating to the licensing and inspection of certain facilities located outside the state; relating to drug supply chain security; and creating a position of executive administrator for the Board of Pharmacy."

- HEARD & HELD

HOUSE BILL NO. 124
"An Act relating to corporations, including benefit corporations, and other entities; and providing for an effective date."

- SCHEDULED BUT NOT HEARD

PREVIOUS COMMITTEE ACTION

BILL: HB 9
SHORT TITLE: PHARMA BD & EMPLOYEES; DRUG DIST/MANUFAC
SPONSOR(s): REPRESENTATIVE(s) SADDLER

01/18/17	(H)	PREFILE RELEASED 1/9/17
01/18/17	(H)	READ THE FIRST TIME - REFERRALS

01/18/17	(H)	L&C, FIN
04/07/17	(H)	L&C AT 3:15 PM BARNES 124

WITNESS REGISTER

REPRESENTATIVE DAN SADDLER
Alaska State Legislature
Juneau, Alaska
POSITION STATEMENT: As the sponsor, introduced HB 9.

LEIF HOLM, PharmD, Master of Public Health (MPH)
Chair, Board of Pharmacy
North Pole, Alaska
POSITION STATEMENT: Testified in support of HB 9.

DIRK WHITE, Pharmacist
Sitka, Alaska
POSITION STATEMENT: Testified in support of HB 9.

BARRY CHRISTENSEN, Registered Pharmacist (RPh)
Co-Chair, Legislative Committee
Alaska Pharmacists Association
Ketchikan, Alaska
POSITION STATEMENT: Testified in support of HB 9.

DELLA CUTCHINS, Pharmacist
President, Alaska Pharmacists Association
Anchorage, Alaska
POSITION STATEMENT: Testified in support of HB 9.

SCOTT WATTS, Pharmacist
Juneau, Alaska
POSITION STATEMENT: Testified in support of HB 9.

ACTION NARRATIVE

3:17:11 PM

CHAIR SAM KITO called the House Labor and Commerce Standing Committee meeting to order at 3:17 p.m. Representatives Kito, Sullivan-Leonard, Stutes, Knopp, Birch, Josephson, and Wool were present at the call to order.

HB 9-PHARMA BD & EMPLOYEES; DRUG DIST/MANUFAC

3:17:50 PM

CHAIR KITO announced that the first order of business would be HOUSE BILL NO. 9, "An Act relating to the Board of Pharmacy; relating to the licensing and inspection of certain facilities located outside the state; relating to drug supply chain security; and creating a position of executive administrator for the Board of Pharmacy."

3:18:42 PM

REPRESENTATIVE WOOL moved that the committee adopt the proposed committee substitute (CS) for HB 9, Version 30-LS0131\J, Bruce, 4/6/17, as the working document. There being no objection, Version J was before the committee.

3:19:04 PM

REPRESENTATIVE DAN SADDLER, Alaska State Legislature, sponsor, explained that HB 9 is about strengthening the integrity of Alaska's prescription drug supply chain. It would do so by making Alaska comply with the federal Drug Quality and Security Act (DQSA) of 2013. Alaska is one of the last states to adopt this and comply, he pointed out, and if Alaska doesn't do this itself the federal government will do it for the state. He said the bill would give Alaska's Board of Pharmacy the authority to license and inspect three kinds of facilities: out of state wholesale drug distributors; third party logistics providers, which are people who coordinate shipping or warehousing of pharmaceuticals but they don't actually own the drugs or direct the sale; and outsourcing facilities that ship pharmaceuticals to Alaska, which are places that might compound or create sterile drugs in one place for delivery to another.

REPRESENTATIVE SADDLER stated that to accomplish this compliance goal, HB 9 would create a new category of pharmacy license that covers all three of the aforementioned facilities. It is called an out of state wholesale or distributor license. The bill would require that any out of state wholesale drug distributor, third party logistics provider, or outsourcing facility hoping to work in Alaska obtain this out of state license. The bill would authorize the Board of Pharmacy to inspect each facility or to have an inspection done by somebody designated by the board, he continued. The bill would require such facilities to appoint an agent in Alaska before it advertises its services or ships drugs to Alaska. He noted that to help implement these changes, HB 9 would also authorize the Board of Pharmacy to create a new position of executive administrator. The person holding this position would help manage the workload to meet

this federal act and other increasing Federal Drug Administration (FDA) regulations, he said. The administrator would also help manage the current licensing burden and serve as a liaison to the legislature, the executive branches of other states, and the pharmacy boards of other states.

REPRESENTATIVE SADDLER advised that the risks of failing to comply with this federal act and provide these protections for Alaska's drug chain are tremendous and fatal. The case study of the need for doing this, he said, is the 2012 national outbreak of fungal meningitis that infected 751 people in 20 states, of which 64 people died. The investigators after the fact traced the cause to a compounding facility in Massachusetts, which was producing medication in unsanitary conditions and shipping the medications across the country.

REPRESENTATIVE SADDLER summarized by saying that HB 9 would give the State of Alaska and its Board of Pharmacy the tools to ensure that Alaskans get safe, controlled, non-counterfeit medications. The bill would close loopholes in the regulatory system and would apply the same regulations that wholesalers shipping drugs within the state must follow to those importing drugs from out of the state.

3:22:33 PM

REPRESENTATIVE BIRCH inquired whether HB 9 would apply just to the drugs that are behind a pharmacy counter or would also apply to those drugs in front of the counter.

REPRESENTATIVE SADDLER replied it would apply to prescription medications, not over the counter drugs such as pre-packaged ibuprofen.

3:23:10 PM

REPRESENTATIVE KNOPP asked whether he is correct in understanding that HB 9 would provide for the inspecting and licensing of facilities that are out of state. He further asked whether there would be anything in the state.

REPRESENTATIVE SADDLER responded that currently the state does inspect the one wholesale distributor located in state. The bill envisions the inspecting of some 400 facilities that meet those three definitions that would be doing business in Alaska. As for the actual inspections and standards and what the inspections would consist of, he deferred an answer to one of

the experts on the Board of Pharmacy. He noted that HB 9 has an effective date of 2018 for the regulations to take place. He added that the effective date for the executive administrator would be immediate because there is a backlog of work that needs to be done as well as a fair amount of work that needs to be done in advance of these inspections.

REPRESENTATIVE KNOPP offered his understanding that if HB 9 is not adopted the federal government would impose regulations.

REPRESENTATIVE SADDLER addressed the question of what happens if Alaska does not do this. Some folks, he related, have said that other states within which a compounding facility is located might have their own standards and the State of Alaska might save money by adhering to and trusting those standards. However, as seen by the case study about meningitis, he advised, it might not be to the best interests of Alaskans to trust some other place. He deferred to Dr. Leif Holm, chair of the Board of Pharmacy, to further answer the question regarding what would happen if the federal government were to take over.

3:25:44 PM

REPRESENTATIVE JOSEPHSON stated he likes HB 9 but needs to understand it better. Regarding drug manufacturers in the Lower 48, he inquired whether there are 48 states that send an investigator to the same factory to inspect the facility. He said it seems odd that everyone would be doing this.

REPRESENTATIVE SADDLER allowed that it does seem redundant and he isn't sure whether that actually is the situation. There are some standards that a facility in any location meets, he said, and it would receive that certification and that would be good for all the other states. Some facilities serve so many states that, yes, it is important to do that. He deferred to Dr. Holm to further answer the question.

3:26:44 PM

REPRESENTATIVE WOOL offered his understanding that it is a supply chain that is being talked about. He said he is unsure how many stops a pill makes from the time it is fabricated until the time it is in the pharmacy. He surmised that the inspection point is what is being questioned; for example, food products are inspected by the FDA and then distributed to many states and he expects that this would be the same for a drug product. He

said he is therefore confused as to why every state would send an inspector to a particular facility.

REPRESENTATIVE SADDLER deferred to those who "deal with the pills" to provide an answer.

3:27:42 PM

CHAIR KITO inquired whether a PowerPoint presentation is going to be provided by the sponsor.

REPRESENTATIVE SADDLER replied that [six slides in a PowerPoint presentation, entitled "SB 37 & HB 9: Why license wholesale drug distributors?"] are included in the committee packet, but that he doesn't plan to provide them as an audio-visual presentation.

3:28:10 PM

LEIF HOLM, PharmD, Master of Public Health (MPH), Chair, Board of Pharmacy, testified in support of HB 9. He said the bill is important on many fronts for the board's utmost concerns for the safety of the state's patients. Alaska is one of the last states in the union attempting to fill the requirements of the DQSA that manage licensing of wholesale drug distributors and 503B outsourcing facilities. He pointed out that it's important to license out of state entities so that Alaska, as a state, has a better control and an increased confidence in its drug supply. The control would develop and maintain standards for Alaska facilities doing business in the state and there would be confidence that medications provided to Alaskan patients are of the highest quality and not counterfeit medications.

DR. HOLM stated that of equal importance to the Board of Pharmacy is the executive administrator position included in the bill. As proposed, he explained, this position would serve as a liaison to the legislature and to other state boards of pharmacy, as well as assisting the current full-time examiner position's licensing duties. With the ever-increasing amount of pharmacy issues and their complexity, he continued, the Board of Pharmacy is already falling behind with regard to regulation standards amongst other states and the board will only fall farther behind without additional assistance. Licensing is on the rise at a rapid pace due to out of state pharmacies being licensed and having a single licensing examiner to oversee this is no longer reasonable or very effective. This burden is only going to increase with the request that [the Board of Pharmacy]

begin licensing out of state wholesalers and outsourcing facilities. The bill is much needed and long overdue, he emphasized, and the Board of Pharmacy is in full support of the current form.

3:29:53 PM

REPRESENTATIVE JOSEPHSON noted that legislators have REAL ID on their minds and have been told about things that could happen to Alaska soon if it doesn't pass REAL ID. He asked what would happen if Alaska didn't comply with the federal law in question.

DR. HOLM replied that the federal government would come in and license. An issue with that is that there is no procedure in place for the federal government to do that, and this is widely understood by the organizations that are involved with this, such as the National Association of Boards of Pharmacy (NABP) and the National Community Pharmacy Association (NCPA). He said it is believed that the federal government is ill equipped to do it since it would be a new licensing procedure for them. With most states already licensing their instate and out-of-state wholesalers it is believed that this is really a back-burner thing for the FDA and the federal government and that they might not in a very timely fashion proceed with any type of licensing. In the meantime, he continued, [the Board of Pharmacy] has no oversight and even if [facilities] are licensed in another state, if [the Board of Pharmacy] doesn't license them then the board has no jurisdiction. He advised that it would open the floodgates for [Alaska] having no system controls in place and wholesalers can work and operate in Alaska in any way they want and [the Board of Pharmacy] has no authority to inspect them or even monitor an inspection or require that they operate in a certain way. They can basically do whatever they want and [the Board of Pharmacy] ends up where it is now, which is questioning if there are counterfeit drugs in Alaska and drugs diverted in Alaska. He said this is unknown because [the board] allows them to operate without a license.

3:31:43 PM

REPRESENTATIVE KNOPP asked how many out of state wholesalers and facilities would be inspected, what would be the frequency of inspections, and whether there would be a requirement timeframe for frequency and quantity.

DR. HOLM responded that there is a misunderstanding that [the Board of Pharmacy] is going to inspect these facilities, which

is an option, but not a requirement. The intent is that [the board] would require that they be inspected. There are national third-party inspectors where they can become certified through a verified wholesale inspection through the NABP. It is quite expensive for these states to do, he said, but once they complete it, most states recognize that as a quality inspection and that the facility is a quality operating facility. So, he reiterated, [the Board of Pharmacy] wouldn't necessarily be inspecting all the facilities, the number of which he believes to be just fewer than 1,200 wholesale distributors licensed in each individual state. [The Board of Pharmacy] would not physically fly someone down to inspect 1,200 different wholesale distributors. The board would be monitoring them as a board as they came in through a licensing application and monitoring whether they did what the board deems is an appropriate inspection. The board would then have access to monitor and look at the inspection to see if it is acceptable by the state's standards.

3:33:35 PM

REPRESENTATIVE WOOL remarked he is unfamiliar with how the pharmaceutical industry works. He inquired as to what point in the supply chain the Board of Pharmacy would be inspecting. For example, whether it would be where the drugs are being made or the wholesale distribution. He further inquired as to what exactly would be inspected given Mr. Holm is talking about inspecting licenses. He surmised the thrust of the bill is to prevent counterfeit drugs from coming into Alaska or improper compounding. He requested Mr. Holm to walk the committee through the supply line of a pharmaceutical; for example, if it is produced overseas whether it comes to a wholesaler or distributor or pharmacy in the U.S.

DR. HOLM answered that a manufacturer sells to wholesale distributors, and most of the major wholesale distributors are large corporations that do a large percentage of the medications that are brought into every state. However, he continued, there are a lot of secondary wholesalers and pharmacies that operate under less than good standards in what is called a grey market. They purchase large amounts of medication through wholesalers that are outside of a normal supply chain and [these wholesalers] procure the drug through an illegal means or produce the drug in a counterfeit form. These secondary wholesalers purchase these medications from these counterfeit manufacturers and sell them to pharmacies that don't necessarily know where the origin of the drug came from. The licensing

procedure under HB 9 would require a transaction history. Currently a transaction history is not required, so [the Board of Pharmacy] has no authority to look at where a drug came from each step of the way.

DR. HOLM added that it is a very confusing procedure where someone gets these medications. [The Board of Pharmacy] cannot inspect the facility, so it could be that a wholesaler is operating out of his or her house and could be procuring common drugs through a diverted means. There is counterfeiting going on with Medicaid, he noted. Patients will get numerous drugs under Medicaid and when they don't need the drugs, they will resell them to wholesalers who will then hold on to the drugs until they can find a very high-priced market for them and then release them into the supply chain. That would be a diversion tactic.

3:37:26 PM

The committee took a brief at-ease.

3:38:45 PM

DR. HOLM addressed the PowerPoint slides in the committee packet to further continue his answer to Representative Wool. He drew attention to the fifth slide entitled, "Trail of Counterfeit Avastin," and said it provides a good representation of what the Board of Pharmacy is trying to get at with HB 9. He explained that the trail begins when clinics order a medication, a middleman procures the medication from an unknown supplier, and that supplier then supplies the medication to the various clinics that have ordered it. Most affected are physicians' offices that don't order from the larger and more reputable wholesaler manufacturers and instead order from the cheapest place they can find. There are a lot of secondary wholesalers, he continued, 1,200 that are licensed within the states. So, physicians are ordering from all sorts of places and it is not known where those drugs are coming from. He pointed out on the slide that the counterfeit Avastin ended up in numerous U.S. clinics where medications were needed for cancer.

REPRESENTATIVE SADDLER added that while people might have in mind the idea that there is a manufacturer, a wholesaler, the retail seller, and then the customer, slide 5 shows that drugs may go through a convoluted chain of custody, and over time and the course of many transactions the trail can be lost so that it is unknown where a drug came from and whether it is a legitimate

original drug. Under HB 9, he said, the licensing would require a chain of custody so that each time a drug was shipped from one place to another there would be documentation, thereby providing a chain of accountability all the way back to the manufacturer.

3:41:34 PM

REPRESENTATIVE SULLIVAN-LEONARD requested an overview of what the sponsor foresees as the duties and oversight of the proposed executive administrator position.

REPRESENTATIVE SADDLER replied that HB 9 proposes a high-level position at range 23. The position would be paid for out of increasing the license fees that would be assessed to the out-of-state wholesalers, he emphasized. The administrator would assist the Board of Pharmacy in ensuring that whoever is providing drugs will have that licensure in effect. The administrator would coordinate with other state legislatures, executive agencies, and pharmacy boards to verify inspections. The administrator would process the applications for licensure that are received by the Board of Pharmacy. Representative Saddler estimated that about 400 facilities would be applying for this licensure, which would require a fair amount of paperwork and coordination. As it stands now with the amount of work required under the different [federal] healthcare mandates, the current staff person to the Board of Pharmacy is overwhelmed and the workload is weeks and months behind schedule. The executive administrator would primarily help with implementation of HB 9, he said, but would also help with other things.

3:43:12 PM

REPRESENTATIVE JOSEPHSON offered his understanding that HB 9 would only affect prescriptions, not over the counter drugs.

REPRESENTATIVE SADDLER responded correct.

REPRESENTATIVE JOSEPHSON surmised that a drug store pharmacist would be able to say from what location the drug was obtained, but that going any farther back would run into a brick wall.

REPRESENTATIVE SADDLER answered that in essence, it would get foggy - where a person might assume good will but couldn't verify it. Unless dealing with a very short chain, a person doesn't know how many transactions have happened.

3:44:00 PM

CHAIR KITO returned to the PowerPoint slides and brought attention to the fourth slide entitled, "What Do Counterfeit Drugs Look Like? They are hard to detect!" He pointed out that the photograph compares an authentic versus counterfeit [tablet of Tamiflu].

DR. HOLM explained that he owns independent pharmacies and through day-to-day business his pharmacies are constantly on the lookout for positive reimbursement in medications. He said he deals with 6-10 secondary wholesalers daily that he is fairly certain are operating under good circumstances. However, he doesn't know that for sure because they are not licensed by the state of Alaska and so he tries to use them as minimally as possible. For the times that he needs to use a secondary wholesaler, he continued, he would like to know that Alaska is being responsible in licensing them and knowing as a pharmacist that in day-to-day business any wholesaler that he might come across within his state has been vetted by his state. But right now, he reiterated, he does not know that.

3:45:30 PM

REPRESENTATIVE JOSEPHSON inquired whether the counterfeits are normally benign placebos or are harmful.

DR. HOLM offered his understanding that they are generally sugar and are non-harmful, non-medicated, and no active drugs within them. He related that about 150 countries manufacture the drugs coming into the U.S.; 40 percent of the total drug supply is manufactured out of country; and 80 percent of all the active ingredients are manufactured out of country.

REPRESENTATIVE SADDLER added that the motivation for fraud is tremendous. Everyone has heard horror stories of $500 per pill or $40,000 a month for injectable cancer treatments. Bad actors receive inexpensive placebos or contaminated drugs and pass them on to end-user pharmacy clients, pocketing the money and not caring that the results could be fatal or damaging to the patient. Every country has bad actors and given how many trillions of dollars the pharmaceutical business represents, there is powerful motivation to take advantage of weaknesses. If Alaska is the last state that has this protection, he advised, then those bad actors are going to migrate to Alaska and take advantage of the state's low threshold of safety.

3:47:31 PM

REPRESENTATIVE BIRCH asked whether the supply chain is looked at through such things as radio-frequency identification (RFID) tags. He surmised there would be some sort of tracking mechanism for some drugs more than others.

REPRESENTATIVE SADDLER replied that there might be such, but he is unsure. He deferred to Dr. Holm to provide an answer.

DR. HOLM stated he is unfamiliar with RFIDs.

CHAIR KITO explained that it is a radio-frequency tag associated or affiliated with a batch that was manufactured.

DR. HOLM responded that the [2013] federal Drug Supply Chain Security Act (DSCSA) intends that by the year 2023 a Quick Response Code (QR Code) be placed on medication bottles. By scanning this code, he explained, the entire history of that bottle of medication will be seen from start to finish, but that currently there is no capability to do this.

3:49:50 PM

DIRK WHITE, Pharmacist, testified in support of HB 9. He noted he is the Past President of the Board of Pharmacy, and Past President of the Alaska Pharmacists Association, and stated that Dr. Holm's father was on the Board of Pharmacy when it originally started working on this issue about five years ago. He urged that HB 9 be passed for the health and safety of Alaska's citizens. Had such a bill been passed, he advised, it is possible that the New England Compounding Center, which produced the contaminated injectable steroid that killed about 300 people and maimed 1,000 more, would have been caught. Had the center been inspected on a regular basis, he continued, it would have been caught and would have prevented the loss of life and loss of quality of life.

MR. WHITE addressed the question about the pedigree of medications and chain of custody. He pointed out that without that pedigree on a medication and the chain of custody that comes with it, he becomes liable for anything that might go wrong. [Alaska] doesn't have anything that verifies that a wholesaler, from which [pharmacies] are buying, is qualified to provide the medications. He pointed out that parameters are associated with medications, such as the need to be kept at a certain temperature and humidity while stored for large quantities of time. Parameters that are looked at in an

inspection include whether a medication needs refrigeration and remains constantly refrigerated throughout its life from manufacturer to wholesaler to secondary wholesaler to pharmacy. The pedigree includes whether a medication has been kept correctly, shipped correctly, or diverted somehow, and without that pedigree none of this is known, he said.

MR. WHITE noted that RFID tracking was looked at years ago for putting the tags all the way down to the tablets. However, no one was able to come up with a tag that was compatible with the FDA requirement, he advised, so [the FDA] will probably stick with the QR Code, which can be scanned to pop up much of the pedigree. He urged that HB 9 be passed.

3:53:31 PM

BARRY CHRISTENSEN, Registered Pharmacist (RPh), Co-Chair, Legislative Committee, Alaska Pharmacists Association, testified in support of HB 9. He said moving this legislation forward has been the number one priority for his association for several years. He stated he won't repeat what was said by Dr. Holm and Mr. White but added that pharmacists like himself need to be able to go to the Alaska statewide website and see that the medications they are buying or contemplating to buy are coming from a verified source. There is a need to create the executive administrator position, he continued, to help the board and ensure it can do its current job as well as the additional strains of this legislation as well as several other bills. He urged the passage of HB 9.

3:55:04 PM

CHAIR KITO opened public testimony on HB 9.

3:55:22 PM

DELLA CUTCHINS, Pharmacist, President, Alaska Pharmacists Association, testified in support of HB 9. She said the bill is vital to bring the state into compliance with federal requirements that all wholesalers distributing prescription drugs in Alaska be licensed. The Alaska Pharmacists Association represents over 250 pharmacists and pharmacy technicians in Alaska, she noted. The association's mission is to preserve, promote, and lead the profession of pharmacy in Alaska, and HB 9 strongly aligns with that mission, as it will ensure that Alaska is in line with the FDA mandate. She reiterated the association's support of HB 9.

3:56:30 PM

REPRESENTATIVE WOOL recalled it being mentioned that if Alaska doesn't do anything the federal government will come in and regulate. He asked if that has happened in any other state.

MS. CUTCHINS deferred to Dr. Holm to answer the question.

DR. HOLM responded that there have been no repercussions at this time because the FDA has not yet put forth a licensing procedure. He offered his belief that three or four other states have not yet licensed and are therefore in the same situation as Alaska and do not monitor the drugs coming into the state. However, he continued, years down the road when the FDA gets around to it, the FDA would be in charge and have all the rules and regulations fall under whatever the FDA requires and not necessarily what Alaska thinks is important.

REPRESENTATIVE WOOL remarked that it looks like a couple of the situations mentioned are different - for example, the compounder in Massachusetts was bad practice or fraud, rather than counterfeit. He surmised that that was not a supply chain problem as illustrated on [slide 5]. He inquired whether Dr. Holm agrees that the compounding problem was a different thing.

DR. HOLM concurred that the compounding problem is a different thing and advised that that is a reason for licensing. While wholesaler drug distributors have been referenced, it also includes outsourcing facilities, which that facility would have fallen under. It goes back to inspections, he said, and that facility would have been required to have some form of inspection that [the Board of Pharmacy] would have had to accept before allowing the facility to operate in Alaska. Without an inspection, [the board] would not have allowed the facility to ship anything into Alaska. Based on what has been on the news, that facility would not have passed, period.

3:59:26 PM

REPRESENTATIVE SADDLER, regarding what would happen if the state doesn't pass the bill, added that unless and until the federal government required that licensing federally, there would be no stick that the State of Alaska could use to punish someone. For example, if the compounding facility in Massachusetts shipped to Alaska and it did not produce good product, Alaska would have no

statute with which to prosecute the facility because there would be no law requiring them to be inspected to get a license.

4:00:20 PM

SCOTT WATTS, Pharmacist, testified in support of HB 9. He said he is the owner of several pharmacies in Juneau and explained that a pharmacist's main responsibility is ensuring that the right person gets the right medication in the right dose. Pharmacists can do all of that in their pharmacies, he noted, but they do need to make sure that that pill is the right pill that is being ordered. He advised that pharmacists are getting a lot of constraints from pharmacy benefit managers (PBMs), middlemen that the committee may be hearing about.

MR. WATTS, regarding maximum allowable cost (MAC) prices, related that at times pharmacists have difficulty finding a medication from the larger wholesalers at that [MAC] price. This forces pharmacies to go out to the smaller wholesalers, he said. For example, he gets phone calls daily from small wholesalers saying they have this medication at this price – much lower than what his wholesalers are offering it for. He pointed out that pharmacists don't know if this small wholesaler is calling from a garage without having verification that they've been licensed or at least that the state has the ability to license that.

MR. WATTS noted that a pharmacist sending out prescriptions to other states must be licensed in the state that the prescription is being sent to, and the pharmacy must also be licensed. The other states want to verify that a pharmacist isn't doing things under the table or incorrectly. He reiterated his strong support for HB 9.

4:02:25 PM

REPRESENTATIVE BIRCH shared that long ago he studied some analysis techniques for minerals to get a detailed analysis. He asked how a pharmacist confirms that a pharmaceutical is what it is purported to be.

MR. WATTS replied that there are no ways in-house to test a medication. Pharmacists are relying on the manufacturers and whether the drug can be tracked from the manufacturer to the wholesalers. The FDA inspects the manufacturers, he said, and that's where the assurance is that that is the appropriate drug. Also, there are markings for identifying a drug. When that

supply chain is not clear it is hard, he added, and that is where pharmacists need the assurance that that pill and that bottle is what it is purported to be.

REPRESENTATIVE BIRCH noted there are often five pages of tiny print stating what a drug might do, while street drugs are often something that an amateur chemist has tweaked. He asked whether a pharmacist can get a rock-solid signature for a drug, so it is known what it is.

MR. WATTS responded that at the pharmacy level, the pharmacist is looking at appearance and markings of the tablet.

4:05:24 PM

CHAIR KITO held over HB 9.

4:05:35 PM

ADJOURNMENT

There being no further business before the committee, the House Labor and Commerce Standing Committee meeting was adjourned at 4:06 p.m.