MICROFILM DIVIDER

OMB/RECORDS MANAGEMENT DIVISION
SFN 2053 (2/85) 5M

ROLL NUMBER

1455

DESCRIPTION

2007 HOUSE JUDICIARY

HB 1455

2007 HOUSE STANDING COMMITTEE MINUTES

Bill/Resolution No. HB 1455

House Judiciary Committee

☐ Check here for Conference Committee

Hearing Date: 1/30/07

Recorder Job Number: 2236

Committee Clerk Signature

Minutes:

Chairman DeKrey: We will open the hearing on HB 1455.

Rep. Blair Thoreson: I am a sponsor of this bill. I support HB 1455. Ninety percent (90%), is the amount of increase that the investigations of counterfeit drugs that FDA saw between 2003 and 2004; which were the most current statistics that I could find. This was a dramatic increase, it was a direct result from a growing practice of criminals who are willing to cause harm to persons who are using prescriptions pharmaceuticals, as they criminals attempt to enrich themselves. These are bad actors that are infiltrating the drug supply chain and are introducing into it drugs that have little or no benefits, or worse yet, can cause substantial harm. The actual numbers of these cases may be small compared to the overall volumes of drugs purchased, but the risk to patients from a single case of counterfeit drugs can cause serious harm or even be life threatening. In 2002, there were vials of a drug Procrit, labeled as containing 40,000 units, which actually only had 2,000 units of the active ingredient in them. Later that year, other vials of the pharmaceutical were found containing nothing but Miami tap water. In 2003, there were reports that there were some cases of Lipitor, the pills tasted bitter, caused burning sensations on the tongue and were too large for the actual size of the pill. In 2004, there were several websites that sold unsuspecting consumers contraceptives which

had no active ingredient in them. This bill is before you because I made a decision to introduce it after attending a presentation last summer on counterfeit drugs. The presenter at that meeting, was a state senator from Indiana, and works outside the legislature as a registered pharmacist. He made a compelling case for ensuring the safety of prescription drugs and he made me look at what protections ND now has in place and how we could make our laws even stronger. My hope is that we could pass legislation in advance of this problem coming to our state; however, I just recently found out that we've already had a case here dealing with this issue. I ask for a favorable recommendation on HB 1455 so that our citizens will know that they an added level of safety when using medications that were designed to help and not harm you.

Chairman DeKrey: Thank you. Further testimony in support.

Rep. Kim Koppelman: I am a co-sponsor of this bill. This is a preventative measure rather than to correct a problem. Do you ever wonder if what is in the prescription bottle is really what it is supposed to be. Well I never did wonder that until I became aware of this situation as well. I attended the meeting that Rep. Thoreson referred to. Senator Marvin Riegsocker is from IN is a pharmacist and he said that a patient came to him and asked him to tell him that what's in the bottle, is what it says it is. Can you assure me of that. He thought about it and agonized over it and he said I really can't. Because the pharmacist doesn't control the product from the time it's manufactured until the time it ends up in his shelf. We like to trust our lines of distribution and historically they've trustworthy. But criminals are getting into the act of messing with legal drugs, just like they have messed with illegal drugs. As a result, we need to do something about this. Several states are enacting legislation similar to this and I believe that ND should enact it, not so much because we have a terrible problem; although as Rep. Thoreson indicated, there has been one case that I'm aware of and you will hear more

about that from another presenter, but also because as other states close their loopholes, the bad actors could look for states that still have the loopholes and end up in ND. (showed slides, attached Colombian Drug Operation). There is also some action on the federal level. Trends show increased levels of these counterfeit drugs are making their way to the US. The dumping final ground is the United States. A lot of the drugs end up here. According to the World Health Organization a counterfeit drug is a product that is deliberately and fraudulently mislabeled with respect to identity and source. This is a distribution problem. I understand that there is going to be a suggestion for an amendment in the bill that our state's Board of Pharmacy has asked for and I believe that Joel Gilbertson is working on this bill to bring something forward also. We currently license manufacturers. I think the bill may be changes that but we're going to fix that with an amendment because there is no intent to quit doing that. The problem isn't really with the manufacturer, it tend to be in the line of distribution. What tends to happen, in the wholesale process, is where a lot of manufacturers or the mail order process. There is a snag between where the product is manufactured and where it ends up in your local pharmacy and the patients. Is it a huge problem in ND, no but it's an emerging one and I think we as the legislature, since we only meet every other year, really need to deal with it. We need to be proactive before the problem gets worse.

Rep. Delmore: You alluded to mail order. Is there something in here that would affect that and in what way.

Rep. Koppelman: I believe there is, but I would ask another presenter to deal with that specifically, but you make a great point. More and more of our citizens are getting their drugs through mail order processes, and I believe this bill will get at that as well; if it doesn't we need to make sure that it does. Because our local pharmacies are not our only source of medication.

Rep. Klemin: Is there anything in here that a pharmacy company, or a pharmacist, isn't making a warranty that when they fill a prescription that what they're saying is actually in the bottle is in the bottle.

Rep. Klemin: I don't know if there is any immunity provision like that, if that's what you're getting at. I certainly would not be opposed to that because again they are in a position where they can't really know, but we're trying to tighten it up so hopefully they can.

Chairman DeKrey: Thank you. It sounds like there are going to be some amendments offered and more work to be done on this bill. I will appoint a subcommittee of Rep. Heller, Rep. Onstad and yourself to work on this bill. Further testimony in support.

Matthew van Hook, partner in Food and Drug Law Firm in Washington and on behalf of PhrMA: We support this bill. For many years, I've been following very closely challenges to the drug distribution system involving counterfeits. This legislation is much needed and appropriately timed because it will provide protection to the consumers of ND when they go to their pharmacies this will help ensure that the product they get is exactly what the doctor ordered. I'll just touch on why this problem deserves attention right now and what the federal government has been doing and more importantly what this bill would help ND do to contribute to combating counterfeits. There has been a growing problem with counterfeit drugs. This country, of all the counties in the world, has the most closed and safe drug distribution system. Nevertheless, there is growing incidents of counterfeit drugs hitting the market. Bad actors have discovered that they can make a lot of money with counterfeit drugs. The state of FL is one of the worst places that experienced counterfeit problems in this country. They found that people who were involved in this, discovered that they could make as much, or more money counterfeiting prescription drugs than they could with narcotics. That's a pretty scary prospect. There is money to be made by bad actors. Congress passed a law to protect consumers that

had two approaches to try and make sure that the distribution system between the manufacturer and the pharmacy was safe. Number 1 was to require wholesalers to be licensed by every state; and 2) have a pedigree requirement. A requirement that unless you are the manufacturer or an authorized distributor of the manufacturer, you had to pass a pedigree paper showing where the drug came from and where it was going to So that there would be a chain of custody for the drug. That was the system envisioned at the federal level. Much of that has been put in place, many states have basic licensing laws. FDA has been anticipating that when it comes to pedigree, the advent of electronic track and trace technology. These little chips that are increasingly being imbedded in many things and can do miraculous things in terms of identifying objects and tracking what happens. The thought was that this would be practical to use in protecting the drug supply system enacted by this year. So the FDA did with their detailed pedigree regulations, they held those in abeyance, thinking that this electronic technology would take care of any issues or complications and cover everything. That hasn't happened yet. All the stakeholders involved here, the pharmaceutical manufacturers, the wholesalers, the pharmacies, everyone is supporting of the development of this technology, it's going on intensively, but it's not rolled out yet and we're not sure when this is going to happen as work goes on. The FDA, as of December 1, 2006, said okay, counterfeit has gotten to be too great of a problem and we've got to have these pedigree requirements at the federal level go into effect. This legislation is very timely because there is a loop hold in the federal law. You might recall, I referred to the fact that under federal law, with the pedigree paper requirement, if you're the manufacturer, you're not required to pass the pedigree because you made the drug, you are heavily regulated by FDA, you have an FDA license. The manufactured authorized distributor of record doesn't have to pass the pedigree. When congress did oversight that was not the source of counterfeits. Counterfeits tend to come from

so-called grey market sources, or bad actors that injected into the drug distribution system. The loophole in federal law, is that there have been incidents documented, and it's unfortunate, where wholesalers who are even authorized distributors purchased some product from the grey market and turned around and sold it in the normal course of business on the way to the pharmacy and it turned out, I'm sure not with their intent, but it turned out that they were purchasing some product that was counterfeited or adulterated. Under federal law to this day, under the loophole that exists, when an authorized distributor purchases from a grey market source they don't have to pass a federal pedigree. I'm describing that because, as I go through HB 1455, your legislation would address that loophole and close it. The approach in HB 1455, is to have minimum requirements for licensure for wholesalers. It will tighten those minimum requirements so that any wholesalers involved in business in ND bringing drugs in or distributing those drugs, would have tighter licensing requirements. These would include stricter criminal background checks, having a designated representative for who's involved in that distribution activity and having a bonding requirement. Manufacturers would continue to be subject to wholesale licensing whether they are engaged in distribution, but would not be subject to the increased requirements beyond the minimum qualifications in federal law. In other words, manufacturers would not have to be fingerprinted and be bonded. The rationale being that the manufacturers have never been associated with any of these counterfeit problems and hence there's no need for the increased licensing qualifications. As Rep. Koppelman alluded to, we wanted to make clear that the manufacturers would continue to be subject to licensing. That would certainly continue. That's in section 45-15.3-03, page 8 of the bill. That's where the requirements for the licensing are set forth. The pedigree, the other element I was talking about, that's in section 45-15.3-06, beginning on page 14. Let me describe the mechanism that's in the legislation which is important. The legislation says that if

the drug stays within the normal distribution channel, from the manufacturer to the pharmacy that you don't need a pedigree because experience has shown that when it is in that chain of distribution, the risk is very low and we won't need a pedigree. You would need a pedigree for the drug if it left the normal distribution chain. The key difference from federal law, unlike federal law if it goes out that chain but then comes back into the hands of an authorized distributor the pedigree is not required any more. Under this legislation, if it ever left that chain, everyone subsequently would have to pedigree it to the pharmacy. It is an additional level of protection. It also further limits the number of lateral transactions that can happen. If there is a transaction except between certain specified special manufacturer authorized wholesalers, if there is more than one lateral transaction among the distributors, it has to be pedigreed even if you are an authorized distributor. States like NV and FL found that as there are more transactions between distributors before it gets to the pharmacy there is more opportunity for concerns to have counterfeit drugs to come into the system. An approach that some states, and is reflected in this bill, ND would limit the number of lateral transactions that have to be before pedigree is required. I talked earlier about the hopes of electronic pedigree. Your bill provides for that. It identifies dates by which your Board of Pharmacy would anticipate that it would be practical to have and specifies a date when it would be implemented, with provisions for that day, in this legislation is July 1, 2010 to be put off, if that technology is not available. As soon as it's available as set forth in the bill, it would be required here. This legislation would provide for that. Finally, the bill provides identifies prohibited acts, including tinkering with the labeling on the drug and not complying with your licensing requirements and then penalty provisions. These are in section 43.15.3-08 and -09 and are on pages 17 and 18 of the bill. Now, I alluded to the fact that counterfeit is increasing throughout the US and one thing I wanted to have put into the record, is a news release about a Minot man who was

involved in illegal distribution of controlled substances and mislabeled drugs (see attached). I just wanted to make you aware that it can happen here. The other thing to bear in mind is that each state in this country relies on the other states to take care of their share of the protection as well. There are drugs that are distributed into ND, there can be drugs distributed out of ND. I think it's important for states like ND to step up to the plate and this is one of the pioneering pieces of legislation following that federal change in direction on December 1, to tighten up wholesaler licensing and pedigree requirements. This legislation would help do that.

Rep. Delmore: The mail order component. I'm not addressing websites that people use, I prefer to go to my pharmacist, but I know that there are people are commonly using some type of mail order. I'm just curious how this affects that.

Matthew van Hook: Mail order pharmacies play an important role in providing drugs legitimately. They are licensed where they are located, just like other pharmacies. When I was talking about each state doing their part, wherever a mail order pharmacy is located, it should be legitimately licensed by its home state, and its distribution should be legal under both federal and state law. This would apply to mail order pharmacy as well. One thing you get when you go to a pharmacy in Bismarck, you have a right to expect that the drug you get there are what the doctor ordered and what they purport to be and that they are legitimate. You have the right to expect the same thing from a mail order pharmacy. If you go to a ND pharmacy, if you go to a legitimate mail order or on-line pharmacy you have a right to expect that they are legitimate. Likewise if you go to a source outside of that, you can't expect that those drugs have been distributed under the American Pedigree requirements or the ND pedigree requirements. That's one thing you can look for in a pharmacy.

Rep. Onstad: On the fiscal note, it makes a note that this bill exempts 126 wholesale manufacturers. Then it makes another 536 ineligible, including all those located in ND. Why would they be ineligible if they are currently located here.

Matthew van Hook: We have an amendment that proposes a number of items that would clarify that, indeed, there was no intent to exempt manufacturers from being licensed as wholesalers to the extent they are today and will continue to be subject to licensing. When it comes to other distributors in ND, I'm not aware of any provision that would preclude a distributor from being licensed, if they meet the licensing requirement.

Rep. Onstad: You said that there's going to be costs to the wholesaler and the licensing requirement of it. When it asks for a criminal history check, who's going to be responsible for paying that.

Matthew van Hook: The way that the legislation is set up, it refers to existing provisions in ND law, that provide for criminal history record checks for various agencies and activities in ND and this would add wholesaler licensing to that. I don't know whether the licensing fee itself is meant to cover this section.

Rep. Onstad: We don't know if the Board of Pharmacy's responsibility, the state's responsibility, or the individual who is applying for the license. We don't know who pays the cost.

Matthew van Hook: I don't know how the section 12-60-24 criminal history record checks for various agencies are funded here in ND. I'm sure we can find out.

Rep. Koppelman: I can actually shed some light on that. We have another bill that was introduced on the Senate side right now, regarding criminal background checks; which greatly expand the number of individuals and categories that we're going to require them for. This would be added to that statute. Typically, the way it works is when somebody applies for,

whether a job at a correctional facility or licensed nurse, or in this case, a license for a wholesale distributor of pharmaceuticals, they would pay the fee to the state to do that.

Rep. Kretschmar: Typically how do these drugs get into the chain.

Matthew van Hook: A manufacturer, at its manufacturing site, will distribute it a number of ways; typically through one of their authorized distributors. Each manufacturer will identify its own authorized distributors and those distributors will ship the drugs to their wholesaler where it can be in one or more parts of the US, and then those are further distributed to local pharmacies. There are also, as provided for in this bill, drop ship situations, sometimes where because of urgency or situation, a manufacturer may directly through a common carrier send a drug right to a pharmacy or doctor, for example, but the legal chain goes through a wholesaler and the wholesaler takes care of the paperwork and under FDA guidelines, that wholesaler is responsible for that pedigree if they have a pedigree obligation. If they are an authorized distributor, they may not. There is a fairly robust system in the US that gets drugs from one place to the other, depending on the circumstances. Typically, it goes from the manufacturer to the wholesaler, to the pharmacy and that's how when these laws were first passed 20-25 years ago, it was envisioned that would always be the case. Now it's gotten a little more complicated, if some specialty wholesalers that some manufacturers use to distribute directly to patients. There are some situations where there are multiple distribution plans that are perfectly legitimate.

Rep. Kretschmar: How do the counterfeit drugs get into the state.

Matthew van Hook: What happens, partly because of the cost of some drugs, some distributors in that distribution chain, can find that there have been economic incentives to source the drugs cheaper than they can get from another wholesaler or directly from the manufacture. When they resell it to a pharmacy, etc. there are economic incentives because

they can pocket the difference between the market retail price and what they bought them for. The FL grand jury documented situations where some drugs had been sourced from out of the trunk of a car at an airport, and then by folks working for an other wise legitimate wholesaler, and once it's in their hands, then it's sort of no questions asked, which is an unfortunate kind of circumstances. This legislation is aimed at shedding light on this problem and clarifying it.

Rep. Klemin: You mentioned this loophole in the federal law and wholesalers purchasing drugs from grey market source, what is a grey market source.

Matthew van Hook: A grey market source could be any source that is not an authorized distributor of record or does not have the documentation, does not have a pedigree. FDA requires if you are buying distributed drugs, you have an obligation to receive a pedigree and if you're not an authorized distributor, to pass it on. The grey market drugs, in the case of prescription drugs, would be a source that is supposed to have a pedigree and does not. The situation is where there has been one transgression of law but that the subsequent sale is not a transgression of law. It is sort of miraculously cured under existing federal law.

Rep. Klemin: A grey market, is that something that is fairly widespread or....

Matthew van Hook: It was widespread enough, that when they did the original oversight hearings in the 1980's in Congress, much of the source of those drugs was actually drugs returned from abroad, and those drugs returned from abroad were found to be postdated drugs, the labels were changed, they were adulterated or they were outright counterfeited and having been returned to this country ostensibly to be returned to the manufacturer, they never made it back to that distribution chain and were reinjected into the American distribution system. In recent years, people even set up counterfeit labs. Then you can go look for willing buyers in the drug distribution system that are presumably looking for a break on price and can enter the system that way. It takes two to tango. It can take people who are naïve in the drug

distribution system that don't realize that you are dealing with a bad actor, that's another danger. It's happening and happening with increased frequency, which I think is why the FDA is concerned and many of your colleagues in other states are concerned to take this kind of action.

Rep. Meyer: It's my understanding that upwards of 80-85% of our prescription drugs are manufactured in Puerto Rico in San Juan. It kind of piggy backs on to a previous question, when they get the illegal drugs made in Colombia, do they ever enter at the manufacturing level or is it always at the wholesale level and how do they get into the US to start with.

Matthew van Hook: I can't speak to the % of drugs manufactured in Puerto Rico for the American market. I don't believe it's that high. The raw materials can be shipped in bulk, they're not always intercepted in customs. They're not always identified as prescription drugs. They can be shipped through containers from abroad in raw chemical form, and then all you need is one of those pill making machines, that Rep. Koppelman showed earlier, in your garage and you can turn them into pills. It can be difficult to guard the borders with what's coming in, even in pill form, the data shows in the air freight, there are 10-12 major airfreight incoming places in the US where customs looks at airfreight as it comes in. They've thrown up their arms, the FDA, the Dept of Homeland Security did a couple of trials where they look at every piece of airmail coming in on a couple of different days and discovered that there is a tremendous amount of illegal drugs coming in mislabeled, adulterated counterfeit. But there is no practical way to identify that coming through the mail. The incoming mail and freight is a fairly porous system. A lot of the raw materials, if not the pills themselves, can arrive in the country. Then it becomes a question of entry into the normal distribution channels and that's where the job here, with legislation like this is to tighten the control over that, at least, to make it harder for the illegal drugs to get into the distribution system. Once it gets into the

distribution system, you can have these horror stories where people go to their local pharmacy and gotten counterfeit or adulterated or diluted drugs. We all want to do what we can to avoid that.

Rep. Klemin: Thank you.

Chairman DeKrey: Further testimony in support.

Howard Anderson, Executive Director, ND State Board of Pharmacy: (see attached testimony and amendments). I would like to see legend drug products be licensed.

Rep. Onstad: Do you have control over drugs that come from Canada's prescription drug system. Are we in charge of that.

Howard Anderson: Importation is technically illegal. The Prescription Drug Marketing Act, says specifically only the manufacturer can reimport drugs to the country. Those importations are technically illegal now, FDA does use enforcement discretion, so that you can bring in a 90 day supply for individuals. In an effort to lower prices for drugs, I think nationally, and Sen. Dorgan has one of the activists in trying to get us to lower the prices for manufacturers and those importations are technically illegal. But if you are bringing them in for yourself, they've allowed that, under enforcement discretion. There is no licensing authority to do that because importation is illegal. If, we could make that legal federally, we would license the Canadian pharmacies just like we do the MN pharmacies; and then I would rely on my counterpart in Manitoba to regulate those. Right now, I do that. If I find somebody who is bringing something in from Canada, I write them a letter and ask them to stop and send a copy to Canada. Then they address those issues as far as their laws will go. But all I have the power to do here is to ask them to stop.

Rep. Onstad: You mentioned the situation, is there something at the federal level. I am assuming that 1455 is something that is going to try and be adopted not only here in the state,

but in other states because it seems to be a problem. Is this going to be addressed at the federal level.

Howard Anderson: If you look at this, it already has been addressed at the federal level, but the pedigree requirements, they have been unable to implement because if it's not universally available, we don't have to do it yet. That's what they've done federally as the same excuse. They say since it's not universally available so I don't have to do it yet. They've said if it's not an electronic pedigree, it's too expensive and too hard for us to do. I think there are some positive things that we can do. The wholesalers know that they're going to have to do it eventually so they're getting ready for it. I talked with Dakota Drug in our state about this when I saw this bill, and they said they don't see a problem with it. We know we are going to have to do it eventually, so the legitimate wholesalers are going to get ready to provide the pedigree as quick as they can. There may be a few out there that say they can't do it, but in ND we'll say, you can't ship it in here. The Lipitor we had was made in China, introduced into the channel by a repackager who didn't pay enough attention to where he bought it from, or perhaps somebody on his payroll took some money to get those containers of torostatin and then they repackaged them. Then our wholesalers, including Dakota Drug in Minot and all the rest of the wholesalers thought they were legitimate products, repackaged. You couldn't tell the difference unless you laid them side by side on the tablet counter. That happened. Dakota Drug quit buying from those people. That was their only choice at that time, was to quit buying from them because you couldn't no longer guarantee it was legitimate stuff anymore.

Chairman DeKrey: Thank you. Further testimony in support. Testimony in opposition. Testimony neutral.

Dan Bellingham, Associate Director of Healthcare Distribution Management Association: (see attached testimony).

Rep. Koppelman: In the states where you proposed these amendments, I think you said 20 states or something like that, how many of those states have adopted the amendments. Are they picking and choosing.

Dan Bellingham: Unfortunately, we like to stress uniformity with all these states. To that point, FL initially had the worst situation. As they strengthened their licensure requirements, wholesalers have gone to states with weaker requirements. To answer your question, they've all started at different levels and so we haven't had to offer these exact amendments in most state. In terms of accreditation, of about the 7 or 8 states that have considered accreditation, only the one has made it a requirement for licensure. So we've been successful in all the others.

Rep. Koppelman: So if we were to adopt the amendments you suggest as you presented them, would that make us one of the weaker states or one of the stronger states.

Dan Bellingham: I believe you will still be one of the strongest states, because of the licensure requirements. As the Board of Department of Health reported, they passed their bill in 2002 or 2003, one of the first states to do so and before all their pedigree requirements kicked in, it was kind of a two pronged approach. You've got your licensure requirements and you've got your pedigree requirements to get at this problem. Before the pedigree requirement kicked in, they saw in the first year, a 35% decline in their licensed wholesalers. Granted they started with over 1,000, so it is still too many, but we saw that quick of a response.

Rep. Onstad: Go back and explain the part of the wholesalers and manufacturers depend on these wholesale distributors. Your statement is that it should go further back.

Dan Bellingham: We believe that if it is good enough for our legitimate members, it should be a good enough requirement for the legitimate members because our guys don't have anything to worry about in terms of criminal penalties, we wouldn't think their members would

be. Most states, as ND does, does license manufacturers as wholesalers. We just believe logically that it makes sense.

Chairman DeKrey: Thank you. Further testimony neutral.

Hank Wienmaster, Director of Operations for the Carrolton, IL McKesson facility: We are currently going through our **VAWD** accreditation for certification. McKesson is the largest pharmaceutical wholesaler in North America. We provide pharmaceuticals, over the counter health and beauty aids, as well as herbal medical items. Things that are ordered from our customers yesterday, are being delivered this morning across the state of ND; this would include Gateway Pharmacy in Bismarck and the VA Medical Center. As HDMA's largest member company, McKesson, we support their comments. I would like to discuss a few of the concerns that we have specific to the VAWD certification process. Primarily the length of time that it takes to become VAWD certified. In our case, we've found that there's no criteria, no timeframes that are set up as part of the VAWD certification process. Their web site simply states that it varies and provides no detail beyond that. An example of that would be that we applied for the VAWD certification process through their application in early July of 2006 and have an inspection date set up now in late February of 2007, which means we are waiting for 7 months. The time post inspection to receive our certification at this point in time, obviously will take an additional few weeks and it is unknown at this point in time, and there is no set timeframe. Whenever we do make contact, myself or members of my staff, as we work through this process, the normal response that we receive is that it is in process. As a result of the lengthy processing, the state of IN had to amend their state wholesale license renewal process from the original date of September 30, 2006 and was modified to provide temporary license in which we are participating with right now and is contingent upon us proving that we have applied for VAWD certification prior to September 30, 2006, and then it was renewed

contingent upon completion of certification and that date is open at this period of time, because they are waiting for all the wholesalers who are licensed in the state of IN to follow through on the VAWD certifications. There is no criteria or documentation that references what transpires after the facility inspection, based off the inspector's notes, comments, observations and/or recommendations; what the expectations are or will be at this point in time are unknown; will there be suggestions or mandatory modifications to current processes; to physical structures; what will the time frame be to respond or comply with these and how does this impact final certification. These are all currently unknown to us. In addition, McKesson has provided identical applications from the four facilities that applied for VAWD certification and we received succession to that, different requests for additional or different information from the facilities. It was not consistent across the board. The unintended consequences of VAWD requirement has reduced from 30 McKesson facilities with the capability to ship into the state of IN, to four that are pursuing and have applied formally for the VAWD certification. Ultimately, this could affect our ability to service our customers and their patients within the state. Currently, we are inspected by the State Board of Pharmacy, the FDA, the DEA and have several internal tools and mechanisms that we use to maintain and evaluated our internal processes. Lastly, the storage or retention and the accessibility of all the provider confidential and proprietary information from both the company's perspective as well as the designated reps that are senior most ranking manager at that facility that has responsibility for all day-to-day operations, at this point in time, it's not clearly documented or outlined. Having said all that, I would like to thank you for your time and attention to this important matter and to let you know that McKesson does stand ready to try and help protect and enhance security in the supply chain.