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Bill/Resolution No. HB 1455

House Judiciary Committee

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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.

Rep. Koppelman: You have raised a lot of questions and not given us many answers. I think it's going to need to go to the subcommittee, full committee, and legislature to work with manufacturers, distributors, wholesalers like yourself and our retail and Board of Pharmacy because you folks manufacture, distribute and dispense products that help save the lives and health of our citizens. That's important. What are you suggesting. You criticized the certification program, and didn't make any recommendations.

Hank Wienmaster: I was here to try to outline and provide detail about some of the areas that are within the VAWD certification process at this time.

Rep. Koppelman: Is there a solution.

Hank Wienmaster: I think potentially there are some other options, I know the State Board of Pharmacy certifications has been appropriate for this point in time, although McKesson does support stronger licensure processes, we want to make sure that the supply chain is intact.

Rep. Onstad: I recognize the problem continues to grow and your own company. What kind of security do you have in place as a company as a whole to try and keep this from happening.

Hank Wienmaster: We have a thorough process when we receive product in to evaluate it, to look at it, also when we receive returns to evaluate them. We review them and there is an escalation process if there are issues with them. We also manage and monitor our delivery network, companies within and companies that bring in products as well.

Rep. Onstad: Is that an FDA requirement or is that just something that you do on your own.

Hank Wienmaster: We're doing that on our own at this point in time.

Chairman DeKrey: Thank you. Further testimony in HB 1455.

Mike Ruud, ND Retail Association and the National Association of Chain Drug Stores: (see attached testimony of Diane Darvey, Director of Pharmacy Regulatory Affairs for NACDS). We support this with the following amendments that she provided there.

Rep. Koppelman: I notice that you have one of the amendments you are offering, you are recommending that it exempts the pharmacy warehouses. I'm just wondering, are you certain that's not a problem in terms of distribution chains. Once it is in the possession of the warehouse of that particular company, that it is secure and nothing to worry about.

Mike Ruud: I can get you an answer to that.

Chairman DeKrey: Thank you. Further testimony in HB 1455. We are going to close the hearing.

2007 HOUSE STANDING COMMITTEE MINUTES

Bill/Resolution No. HB 1455

House Judiciary Committee

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Hearing Date: 2/5/07

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Committee Clerk Signature

Minutes:

Chairman DeKrey: We will take a look at HB 1455.

Rep. Koppelman: The subcommittee met and we have met with the pharmaceutical folks, with the State Board of Pharmacy and looked carefully at the amendments offered by the wholesalers and essentially what we've done is basically melded those together into something that I think the parties all agreed to. We didn't have the wholesalers at the meeting, but we addressed most of their concerns. The amendments before you is basically what everyone has agreed on and I don't think there is anything really substantive there, it's primarily just dealing with semantics and specifics. I move the amendments.

Rep. Kingsbury: Second.

Rep. Delmore: We're covering the manufacturers as well as the distributors, with your amendment.

Rep. Koppelman: The manufacturers are covered in terms of their licensing requirements, which is what they have now. We didn't put them under the state inspection process, and Howard is fine with that because 1) we don't have many manufacturers in the state; 2) I don't think they want to do that work; and 3) they are already heavily regulated by the FDA on the

federal level. It's more getting at the wholesale chain, where the counterfeits are slipping into the process. Howard was here, and Joel was here and they are agreed on this.

Rep. Delmore: Did you talk about mail order, is that already covered in this.

Rep. Koppelman: We didn't deal with that in the amendments, so I think the bill does that initially and it's still there.

Rep. Onstad: Just want to add that the actual deadline for this...this notice is to get people on board, these companies, because the deadline was December 31, 2008.

Rep. Koppelman: The reason for that is that this VAWD certification and these things that they are in the process of working through, are still in process. We are on the cutting edge, we are probably only the second state to pass this legislation. There will be other states that follow.

Chairman DeKrey: We will take a voice vote on the amendments. Motion carried. We now have the bill before as amended. What are the committee's wishes in regard in HB 1455.

Rep. Koppelman: I move a Do Pass as amended.

Rep. Delmore: Seconded.

13 YES 0 NO 1 ABSENT DO PASS AS AMEND CARRIER: Rep. Koppelman

2007 HOUSE STANDING COMMITTEE MINUTES

Bill/Resolution No. HB 1455

House Judiciary Committee

☐ Check here for Conference Committee

Hearing Date: 2/7/07

Recorder Job Number: 3008

Committee Clerk Signature JRenose

Minutes:

Chairman DeKrey: We will reopen HB 1455.

Rep. Koppelman: Explained the amendment. It will say that the manufacturers engaged in wholesale distribution are subject to licensing; however, unless particular requirements are deemed necessary and appropriate following rule making. The manufacturers are fine with this and it does not really change the substance of the bill. It is just new wording to make it fit so I move the amendment.

Rep. Dahl: Seconded.

14 YES 0 NO 0 ABSENT DO PASS AS AMENDED CARRIER: Rep. Koppelman

FISCAL NOTE

Requested by Legislative Council
02/12/2007

Amendment to: HB 1455

1A. **State fiscal effect:** *Identify the state fiscal effect and the fiscal effect on agency appropriations compared to funding levels and appropriations anticipated under current law.*

	2005-2007 Biennium		2007-2009 Biennium		2009-2011 Biennium	
	General Fund	Other Funds	General Fund	Other Funds	General Fund	Other Funds
Revenues	$0	$0	$0	($22,500)	$0	($45,000)
Expenditures	$0	$4,000	$0	$30,000	$0	$25,000
Appropriations	$0	$0	$0	$0	$0	$0

1B. **County, city, and school district fiscal effect:** *Identify the fiscal effect on the appropriate political subdivision.*

2005-2007 Biennium			2007-2009 Biennium			2009-2011 Biennium		
Counties	Cities	School Districts	Counties	Cities	School Districts	Counties	Cities	School Districts
$0	$0	$0	$0	$0	$0	$0	$0	$0

2A. **Bill and fiscal impact summary:** *Provide a brief summary of the measure, including description of the provisions having fiscal impact (limited to 300 characters).*

We have 702 Whol/manf/dists licensed now. Some (300) of those currently licensed, may no longer qualify for licensure after VAWD is required.The flexibility given to the board with the amendments should ameliorate the financial consequences, by spreading it over a longer time period.

B. **Fiscal impact sections:** *Identify and provide a brief description of the sections of the measure which have fiscal impact. Include any assumptions and comments relevant to the analysis.*

The bill now exempts manufacturers only from the bond, fingerprint and pedigree requirement, not from being licensed.There are currently only 48 VAWD certified, but the flexibility to extend the date 1 year will allow many of those currently licensed to complete the process. The requirement to inspect now focuses on our in state licensees, with the VAWD certification taking care of most of the rest.The background checks will be paid for by the applicants, so should have no net fiscal impact.Rule making will cost about $4000

3. **State fiscal effect detail:** *For information shown under state fiscal effect in 1A, please:*
   A. **Revenues:** *Explain the revenue amounts. Provide detail, when appropriate, for each revenue type and fund affected and any amounts included in the executive budget.*

Revenue for the board of pharmacy would decrease, as some of our current licensees will not be eligible,or may choose not to renew. An estimate of 150 in the next biennium and 300 in the 2009-2011 period under current license fees of $150 per year, would reduce revenue somewhat, and might need to be made up with license fee increases, for those actually in the distribution business. This should not be a problem as North Dakota is currently amoung the lowest in the country. The board has adequate reserves to transition them over this uncertain period.

B. **Expenditures:** *Explain the expenditure amounts. Provide detail, when appropriate, for each agency, line item, and fund affected and the number of FTE positions affected.*

The board would need to retain an inspector at about one-fourth time, to fulfill the inspection criteria. $5000 extra is included in the first year to provide training.

C. **Appropriations:** *Explain the appropriation amounts. Provide detail, when appropriate, for each agency and fund affected. Explain the relationship between the amounts shown for expenditures and appropriations. Indicate whether the appropriation is also included in the executive budget or relates to a continuing appropriation.*

No appropriations should be necessary, as the Boards licensing program should be self sustaining. The board has adequate reserves to transition them through the period when potential licensees are adjusting to the new requirements.

Name:	Howard C. Anderson	**Agency:**	Board of Pharmacy
Phone Number:	328-9535	**Date Prepared:**	12/12/2007

FISCAL NOTE

Requested by Legislative Council
01/16/2007

Bill/Resolution No.: HB 1455

1A. **State fiscal effect:** *Identify the state fiscal effect and the fiscal effect on agency appropriations compared to funding levels and appropriations anticipated under current law.*

	2005-2007 Biennium		2007-2009 Biennium		2009-2011 Biennium	
	General Fund	Other Funds	General Fund	Other Funds	General Fund	Other Funds
Revenues	$0	$0	$0	($99,100)	$0	($99,100)
Expenditures	$0	$4,000	$0	$72,000	$0	$76,320
Appropriations	$0	$0	$0	$0	$0	$0

1B. **County, city, and school district fiscal effect:** *Identify the fiscal effect on the appropriate political subdivision.*

2005-2007 Biennium			2007-2009 Biennium			2009-2011 Biennium		
Counties	Cities	School Districts	Counties	Cities	School Districts	Counties	Cities	School Districts
$0	$0	$0	$0	$0	$0	$0	$0	$0

2A. **Bill and fiscal impact summary:** *Provide a brief summary of the measure, including description of the provisions having fiscal impact (limited to 300 characters).*

We have 702 Whol/manf/dists licensed now. This bill would exempt 126 of those and make another 536 of them ineligible, including all of those located within North Dakota. We would be required to inspect the rest, wherever they are located.

B. **Fiscal impact sections:** *Identify and provide a brief description of the sections of the measure which have fiscal impact. Include any assumptions and comments relevant to the analysis.*

43-15.3-03 would exempt 126 of our current licencees and make another 536 of them ineligible, as there are currently only 40 VAWD with none of those located within North Dakota. We would be required to inspect the rest, wherever they are located. The backgroud check provision would be paid for by the applicants, so should have no net fiscal impact.

3. **State fiscal effect detail:** *For information shown under state fiscal effect in 1A, please:*
   A. **Revenues:** *Explain the revenue amounts. Provide detail, when appropriate, for each revenue type and fund affected and any amounts included in the executive budget.*

Revenue for the board of pharmacy would decrease, as many of our current licensees would be exempt and others would be ineligible. The 40 left would bring in only $6000 under current license fees of $150 per year.

B. **Expenditures:** *Explain the expenditure amounts. Provide detail, when appropriate, for each agency, line item, and fund affected and the number of FTE positions affected.*

The board would need to retain an inspector at about half time, if the current inspection criteria stand

C. **Appropriations:** *Explain the appropriation amounts. Provide detail, when appropriate, for each agency and fund affected. Explain the relationship between the amounts shown for expenditures and appropriations. Indicate whether the appropriation is also included in the executive budget or relates to a continuing appropriation.*

No appropriations should be necessary, as the Boards licensing program should be self sustaining.

Name:	Howard Anderson	**Agency:**	Board of Pharmacy
Phone Number:	328-9535	**Date Prepared:**	01/19/2007

Prepared for Rep. Koppleman
By Erica Shively

PROPOSED AMENDMENTS TO H.B. 1455

Page 4, line 12, remove "any"

Page 4, line 13, remove "one of"

Page 4, line 15, replace "or" with "and"

Page 5, line 8, replace "store" with "stored"

Page 5, line 20 after "goes" insert ",directly or by drop shipment,"

Page 6, line 15, replace "individual" with "person"

Page 8, line 17, remove "The board shall exempt manufacturers"

Page 8, remove lines 18, 91, 20, and 21

Page 8, line 17, after the period insert "While manufacturers engaged in wholesale distribution are subject to licensing, information and qualification requirements for licensure beyond that required by federal law or regulation do not apply to manufacturers distributing their own United States Food and Drug Administration-approved drugs, unless particular requirements are deemed necessary and appropriate following rulemaking."

Page 10, line 15, replace "thirty" with "one hundred eighty"

Page 10, overstrike lines 19 and 20 and insert immediately thereafter "Inspects or appoints a third party recognized by the board for the purpose of inspecting the wholesale distribution operations of the facility prior to initial licensure and continues to inspect periodically thereafter in accordance with a schedule to be determined by the board, but not less than every three years. Manufacturing facilities are exempt from inspection by the board if the manufacturing facilities are currently registered with the FDA in accordance with Section 510 of the Federal Act."

Page 11, line 29, after "state." insert "Any chain pharmacy warehouse that is engaged only in intra-company transfers is exempt from the bond requirement."

Page 12, line 10, replace "or" with ","

Page 12, line 10, after "revoke" insert "or not renew"

Page 12, line 16, replace "this section" with "subdivision h of subsection 2 of section 43"

Page 12, line 25, after "board." insert "The deadline date may be extended through December 31, 2008 by action of the Board."

Page 16, line 19, after "law" insert "or the board"

Page 16, after line 14, insert "(7) National Drug Code (NDC) number"

Page 19, line 1, replace "one" with "ten"

Page 19, line 12, after "resides" insert "in the state"

Date: 2/5/07
Roll Call Vote #: 1

2007 HOUSE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. 1455

House JUDICIARY Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number

Action Taken Do Pass as Amended

Motion Made By Rep. Koppelman Seconded By Rep. Delmore

Representatives	Yes	No	Representatives	Yes	No
Chairman DeKrey	✓		Rep. Delmore	✓	
Rep. Klemin	✓		Rep. Griffin	✓	
Rep. Boehning	✓		Rep. Meyer	✓	
Rep. Charging	✓		Rep. Onstad	✓	
Rep. Dahl	✓		Rep. Wolf	✓	
Rep. Heller	✓				
Rep. Kingsbury	✓				
Rep. Koppelman	✓				
Rep. Kretschmar	✓				

Total (Yes) 13 No 0

Absent 1

Floor Assignment Rep. Koppelman

If the vote is on an amendment, briefly indicate intent:

Date: 2-7-07
Roll Call Vote #: 1

2007 HOUSE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. HB1455

House JUDICIARY Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number

Action Taken Do Pass as Amended

Motion Made By Rep. Koppelman Seconded By Rep. Dahl

Representatives	Yes	No	Representatives	Yes	No
Ch. DeKrey	✓		Rep. Delmore	✓	
Rep. Klemin	✓		Rep. Griffin	✓	
Rep. Boehning	✓		Rep. Meyer	✓	
Rep. Charging	✓		Rep. Onstad	✓	
Rep. Dahl	✓		Rep. Wolf	✓	
Rep. Heller	✓				
Rep. Kingsbury	✓				
Rep. Koppelman	✓				
Rep. Kretschmar	✓				

Total (Yes) 14 No 0

Absent 0

Floor Assignment Rep. Koppelman

If the vote is on an amendment, briefly indicate intent:

REPORT OF STANDING COMMITTEE

HB 1455: Judiciary Committee (Rep. DeKrey, Chairman) recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends **DO PASS** (14 YEAS, 0 NAYS, 0 ABSENT AND NOT VOTING). HB 1455 was placed on the Sixth order on the calendar.

Page 4, line 12, remove "any"

Page 4, line 13, remove "one of"

Page 4, line 15, replace "or" with "and"

Page 5, line 8, replace "store" with "stored"

Page 5, line 20, after "goes" insert ", directly or by drop shipment,"

Page 6, line 15, replace "an individual" with "a person"

Page 8, line 17, replace "The board shall exempt manufacturers" with "However, information and qualification requirements for licensure beyond that required by federal law or regulation do not apply to manufacturers distributing their own United States food and drug administration-approved drugs, unless particular requirements are deemed necessary and appropriate following rulemaking."

Page 8, remove lines 18 through 21

Page 10, line 15, replace "thirty" with "one hundred eighty"

Page 10, line 19, replace "Conducts a physical inspection of the facility at the address provided by the" with "Inspects or appoints a third party recognized by the board for the purpose of inspecting the wholesale distribution operations of the facility before initial licensure and continues to inspect periodically thereafter in accordance with a schedule to be determined by the board, but not less than every three years. Manufacturing facilities are exempt from inspection by the board if the manufacturing facilities are currently registered with the federal food and drug administration in accordance with section 510 of the federal Food, Drug, and Cosmetic Act [21 U.S.C. 301]; and"

Page 10, remove line 20

Page 11, line 29, after the underscored period insert "Any chain pharmacy warehouse that is engaged only in intra-company transfers is exempt from the bond requirement."

Page 12, line 10, replace "or" with an underscored comma and after "revoke" insert ", or refuse to renew"

Page 12, line 16, replace "this section" with "subdivision h of subsection 2"

Page 12, line 25, after the underscored period insert "By action of the board, the deadline may be extended through December 31, 2008."

Page 16, line 13, remove "and"

Page 16, line 14, after "form" insert "; and

(7) National drug code (NDC) number"

Page 16, line 19, after "law" insert "or the board"

Page 19, line 1, replace "one" with "ten"

Page 19, line 11, after the second "county" insert "in the state"

Renumber accordingly

2007 SENATE HUMAN SERVICES

HB 1455

2007 SENATE STANDING COMMITTEE MINUTES

Bill/Resolution No. 1455

Senate Human Services Committee

☐ Check here for Conference Committee

Hearing Date: 3-13-07

Recorder Job Number: 4971, 4975

Committee Clerk Signature Veronica Spurling

Minutes:

JOB # 4971

Roll was taken and all members were present.

Senator Judy Lee, Chairman, opened the public hearing on HB 1455.

Representative Blair Thoreson from District 44 spoke in support of HB 1455. He passed out copies of an article that came out several weeks ago in Parade Magazine that comes out in the Sunday paper. The article talked about counterfeit drugs and the danger to our health. The FDA investigated 53 cases of counterfeit drugs last year. This is up from just 6 a year or two before that. There has been a case of counterfeit pharmaceuticals in our state. People need to be able to trust the pharmaceuticals they are getting will help them and not harm them.

Representative Kim Koppelman from District 13 presented a powerpoint (printed on paper) to the committee. See attachment # 1. When you go to your pharmacy to have your prescription filled are you sure that what it says on the bottle is what is in the bottle? Are you sure the dosage is correct? Is your pharmacist sure? The person who prepared the powerpoint is State Senator Marvin Riegsecker from Indiana. The problem is the counterfeits get into the wholesale supply chain. On page three of attachment #1 the picture in the upper left shows a tube bringing a yellow substance. The substance in this case was highway paint. On the

bottom of page three of attachment #1 in shows counterfeits and the real thing side by side. The real tablet actually looks rougher because the mold is more worn. Sometimes the dosage in counterfeits is changed which can be life threatening to the patient. Hopefully this bill will allow our Board of Pharmacy in North Dakota to insure as much as possible that the drugs are authentic and they are what they say they are.

Senator Dever asked if this bill is modeled after a bill in some other state.

Representative Koppelman said he and Representative Thoreson were attending the Midwest Legislative Conference in Chicago this summer where they saw this presentation by Senator Riegsecker. They decided to introduce the bill together. It was modeled after the Indiana bill but then they conferred with the PhRMA folks in the interim. The Indiana bill was adopted by the Council State Governments in its suggested state legislation volume. It has been amended somewhat to deal with the individual nature of each state. They did pick up a few ideas from wholesalers in the House Judiciary Committee.

Senator Dever asked if the Indiana bill was recent enough that they don't have experience to share.

Representative Koppelman said we are on the cutting edge of this. Indiana has obviously done it but not many other states. He is expecting to see a wave of others. Indiana put their Board of Pharmacy in charge of the process. They already license the wholesalers and the pharmacists. There is not a long history because we are pioneering this. The PhRMA bill which is their model is very similar also to what we will be doing in North Dakota.

Senator Lee said she has attended several meetings on this topic in the last number of years. She knows it is a problem but she is not sure taking action on it at the state level is the right approach because it is a global issue.

Representative Koppelman said the Senator from Indiana took action because he felt the federal government was not moving on it fast enough and the public was in jeopardy. He is pleased that PhRMA has come up with a model bill and he feels that it will become what she is talking about. It will be a standard approach state by state at this point but if the federal government comes along and decides to do it through the commerce clause they can do that. In the mean time our citizens will be safer.

Howard Anderson Jr., Executive Director of the North Dakota State Board of Pharmacy, handed out attachment #2. In 1989 the Prescription Drug Marketing Act was passed at the federal level. It pretty much moved licensing of the wholesalers to the states rather than the federal level. If they were going to be a wholesaler they needed to be licensed in the state where they were doing business. That is one reason why they are doing it at the state level. Florida was the first state to adopt wholesale licensing regulations. They did it there because Florida was one of the states where there was the most trouble. Subsequent to that the National Association of Boards of Pharmacy put some language in their model act and the model wholesale licensing statute which contains most of the things that we see in our bill. There is some history to this process. There is legislation at the federal level but it has not been implemented. The vision is to have an electronic pedigree and that is this information would all be electronic as you ordered your products and it would come through to you electronically. The technology for that is not yet endemic in the wholesale business. There is language in the bill that states it will be done once it is in place federally. One thing that is holding it up at the federal level is that it is not endemic and some wholesaler is always saying they don't yet have the technology. This gives them the option of setting the date in the future. There will be another legislative session before they have to set an electronic pedigree date. They will bring any changes to the next legislative session if it needs to be changed. The

pedigree is important to keep counterfeit drugs out of the distribution system. In talking with wholesalers they feel these timetables are realistic. Wholesalers feel they will have to go to this eventually and don't feel it is much besides filling out an application. He feels the amendments adequately address the problems they saw with the bill in the House.

Senator Heckaman asked if this would apply to samples that pharmaceutical companies give to doctors.

Mr. Anderson said it will apply to manufacturers. They do have to get licensed; they do not have to do the bonding and background checks and the pedigree. He feels eventually the manufacturers will have to do the pedigree because if you want a pedigree you have to start at the beginning. Manufacturers wanted to be exempted from this bill because most of the problems are in the reintroducing of the products into the wholesale system. That's what this bill requires. If you are going to reintroduce it you have to be able to supply the pedigree. The sample itself will not have a pedigree, but the manufacturers and reps that distribute samples are agents of the manufacturer who is licensed. There are already regulations and penalties in place for manufacturers.

Senator Lee said she supports the concept of the bill but it seems extraordinarily detailed.

Mr. Anderson said the wholesale statute we have now is pretty large already. What you see here is when you are developing a model act at the national level you need to get all of that in to keep everybody happy. It also keeps consistency from state to state. The specificity lets people know upfront what the requirements will be.

Senator Lee asked if a manufacturer were located in North Dakota would they be added.

Mr. Anderson said manufacturers presently are required to license with the North Dakota State Board of Pharmacy if their product is in North Dakota. In the bill the definition of wholesaler starts on page 7, line 27 and this bill is about wholesalers. There are some exemptions for

manufacturers for bonding, fingerprinting etc. because they are already licensed by the FDA. They also have to be licensed in North Dakota.

Senator Lee asked if there would be any reason to delay the implementation of this bill.

Mr. Anderson said there are already some provisions in there like the bond requirement that says December 31, 2007 with the option to extend that for a year. The provision for the electronic pedigree doesn't kick in until July 1, 2009. This bill puts in place the requirement for the pedigree for those drugs that come from the outside.

Matt Van Hook from a small Food & Drug law firm in DC, Engel & Novitt, spoke on behalf of PhRMA in support of the bill. See attachment # 3. The understanding of what the minimal federal requirements are has changed even in the last 3 months. This law would make sure they meet the minimal federal requirements. It also closes the federal loophole and requires pedigrees for more transactions than are required under federal law. It sets the stage for the electronic track and trace technology. One reason for the FDA's delay is they hoped to bypass all the difficulties and logistical challenges of paper pedigrees by getting right to electronic track and trace pedigree technology. They thought that would happen this year but the details are much more difficult than anyone had envisioned. Everyone involved is saying this is desirable but getting there is difficult. This bill sets target dates for track and trace technology. When that happens they will have better control than paper pedigrees, but paper pedigrees are the best thing we have today. This is a very timely and welcome reform.

Senator Lee asked if there was anything in the bill Mr. Van Hook would like to see changed.

Mr. Van Hook said PhRMA very much supports the engrossed version from the House.

Senator Lee referred to a testimony from Daniel Bellingham that she distributed to the committee members. See attachment # 4.

Opposition: -

Neutral: -

Senator Lee commented that the testimony from Daniel Bellingham contained some proposed amendments which they can discuss after they have a chance to read over them.

Chairman Judy Lee closed the public hearing on HB 1455.

JOB # 4975

Chairman Judy Lee opened discussion on HB 1455 and the proposed amendments from Daniel Bellingham. Senator Lee mentioned that someone had commented that they thought these were the same amendments they considered on the House side and they had turned them down.

Senator Warner asked if anyone was aware if there would be any implications for importing prescription drugs from Canadian pharmacies.

Mary Koenecke from Glaxo Smith Kline said it should not apply to someone who particularly is going across the border to get it because it applies to wholesalers.

Scott Setzepfandt with HLR Service Corp said he believes it only applies to the distribution system within the United States so it is only if it is bought within the United States.

Joel Gilbertson mentioned that Matt Van Hook would be arriving shortly with a written response to the amendments proposed by Daniel Bellingham.

Matt Van Hook speaking on behalf of PhRMA presented his response to the amendment proposed by Daniel Bellingham. He had looked at the minutes from the House. These same amendments had been considered by the House and the House had rejected them. See attachment # 5.

Chairman Judy Lee closed the discussion on HB 1455.

The committee will wait until a later date to act on this bill.

2007 SENATE STANDING COMMITTEE MINUTES

Bill/Resolution No. 1455

Senate Human Services Committee

☐ Check here for Conference Committee

Hearing Date: 3-14-07

Recorder Job Number: 5086

Committee Clerk Signature Mona Appelling

Minutes:

JOB # 5086

All members of the committee were present.

Chairman Judy Lee opened discussion on HB 1455. This bill is trying to make sure North Dakota is at the front of the line in tightening up the rules and regulations about counterfeit drugs. There was no opposition except for the amendments offered by Daniel Bellingham, the Associate Director of State Government Affairs for Healthcare Distribution Management Association. Those same recommendations had been considered by the House and had been discarded. A few people who had testified mentioned to Senator Lee that they were opposed to those amendments. The amendments offered by Mr. Bellingham would have included the manufacturers and there was a fair amount of consensus among the people testifying that that didn't need to be done at this point. Distribution was another area he had a concern about. He also wanted a track and trace system such as the RFID.

Senator Erbele made a motion to pass engrossed HB 1455.

Senator Pomeroy seconded the motion.

Roll Call Vote: Yes 6 No 0 Absent 0

Carrier: Judy Lee

Date: 3-14-07

Roll Call Vote #: _____

2007 SENATE STANDING COMMITTEE ROLL CALL VOTES

BILL/RESOLUTION NO. HB 1455

Senate **HUMAN SERVICES** Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number _____

Action Taken Do Pass

Motion Made By Sen. Erbele Seconded By Sen. Pomeroy

Senators	Yes	No	Senators	Yes	No
Senator Judy Lee, Chairman	✓		Senator Joan Heckaman	✓	
Senator Robert Erbele, V. Chair	✓		Senator Jim Pomeroy 2	✓	
Senator Dick Dever	✓		Senator John M. Warner	✓	

Total (Yes) 6 No 0

Absent 0

Floor Assignment Senator Lee

If the vote is on an amendment, briefly indicate intent:

REPORT OF STANDING COMMITTEE

HB 1455, as engrossed: Human Services Committee (Sen. J. Lee, Chairman) recommends **DO PASS** (6 YEAS, 0 NAYS, 0 ABSENT AND NOT VOTING). Engrossed HB 1455 was placed on the Fourteenth order on the calendar.

2007 SENATE HUMAN SERVICES

HB 1455

2007 SENATE STANDING COMMITTEE MINUTES

Bill/Resolution No. 1455

Senate Human Services Committee

☐ Check here for Conference Committee

Hearing Date: 3-13-07

Recorder Job Number: 4971, 4975

Committee Clerk Signature

Minutes:

JOB # 4971

Roll was taken and all members were present.

Senator Judy Lee, Chairman, opened the public hearing on HB 1455.

Representative Blair Thoreson from District 44 spoke in support of HB 1455. He passed out copies of an article that came out several weeks ago in Parade Magazine that comes out in the Sunday paper. The article talked about counterfeit drugs and the danger to our health. The FDA investigated 53 cases of counterfeit drugs last year. This is up from just 6 a year or two before that. There has been a case of counterfeit pharmaceuticals in our state. People need to be able to trust the pharmaceuticals they are getting will help them and not harm them.

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Senator Dever asked if this bill is modeled after a bill in some other state.

Representative Koppelman said he and Representative Thoreson were attending the Midwest Legislative Conference in Chicago this summer where they saw this presentation by Senator Riegsecker. They decided to introduce the bill together. It was modeled after the Indiana bill but then they conferred with the PhRMA folks in the interim. The Indiana bill was adopted by the Council State Governments in its suggested state legislation volume. It has been amended somewhat to deal with the individual nature of each state. They did pick up a few ideas from wholesalers in the House Judiciary Committee.

Senator Dever asked if the Indiana bill was recent enough that they don't have experience to share.

Representative Koppelman said we are on the cutting edge of this. Indiana has obviously done it but not many other states. He is expecting to see a wave of others. Indiana put their Board of Pharmacy in charge of the process. They already license the wholesalers and the pharmacists. There is not a long history because we are pioneering this. The PhRMA bill which is their model is very similar also to what we will be doing in North Dakota.

Senator Lee said she has attended several meetings on this topic in the last number of years. She knows it is a problem but she is not sure taking action on it at the state level is the right approach because it is a global issue.

Representative Koppelman said the Senator from Indiana took action because he felt the federal government was not moving on it fast enough and the public was in jeopardy. He is pleased that PhRMA has come up with a model bill and he feels that it will become what she is talking about. It will be a standard approach state by state at this point but if the federal government comes along and decides to do it through the commerce clause they can do that. In the mean time our citizens will be safer.

Howard Anderson Jr., Executive Director of the North Dakota State Board of Pharmacy, handed out attachment #2. In 1989 the Prescription Drug Marketing Act was passed at the federal level. It pretty much moved licensing of the wholesalers to the states rather than the federal level. If they were going to be a wholesaler they needed to be licensed in the state where they were doing business. That is one reason why they are doing it at the state level. Florida was the first state to adopt wholesale licensing regulations. They did it there because Florida was one of the states where there was the most trouble. Subsequent to that the National Association of Boards of Pharmacy put some language in their model act and the model wholesale licensing statute which contains most of the things that we see in our bill. There is some history to this process. There is legislation at the federal level but it has not been implemented. The vision is to have an electronic pedigree and that is this information would all be electronic as you ordered your products and it would come through to you electronically. The technology for that is not yet endemic in the wholesale business. There is language in the bill that states it will be done once it is in place federally. One thing that is holding it up at the federal level is that it is not endemic and some wholesaler is always saying they don't yet have the technology. This gives them the option of setting the date in the future. There will be another legislative session before they have to set an electronic pedigree date. They will bring any changes to the next legislative session if it needs to be changed. The

pedigree is important to keep counterfeit drugs out of the distribution system. In talking with wholesalers they feel these timetables are realistic. Wholesalers feel they will have to go to this eventually and don't feel it is much besides filling out an application. He feels the amendments adequately address the problems they saw with the bill in the House.

Senator Heckaman asked if this would apply to samples that pharmaceutical companies give to doctors.

Mr. Anderson said it will apply to manufacturers. They do have to get licensed; they do not have to do the bonding and background checks and the pedigree. He feels eventually the manufacturers will have to do the pedigree because if you want a pedigree you have to start at the beginning. Manufacturers wanted to be exempted from this bill because most of the problems are in the reintroducing of the products into the wholesale system. That's what this bill requires. If you are going to reintroduce it you have to be able to supply the pedigree. The sample itself will not have a pedigree, but the manufacturers and reps that distribute samples are agents of the manufacturer who is licensed. There are already regulations and penalties in place for manufacturers.

Senator Lee said she supports the concept of the bill but it seems extraordinarily detailed.

Mr. Anderson said the wholesale statute we have now is pretty large already. What you see here is when you are developing a model act at the national level you need to get all of that in to keep everybody happy. It also keeps consistency from state to state. The specificity lets people know upfront what the requirements will be.

Senator Lee asked if a manufacturer were located in North Dakota would they be added.

Mr. Anderson said manufacturers presently are required to license with the North Dakota State Board of Pharmacy if their product is in North Dakota. In the bill the definition of wholesaler starts on page 7, line 27 and this bill is about wholesalers. There are some exemptions for

manufacturers for bonding, fingerprinting etc. because they are already licensed by the FDA. They also have to be licensed in North Dakota.

Senator Lee asked if there would be any reason to delay the implementation of this bill.

Mr. Anderson said there are already some provisions in there like the bond requirement that says December 31, 2007 with the option to extend that for a year. The provision for the electronic pedigree doesn't kick in until July 1, 2009. This bill puts in place the requirement for the pedigree for those drugs that come from the outside.

Matt Van Hook from a small Food & Drug law firm in DC, Engel & Novitt, spoke on behalf of PhRMA in support of the bill. See attachment # 3. The understanding of what the minimal federal requirements are has changed even in the last 3 months. This law would make sure they meet the minimal federal requirements. It also closes the federal loophole and requires pedigrees for more transactions than are required under federal law. It sets the stage for the electronic track and trace technology. One reason for the FDA's delay is they hoped to bypass all the difficulties and logistical challenges of paper pedigrees by getting right to electronic track and trace pedigree technology. They thought that would happen this year but the details are much more difficult than anyone had envisioned. Everyone involved is saying this is desirable but getting there is difficult. This bill sets target dates for track and trace technology. When that happens they will have better control than paper pedigrees, but paper pedigrees are the best thing we have today. This is a very timely and welcome reform.

Senator Lee asked if there was anything in the bill Mr. Van Hook would like to see changed.

Mr. Van Hook said PhRMA very much supports the engrossed version from the House.

Senator Lee referred to a testimony from Daniel Bellingham that she distributed to the committee members. See attachment # 4.

Opposition: -

Neutral: -

Senator Lee commented that the testimony from Daniel Bellingham contained some proposed amendments which they can discuss after they have a chance to read over them.

Chairman Judy Lee closed the public hearing on HB 1455.

JOB # 4975

Chairman Judy Lee opened discussion on HB 1455 and the proposed amendments from Daniel Bellingham. Senator Lee mentioned that someone had commented that they thought these were the same amendments they considered on the House side and they had turned them down.

Senator Warner asked if anyone was aware if there would be any implications for importing prescription drugs from Canadian pharmacies.

Mary Koenecke from Glaxo Smith Kline said it should not apply to someone who particularly is going across the border to get it because it applies to wholesalers.

Scott Setzepfandt with HLR Service Corp said he believes it only applies to the distribution system within the United States so it is only if it is bought within the United States.

Joel Gilbertson mentioned that Matt Van Hook would be arriving shortly with a written response to the amendments proposed by Daniel Bellingham.

Matt Van Hook speaking on behalf of PhRMA presented his response to the amendment proposed by Daniel Bellingham. He had looked at the minutes from the House. These same amendments had been considered by the House and the House had rejected them. See attachment # 5.

Chairman Judy Lee closed the discussion on HB 1455.

The committee will wait until a later date to act on this bill.

2007 SENATE STANDING COMMITTEE MINUTES

Bill/Resolution No. 1455

Senate Human Services Committee

☐ Check here for Conference Committee

Hearing Date: 3-14-07

Recorder Job Number: 5086

Committee Clerk Signature

Minutes:

JOB # 5086

All members of the committee were present.

Chairman Judy Lee opened discussion on HB 1455. This bill is trying to make sure North Dakota is at the front of the line in tightening up the rules and regulations about counterfeit drugs. There was no opposition except for the amendments offered by Daniel Bellingham, the Associate Director of State Government Affairs for Healthcare Distribution Management Association. Those same recommendations had been considered by the House and had been discarded. A few people who had testified mentioned to Senator Lee that they were opposed to those amendments. The amendments offered by Mr. Bellingham would have included the manufacturers and there was a fair amount of consensus among the people testifying that that didn't need to be done at this point. Distribution was another area he had a concern about. He also wanted a track and trace system such as the RFID.

Senator Erbele made a motion to pass engrossed HB 1455.

Senator Pomeroy seconded the motion.

Roll Call Vote: Yes 6 No 0 Absent 0

Carrier: Judy Lee

Date: 3-14-07

Roll Call Vote #: _____

2007 SENATE STANDING COMMITTEE ROLL CALL VOTES

BILL/RESOLUTION NO. HB 1455

Senate **HUMAN SERVICES** Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number _____

Action Taken Do Pass

Motion Made By Sen. Erbele Seconded By Sen. Pomeroy

Senators	Yes	No	Senators	Yes	No
Senator Judy Lee, Chairman	✓		Senator Joan Heckaman	✓	
Senator Robert Erbele, V. Chair 1	✓		Senator Jim Pomeroy 2	✓	
Senator Dick Dever	✓		Senator John M. Warner	✓	

Total (Yes) 6 No 0

Absent 0

Floor Assignment Senator Lee

If the vote is on an amendment, briefly indicate intent:

REPORT OF STANDING COMMITTEE

HB 1455, as engrossed: Human Services Committee (Sen. J. Lee, Chairman) recommends **DO PASS** (6 YEAS, 0 NAYS, 0 ABSENT AND NOT VOTING). Engrossed HB 1455 was placed on the Fourteenth order on the calendar.

2007 TESTIMONY

HB 1455

News Releases

June 30, 2006

Minot man sentenced to five years for selling designer and misbranded drugs, violating customs laws

BISMARCK, N.D. -- A former Minot, N.D., man was sentenced today to five years in prison for selling designer and misbranded drugs over the Internet, claiming they were intended for research purposes, and for violating Federal import laws.

U.S. District Court Chief Judge Daniel L Hovland sentenced Lee Michael Badrak, 34, to 60 months' imprisonment to be followed by four years of supervised release. Badrak's sentence was also based upon a conviction in a separate case for conspiracy to possess with intent to distribute and distribute cocaine, to which Badrak pleaded guilty July 14, 2005.

The sentencing was the result of a joint investigation conducted by the U.S. Food and Drug Administration Office of Criminal Investigation (FDA-OCI) in Minneapolis; U.S. Immigration and Customs Enforcement (ICE) in Minot; and the Drug Enforcement Administration (DEA) in Fargo and Bismarck.

Badrak pleaded guilty January 19, 2006, to one count of conspiracy to distribute and possess with intent to distribute controlled substance analogues 5-Methoxyalpha-methyltryptamine HCl (5-MeO-AMT) and 5-Methoxy-N, N-Disopropyltyptamine HCl (5-MeODIPT); one count of introducing the misbranded drug 2,4 Dinitrophenal (DNP) into interstate commerce; and one count of introducing the misbranded drug Nalbuphine HCl into interstate commerce.

LTK Research Products LLC (LTK), a company owned by Badrak and his wife Melissa Ashley Badrak, operated between 2000 and 2004 out of Minot, selling chemicals over its Web site, **www.ltkresearchproducts.com** , to thousands of individuals throughout the United States.

LTK pleaded guilty January 19, 2006, to one count of conspiracy to distribute and possess with intent to distribute controlled substance analogues in connection with sales of Alpha-methyltryptamine (AMT), (5-MeO-AMT), and (5-MeO-DIPT); and one count of importing goods, the chemical Dextromethorphan Hydrobromide (DXM), into the United States by means of false statements.

LTK, which is no longer operating as a company, was ordered to pay a special assessment of $200, and to forfeit all chemicals, office equipment, records, computers, and other assets to the FDA, the DEA, ICE, the North Dakota Bureau of Criminal Investigation, and Ward County Narcotics Task Force.

LTK's Web site suggested that it was in business to provide chemicals to researchers. However, the company had a history of selling hazardous chemicals that were abused as recreational hallucinogens. The investigation revealed that nearly all shipments of the chemicals were sent to individuals rather than research institutions or facilities, as portrayed by the LTK Web site. Many of the chemicals advertised for sale by Badrak and LTK were controlled substance analogues, which are similar in chemical structure and physiological effects to illegal scheduled controlled substances, primarily hallucinogens. LTK offered for sale hallucinogenic chemicals similar in effects to 3,4 -- methylenedioxymethamphetamine (MDMA), known on the street as Ecstasy or X, a Schedule I Controlled Substance.

Designer drug sellers try to evade the law by selling newly created analogue drugs that are similar to Ecstasy, but have not yet been scheduled as illegal drugs by the Drug Enforcement Administration. Sales of the dangerous designer drugs for personal consumption are illegal under Federal drug laws, and numerous overdoses have been traced to these illegal analogue designer drugs.

When sold as hallucinogens without directions for use or warnings, as required by the FDA, these chemicals are also considered to be "misbranded drugs." Other chemicals included in the inventory of LTK that were being illicitly sold and used are as follows: absinthe oil; Nalbuphine HCl (an analgesic opiate approved for use by the FDA when lawfully sold as a prescription pain drug, but widely abused by bodybuilders to treat pain); 2,4-Dinitrophenol (DNP), also known as "2,4 D" (widely used by bodybuilders for weight loss); Scopolamine HBR (commonly used as a motion sickness medicine); and Dextromethorphan HBR (DXM), which is the active ingredient in several over-the-counter brands of cough medicine.

DXM is a disassociative analgesic, which is similar in effects to Ketamine (known on the street as "Cat" or "Special K") and Phenylcyclidine (PCP), known on the street as "Angel Dust," both of which are Schedule I controlled substances. DXM is widely abused by teenagers, who will often drink several bottles of cough syrup at a time. There have been several overdoses attributed to DXM, as well as several deaths of individuals under DXM intoxication. These drugs were also sold with no directions for use or adequate warnings against use as required by law, making these drugs misbranded.

Sentencing for Badrak and LTK marks the conclusion of the North Dakota portion of a coordinated nationwide investigation of several companies that sold "designer drugs" and related chemicals over the Internet, primarily to teenagers and young adults, under the guise of "research chemicals."

According to U.S. Attorney Wrigley, the nationwide investigation targeted a number of

internet chemical sellers operating through Web sites under the guise of being legitimate companies selling chemicals to researchers. In addition to LTK Research Products, those sellers included: **www.racresearch.com**; **www.americanchemicalsupply.com**; **www.pondman.nu**; **www.duncanlabproducts.com**; and **omegafinechemicals.com**.

"The sale and consumption of dangerous chemicals publicly offered for sale by LTK and other Internet companies is illegal and a serious health and safety problem for our citizens," said Wrigley. "The coordinated efforts of state and Federal agencies throughout the country closed them down."

"This is a prime example of how cooperative law enforcement can root out criminals who believe they can use the Internet to hide their actions," said Mark Cangemi, special agent in charge of the Office of Investigations for U.S. Immigration and Customs Enforcement (ICE) in Bloomington, Minn. "The complexity of this case required the combined efforts of local, county, state and federal law enforcement. No single agency could have done it alone."

Although Badrak and LTK were put out of business following the execution of state and federal search warrants in April 2004, other illegal chemical sellers often rise up to take their place. Anyone who is aware of companies selling these dangerous chemicals to the general public rather than to legitimate research labs and companies should contact the Food and Drug Administration Office of Criminal Investigation at 1-800-521-5782 or the Drug Enforcement Administration at 1-701-250-4550 in Bismarck, N.D.

The North Dakota portion of the nation-wide investigation, designated Operation Web Tryp, was conducted by agents of the U.S. Food and Drug Administration Office of Criminal Investigation (FDA-OCI) in Minneapolis; the Drug Enforcement Administration (DEA) in Fargo and Bismarck, N.D.; Immigration and Customs Enforcement (ICE) in Minot, N.D.; the United States Postal Inspection Service in St. Paul, Minn., and the Ward County Narcotics Task Force (comprised of agents from North Dakota Bureau of Criminal Investigation, Ward County Sheriff's Department and Minot Police Department); with assistance from the FDA Forensic Chemistry Center, the Ward County State's Attorney's Office and Minnesota National Guard.

Assistant United States Attorney Scott J. Schneider prosecuted the case.

Vanhook

PROPOSED AMENDMENTS TO HB 1455

Page 4, line12, remove "any"

Page 4, line 13, remove "one of"

Page 4, line 15, replace "or" with "and"

Page 5, line 8, replace "store" with "stored"

Page 6, line 15, replace "individual" with "person"

Page 8, line 17, remove "The board shall exempt manufacturers"

Page 8, remove lines 18, 19, 20 and 21

Page 8, line 17, after the period insert "While manufacturers engaged in wholesale distribution are subject to licensing, information and qualification requirements for licensure beyond that required by federal law or regulation do not apply to manufacturers distributing their own United States Food and Drug Administration-approved drugs, unless particular requirements are deemed necessary and appropriate following rulemaking."

Page 10, line 20, after "2" insert "unless the board decides such inspection is not necessary"

Page 12, line 10, replace "or" with ","

Page 12, line 10, after "revoke" insert "or not renew"

Page 12, line 18, after the period insert "The board is not precluded from making public the names of licensees and identifying licensed facilities or changes in licensing status."

Page 12, line 21, replace "obtaining and maintaining" with "having applied for"

Page 12, line 25, after the period insert "If at any time an accreditation body rejects an application, or if any existing accreditation lapses or fails to be maintained for any reason, the board shall be informed immediately and shall cancel the license unless the board explicitly decides to continue or reissue that license."

Page 16, line 19, after "law" insert "or the board"

Page 19, line 1, replace "one" with "ten"

Page 19, line 12, after "<u>resides</u>" insert "<u>in the state</u>"

Renumber accordingly

BOARD OF PHARMACY
State of North Dakota

John Hoeven, Governor

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Bismarck
Laurel Haroldson, R.Ph.
Jamestown
William J. Grosz, Sc.D., R.Ph.
Wahpeton, Treasurer

HOUSE BILL No. 1455 – Pedigree for Wholesale Drugs
House Judiciary Committee
8:30 AM - Tuesday – January 30th, 2007Prairie Room

Chairman DeKrey and members of the House Judiciary Committee, for the record I am Howard C. Anderson Jr., R.Ph, Executive Director of the North Dakota State Board of Pharmacy. Thank you for the opportunity to speak with you today.

The Board of Pharmacy is testifying in favor of this legislation, because we feel that a pedigree is important. However, we did not feel it was necessary to introduce the bill in this session, but, some of our Senators and Representatives felt we did, so we are not going to oppose that idea.

The Board of Pharmacy currently has 702 licensed under our Wholesale Licensing Statute, which is NDCC 43-15.1 and NDAC 61-10.

I was on the Executive Board of the National Association of Boards of Pharmacy (NABP) when we first adopted the Wholesale Licensing Model Act pertaining to pedigrees.

I have been in discussions with Mr. Joel Gilbertson, and he is preparing some amendments for this bill, which address both of our concerns. I was not happy when I saw that the manufacturer's, who provided much of the information for this bill, decided to exempt themselves.

Of the 702 Wholesalers currently licensed 62 of them are located in North Dakota. For your information, I have provided you lists of the wholesalers, both in and out of state. You will see that this bill exempts 102 of our current licensees, who are manufacturers. However, Mr. Gilbertson is bringing in an amendment which says that we *will not* exempt those manufacturers who are in wholesale distribution. The reason I asked for this, is if we are going to establish a pedigree for a drug, we need to start that pedigree with the manufacturer. Just as with a dog, horse or bull, you need to be able to go back to the beginning if you are going to have a verifiable pedigree.

As you can see from the provided list, many of our North Dakota licensed wholesalers are medical gas suppliers and off site intravenous solution storage facilities for our hospitals. We do want to license these facilities, so that we can keep track of them and so that they can receive drugs from the other wholesalers and manufacturers, but we need to have the flexibility to exempt them from the bonding requirements.

If I had my druthers, I would have liked to have included legend devices in this bill as well, as we are increasingly getting requests from manufacturers, suppliers, wholesalers and end users about the security and integrity of the distribution channel for legend devices. Many of our legend devices are beginning to include drugs, such as drug eluting stints, refilled syringes, respiratory therapy products and many others, which should be controlled under the wholesale licensing statute, as they are just as important to the care and mitigation of disease as are the drugs themselves. We can bring those things to you next session.

This page on my testimony delineates specific spots on the bill, where I thought there should be amendments:
On page 5 line 8 should say store**d** instead of store;
On page 6 line 15 should say person instead of individual;
On page 8 on lines 17-18 & 19 are where I feel we should remove the exemption for manufacturers and in that same vein, on page 14 line 27 remove the language that says – but excluding the original manufacturer, because as I have said, a pedigree must start from the beginning;
On page 10 line 6 names should be changed to named; also on page 10 lines 19 & 20 should of course give the Board inspection power and we should inspect every facility within North Dakota. But, we should have the flexibility to rely on an inspection from the state of residence for out-of-state wholesalers, or to rely on their BAWD Certification.
On page 12, line 10 - I believe we have a change coming which will say that the Board may suspend, revoke or not renew the license of a wholesaler who no longer qualifies.
Also on page 12, line 16 – should say information provided under section **2h** may not be disclosed to any person. This applies to the information collected on the background check and should not apply to any other of the information, such as name, address, principals, etc which applies to the licensed wholesaler.
On page 15, line 10 - I would like to discuss the determination that the pedigree technology is universally available – this language *may* give some non-compliant wholesalers the ability to hold this up indefinitely, claiming that the technology is *not* universally available, to them. However, for now, I believe the language is acceptable, as we will have another legislative session before July 1, 2009 and we could revisit that with you, should it appear to be causing problems across the country.
On page 16, lines 18 & 19, we *need* to add the Board of Pharmacy, as we will be the inspecting authority in the state of North Dakota, although I do not believe the Attorney General's office would call us an authorized officer of the law.
And again, on line 25 of page 16, I would remove *other than a manufacturer*, as, if someone has violated a provision in this chapter, whether they are a manufacturer or not, they should be subject to the same restrictions.
On page 18, lines 1, 2 & 3, again we are exempting manufactures.
And, on lines 7, 8 & 9, I cannot imagine why wholesalers would want to be exempted from the provisions against adulterating, misbranding or counterfeiting any prescription drug.

Thank for your time and attention.

FIRST_NA	LAST_NAME	COMPANY	ADDRESS	ADDRESS_LINE_2	CITY	STATE	ZIP	LICENSE
Ron	Hodge	AMC Wholesale, Inc.	1720 Burnt Boad Drtive		Bismarck	ND	-58501	13
John	Schreier	North Central Healthcare Alliance	1300 Industrial Drive #2		Bismarck	ND	58501	432
Randy	Amelsberg	Hubbard Feeds Inc.	1503 Yege	PO Box 1877	Bismarck	ND	58502-1877	139
Ronald	Hodge	Mandaree Medical Company	1720 Burnt	PO Box 1791	Bismarck	ND	58502-1791	175
Henry	Milkey	MedCenterOne, Inc. (Warehouse)	1112 S 12th Street		Bismarck	ND	58504-000	468
John	Schreier	St Alexius Medical Center	1300 Industrial Drive		Bismarck	ND	-58501	400
Connie	Morris	United Blood Services	517 South	PO Box 2052	Bismarck	ND	58502-2052	291
Tracy	Voegele	Meritcare Healthcare Accessories LLC	121 E Century Ave		Bismarck	ND	58503	415
Steven	Jacobchick	MedEquip One, LLC	626 6th Street North		Bismarck	ND	58501	606
Mary	Myers	Praxair Distribution Inc	820 E Front Ave		Bismarck	ND	58504	969
Judy	Jordan	TWL Billing Service & Supplies Inc	Warehouse	1600 Basin Ave #2	Bismarck	ND	58504	812
Lynn	Engelstad	H.E. Everson Company of Bottineau	207 11th Street East		Bottineau	ND	58318	690
Ed	Fritel	H.E. Everson Company of Cando Inc	512 Main		Cando	ND	58324	711
Ernie	Fritel	H.E. Everson Company of Cooperstown Inc	806 Burrel Ave SW - Box 688		Cooperstown	ND	58425	693
Jeffrey	Zak, R.Ph.	Altru Renal Unit at Mercy Hospital	1031 7th Street		Devils Lake	ND	-58301	414
Frank	Fritel	H.E. Everson Company of Devils Lake	211 College Drive South		Devils Lake	ND	58301	691
Donn	Lang	A-1 Welding Products	677 26th Ave East		Dickinson	ND	-58601	155
Arnold	Rummel	Rummel's Auto Wrecking & Welding Supplies	1132 West Villard		Dickinson	ND	58601-5453	839
Mary	Myers	Praxair Distribution Inc	677 26th Ave E		Dickinson	ND	58601	846
Angie	Leiss	PSI Health Care, Inc/dbaArrowhealth Medical Supply	4025 4th Ave SW		Fargo	ND	-58103	456
Melissa	Fiedler	White Drug #61	708C 38th Street NW		Fargo	ND	58102	348
Gerald	Finken	Clinical Supplies Management Inc	4733 Amber Valley Parkway		Fargo	ND	-58104	76
Larry	Solberg	Dakota Clinic Pharmacy	1702 S University Dr		Fargo	ND	-58103	89
Legal	Department	DMS Health Technologies Inc.	2131 16th Street North		Fargo	ND	58102	94
Russ	Nylander	Meritcare Healthcare Accessories LLC	3223 32nd Ave SW		Fargo	ND	-58103	138
Deborah	Barrick	Lincare, Inc.	1535 S University Drive		Fargo	ND	58103	311
Dean	Kusler	MedEquip One, LLC	4310 17th	P O Box 6202	Fargo	ND	58106-6202	430
Duane	Pearson	MeritCare Enterprises, Inc	501 N 4th Street		Fargo	ND	-58102	478
Richard	Larson	Midland Hospital Supply Inc.	2011 Grea	P O Box 2685	Fargo	ND	58102	344

David	Gray, R.Ph.	Paracelsus Healthcare Corp of	1711 S University Drive	Fargo	ND	-58103	394	
Alden	Iverson	Patterson Dental Supply Inc.	3321 4th Ave SW	Fargo	ND	58103	222	
Fran	Milner	Blood Systems dba United Blood Services	3231 S. 11th Street	Fargo	ND	58104	373	
Lois	Bylund	Universal Hospital Services, Inc.	918 Page Drive	Fargo	ND	-58103	560	
Gayle	Ziegler	MeritCare Hospital-South University	1720 S University Drive	Fargo	ND	58103	601	
Michelle	Traxler	Northwest Respiratory Services LLC	4445 2nd Ave SW	Fargo	ND	58103	86	
Brent	Johnson	Airgas North Central Inc	1106 38th St NW Suite A	Fargo	ND	58102-2947	686	
Mary	Myers	Praxair Distribution Inc	521 19th Street N	Fargo	ND	58102	970	
Jan	Voeller	Dakota Drug Inc	4121 12th Ave NW	Fargo	ND	58102	717	
Gerald	Finken	Dakota Pharmaceutical Packaging, LLC	4733 Amber Valley Parkway	Fargo	ND	58104	558	
Bob	Meyer	H. E. Everson Company of Grafton Inc	106 East 12th Street	Grafton	ND	58237	702	
Allen	Taylor	Grafton Pharmaceutical Distribution LLC	508 Hill Av P O Box 545	Grafton	ND	58237-0545	833	
Sheila Sturlaugson		Lincare, Inc	2100 S Columbia Road	Grand Forks	ND	58201	312	
Mary	Ringstad	Airgas North Central Inc	2808 Gateway Drive	Grand Forks	ND	58203	687	
Mary	Myers	Praxair Distribution Inc	2205 N Washington Street	Grand Forks	ND	58202	971	
Lori	Morin	Meritcare Healthcare Accessories LLC	1023 10th St SE	Jamestown	ND	58401	450	
Mary	Myers	Praxair Distribution Inc	602 20th S P o Box 2134	Jamestown	ND	58402-2134	972	
Steve	Heick	American Welding Supplies Inc	2320 Memorial Highway	Mandan	ND	58554	849	
Jan	Voeller	Dakota Drug Inc.	P O Box 50 28 N Main Street	Minot	ND	58702-5009	88	
Roger	Gonzalez	Meritcare Healthcare Accessories LLC	116 1st Street SW	Minot	ND	58701	451	
Brad Morrison, R.Ph.		Option Care	601 18th Ave SE #103	Minot	ND	-58701	553	
Mary	Myers	Praxair Distribution Inc #422	2816 S Broadway	Minot	ND	-58701	234	
Kevin	Seehafer	Trinity Health	3100 4th Ave SE	Minot	ND	-58701	523	
Lonnie	Olson	Wholesale Supply Co Inc.	3500 Burdi P O Box 1948	Minot	ND	58702-1948	278	
Mary	Lentz	Praxair Healthcare Services Inc.	2816 South Broadway	Minot	ND	58701	614	
Brian	VP	Amercian Welding Supplies Inc	2900 Burdick Expressway E	Minot	ND	58701	847	
		Mitchs Drug Emporium	13 1st ave sw	MitchTown	ND	58666	10000	
Michael	Warner	Agriceutical Resources LLC	709 River Bend Road	Oxbow	ND	58047	710	
Kirk	Sand	H. E. Everson Company of Rolla Inc	101 Front St - Box 817	Rolla	ND	58367-0817	684	
Duane	Paul	H. E. Everson Company of Rugby Inc	703 1st St N Box 166	Rugby	ND	58368-0166	685	

Deborah	Licensing	Lincare, Inc	[redacted] Dakota Ave	Wahpeton	ND	58075-4414	313	
Selmer	Tendeland	American Welding Supplies & Fire Equip	1800 East Main Ave.	West Fargo	ND	58078-0613	17	
Mary	Myers	Praxair Distribution Inc	2912 2nd A P O Box 1654	Williston	ND	58802-1654	973	

	Dispensing Solutions Inc	Santa Ana	CA	92704	840	DIST
	Questcor Pharmaceuticals Inc	Union City	CA	94587	841	DIST
	A + Z Pharmaceutical LLC	Pittsburgh	PA	15220	842	DIST
	Novis Pharmaceutical LLC	Plymouth Meeting	PA	19462	843	DIST
	Jazz Pharmaceuticals Inc	Palo Alto	CA	94304	844	DIST
	Life Science Logistics LLC	Louisville	KY	40258	845	DIST
	Praxair Distribution Inc	Dickinson	ND	58601	846	DIST
	Amercian Welding Supplies Inc	Minot	ND	58701	847	DIST
	American Welding Supplies Inc	Mandan	ND	58554	849	DIST
	SAJ Distributors	Pine Bluff	AR	71603	852	DIST
	Walgreen Co	Perrysburg	OH	43551	853	DIST
	A.F. Hauser Inc	Valparaiso	IN	46383	854	DIST
	Priority Air Express dba Priority Solutions Inte	Swedesboro	NJ	8085	855	DIST
	Quinnova Pharmaceutical Inc	Newtown	PA	18940	856	DIST
	Fresenius Medical Care North America	Ogden	UT	84404	857	DIST
	McKesson Trading Company	Aurora	CO	80011	281	DIST
	3M Pharmaceuticals	Northridge	CA	91324	1	MAN
	Altana Inc.	Melville	NY	11747-2006	11	MAN
	Alza Corporation	Mountain View	CA	94043	12	MAN
	Abraxis BioScience Inc	Schaumburg	IL	60173	375	MAN
	American Regent, Inc.	Shirley	NY	-11967	16	MAN
	AmeriSource Health Service/dba American H	Columbus	OH	-43217	21	MAN
	ZLB Behring LLC	Kankakee	IL	60915	562	MAN
	Sanofi Pasteur Inc	Swiftwater	PA	18370	81	MAN
	B.F. Ascher & Company, Inc.	Lenexa	KS	-66219	31	MAN
	Bausch & Lomb Incorporated	Tampa	FL	-33637	37	MAN
	PharMedium Services LLC	Edison	NJ	-8817	720	MAN
	PharMedium Services LLC	Sugar Land	TX	77478	397	MAN
	Bayer Pharmaceuticals Corporation	West Haven	CT	66216	42	MAN
	Beach Products dba Pharmaceutical Associat	Greenville	SC	-29605	45	MAN
	Biogen Idec U.S. Corporation	Cambridge	MA	-2142	53	MAN
	Novartis Pharmaceuticals Corp	Suffern	NY	10901	506	MAN
	Braintree Laboratories Inc.	Braintree	MA	02185-0929	57	MAN
	UCB Manufacturing Inc.	Rochester	NY	-14623	182	MAN
	ALK-Abello, Inc.	Port Washington	NY	-11050	68	MAN
	Centocor Inc.	Malvern	PA	19355	69	MAN
	Church & Dwight Co Inc	Princeton	NJ	8543	233	MAN
	Combe Incorporated	White Plains	NY	10604-3597	80	MAN
	CooperSurgical Inc.	Trumbull	CT	6611	83	MAN
	West-Ward Pharmaceutical Corp	Eatontown	NJ	7724	525	MAN
	Dey LP	Napa	CA	-94558	93	MAN
	DPT Laboratories Ltd.	San Antonio	TX	-78215	363	MAN
	Eon Labs Inc dba Sandoz	Laurelton	NY	-11413	388	MAN
	Valera Pharmaceuticals Inc	Cranbury	NJ	08512-3617	541	MAN
	Exel Inc	Fontana	CA	92335	111	MAN
	Exel Inc	Mechanicsburg	PA	17050	112	MAN
	Exel Inc	Olive Branch	MS	-38654	113	MAN
	Ferndale Laboratories Inc.	Ferndale	MI	-48220	119	MAN
	Fleming & Company Pharmaceuticals	Fenton	MO	-63026	120	MAN

COMPANY	CITY	STATE	ZIP	LICENSE	Wholesaler Type
Abbott Laboratories, Inc.	Abbott Park	IL	60064-3500	3	DIST
Avanir Pharmaceuticals	San Diego	CA	92121	561	DIST
Adams Respiratory Operations Inc	Fort Worth	TX	-76155	494	DIST
Akorn, Inc.	Buffalo Grove	IL	-60089	342	DIST
Cardinal Health	Champlin	MN	-55316	6	DIST
Allscripts LLC	Libertyville	IL	-60048	8	DIST
Actavis Mid Atlantic LLC	Columbia	MD	-21046	789	DIST
sanofi-aventis U.S. Inc.	Des Plaines	IL	60018	322	DIST
American Drug Stores/Osco Distribution Cent	Elk Grove Village	IL	-60007	217	DIST
American Medical Distributors, Inc	N Amityville	NY	-11701	446	DIST
American Welding Supplies & Fire Equip	West Fargo	ND	58078-0613	17	DIST
Ameri Source Bergen Drug Corp	Eden Prairie	MN	-55344	20	DIST
Smart-Fill	Austin	MN	55912	391	DIST
Amgen Inc	Thousand Oaks	CA	91320-1799	14	DIST
Anda , Inc.	Weston	FL	-33331	357	DIST
AR Scientific Inc	Philadelphia	PA	19111	336	DIST
PSI Health Care, Inc/dbaArrowhealth Medical	Fargo	ND	-58103	456	DIST
Oncology Supply	Dothan	AL	36303-1038	329	DIST
ASD Specialty Healthcare Inc	Brooks	KY	40109	325	DIST
American Medical Distributors, Inc	Brea	CA	92621	27	DIST
AstraZeneca Pharmaceuticals In	Newark	DE	19714-4250	314	DIST
AstraZeneca, L P	Westborough	MA	-1581	353	DIST
Atrion Medical Products Inc	Arab	AL	-35016	484	DIST
sanofi-aventis U.S. LLC	Kansas City	MO	64132	144	DIST
Victory Pharma Inc	San Diego	CA	92130	520	DIST
Barr Laboratories Inc.	Forest	VA	-24551	36	DIST
Bausch & Lomb Incorporated	Greenville	SC	-29615	467	DIST
Bausch & Lomb Incorporated	Lynchburg	VA	-24502	386	DIST
Baxter Healthcare Corporation	Los Angeles	CA	90039	39	DIST
Baxter Healthcare Corporation	Memphis	TN	38118	40	DIST
Bayer Healthcare LLC Animal Health Div	Shawnee Mission	KS	66201-0390	389	DIST
Bayer Healthcare LLC	Berkeley	CA	94710-1986	41	DIST
Body Dynamics dba BDI Marketing	Carmel	IN	-46032	55	DIST
Ben Venue Labs dba Bedford Laboratories	Walton Hills	OH	-44146	46	DIST
Meritcare Healthcare Accessories LLC	Jamestown	ND	58401	450	DIST
Biovail Pharmaceuticals Inc.	Memphis	TN	38141	361	DIST
Bristol-Myers Squibb Medical Imaging	N. Billerica	MA	01862-0272	98	DIST
Corporate Mailings Inc	West Caldwell	NJ	7006	66	DIST
Cardinal Health	Hudson	WI	54016	59	DIST
Baxter Healthcare Corporation	Ontario	CA	91761	459	DIST
Coram Alternate Site Services Inc	Malvern	PA	19355	181	DIST
Central Admixture Pharmacy Services CAPS	Houston	TX	-77054	70	DIST
Cardinal Health / Specialty Pharmaceutical Se	Lavergne	TN	-37086	85	DIST
Chapin Drug Company	Annaheim Hills	CA	92807	72	DIST
Chiron Corporation	Emeryville	CA	-94608	74	DIST
Colgate Oral Pharmaceuticals Inc	Carrollton	TX	75006-5410	78	DIST
Colgate-Palmolive Company	Piscataway	NJ	08855-1343	346	DIST
Connetics Corporation	Palo Alto	CA	943034	82	DIST

	Cook Medical Incorporated	Bloomington	IN	47402-4195	77	DIST
	CSC High Plains LTD	Sioux Falls	SD	-57104	463	DIST
	Glenmark Pharmacetuicals Inc, USA	Mahwah	NJ	7430	449	DIST
	Dakota Drug Inc.	Minot	ND	58702-5009	88	DIST
	Darby Group Companies Inc	Memphis	TN	-38117	448	DIST
	Henry Schein Inc	Jacksonville	FL	32219	90	DIST
	DDN/Obergfel LLC	Ontario	CA	-91761	91	DIST
	DDN/Obergfel LLC	Memphis	TN	-38141	92	DIST
	Dey, L.P.	Allen	TX	-75013	436	DIST
	Centric Health Resources, Inc.	Chesterfield	MO	63005	522	DIST
	Richie Pharmacal Company LLC	Glasgow	KY	42141	188	DIST
	E.R. Squibb & Sons, LLC	Mt Vernon	IN	47620	362	DIST
	ASD Specialty Healthcare Inc	Reno	NV	89502	501	DIST
	Eli Lilly and Company (CA)	Fresno	CA	-93725	105	DIST
	Eli Lilly and Company	Indianapolis	IN	-46285	108	DIST
	Emergency Medical Products Inc	Waukesha	WI	-53186	495	DIST
	ENZON Pharmaceuticals Inc.	S Plainfield	NJ	-7080	426	DIST
	Talecris Biotherapeutics Inc	Clayton	NC	27520	540	DIST
	Ethex Corporation	Bridgeton	MO	-63044	110	DIST
	Exel Inc	Middletown	PA	-17057	115	DIST
	Express Scripts Specialty Distribution Service	Maryland Heights	MO	-63043	500	DIST
	Meritcare Healthcare Accessories LLC	Minot	ND	58701	451	DIST
	Midlothian Laboratories LLC	Montgomery	AL	36116-5125	117	DIST
	Mayne Pharma (USA) Inc	Paramus	NJ	7652	395	DIST
	FFF Enterprises Inc.	Temecula	CA	92591	349	DIST
	Fairview Health Services	Minneapolis	MN	55455	100	DIST
	Sciele Pharma, Inc.	Alpheretta	GA	30005	399	DIST
	PDA Services instaCare Corp	Westlake Village	CA	91361	464	DIST
	Forest Pharmaceuticals Inc.	St. Louis	MO	-63045	125	DIST
	Galderma Laboratories L.P.	Fort Worth	TX	-76177	126	DIST
	APL Logistics WMS	Suwanee	GA	30024	127	DIST
	Gebauer Company	Cleveland	OH	44128	128	DIST
	Sandoz Inc.	Broomfield	CO	80038-0446	131	DIST
	Accredo Health Group, Inc	Warrendale	PA	-15086	212	DIST
	JACE Pharmaceuticals Inc	Paramus	NJ	7652	213	DIST
	McKesson Drug Company	Carol Stream	IL	60188	123	DIST
	UPS Supply Chain Solutions Inc	Harrisburg	PA	17112	487	DIST
	Fort Dodge Laboratories, Inc.	Fort Dodge	IA	50501	264	DIST
	Perrigo of SC / Perrigo Pharmaceuticals Com	Greenville	SC	29607	355	DIST
	Tercica Inc	Brisbaine	CA	94005	552	DIST
	Dispensing Solutions Inc	Santa Ana	CA	92704	95	DIST
	Guardian Laboratories Div	Hauppauge	NY	-11788	135	DIST
	MGI Pharma Inc	Baltimore	MD	-21224	514	DIST
	McKesson Medical-Surgical Inc	Grapevine	TX	76051	137	DIST
	Health Coalition Inc.	Miami	FL	33122	343	DIST
	Meritcare Healthcare Accessories LLC	Fargo	ND	-58103	138	DIST
	Hubbard Feeds Inc.	Bismarck	ND	58502-1877	139	DIST
	Henry Schein Inc	Sparks	NV	89434	141	DIST
	Henry Schein Inc.	Denver	PA	-17517	328	DIST

	Henry Schein Inc.	Grapevine	TX	-76051	356	DIST
	Henry Schein Inc.	Indianapolis	IN	-46268	140	DIST
	Intervet Inc	Millsboro	DE	19966-0318	339	DIST
	Hoffmann La Roche Inc.	Joppa	MD	-21085	145	DIST
	Valeant Puerto Rico LLC	Humacao	PR	00791-9731	369	DIST
	Ocusoft Inc	Rosenberg	TX	77471	146	DIST
	IDEXX Operations Inc	Memphis	TN	-38141	461	DIST
	Insource Inc.	Bastian	VA	-24314	148	DIST
	InterMune Inc.	Brisbane	CA	-94005	393	DIST
	InterPharm Inc.	Hauppauge	NY	11788-3605	150	DIST
	Kenco Durham	Durham	NC	27713	380	DIST
	IVAX Pharmaceuticals, Inc.	Walton	KY	-41094	315	DIST
	J. Knipper and Company, Inc.	Lakewood	NJ	-8701	156	DIST
	Jacobson Warehouse Company, Inc	Ankeny	IA	50021	563	DIST
	McKesson Corporation	Aberdeen	SD	57402-1240	678	DIST
	JMI Daniels Pharmaceuticals, Inc	St Petersburg	FL	-33713	477	DIST
	McGuff Company	Santa Anna	CA	92704	359	DIST
	DSM Pharmaceuticals Inc	Greenville	NC	27834	157	DIST
	King Pharmaceuticals, Inc.	Bristol	TN	-37620	158	DIST
	Critical Therapeutics Inc	Lexington	MA	2421	159	DIST
	Barrier Therapeutics Inc	Princeton	NJ	8540	226	DIST
	L. Perrigo Company	Allegan	MI	-49010	169	DIST
	Forum Products dba SourcePharma	Southampton	NY	11968	162	DIST
	Lee Pharmaceuticals, Inc.	South El Monte	CA	-91733	164	DIST
	Lil' Drug Store Products, Inc.	Cedar Rapids	IA	52402	168	DIST
	Lincare, Inc	Wahpeton	ND	58075-4414	313	DIST
	Lincare, Inc	Grand Forks	ND	58201	312	DIST
	Lincare, Inc.	Fargo	ND	58103	311	DIST
	UPS Supply Chain Solutions Inc	Decatur	GA	-30034	376	DIST
	UPS Supply Chain Solutions Inc	Memphis	TN	-38114	413	DIST
	UPS Supply Chain Solutions, Inc	Newark	DE	-19702	171	DIST
	UPS Supply Chain Solutions Inc	Rancho Cucamonga	CA	-91730	170	DIST
	Exel Inc	Mechanicsburg	PA	17050	566	DIST
	The Harvard Drug Group / Major Pharmaceut	Indianapolis	IN	-46268	851	DIST
	Rx C Acquisitions dba Rx Crossroads 3PL	Louisville	KY	-40218	568	DIST
	Martec USA, LLC	Kansas City	MO	-64120	176	DIST
	McKesson R D C	Memphis	TN	-38141	323	DIST
	McKesson Specialty Distribution LLC	Memphis	TN	-38141	372	DIST
	McKesson Corporation/Drug Company	West Sacramento	CA	95691-3472	434	DIST
	McKesson Corporation	Salt Lake City	UT	-84104	423	DIST
	McKesson Drug Co.	Everett	WA	-98204	402	DIST
	McKesson Drug Co.	Little Canada	MN	-55117	178	DIST
	McKesson Corporation	Memphis	TN	38141	365	DIST
	McKesson Corporation	Livonia	MI	-48150	412	DIST
	McKesson Medical Surgical Inc.	Kansas City	MO	64120	583	DIST
	McKesson Medical-Surgical MN Supply Inc.	Maple Grove	MN	-55369	384	DIST
	UPS Supply Chain Solutions Inc	Louisville	KY	40219	180	DIST
	MedCenterOne, Inc. (Warehouse)	Bismarck	ND	58504-000	468	DIST
	Medi-Physics Inc dba GE Healthcare	West Milwaukee	WI	-53215	548	DIST

	Targacept Inc	Winston Salem	NC	27101	452	DIST
	Medisca Inc.	Plattsburgh	NY	-12901	189	DIST
	Total Health Rewards Inc	New York	NY	10001	490	DIST
	Merck & Co., Inc	Duluth	GA	-30097	536	DIST
	Merck & Co., Inc.	Reno	NV	-89502	367	DIST
	Merial Limited	Athens	GA	-30601	191	DIST
	Methapharm, Inc.	Coral Springs	FL	-33065	572	DIST
	MGI PHARMA, INC.	Bloomington	MN	55437-3174	194	DIST
	Midland Hospital Supply Inc.	Fargo	ND	58102	344	DIST
	Midwest Drug Supply LLC	Jackson	MI	49202-3925	335	DIST
	Midwest Veterinary Supply Inc	Burnsville	MN	-55337	195	DIST
	MWI Veterinary Supply Co	Nampa	ID	-83687	202	DIST
	MWI Veterinary Supply Co	Aurora	CO	80011	455	DIST
	Mylan Pharmaceuticals, Inc.	Morgantown	WV	26505-2730	320	DIST
	Cardinal Health	La Vergne	TN	37086	205	DIST
	Bioscrip Pharmacy Services	Columbus	OH	43228	208	DIST
	Novartis Pharmaceuticals Corp	E Hanover	NJ	-7936	210	DIST
	Cardinal Health dba Specialty Pharmaceutica	LaVergne	TN	37086	424	DIST
	Global Pharmaceutical Sourcing	Bethesda	MD	20814	443	DIST
	Odyssey Pharmaceuticals Inc	East Hanover	NJ	7936	496	DIST
	OTN Parent Corp	South San Francisc	CA	-94080	214	DIST
	OraPharma Inc	Warminster	PA	-18974	528	DIST
	AmerisourceBergen Drug Corporation	Kansas City	MO	64153	471	DIST
	Zydus Pharmaceuticals USA Inc	Princeton	NJ	8540	542	DIST
	Par Pharmaceutical Inc.	Montebello	NY	10901	219	DIST
	Parmed Pharmaceuticals Inc.	Niagara Falls	NY	-14305	221	DIST
	PDI Enterprises Inc.	Valencia	CA	-91355	223	DIST
	Aton Pharma Inc	Lawrenceville	NJ	8648	225	DIST
	Pfizer Inc	Lincoln	NE	-68521	518	DIST
	Pfizer Inc.	Memphis	TN	-38134	228	DIST
	Pfizer Inc	Parsippany	NJ	7054	575	DIST
	Pfizer Inc	Guilderand Center	NY	-12085	519	DIST
	Pfizer Inc	South Bend	IN	-46628	516	DIST
	Pfizer Inc	Reno	NV	89521	574	DIST
	Pfizer Inc	Lee's Summit	MO	-64081	517	DIST
	Pfizer Inc.	Marietta	GA	-30062	515	DIST
	Pfizer Inc.	Fort Worth	TX	-76140	521	DIST
	Factor Health Management LLC	Boca Raton	FL	33487	573	DIST
	DVM Resources / Walco International	Spencer	IA	51301	231	DIST
	UPS Supply Chain Solutions Inc	Stead	NV	89506	555	DIST
	Gtx Inc	Memphis	TN	38163	539	DIST
	Phoenix Marketing Group LLC	Towaco	NJ	7082	586	DIST
	Phoenix Marketing Group LLC	Lincoln Park	NJ	-7035	585	DIST
	Praxair Distribution Inc #422	Minot	ND	-58701	234	DIST
	CuraScript SD Specialty Distribution	Grove City	OH	-43123	378	DIST
	Procter & Gamble Pharmaceuticals	Cincinnati	OH	-45249	569	DIST
	PromoTech Research Associates	Louisville	CO	-80027	466	DIST
	Actavis Elizabeth LLC	Elizabeth	NJ	-7207	242	DIST
	QK Healthcare Inc.	Ronkonkoma	NY	-11779	245	DIST

	Qualitest Pharmaceuticals Inc.	Huntsville	AL	-35811	243	DIST
	Quality Assured Services Inc	Orlando	FL	32804-6103	526	DIST
	Bound Tree Medical LLC	Tempe	AZ	85282	87	DIST
	Merridian Medical Technologies	St Louis	MO	63146	584	DIST
	R & S Sales LLC	Fountain Run	KY	-42133	249	DIST
	Ranbaxy Pharmaceuticals	Jacksonville	FL	32257-3644	534	DIST
	Boehringer Ingelheim Roxane, Inc.	Columbus	OH	43228	248	DIST
	Blood Diagnostics Inc	Temecula	CA	92590	251	DIST
	Schering Corporation	Reno	NV	89506-1600	255	DIST
	Seacoast Pharmaceutical Inc	Omaha	NE	68138	549	DIST
	Accredo Health Group Inc	Memphis	TN	38134-0180	247	DIST
	Sirius Laboratories Inc	Vernon Hills	IL	-60061	559	DIST
	Somerset Pharmaceuticals Inc.	Tampa	FL	-33607	265	DIST
	Southern Anesthesia & Surgical	West Columbia	SC	-29169	661	DIST
	STAT Pharmaceuticals Inc.	Santee	CA	92071	577	DIST
	Astellas Pharma Manufacturing Inc	Grand Island	NY	14072	271	DIST
	Stiefel Laboratories Inc.	Oak Hill	NY	12460	272	DIST
	Dendrite Interactive Marketing LLC	Totowa	NJ	7512	692	DIST
	Takeda Pharmaceuticals America	Deerfield	IL	60015	408	DIST
	TEVA Pharmaceuticals USA	North Wales	PA	19454-1090	279	DIST
	Fort Dodge Animal Health	Wilmington	OH	45177	337	DIST
	Sun Belt Medical / Emergi-Source	Hilton Head Island	SC	29926	58	DIST
	Cardinal Health	Anoka	MN	-55303	327	DIST
	The Harvard Drug Group / RSV Veterinary Su	Livonia	MI	-48150	850	DIST
	Tyco Healthcare Group LP	Joliet	IL	-60431	370	DIST
	The P.F. Laboratories Inc.	Totowa	NJ	-7512	352	DIST
	Ther-Rx Corporation	Bridgeton	MO	-63044	396	DIST
	Thrifty Drug Stores Inc	Maple Grove	MN	-55369	285	DIST
	Trinity Health	Minot	ND	-58701	523	DIST
	Triplefin LLC	Cincinnati	OH	-45242	143	DIST
	Upsher-Smith Laboratories Inc	Maple Grove	MN	55369-6026	294	DIST
	UCB Pharma Inc.	Birmingham	AL	-35244	289	DIST
	Reliance Pharmaceuticals dba Med-Search	Ft Lauderdale	FL	33309	407	DIST
	Blood Systems dba United Blood Services	Fargo	ND	58104	373	DIST
	United Blood Services	Bismarck	ND	58502-2052	291	DIST
	Universal Hospital Services, Inc.	Fargo	ND	-58103	560	DIST
	UPS Supply Chain Solutions Inc	Ft. Worth	TX	-76177	491	DIST
	Upsher-Smith Laboratories Inc	Minneapolis	MN	55447-4709	293	DIST
	Spear Dermatology	Louisville	KY	40218	437	DIST
	Valmed Pharmaceutical Inc d/b/ VIP	Grand Island	NY	-14072	295	DIST
	Meritcare Healthcare Accessories LLC	Bismarck	ND	58503	415	DIST
	Vet Pharm Inc.	Sioux Center	IA	-51250	481	DIST
	VWR International Inc	Batavia	IL	-60510	298	DIST
	Walgreens Co	Windsor	WI	-53598	299	DIST
	Warner-Lambert Company	Lititz	PA	-17543	368	DIST
	Warrick Pharmaceuticals Corporation	Reno	NV	89506-1600	302	DIST
	Watson Pharma Inc	Gurnee	IL	-60031	360	DIST
	Ascend Therapeutics Inc	LaVergne	TN	37086	444	DIST
	Merck & Co, Inc	West Point	PA	19486	303	DIST

	Wholesale Supply Co Inc.	Minot	ND	58702-1948	278	DIST
	Purdue Pharmaceuticals LP	Wilson	NC	27893	306	DIST
	Wyeth Pharmaceuticals Div of Wyeth	Sparks	NV	-89434	310	DIST
	PharmaCare Pharmacy #2921	Pittsburgh	PA	15235	84	DIST
	Stiefel Laboratories, Inc	Suwanee	GA	30024	587	DIST
	JOM Pharmaceutical Services Div of Ortho-M	Somerset	NJ	8873	589	DIST
	Schering Corporation	Branchburg	NJ	8876	590	DIST
	Schering Corporation	Suwanee	GA	30024	591	DIST
	Warrick Pharmaceuticals Corporation	Branchburg	NJ	8876	594	DIST
	Warrick Pharmaceuticals Corporation	Suwanee	GA	30024	595	DIST
	JOM Pharmaceutical div of Ortho-McNeil	Bridgewater	NJ	8807	596	DIST
	HealthCare Logistics LLC d/b/a Pharmagistics	Somerset	NJ	8873	597	DIST
	Dixon-Shane LLC d/b/a R & S Northeast LLC	Philadelphia	PA	19115	598	DIST
	Metro Medical Supply, Inc.	Nashville	TN	37228	599	DIST
	Adolor Corporation	Exton	PA	19341	600	DIST
	Genzyme Corporation	Framingham	MA	1701	579	DIST
	McKesson Corporation	Wilsonville	OR	97070	602	DIST
	Gulf South Medical Supply, Inc	Omaha	NE	68138	38	DIST
	Northwest Respiratory Services LLC	Fargo	ND	58103	86	DIST
	Prasco Laboratories	Cincinnati	OH	45249	160	DIST
	Niftus LLC	Wytheville	VA	24382	284	DIST
	SkyePharma Inc	San Diego	CA	92121	288	DIST
	KENCO VPI	Chattanooga	TN	37419	308	DIST
	Tower Laboratories Ltd	Centerbrook	CT	6409	316	DIST
	sanofi-aventis U.S. LLC	Portage	IN	46368	326	DIST
	DIT Healthcare Distribution Inc	West Chester	OH	45246	358	DIST
	Hospira Worldwide Inc	Pleasant Prairie	WI	53158	364	DIST
	Baxter Healthcare Corporation	Thousand Oaks	CA	91320-2530	385	DIST
	Merridian Medical Technologies	St Louis	MO	63144	581	DIST
	Exel Inc	New Kingstown	PA	17072	604	DIST
	MedEquip One, LLC	Bismarck	ND	58501	606	DIST
	Verus Pharmaceuticals Inc	San Diego	CA	92130	607	DIST
	MWI Veterinary Supply Company	Grand Prairie	TX	75050	610	DIST
	Saddle River Marketing Concepts Inc	Paramus	NJ	7652	613	DIST
	Praxair Healthcare Services Inc.	Minot	ND	58701	614	DIST
	Precision Dose Inc	South Beloit	IL	61080	617	DIST
	Parenta Pharmaceuticals Inc	West Columbia	SC	29169	618	DIST
	Priority dba CuraScript SD Specialty Distributi	Sparks	NV	89431	790	DIST
	Genta Incorporated	Berkeley Heights	NJ	7922	509	DIST
	Smith Drug Company	Paragould	AR	72450	623	DIST
	Genpharm, L.P. % Dey LP	Allen	TX	75013	624	DIST
	Rebel Distributors Corp	Thousand Oaks	CA	91320	625	DIST
	FMC Distributors Inc	Ponce	PR	00716-2007	626	DIST
	Medical Specialties Distributors LLC	City of Industry	CA	91748	627	DIST
	Medical Specialties Distributors LLC	Smyrna	GA	30080	628	DIST
	Medical Specialties Distributors LLC	Streetsboro	OH	44241	629	DIST
	Medical Specialties Distributors LLC	Stoughton	MA	02072-4707	630	DIST
	Medical Specialties Distributors LLC	Irving	TX	75063	631	DIST
	Elan Pharmaceuticals	Memphis	TN	38141	634	DIST

	QOL Medical LLC	Kirkland	WA	98033	635	DIST
	Shire LLC	Florence	KY	41042	638	DIST
	Triax Pharmaceuticals LLC	Cranford	NJ	7016	639	DIST
	GlaxoSmithKline	Knoxville	TN	37921	641	DIST
	NitroMed Inc	Lexington	MA	02421-7801	643	DIST
	Bound Tree Medical LLC	South Haven	MS	38671	645	DIST
	US Oncology Specialty, LP	Fort Worth	TX	76177-3237	647	DIST
	Masters Pharmaceutical Inc.	Cincinnati	OH	45240	648	DIST
	Anda Pharmaceuticals, Inc.	Groveport	OH	43125	959	DIST
	McKesson Specialty Distribution LLC	Washington Courthc	OH	43160	767	DIST
	Heartland Repack Services LLC	Toledo	OH	43615	964	DIST
	Smith Drug Company	Spartanburg	SC	29301	656	DIST
	SkinMedica Inc.	Carlsbad	CA	92010	657	DIST
	Edwards Lifesciences Research Medical Inc	Midvale	UT	84047	662	DIST
	Andrx Pharmaceuticals, Inc.	Davie	FL	33314	663	DIST
	MedVantx, Inc.	San Diego	CA	92121	664	DIST
	Henry Schein Inc	Sparks	NV	89434	667	DIST
	CuraScript SD Specialty Distribution	Groveport	OH	43125	671	DIST
	Sanofi Pasteur Inc - Kansas City Distribution (	Kansas City	MO	64120	23	DIST
	Sanofi Pasteur Inc. - Sparks Distribution Cent	Sparks	NV	89434	24	DIST
	Sanofi Pasteur Inc - Scranton Distribution Cer	Taylor	PA	18517	25	DIST
	Nabi Biopharmaceuticals	Boca Raton	FL	33487	203	DIST
	Biomed Plus Inc	Miami	FL	33143	672	DIST
	Intervet Inc	DeSoto	KS	66018	677	DIST
	Butler Animal Health Supply LLC	Columbus	OH	43204	681	DIST
	Baxter Healthcare Corporation	Memphis	TN	38141	682	DIST
	Airgas North Central Inc	Grand Forks	ND	58203	687	DIST
	Bradley Pharmaceuticals	Fairfield	NJ	07004-2402	688	DIST
	H.E. Everson Company of Cooperstown Inc	Cooperstown	ND	58425	693	DIST
	Jacobson Warehouse Company, Inc	Memphis	TN	38118	694	DIST
	Webster Veterinary Supply Inc.	Sterling	MA	1564	695	DIST
	Distribution Solutions dba Priority Solutions In	Memphis	TN	38141-8210	696	DIST
	Auxilium Pharmaceuticals Inc	Malvern	PA	19355	96	DIST
	B. Braun Medical Inc	Breinigsville	PA	18031	701	DIST
	Ivers-Lee Corp dba Sharp Corporation	Fairfield	NJ	7004	197	DIST
	sanofi-aventis U.S. LLC	Decatur	GA	30034	966	DIST
	sanofi-aventis U.S. LLC	Sparks	NV	89431	967	DIST
	Hospira Worldwide Inc	Stone Mountain	GA	30083	703	DIST
	Hospira Worldwide Inc	Farmers Branch	TX	75244	704	DIST
	Hospira Worldwide Inc	King of Prussia	PA	19406	705	DIST
	Hospira Worldwide Inc	Santa Fe Springs	CA	90670	706	DIST
	Heartland Repack Services LLC	Maumee	OH	43537	708	DIST
	Praxair Distribution Inc	Bismarck	ND	58504	969	DIST
	Praxair Distribution Inc	Fargo	ND	58102	970	DIST
	Praxair Distribution Inc	Grand Forks	ND	58202	971	DIST
	Praxair Distribution Inc	Jamestown	ND	58402-2134	972	DIST
	Praxair Distribution Inc	Williston	ND	58802-1654	973	DIST
	H.E. Everson Company of Cando Inc	Cando	ND	58324	711	DIST
	Abrika Pharmaceuticals, Inc.	Sunrise	FL	33325	712	DIST

	Eon Labs Inc dba SANDOZ	Wilson	NC	27893	713	DIST
	The Red Horse LLC	Norwood	NJ	7648	715	DIST
	Dakota Drug Inc	Fargo	ND	58102	717	DIST
	Alamo Pharmaceuticals, Div. Avanir Pharmac	Beverly Hills	CA	90211	721	DIST
	Mutual Pharmaceutical Company Inc	Philadelphia	PA	19111	723	DIST
	United Research Laboratories Inc	Philadelphia	PA	19111	725	DIST
	Integrated Rx Solutions, Inc.	Longwood	FL	32750	730	DIST
	Cedardale Distributors LLC	Carlstadt	NJ	7072	736	DIST
	Dubin Medical Inc	San Diego	CA	92109	565	DIST
	Fresenius Medical Care North America	Pleasant Prairie	WI	53158	738	DIST
	Synthon Pharmaceuticals Inc	Research Triangle P	NC	27709	741	DIST
	F M Howell & Company	Elmira	NY	14902-0286	744	DIST
	Schering Plough Animal Health Corp	Omaha	NE	68127	743	DIST
	OTN Paret Corp dba Oncology Therapeutics	LaVergne	TN	37086	745	DIST
	Hospira Worldwide, Inc	Morgan Hill	CA	95037	755	DIST
	Santarus Inc	San Diego	CA	92130	473	DIST
	Oscient Pharmaceuticals Corporation	Waltham	MA	2451	499	DIST
	Medco Supply Company, Inc.	Tonawanda	NY	14150	236	DIST
	Aurobindo Pharma USA Inc	Cranbury	NJ	8512	758	DIST
	Duramed Pharmaceuticals Inc	Cincinnati	OH	45213	511	DIST
	Leitner Pharmaceuticals LLC	Piney Flats	TN	37686	608	DIST
	Butler Animal Health Supply LLC	Des Moines	IA	50313	759	DIST
	Armstrong Pharmaceuticals Inc	Canton	MA	2021	334	DIST
	Brighton Pharmaceuticals Inc	Cary	NC	27518-8696	760	DIST
	Enzon Pharmaceuticals	Indianaplis	IN	46268	475	DIST
	Advantage Logistics	Oglesby	IL	61348	763	DIST
	AmerisourceBergen Drug Co	Lockbourne	OH	43137	764	DIST
	Midland Healthcare LLC	Kansas City	KS	66103	109	DIST
	MedSource Direct	Woods Cross	UT	84087	689	DIST
	Centrix Pharmaceutical Inc	Birmingham	AL	35242	244	DIST
	Pierre Fabre Pharmaceuticals	Parsippany	NJ	7054	619	DIST
	Abbott Laboratories Inc / Crown	Rocky Mount	NC	27804	769	DIST
	Abbott Laboratories Inc / Exel Logistics	Ontario	CA	91761	770	DIST
	Abbott Laboratories Inc / Kuehne & Nagel	Dallas	TX	75212	771	DIST
	Matthews Book Company	Maryland Heights	MO	63043	482	DIST
	Genentech Inc	Louisville	KY	40258	772	DIST
	Praxair Inc	Inver Grove Height	MN	55075	773	DIST
	Vernalis Pharmaceuticals Inc	Morristown	NJ	7960	774	DIST
	Benco Dental Supply Co	Fort Wayne	IN	46808	787	DIST
	Cardinal Health	Waukegan	IL	60085	776	DIST
	Cobalt Laboratories Inc	Bonita Springs	FL	34134	780	DIST
	CVS Indiana LLC	Indianapolis	IN	46219	784	DIST
	Encysive Pharmaceuticals	Houston	TX	77081	781	DIST
	Indevus Pharmaceuticals Inc	Lexington	MA	2421	777	DIST
	PDL BioPharma Inc c/o SPS Cardinal Health	LaVergne	TN	37086	785	DIST
	Reliance Wholesale Inc	Cordova	TN	38018	786	DIST
	WellSpring Pharmaceutical Corporation	Bradenton	FL	34202	778	DIST
	Reckitt Benckiser Pharmaceuticals Inc	Richmond	VA	23235	783	DIST
	CSL Behring LLC	Bradley	IL	60915	779	DIST

	Eli Lilly and Company	Enfield	CT	6082	106	DIST
	Eastman Kodak Company	Whittier	CA	90606	543	DIST
	UPS Supply Chain Solutions Inc	Louisville	KY	40219	791	DIST
	Southwood Pharmaceuticals Inc	Lake Forkest	CA	92630	538	DIST
	Professional Veterinary Prodcuts dba ProCon	Omaha	NE	68138	795	DIST
	Professional Veterinary Prodcuts dba ProCon	York	PA	17402	796	DIST
	Universal Footcare Products Inc	Northbrook	IL	60062	698	DIST
	Sciele Pharma Sales Inc	Atlanta	GA	30328	797	DIST
	Artes Medical Inc	San Diego	CA	92121	798	DIST
	Auriga Laboratories Inc	Norcross	GA	30092	799	DIST
	Xanodyne Pharmaceuticals Inc	LaVergne	TN	37086	800	DIST
	Sunset Pharmaceuticals Inc	San Diego	CA	92117	801	DIST
	Boehringer Ingelheim Pharmaceuticals, Inc	Ridgefield	CT	6877	802	DIST
	Boehringer Ingelheim Roxane, Inc	Reno	NV	89502	803	DIST
	Boehringer Ingelheim Roxane, Inc	Columbus	OH	43228-9396	804	DIST
	Roxane Laboratories, Inc	Columbus	OH	43228	805	DIST
	Corepharma LLC	Middlesex	NJ	8846	806	DIST
	Baxter Healthcare Corporation	Morrow	GA	30260	807	DIST
	DEPOMED INC	Menlo Park	CA	94025-1436	808	DIST
	Healthcare & Diagnostic Solutions Inc	Loxley	AL	36551	809	DIST
	Jacobson Warehouse Company	Delano	PA	18220	810	DIST
	Onset Therapeutics LLC	Cumberland	RI	02864-1788	811	DIST
	TWL Billing Service & Supplies Inc	Bismarck	ND	58504	812	DIST
	Novartis Consumer Health Inc	Lincoln	NE	68501-3288	813	DIST
	Darby Dental Supply LLC	Memphis	TN	38118	814	DIST
	Baxter Healthcare Corporation	Fife	WA	98424	816	DIST
	Atlantic Biologicals Corp	Tucson	AZ	85705	817	DIST
	Atlantic Biologicals Corp	Miami	FL	33179	818	DIST
	Atlantic Biologicals Corp	Goodlettsville	TN	37072	819	DIST
	Fisher Clinical Services Inc	Allentown	PA	18106	820	DIST
	MWI Veterinary Supply Co	Clear Lake	WI	54005	821	DIST
	ANIP Acquisition daba ANI Pharmaceuticals I	Gulfport	MS	39501	822	DIST
	Ballard Medical Products	Draper	UT	84020-9414	823	DIST
	Seton Pharmaceuticals LLC	Sea Girt	NJ	8750	824	DIST
	TEVA Pharmaceuticals USA Inc	Chalfont	PA	18914	825	DIST
	BD Distribution Center	Swedesboro	NJ	8085	826	DIST
	BD Distribution Center	Plainfield	IN	46168	827	DIST
	BD Distribution Center	Redlnads	CA	92374	828	DIST
	Darby Dental Supply, LLC	Reno	NV	89502	829	DIST
	Idenix Pharmaceuticals Inc	Cambridge	MA	2139	830	DIST
	KVK-TECH, Inc	Newtown	PA	18940	831	DIST
	Cytogen Corporation	Princeton	NJ	8540	832	DIST
	Grafton Pharmaceutical Distribution LLC	Grafton	ND	58237-0545	833	DIST
	Q Logistics Inc	Florham Park	NJ	7932	834	DIST
	Ebewe Parenta Pharmaceuticals Inc	West Columbia	SC	29169	835	DIST
	FamilyMeds Inc dba FamilyMeds Medical Sup	Farmington	CT	6032	836	DIST
	Valley Apothecary Wholesale	Salem	VA	24153	837	DIST
	Rising Pharmaceuticals Inc	Allendale	NJ	7401	838	DIST
	Rummel's Auto Wrecking & Welding Supplies	Dickinson	ND	58601-5453	839	DIST

	G & W Laboratories Inc.	S Plainfield	NJ	-7080	124	MAN
	Genetco Inc.	Ronkonkoma	NY	-11779	122	MAN
	Sicor Pharmaceuticals Inc.	Irvine	CA	92618-1902	132	MAN
	Gilead Sciences Inc	San Dimas	CA	-91773	341	MAN
	GlaxoSmithKline	Philadelphia	PA	19101	133	MAN
	GlaxoSmithKline	Durham	NC	-27713	486	MAN
	Glenwood LLC	Englewood	NJ	7631	134	MAN
	Halocarbon Products Corporation	River Edge	NJ	-7661	136	MAN
	Hawkins Inc	Minneapolis	MN	55413	183	MAN
	Healthpoint Ltd.	Fort Worth	TX	76107-7253	379	MAN
	Hill Dermaceuticals Inc.	Sanford	FL	-32773	142	MAN
	Humco Holding Group Inc.	Texarkana	TX	75501-0282	333	MAN
	INO Therapeutics Inc	Port Allen	LA	-70767	151	MAN
	International Medication Systems Ltd	South El Monte	CA	-91733	149	MAN
	Inwood Laboratories, Inc.	Commack	NY	-11725	152	MAN
	Wyeth Pharmaceutical Div of Wyeth Holdings	Pearl River	NY	-10965	165	MAN
	Mallinckrodt-Webster Groves Technical Cente	St Louis	MO	63119	167	MAN
	Mallinckrodt Inc	Maryland Heights	MO	-63043	172	MAN
	Mallinckrodt Inc.	St. Louis	MO	-63134	173	MAN
	Medicis Pharmaceutical Corp.	Scottsdale	AZ	-85258	184	MAN
	MedImmune, Inc	Gaithersburg	MD	-20878	556	MAN
	Medi-Physics Inc dba GE Healthcare	South Plainfield	NJ	-7080	551	MAN
	Medi-Physics Inc dba GE Healthcare	Arlington Heights	IL	-60004	550	MAN
	MedPointe Healthcare Inc.	Decatur	IL	62523-1125	65	MAN
	Medtronic USA, Inc.	Columbia Heights	MN	-55421	190	MAN
	Monsanto Company (Manufacturer)	St. Louis	MO	-63167	428	MAN
	Morton Grove Pharmaceuticals Inc.	Morton Grove	IL	-60053	199	MAN
	Mutual Pharmaceutical Company Inc	Philadelphia	PA	-19124	201	MAN
	Novartis Animal Health US Inc	Greensboro	NC	-27408	209	MAN
	Organon USA Inc	Allentown	PA	-18103	215	MAN
	OSG Norwich Pharmaceuticals	North Norwich	NY	-13814	218	MAN
	PD-Rx Pharmaceuticals Inc.	Oklahoma City	OK	-73127	462	MAN
	Pfeiffer Pharmaceuticals Inc.	Atlanta	GA	30315	227	MAN
	PharmPak Inc.	San Rafael	CA	-94901	232	MAN
	Smiths Medical ASD Inc	Keene	NH	-3431	263	MAN
	Spectrum Laboratory Products Inc	Gardena	CA	90248-2027	239	MAN
	PSS World Medical Inc.	Rogers	MN	55374	241	MAN
	Salix Pharmaceuticals Inc.	Morrisville	NC	27560	535	MAN
	Daiichi Sankyo Inc	Parsippany	NJ	-7054	489	MAN
	Schwarz Pharma Manufacturing Inc	Seymour	IN	47274-0328	256	MAN
	Andrx Therapeutics Inc.	Weston	FL	33331	257	MAN
	PLIVA Inc.	East Hanover	NJ	-7936	262	MAN
	Solvay Pharmaceuticals Inc.	Marietta	GA	-30062	266	MAN
	Akorn d/b/a Taylor Pharmaceuticals	Decatur	IL	-62522	277	MAN
	Vivus Inc.	Mountain View	CA	-94040	297	MAN
	Warner Chilcott Inc.	Rockaway	NJ	-7866	300	MAN
	Warner-Lambert Company	Elk Grove Village	IL	-60007	301	MAN
	Fort Dodge Laboratories, Inc.	Fort Dodge	IA	50501	304	MAN
	Genzyme Corporation	Allston	MA	2134	578	MAN

	Ligand Pharmaceuticals Inc	San Diego	CA	92121	580	MAN
	LTS Lohmann Therapy Systems Corp	West Caldwell	NJ	7006	398	MAN
	CollaGenex Pharmaceuticals, Inc.	Newtown	PA	18940	603	MAN
	GlaxoSmithKline	Research Triangle P	NC	27709	611	MAN
	Pharmion Corporation	La Vergne	TN	37086	621	MAN
	Professional Dental Technologies Therapeuti	Batesville	AR	72501	633	MAN
	Ameripharm Inc	Sioux Falls	SD	57104	644	MAN
	Cumberland Pharmaceuticals Inc.	Nashville	TN	37203	660	MAN
	Hill-Rom, Inc.	Charleston	SC	29405	697	MAN
	Amphastar Pharmaceuticals Inc.	Rancho Cucamonga	CA	91730	965	MAN
	Cubist Pharmaceuticals Inc	Lexington	MA	2421	716	MAN
	PharMedium Services LLC	Cleveland	MS	38732	719	MAN
	Leiner Health Products, LLC	Fort Mill	SC	29708	734	MAN
	MedImmune Distribution LLC	Shepherdsville	KY	40165	425	MAN
	ViroPharma Incorporated	Exton	PA	19341	747	MAN
	ISTA Pharmaceuticals Inc	Irvine	CA	92618	753	MAN
	Armstrong Pharmaceuticals Inc	West Roxbury	MA	2132	754	MAN
	Specialty Pharmaceutical Services	LaVergne	TN	37086	530	MAN
	Actavis Totowa LLC	Totowa	NJ	7512	782	MAN
	Par Pharmaceutical Inc	Spring Valley	NY	10977	260	MAN
	Lincare Inc	Miles City	MT	59301	765	MAN
	Lincare Inc	Sidney	MT	59270	766	MAN
	Capital Returns Inc.	Milwaukee	WI	-53218	61	REV
	Clinical Supplies Management Inc	Fargo	ND	-58104	76	REV
	Diagnostic Products Corporation	Los Angeles	CA	-90045	351	REV
	Guaranteed Returns Midwest Division	St Charles	MO	63367	103	REV
	EXP Pharmaceutical Services Corp	Fremont	CA	94539	377	REV
	Superior Medical Supply Inc	Broomfield	CO	80021	531	REV
	National Pharmaceutical Returns	Des Moines	IA	50322-7929	204	REV
	Obagi Medical Products Inc	Carson	CA	90810	483	REV
	Stericycle, Inc.	Indianapolis	IN	46241	330	REV
	Pharmaceutical Returns	Northfield	MN	-55057	381	REV
	PharmaLink, Inc	Largo	FL	33773	345	REV
	Med-Turn, Inc.	Ft Worth	TX	76155	544	REV
	Stericycle Inc	Boynton Beach	FL	33426	371	REV
	Stericycle, Inc.	Conyers	GA	-30013	406	REV
	Taro Pharmaceuticals USA, INC	Canbury	NJ	8512	290	REV
	Akyma Pharmaceuticals LLC	Fountain Run	KY	42133	615	REV
	AmerisourceBergen Drug Corporation	Denver	CO	80216	659	REV
	Heritage Labs	Olathe	KS	66061	727	REV
	Med-Turn Inc	Westfield	IN	46074	729	REV
	Advancis Pharmaceutical Corporation	Germantown	MD	20876	229	REV
	Dakota Pharmaceutical Packaging, LLC	Fargo	ND	58104	558	REV
	Excess Management Systems Inc	Melbourne	FL	32934	762	REV
	Altru Renal Unit at Mercy Hospital	Devils Lake	ND	-58301	414	WARE
	Apotex Corp	Indianapolis	IN	-46268	524	WARE
	MeritCare Enterprises, Inc	Fargo	ND	-58102	478	WARE
	Metro Park Warehouses, Inc.	Kansas City	MO	-66110	440	WARE
	St Alexius Medical Center	Bismarck	ND	-58501	400	WARE

	Walgreen Co	Woodland	CA	-95776	441	WARE
	Cardinal Health Inc.	McGaw Park	IL	60085	653	WARE
	Allergan Sales , LLC	Irvine	CA	92623-9534	7	WHOLE
	Baxter Healthcare Corporation	Catano		962	508	WHOLE
	Amgen USA Inc.	Louisville	KY	-40299	15	WHOLE
	Auburn Pharmaceutical Company	Troy	MI	48083-2512	29	WHOLE
	Banyan International Corporation	Abilene	TX	-79604	34	WHOLE
	Bellco Drug Corp	N Amityville	NY	-11701	447	WHOLE
	Baxter Healthcare Corporation	Grand Prairie	TX	75052	505	WHOLE
	Block Drug Company Inc.	Memphis	TN	38181-0709	331	WHOLE
	Bristol Myers Squibb	Mt Vernon	IN	-47620	547	WHOLE
	Chester Valley Pharmaceuticals Inc	LaVergne	TN	37086	67	WHOLE
	Caraco Pharmaceutical Laboratories Ltd	Detroit	MI	-48202	63	WHOLE
	Caremark Inc.	Redlands	CA	-92374	60	WHOLE
	White Drug #61	Fargo	ND	58102	348	WHOLE
	Dakota Clinic Pharmacy	Fargo	ND	-58103	89	WHOLE
	Eastman Kodak Company	Rochester	NY	14652-0130	332	WHOLE
	Eli Lilly and Company	Plainfield	IN	46168	107	WHOLE
	Fresenius Medical Care NA & Nephromed	Charlotte	NC	-28273	485	WHOLE
	Genentech Inc.	South San Francisc	CA	94080-4990	121	WHOLE
	General Injectables & Vaccines Inc.	Bastian	VA	-24314	130	WHOLE
	Golden State Medical Supply Inc	Ventura	CA	93003	492	WHOLE
	H.D. Smith Wholesale Drug Co	Wood Dale	IL	-60191	504	WHOLE
	Harte - Hanks Direct Marketing	Shawnee	KS	66214-1407	417	WHOLE
	HPS Rx Enterprises Inc	Roanoke	VA	-24018	512	WHOLE
	Independent Pharmacy Cooperative	Sun Prairie	WI	-53590	147	WHOLE
	Integrated Commercial Solutions/ I.C.S.	Brooks	KY	-40109	401	WHOLE
	Jacobus Pharmaceutical Company	Princeton	NJ	-8540	153	WHOLE
	Mallinckrodt Inc.	Hobart	NY	13788-0416	174	WHOLE
	McKesson Corporation	Washington Courtho	OH	-43160	179	WHOLE
	Lehigh Valley Technologies Inc	Allentown	PA	18102	366	WHOLE
	McKesson Corporation	New Castle	PA	-16101	497	WHOLE
	McKesson Corp dba McKesson Drug Co	Santa Fe Springs	CA	-90670	420	WHOLE
	McKesson Corporation	Aurora	CO	-80011	421	WHOLE
	Meretek Diagnostics, Inc.	Lafayette	CO	80026	570	WHOLE
	Moore Medical LLC	New Britain	CT	-6051	700	WHOLE
	Nelson Laboratories Limited Partners	Sioux Falls	SD	-57104	206	WHOLE
	Professional Compounding Ctrs of America	Houston	TX	77099-5132	240	WHOLE
	Hikma Pharmaceuticals USA Inc	Eatontown	NJ	7724	460	WHOLE
	Smith & Nephew Inc	Largo	FL	33773	469	WHOLE
	St Mary's Medical Park Pharmacy	Oro Valley	AZ	-85737	270	WHOLE
	Cardinal Health	St Paul	MN	-55114	567	WHOLE
	Cardinal Health	Moorhead	MN	-56560	545	WHOLE
	TheraCom Inc	Rockville	MD	20850	280	WHOLE
	Top Rx, Inc	Bartlett	TN	-38133	340	WHOLE
	Triple i	Carlstadt	NJ	7072	286	WHOLE
	Kuehne + Nagel	Memphis	TN	-38141	472	WHOLE
	Kuehne + Nagel	Reno	NV	-89502	470	WHOLE
	Baxter Healthcare Corporation	Montgomery	NY	12549	493	WHOLE

	BioRx LLC	Cincinnati	OH	45242	305	WHOLE
	Watson Pharma Inc.	Brewster	NY	-10509	253	WHOLE
	Williams Medical Company	Placentia	CA	-92670	307	WHOLE
	Wyeth Pharmaceuticals Div of Wyeth	Vonore	TN	-37885	427	WHOLE
	Zila Pharmaceuticals Inc.	Phoenix	AZ	85040-1939	317	WHOLE
	South Pointe Wholesale Inc.	Glasgow	KY	42141	593	WHOLE
	MeritCare Hospital-South University	Fargo	ND	58103	601	WHOLE
	GeneraMedix Inc	Liberty Corner	NJ	7938	185	WHOLE
	Perrigo Pharmaceuticals Company	Allegan	MI	49010	390	WHOLE
	Cura Pharmaceutical Company Inc	Eatontown	NJ	7724	616	WHOLE
	Fisher Scientific Company LLC	Somerville	NJ	8876	636	WHOLE
	Lincare Pharmacy Services, Inc.	Clearwater	FL	33762	962	WHOLE
	C T International	San Luis Obispo	CA	93401	654	WHOLE
	Creekwood Pharmaceutical Inc	Birmingham	AL	35242	655	WHOLE
	VaxServe Inc/Scranton Distribution Center	Taylor	PA	18517	658	WHOLE
	INO Therapeutics LLC	Woodridge	IL	60517	665	WHOLE
	Merz Pharmaceuticals, LLC	Greensboro	NC	27410	668	WHOLE
	Millennium Pharmaceuticals	LaVergne	TN	37086	669	WHOLE
	GFCO,Inc.	Hazelwood	MO	63042	675	WHOLE
	VaxServe Inc/Sparks Dist Ctr	Sparks	NV	89431	679	WHOLE
	Global Pharmaceutical Sourcing	Nashville	TN	37211	683	WHOLE
	Agriceutical Resources LLC	Oxbow	ND	58047	710	WHOLE
	Expert-Med Inc	Greenville	SC	29607	652	WHOLE
	E-Z-EM Inc	Westbury	NY	11590-5021	718	WHOLE
	Certified Business Supply dba Purity Medical	Placentia	CA	92870	722	WHOLE
	Watson Pharma, Inc	Corona	CA	92880	732	WHOLE
	Merit Pharmaceutical	Los Angeles	CA	90065	609	WHOLE
	ProEthic Pharmaceuticals Inc	Montgomery	AL	36117	749	WHOLE
	Kenco Knoxville	Knoxville	TN	37921	750	WHOLE
	DAVA Pharmaceuticals	Fort Lee	NJ	7024	751	WHOLE
	Intendis Inc	Pine Brook	NJ	07058-1000	761	WHOLE
	FMC Distributors of Nevada Inc	Las Vegas	NV	89118	768	WHOLE
	Watson Laboratories Inc	Salt Lake City	UT	84108	775	WHOLE
	Baxter Healthcare Corporation	Marion	NC	28752	792	WHOLE
	B. Braun Medical Inc	Santa Ana	CA	92704	793	WHOLE
	B. Braun Medical Inc	DFW Airport	TX	75261-2506	794	WHOLE
	Alcon Manufacturing, Ltd.	Fort Worth	TX	76134-2099	5	
	Cardinal Health Inc	Englewood	CO	80112	383	
	Axcan Scandipharm, Inc.	Birmingham	AL	-35242	252	
	Berlex Inc.	Wayne	NJ	-7470	48	
	Blood Diagnostics Inc.	Irmo	SC	-29063	382	
	DMS Health Technologies Inc.	Fargo	ND	58102	94	
	North Central Healthcare Alliance	Bismarck	ND	58501	432	
	Hollister-Stier Laboratories LLC	Spokane	WA	-99207	409	
	Mylan Pharmaceutical Distribut	Greensboro	NC	-27406	347	
	Patterson Dental Supply Inc.	Fargo	ND	58103	222	
	Pedinol Pharmacal Inc.	Farmingdale	NY	-11735	224	
	Septodont Inc.	New Castle	DE	-19720	258	
	Sigma-Tau Pharmaceuticals Inc	Frederick	MD	-21703	261	

	SuperGen Inc.	Dublin	CA	-94568	273	
	United Research Laboratoires Inc	Philadelphia	PA	-19124	503	
	UpState Pharma LLC	Rochester	NY	14623	620	
	Guerbet LLC	Bloomington	IN	47403	622	
	Redi-Mail Direct Marketing	Fairfield	NJ	7004	642	
	Midwest Med Specialties Inc.	Loogootee	IN	47553	646	
	SourceOne Healthcare Technologies	St Paul	MN	55114	961	
	MD Logistics, Inc.	Plainfield	IN	46168	192	
	Columbia Laboratories Inc	Livingston	NJ	7039	674	
	VaxServe Inc/Kansas City Distribution Ctr	Kansas City	MO	64120	680	
	H. E. Everson Company of Rugby Inc	Rugby	ND	58368-0166	685	
	H.E. Everson Company of Devils Lake	Devils Lake	ND	58301	691	
	B. Braun Medical Inc	Bridgeview	IL	60455	699	
	H. E. Everson Company of Grafton Inc	Grafton	ND	58237	702	
	Premium Health Services Inc	Columbia	MD	21045	724	
	Patterson Dental Supply Inc	Boone	IA	50036	735	
	IVPCare Inc	Frisco	TX	75034	739	

ATTACHMENT A

H.B. 1455 HDMA recommended language:

SECTION 2 [43-15.3-01 (6) & (10)] Definitions - Drop Shipments (page 4-5)

(6) "Drop shipment," means the sale of a prescription drug to a wholesale distributor by the manufacturer of the prescription drug, or that manufacturer's co-licensed product partner, that manufacturer's third party logistics provider, or that manufacturer's exclusive distributor, or by an authorized distributor of record that purchased the product directly from the manufacturer or one of these entities whereby the wholesale distributor or chain pharmacy warehouse takes title but not physical possession of such prescription drug and the wholesale distributor invoices the pharmacy or chain pharmacy warehouse, or other person authorized by law to dispense or administer such drug to a patient, and the pharmacy or chain pharmacy warehouse or other authorized person receives delivery of the prescription drug directly from the manufacturer, or that manufacturer's co-licensed product partner or that manufacturer's third party logistics provider, or that manufacturer's exclusive distributor or from an authorized distributor of record that purchased the product directly from the manufacturer or one of these entities.

(10). "Normal distribution channel" means a chain of custody, including a drop shipment for a prescription drug which goes from a manufacturer of the prescription drug, from that manufacturer to that manufacturer's colicensed partner, from that manufacturer to that manufacturer's third-party logistics provider, or from that manufacturer to that manufacturer's exclusive distributor to:

SECTION 2 [43-15.3-03 (1)] Wholesale drug distributor licensing requirement – Minimum requirements for licensure (page 8)

1. A wholesale distributor that engages in the wholesale distribution of prescription drugs must be licensed by the board under this chapter and must be properly licensed in any other state in which the wholesale distributor engages in the distribution of prescription drugs before engaging in wholesale distributions of wholesale prescription drugs in this state. ~~The board shall exempt manufacturers distributing their own federal food and drug administration approved drugs and devices from any licensing and other requirements of this section, to the extent not required by federal law or regulation, unless particular requirements are deemed necessary and appropriate following rulemaking.~~

SECTION 2 [43-15.3-04 (1) Requirements to Distribute Prescription Drugs (pages 12-13):

All applicants shall be inspected prior to registration. If the applicant is located in North Dakota, inspectors from the North Dakota Board of Pharmacy shall conduct the inspection.

The board shall accept the following as equivalent to a recognized state inspection for distributors located outside the state:

1) An out-of-state inspection conducted by the North Dakota Board of Pharmacy;

2) An individual internal audit and review conducted within the previous two years with criteria approved by the board of pharmacy; and,

3) The out of state wholesaler may be inspected by a board-approved nationally recognized accreditation program or contract inspection service.

The board shall recognize the following and grant, when appropriate, a temporary license:

1) A statement in writing from the appropriate regulatory authority of the resident state certifying that the applicant is licensed in good standing as a wholesale distributor and the applicant will be inspected by the (appropriate state regulatory authority) within six months of the request; or,

2) A statement in writing from a nationally recognized accreditation program or contract inspection service confirming that the applicant will be certified within six months of application.

Any applicant that is denied accreditation and subsequently denied licensure by the state shall have the right of review of the nationally recognized accreditation program or contract inspection service's decision by:

(1) The approved nationally recognized accreditation program or contract inspection service; and
(2) The Board of Pharmacy

The board shall develop criteria for approving third party accreditation or inspection bodies and any recognized accreditation body or inspection service shall ensure that the proprietary information obtained during the accreditation process remains confidential and privileged.

SECTION 2 [43-15.3-06 (1) subsection (b) Substitute the current subsection with the following language (page 15):

(b) Effective at a date established by the Board, pedigrees may be implemented through an approved and readily available system that electronically tracks and traces the wholesale distribution of each prescription drug starting with the sale by a manufacturer through acquisition and sale by any wholesale distributor, until final sale to a pharmacy or other authorized person administering or dispensing the prescription drug. This electronic tracking system will be deemed to be readily available only upon there being available a standardized system originating at the manufacturer and capable of being used on a wide scale across the entire pharmaceutical supply chain which includes manufacturers, wholesale distributors, and pharmacies. Also, consideration must be given, however, to the large-scale implementation of this technology across the supply chain and the technology must be proven to have no negative impact on the safety and efficacy of the pharmaceutical product. "Track and trace" means the ability to locate a product in the supply chain and determine its outbound distribution path.

Daniel Bellingham, Associate Director, State Government Affairs
Healthcare Distribution Management Association (HDMA)
Comments Regarding H.B. 1455
North Dakota House Judiciary Committee
January 30, 2007

Mr. Chairman and members of the Committee, my name is Daniel Bellingham, Associate Director, State Government Affairs with the Healthcare Distribution Management Association (HDMA). I appreciate the opportunity to provide testimony regarding H.B. 1455. HDMA is the trade association representing the nation's primary, full-service healthcare distributors. Ten of these members serve the State of North Dakota.

Each and every day, HDMA member companies safely and efficiently deliver nine million healthcare products to more than 144,000 pharmacies, hospitals, nursing homes, physician offices and clinics in every state in the nation. In fact, nearly 80% of all prescription medicines in this country go through an HDMA member distribution facility on the way from the manufacturer to the pharmacy setting. This essential public health function is provided with tremendous efficiency, saving the nation's healthcare system $10.5 billion each year.

HDMA and its member companies work actively with legislators and regulators, both at the state and federal levels, to identify additional steps to further secure the medicine supply from counterfeit drugs. These steps include:

1. Strengthen the licensure requirements for pharmaceutical distributors.
2. Increase criminal penalties for those who counterfeit medicines or knowingly distribute compromised products.
3. Promote and work toward the development and adoption of current and emerging technologies, such as Radio Frequency Identification (RFID), which can track, trace and authenticate individual prescription medicines as they travel through the supply chain.

While we support the goal of H.B. 1455, we respectfully request that the Committee consider the following amendments:

SECTION 2 [43-15.3-01 (6) & (10)] Definitions - Drop Shipments (page 4-5)

HB 1455 defines "drop shipments" but does not include this term anywhere else in the bill. As currently written, the bill is inconsistent with the FDA's Q & A guidance regarding PDMA implementation. The FDA has pointed out that pedigrees would be required for *non-ADRs* involved in drop ship transactions, but has stated that there would be no such requirement for *Authorized* Distributors of Record (ADRs).

Drop shipments are a necessary occurrence and we believe, must be clearly exempted from pedigree requirements where the federal law allows. As such, HDMA advocates including this type of transaction in the "Normal distribution channel" definition in SECTION 2 [43-15.3-01 (10)]. In the alternative, we would suggest that drop shipments which meet the federal standards be listed as an exception under the definition of "wholesale distribution" In cases where manufacturers are performing the drop shipment on behalf of a wholesaler, SECTION 2 [43-15.3-01 (16). The suggested language included in Attachment A clarifies that ADRs can drop ship as permitted under PDMA.

SECTION 2 [43-15.3-03 (1)] Wholesale drug distributor licensing requirement – Minimum requirements for licensure (page 8)

As currently written, this section exempts manufacturers who distribute drugs from the requirements for licensure in the bill. While HDMA recognizes the critical role of the manufacturer in the supply chain, we do not advocate for a blanket exemption for manufacturers from state requirements aimed at protecting the public. The manufacturer community is as diverse as any other and they collectively play an important role in protecting prescription drug consumers. When a manufacturer is functioning in the capacity of a wholesale distributor (e.g., warehousing and shipping drugs), there is no logical reason to regulate the manufacturer any differently than a wholesale distributor. Manufacturers have argued that they are already subject to the FDA's Good Manufacturing Practice (GMP) regulations and, therefore, they are already highly regulated. The reality is that the GMP regulations focus on manufacturing practices and not to any significant extent on distribution practices. In addition, the penalties included in the GMP regulations (three years for similar violations) are much weaker than the penalties proposed in this model language (up to fifteen years for violations). If a manufacturer is engaging in business in a state, and if they are engaging in wholesale distribution activities, their facilities should be subject to the same scrutiny as other members of the supply chain.

SECTION 2 [43-15.3-04 (1) Requirements to Distribute Prescription Drugs (pages 12-13):

While we are pleased that the committee is interested in strengthening its licensure standards for pharmaceutical distributors, we are deeply concerned about the possibility of making VAWD accreditation a requirement for distributors doing business in North Dakota. HDMA members fully support the need for facility inspections as a mechanism to ensure that distributors are meeting licensure standards, however, we want to discourage the Board of Pharmacy from relinquishing its inspection authority over in-state distributors, and hope to ensure that a degree of choice is maintained for out-of state licensees in order to preserve the safe and efficient supply of prescription drugs to North Dakota patients.

During the past three years, several states have considered VAWD accreditation as a means to ensure that state-licensed facilities are properly inspected. Only one state, Indiana, has made accreditation a condition of licensure. HDMA members have had a variety of experiences with the approved Indiana accreditation program. One of the most serious issues with VAWD in Indiana has been the backlog of inspections. In some instances, the certification process has taken six to nine months from the time of application. This has resulted in some distributors making the ultimate decision to discontinue distributing into the state. The initial goal of the Indiana Board of Pharmacy was to have the hundreds of Indiana licensed wholesalers VAWD certified by September 2006. That Board recognized the backlog of inspections and instead granted temporary licenses to those renewal applicants that applied for VAWD by September 2006. Many of those distributors are still awaiting their VAWD inspection or final certification. While many of our member companies have completed or are in the process of completing their VAWD certification, these are problems that we believe the Board should be aware.

HDMA fully recognizes the necessity for strong regulation of the distribution industry, conducted by appropriate governmental authorities operating under validly enacted laws and regulations. As you know, the inspection of pharmaceutical distribution facilities is a complex undertaking that requires the use of trained and experienced staff, familiarity with the industry, knowledge of applicable laws, and established procedures to ensure the commercial interests of license applicants are lawfully protected. Oftentimes, VAWD inspectors have never been inside a

distribution center until the day of the VAWD inspection. It has been our experience that they do not have any previous experience with pharmaceutical distribution.

Further, HDMA encourages the committee to allow the Board of Pharmacy to consider alternatives for out-of-state distributors. We are not opposed to VAWD as one *option*, however, our members' experience suggests that there is a need for other routes to meet the conditions of licensure. While we strongly encourage the North Dakota Board of Pharmacy to continue to perform inspections of distributors domiciled in the state of North Dakota, if there is a concern about the lack of resources available to carry out this task, we would like to work with you to find a solution.

For North Dakota distributor-licensees located outside the state, we support reciprocity for those distributors licensed in good standing in their resident states. Another alternative would be to accept Board of Pharmacy-approved individual distributor internal audit inspections or audits by approved contract inspection services. Individual distributor internal audits usually consist of, but are not limited to reviews of: safety and security standards; sanitation and product storage rotation practices; inventory management controls and loss prevention controls; narcotic and hazardous material reviews; and, transportation protocols. This method has been adopted in some states, such as California, where distributors' designated representatives are required to conduct a yearly internal audit and submit it, with their certification, to the Board. Additionally, there are several industry contract inspection consultants that have expertise in the distribution industry. While they may not yet have organized "accreditation" programs, we believe there are several existing companies equipped to perform thorough and effective inspections of distribution facilities.

Without necessary alternatives, HDMA is concerned about the continuity of the pharmaceutical supply chain. Our top priority is ensuring that pharmacies, hospitals, nursing homes, and physicians continue to efficiently and safely receive life-saving medicines for their patients.

SECTION 2 [43-15.3-06 (1)] - Pedigree (page 14-15)

HDMA advocates for development of a track and trace system that supports pedigree and tracks the path of a drug from its creation through the supply chain until it is ultimately dispensed to the patient. This type of system is under development but may not be widely available for several years. In the interim HDMA supports additional regulatory controls such as stronger licensure laws, increased penalties, and use of pedigree as a safety mechanism in those instances where drugs are at the highest risk – outside the normal or primary distribution channel.

We believe that tracking technologies such as RFID have the most promise for use in this way by the supply channel. However, any such tracking mechanism must originate at the manufacturer – at the product's inception - in order to ensure that there are no gaps in the chain that might invite counterfeiters or diverters of prescription medicines.

HDMA language clarifies that electronic pedigree would not be utilized until readily available across the entire industry. Such a system would start with the manufacturer and be used at the item level for all drugs, not just those outside of "normal distribution".

Thank you for considering these amendments to this important piece of legislation. HDMA commends you for addressing this issue and we look forward to working with you and other industry stakeholders on this important issue.

News from the Courts

Submitted by Kim Keller Reid, B.S. Pharm., J.D.

Federal Drug Pedigree Requirement Delayed RxUSA Wholesalers, Inc. vs. HHS (E. D. N.Y.) 06-CV-5086

In the Eastern District of New York, on December 8, 2006, Judge Joanna Seybert granted a preliminary injunction to prohibit FDA from implementing a regulation (21 CFR Sec. 203.50(a)) that requires certain information be included in a drug "pedigree" (a statement of origin). The regulation went into effect December 1, 2006. The pedigree requirement is part of a more comprehensive rule to implement portions of the Prescription Drug Marketing Act of 1987 (PDMA) as amended by the Prescription Drug Amendments of 1992.

The PDMA requires that certain wholesalers called "secondary wholesalers" provide a statement of origin (pedigree) prior to each wholesale distribution of prescription drugs. The pedigree requirements do NOT apply to Manufacturers or ARDs (authorized distributors of record)—exempting them from having to pass a pedigree. The PDMA defines an ADR as a wholesale distributor that has an "on-going relationship" with the manufacturer. The PDMA does not define "on-going relationship."

This injunction enjoins FDA from implementing language in 21 CFR Sec.203.50(a) that requires a pedigree *to identify prior sale, purchase or trade of a drug back to the drug's original manufacturer.* In addition, the FDA is enjoined from implementing the language in 21 CFR Sec.203.50(a) that specifies the *different type of information, including lot numbers and container sizes that must be included in a pedigree.*

The enforcement of the federal drug pedigree requirement will call for new recordkeeping requirements for pharmacies who deal with wholesalers/suppliers who are not ADRs. The Food and Drug Administration (FDA) has issued a Question and Answer Guide that may be found at http://fda.gov/cder/regulatory/PDMA/PDMA_qa.pdf.

In addition, the FDA has posted new information on its website explaining its interpretation of the court's order in more detail and further clarifies its expectations regarding compliance with the PDMA generally at: http://www.fda.gov/cder/regulatory/PDMA/pdma_addendum.pdf.

A Compliance Policy Guide that FDA issued in November 2006 may be found at http://www.fda.gov/cder/regulatory/PDMA/PDMA_CPG.pdf.

Noesen v. Medical Staffing Network Inc. et. al., No. 06-C-071-S, 2006 WL 1539664 (W.D. Wis. June 1, 2006)

Submitted by—Frederick Fern ASPL member, counsel for co- defendant, Medical Staffing Network.

Pharmacist Noesen applied with a job with Medical Staffing Network, and advised the company of his religious beliefs (that he would not dispense contraception—and that his license was under investigation by the Wisconsin Examining Board for refusing to process or refer a woman's contraceptive prescription). Medical Staffing referred Noesen to Wal-Mart. Wal-Mart accepted him in a temporary position with knowledge of these restrictions. Noesen even had an official at Wal-Mart sign a document acknowledging that Noesen would not dispense contraceptives articles or participate in any other activity involving contraceptives. The pharmacy stated that it never asked Noesen to have any involvement with contraceptives. Another pharmacist was always on duty to fill prescriptions and answer questions about birth control. At one point, Wal-Mart reminded Noesen that he could not just walk away from customers or leave them on hold indefinitely. At that point Noesen filed a harassment complaint against Medical Staffing to avoid being pressured to wait on customers who needed help with birth control. Then Wal-Mart fired Noesen when he allegedly called another pharmacist a liar and refused to leave the store when asked to do so. The police responded and removed him from the store in a wheelchair because he refused to walk out. Medical Staffing then fired Noesen for his poor performance and disruptive behavior at Wal-Mart.

Noesen filed suit in the U.S. District Court for the Western District of Wisconsin against Medical Staffing and Wal-Mart, alleging religious discrimination in violation of Title VII of the Civil Rights Act of 1964 and violation of his First Amendment right to freedom of religion under 42 U.S.C. Sec. 1985(3) which makes it illegal to conspire to deprive someone of civil rights under federal laws.

The judge granted summary judgment to both defendants. Noesen's Title VII claims fell short of stating a claim under the facts presented. The opinion went on to say that even if the plaintiff had established a *prima facie* case of religious discrimination, both employers had provided legitimate nondiscriminatory reasons for firing him, and both defendants had accommodated his religious beliefs. The judge found that the employer could not reasonably allow the plaintiff to place telephone customers on hold indefinitely or walk away from in-store customers without notifying another pharmacist to fill in.

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

Testimony on House Bill 1455
Diane Darvey, Director of Pharmacy Regulatory Affairs
National Association of Chain Drug Stores (NACDS)
North Dakota House Judiciary Committee
January 30, 2007

Mr. Chairman and members of the Committee, my name is Diane Darvey, Director of Pharmacy Regulatory Affairs with the National Association of Chain Drug Stores (NACDS). NACDS is the trade association representing chain pharmacies and has 16 members operating pharmacies in North Dakota. On behalf of our members, I appreciate the opportunity to provide testimony on House Bill 1455.

The U.S. prescription drug distribution system is one of the safest and most secure in the world. We believe that these results are directly attributable to efforts of stakeholders in the legitimate drug supply distribution system. Chain pharmacy and other stakeholders have taken practical and immediate steps to further ensure the safety and integrity of the drug supply chain including supporting efforts to strengthen wholesale drug distributor licensure requirements. NACDS has worked closely with other industry associations including the Pharmaceutical Manufacturers Association (PhRMA) and the Healthcare Distributors and Manufacturers Association (HDMA) to develop workable means to enhance the integrity of the drug supply chain.

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22313-1480

While we fully support efforts to promote the security and integrity of the U.S. drug distribution system and the goal of House Bill 1455, we respectfully request consideration of the following amendments that we believe add clarity and provide an appropriate degree of regulatory burdens the entities covered by this bill without compromising the legislative goals.

NACDS' recommended amendments are discussed below with the language for the amendments provided in the Attachment.

- **Section 2 for Chapter 43-15.3.01(10) – Amend to add "drop shipments" so that drop shipments are recognized as part of the normal distribution channel:** The bill defines "drop shipments" and that term should be used appropriately in the bill. Drop shipments are a necessary and routine part of the normal distribution channel that occurs when drugs are shipped directly from the drug manufacturer to the pharmacy or chain pharmacy warehouse but the invoice is handled through the wholesaler. This routine and necessary practice should be included in the definition of "normal distribution channel." This is consistent with the FDA's Guidance for implementing the Prescription Drug Marketing Act (PDMA) which provides that pedigrees would not be required for drop shipments conducted on behalf of authorized distributors of record.

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- **Section 2 for Chapter 43-15.3(11) – Definition of Pedigree - Insert "wholesale" before "distribution" for clarification and conformity:** This clarification conforms to the language of the bill which covers wholesale distributions of prescription drugs; and conforms to the federal Prescription Drug Marketing Act which covers wholesale distribution of prescription drugs.
- **Section 2 for Chapter 43-15.3-01(16)(j) - Insert "wholesaler" after manufacturer to allow pharmacy returns to wholesale drug distributors:** This change is necessary to allow for drug returns from pharmacies and chain pharmacy warehouses to wholesale distributors. This change conforms to the FDA Guidance for the PDMA implementation which recognizes drug returns to wholesale distributors or manufacturers from which they were purchased. The FDA Guidance on returns specifically states that the FDA intends to exercise its enforcement discretion to allow pharmacies and physicians' offices to return drugs.
- **Section 2 for Chapter 43-15.3-01(17) - Definition of wholesale distributor - Insert "except for chain pharmacy warehouses" in last sentence to clarify that chain pharmacy warehouses are not required to be ADRs to be considered part of the normal distribution channel:** This change is necessary to address the inconsistency of including chain pharmacy warehouses in the definition of "normal distribution channel" and but then removing them from the normal distribution channel by requiring them to be authorized distributors. Chain pharmacy warehouses are not normally authorized distributors of record because they are not wholesale distributors, and instead purchase prescription drugs primarily from wholesale distributors; however, chain pharmacy warehouses are included in the normal distribution channel.
- **Section 2 for Chapter 45-15.3-03(2)(e)(3) - Amend for corporations seeking wholesale distributor licenses to require providing information on <u>key</u> corporate officers and directors who have responsibility for drug distribution:** This is a reasonable and understandable change for corporations that are already subject to state corporation law requirements. Corporations have many officers and directors that have no responsibility for drug distribution. It would be unnecessarily burdensome and costly to the corporations to have to provide information on many persons that have no relevance or relationship drug distribution and similarly costly to state agencies to collect and manage this unnecessary information.

- **Section 2 for Chapter 45-15.3-03(2)(h)(9) - Amend to allow submission of a photograph of the designated representative taken in the previous 180 days:** This change is reasonable and would establish a workable photograph

requirement. Companies have to begin the licensure process early to allow for their review and preparation in advance so that the application is submitted timely. Having a 30 day photograph requirement will unnecessarily complicate and hinder the application submission in a timely manner without any added benefits.

- **Section for 2 Chapter 43-15.3-03(6) – Amend the Bond requirement to clarify that chain pharmacy warehouses that are not engaged in wholesale distribution are exempt.** This change is reasonable and does not weaken the bill as the bill is directed at wholesale distributors not at chain pharmacy warehouses that do not engage in wholesale distribution of prescription drugs. Only exempting chain pharmacy warehouses that do "intracompany transfers" is meaningless as the distinction relative to the bond is whether an entity engages in wholesale distribution. As such, chain pharmacy warehouses should be exempt as they are not wholesale distributors and have common ownership with pharmacies licensed the state board of pharmacy. The sentence should be amended to read "Any chain pharmacy warehouse that is engaged only in intracompany transfers is exempt from the bond requirement.
- **Section 2 for Chapter 43-15.3-04 – Amend to exempt chain pharmacy warehouses that do not engage in wholesale distribution from the accreditation or certification requirement:** The language should be amended to clarify that chain pharmacy warehouses that do not engage in wholesale distribution are exempt from the requirement to maintain accreditation or certification. This is consistent with the intent of the bill to regulate wholesale distributors. While we support state board inspections of chain pharmacy warehouses, we are concerned with the Board requiring chain pharmacy warehouses that are not wholesale distributors and instead provide distribution services to their own intracompany pharmacies from having to be accredited or certified. This would result in an unnecessary and unreasonable cost and regulatory burden on chain pharmacies.
- **Section 2 for Chapter 43-15.3-05 – Amend to insert "wholesale distributor" after "original manufacturer" for clarity to allow returns to wholesale distributors:** This change is necessary to allow for drug returns from pharmacies and chain pharmacy warehouses to wholesale distributors. This change also conforms to the PDMA according to the FDA Guidance which recognizes drug returns to wholesale distributors or manufacturer from which they were purchased, and FDA's position of enforcement discretion. The FDA Guidance on returns specifically states that the FDA intends to exercise its enforcement discretion to allow pharmacies and physicians' offices to return drugs.
- **Section 2 for Chapter 43-15.3-06 – Amend to add language to clarify that any targeted date for electronic pedigrees determined by the Board of Pharmacy**

does not have a negative impact on drug safety, efficacy or prescription drug costs and is provided through national standards. There are many concerns with a number of states determining implementation dates for electronic pedigrees for drugs. First a national standard is necessary for electronic pedigrees and track and trace technologies (such as RFID) to foster adoption and avoid interruptions in the drug distribution chain that could result if a technology is used in one state but not in others. The drug distribution system is complex and the distribution system operates across state borders. Although emerging electronic pedigree technologies, such as radio frequency identification (RFID) to track and trace the distribution of prescription drugs through the drug distribution system, are promising as future safeguards, significant industry wide challenges must be addressed and overcome before these emerging technologies can become an integral, cost-effective part of the drug distribution system. These technologies need evaluation and testing for wide-spread use across the drug supply chain and extensive pilots are needed to understand the capabilities and accuracy, to measure their operational reliability and scalability for all stakeholders across the drug supply chain, and to resolve any problems related to their use and widespread adoption. This section should be amended to provide that the Board may provide a recommendation only after a national standard has been adopted and implemented that is usable across the drug distribution supply chain.

- **Section 2 for Chapter 43-15.3(3)(b)(1) - Amend to add requirement to include the National Drug Code (NDC) number in the pedigree contents:** The pedigree contents should be amended to include the NDC number of the drug. This is necessary because the NDC number is the recognized number pharmacies use to identify prescription drugs.

Attachment A

Section 2 for Chapter 43-15.3.01(10) – Amend to add "drop shipments" so that drop shipments are recognized as part of the "normal distribution channel":
"Normal distribution channel" means a chain of custody for a prescription drug, **including drop shipments,** which goes from a manufacturer of the prescription drug, from that manufacturer to that manufacturer's co-licensed partner, from that manufacturer to that manufacturer's third-party logistics provider, or from that manufacturer to that manufacturer's exclusive distributor to:

Section 2 at Chapter 43-15.3(11) – Definition of Pedigree - Insert "wholesale" before "distribution" for clarification and conformity:
(11) "Pedigree," a document or electronic file containing information that records each **wholesale** distribution of any given prescription drug;

Section 2 for Chapter 43-15.3-01(16)(j) - Insert "wholesaler" after manufacturer to allow pharmacy returns to wholesale drug distributors:
(j) The sale or transfer from a retail pharmacy or chain pharmacy warehouse of expired, damaged, returned, or recalled prescription drugs to the original manufacturer, **wholesale distributor,** or to a third party returns processor.

Section 2 for Chapter 43-15.3-01(17) - Definition of wholesale distributor - Insert "except for chain pharmacy warehouses" in last sentence to clarify that chain pharmacy warehouses are not required to be ADRs to be considered part of the normal distribution channel:
"Wholesale distributor" means anyone engaged in the wholesale distribution of prescription drugs, including manufacturers; repackagers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses; manufacturer's exclusive distributors; authorized distributors of record; drug wholesalers or distributors; independent wholesale drug traders; specialty wholesale distributors; third party logistics providers; retail pharmacies that conduct wholesale distribution; and chain pharmacy warehouses that conduct wholesale distribution. To be considered part of the normal distribution channel such wholesale distributor **except for a chain pharmacy warehouse** must also be an authorized distributor of record.

Section 2 for Chapter 45-15.3-03(2)(e)(3) - Amend for corporations seeking wholesale distributor licenses to require providing information on key corporate officers and directors who have responsibility for drug distribution:
(e) The name of every owner and operator of the licensee, including:
. . . (3) If a corporation, the name and title of each **key** corporate officer and director **with responsibility for drug distribution**, the corporate names, and the name of the state of incorporation; and

Section 2 for Chapter 45-15.3-03(2)(h)(9) - Amend to allow submission of a photograph of the designated representative taken in the previous 180 days:
(9) A photograph of the individual taken in previous **one hundred and eighty (180)** ~~thirty~~ days.

Section for 2 Chapter 43-15.3-03(6) – Amend the Bond requirement to clarify that chain pharmacy warehouses that are not engaged in wholesale distribution are exempt:
The board shall require every wholesale distributor applying for a license to submit a bond of at least one hundred thousand dollars, or other equivalent means of security acceptable to the state, including an irrevocable letter of credit or a deposit in a trust account or financial institution, payable to a fund established by the state under subsection 7. A chain pharmacy warehouse that is **not** engaged ~~only~~ in **wholesale distribution** ~~intracompany transfers~~ is not subject to the bond requirement. The purpose of the bond is to secure payment of any fines or penalties imposed by the state and any fees and costs incurred by the state regarding that license which are authorized under state law and which the licensee fails to pay thirty days after the fines, penalties, or costs become final. The state may make a claim against the bond or security until one year after the licensee's license ceases to be valid. A single bond may cover all facilities operated by the applicant in the state.

Section 2 for Chapter 43-15.3-04 – Amend to exempt chain pharmacy warehouses that do not engage in wholesale distribution from the accreditation or certification requirement:
A person may not engage in wholesale distributions of prescription drugs without, after December 31, 2007, obtaining and maintaining accreditation or certification from the national association of boards of pharmacy's verified accredited wholesale distributor or an accreditation body approved by the board under subsection 4, obtaining and maintaining a license issued by the board, and paying any reasonable fee required by the board. **Chain pharmacy warehouses that do not engage in wholesale distribution are not subject to the requirement for accreditation or certification.**

Section 2 for Chapter 43-15.3-05 – Amend to insert "wholesale distributor" after "original manufacturer" for clarity to allow returns to wholesale distributors:
A wholesale distributor shall receive prescription drug returns or exchanges from a pharmacy or chain pharmacy warehouse under the terms and conditions of the agreement between the wholesale distributor and the pharmacy or between the wholesale distributor and the chain pharmacy warehouse, including the returns of expired, damaged, and recalled pharmaceutical product to either the original manufacturer, **the wholesale distributor,** or a third party returns processor, and the returns or exchanges are not subject to the pedigree requirement of section 43-15.3-06 if they are exempt from pedigree under the federal food and drug administration's currently applicable guidance for the federal Prescription Drug Marketing Act of 1987 [Pub.L. 100-293; 102 Stat.95]. Wholesale distributors and pharmacies must ensure that the aspects of this operation are secure and do not permit the entry of adulterated and counterfeit product.

Section 2 for Chapter 43-15.3-06 – Amend to add language to clarify that any targeted date for electronic pedigrees determined by the Board of Pharmacy would not have a negative impact on drug safety, efficacy or prescription drug costs and is provided through national standards.
The board shall determine by July 1, 2009, a targeted **recommended** implementation date for electronic track and trace pedigree technology. The determination must be based on consultation with manufacturers, distributors, **chain pharmacies,** and pharmacies responsible for the sale and distribution of prescription drug products in this state. After consultation with interested stakeholders and before implementation of the electronic track and trace pedigree technology, the board must determine that the technology is universally available across the entire prescription pharmaceutical supply chain**, that there is no negative impact on the safety, efficacy, or price of prescription drugs, and that national standards have been adopted**. The implementation date for the mandated electronic track and trace pedigree technology may not be before July 1, 2010, and may be extended by the board in one year increments if it appears the technology is not universally available across the entire prescription pharmaceutical supply chain.

Section 2 for Chapter 43-15.3(3)(b)(1) - Amend to add requirement to include the National Drug Code (NDC) number in the pedigree contents:
b. At a minimum, the pedigree must also include the:
(1) Name of the prescription drug **and National Drug Code (NDC) number**;
(2) Dosage form and strength of the prescription drug;
(3) Size of the container;
(4) Number of containers;
(5) Lot number of the prescription drug; and
(6) Name of the manufacturer of the finished dosage form.

Counterfeit Drugs:

A CLEAR AND PRESENT DANGER

State Senator Marvin Riegsecker, R.Ph.

Prevalence of Drug Counterfeiting

Counterfeit drugs are more prevalent in developing countries.

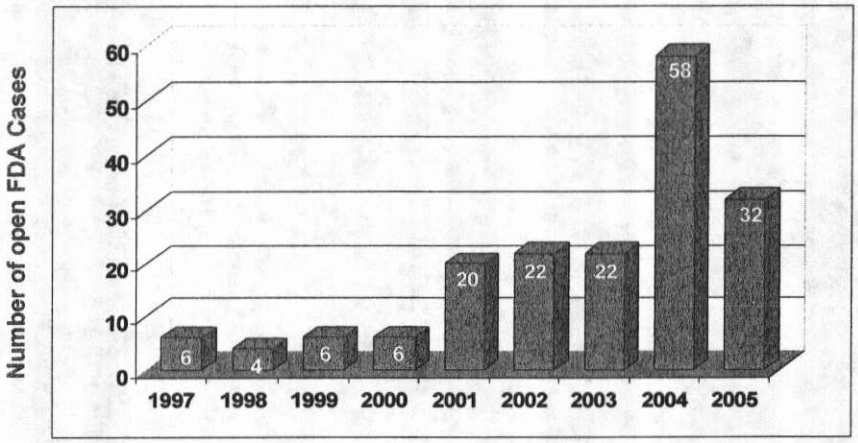
According to the World Health Organization (WHO):

A. Industrialized Countries: 22%

B. Developing Countries: 78%

- Africa: 50-60%
- China: 50%
- Mexico, Argentina, Columbia: 40%
- Brazil: 30-40%
- India: 15-20%

Trends in Counterfeit Drug Cases



Where drug incidents occur

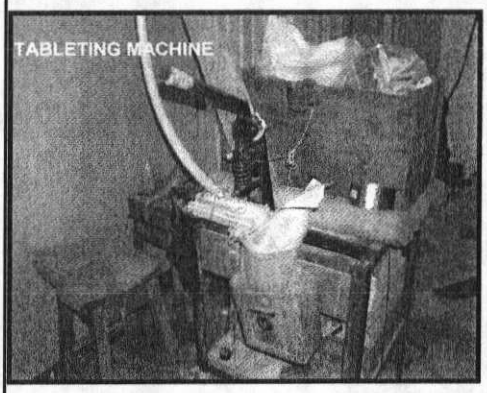
Countries with the most incidents in 2004:

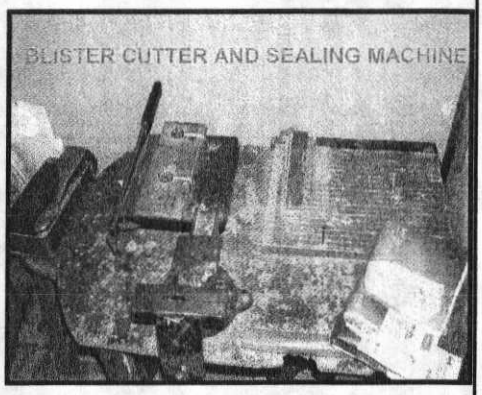
	Fake	Diversion[1]	Theft	Total
USA	32	30	14	76
Colombia	41	15	4	60
China	56	3	0	59
Russia	40	8	2	50
India	36	3	0	39
Peru	21	4	0	25
Ukraine	23	1	0	24
Brazil	3	4	12	19
Israel	17	1	0	18
Mexico	6	5	6	17
U.K.	14	2	1	17

1 — Drugs which have been illegally diverted to a different market, population or region than was initially intended.

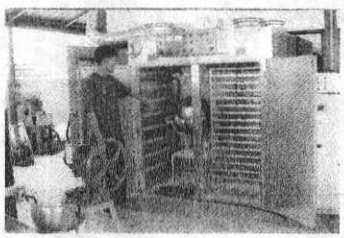
Source: Pharmaceutical Security Institute

Colombian Drug Counterfeiting





Asian Drug Counterfeiting



What is a Counterfeit Drug?

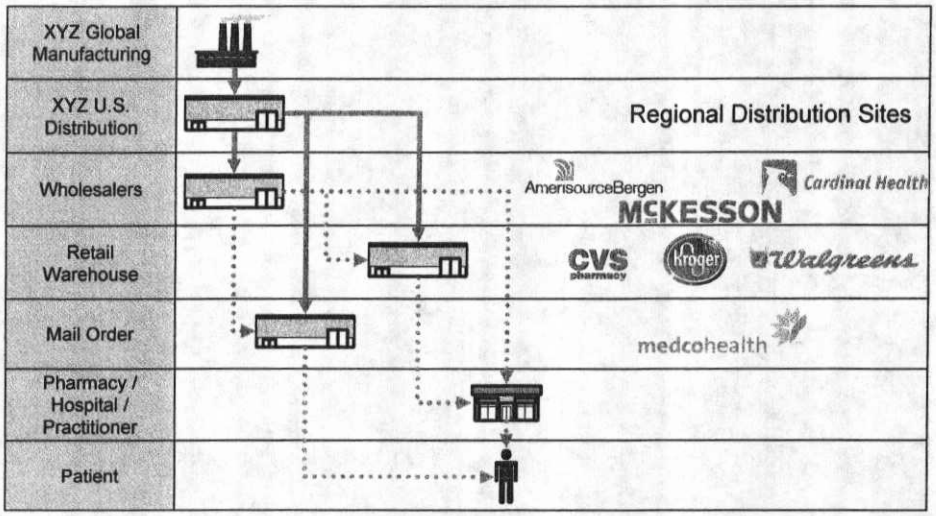
According to WHO:

"[A] product that is deliberately and fraudulently mislabeled with respect to identity and source."

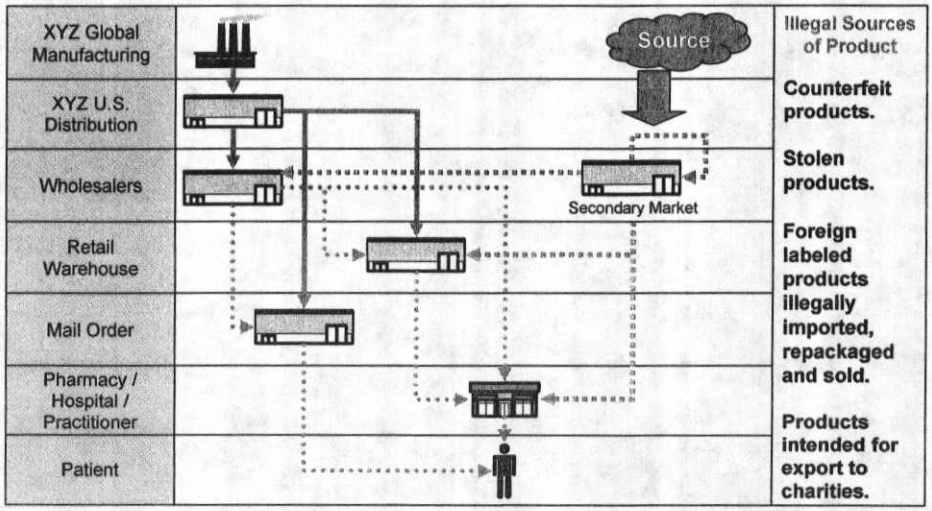
Where is the problem?

- Drug counterfeiting isn't a manufacturing problem, it is a distribution problem.

Basic Product Flow



Secondary Wholesalers/Illegal Sources



Example 1: Lipitor

HOW FAKE LIPITOR WAS SOLD

Convicted cocaine smuggler's plot and loose regulation of pharmaceutical distribution allowed ineffective version of Pfizer's popular cholesterol pill to reach consumers

BY SUSAN TODD • THE STAR-LEDGER

STEP 1
Manufacturing

Cruz **buys and ships the necessary chemicals** and instruments to Costa Rica, where he has partners willing to create counterfeit Lipitor. He also acquired authentic Lipitor from Brazil.

COUNTERFEIT LIPITOR
looks like real Lipitor and contains enough of the medicine's main ingredient to be passable, but not enough to necessarily lower cholesterol.

Sent to Miami

FOREIGN LIPITOR
made for overseas markets, not approved by the FDA for sale in the United States.

Obtained from exporting company in Brazil

U.S. LIPITOR
is made by Pfizer in Ireland and Puerto Rico. It is distributed through authorized wholesalers

STEP 2
Entering the system

Cruz **combines the drugs in warehouses** in Miami and Costa Rica, trying to further conceal their source.

At some point, **forged paperwork is attached** to the medicine to make it seem authentic. Such paperwork normally details the transactions involved in the life of the product.

STEP 3
Distribution

Albers Medical Distributors, **noticed by the low price**, agrees to buy the Lipitor. Kroger arranges for Albers to purchase it from a wholesaler owned by **Michael Carlow (at left)**, who is suspected in other drug-diversion schemes.

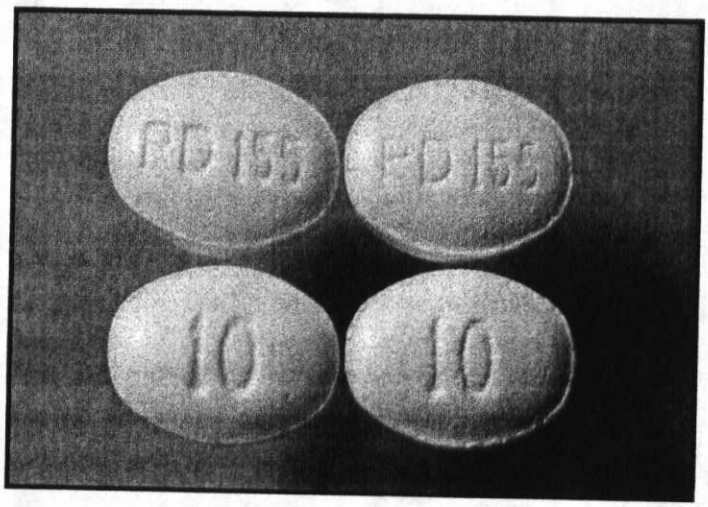
The fake Lipitor is also sold to wholesalers in Illinois, Ohio and New York.

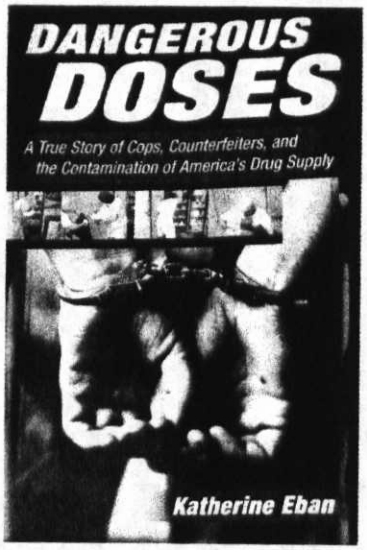
The Lipitor is **repackaged**, a common practice that reduces the bulk quantities into smaller units for retail sales.

The finished **packages are sold to pharmacies and then to consumers**.

SOURCES: Investigators' court documents
ANDREW GARCIA PHILLIPS, THE STAR-LEDGER

Lipitor: Which pill is authentic?

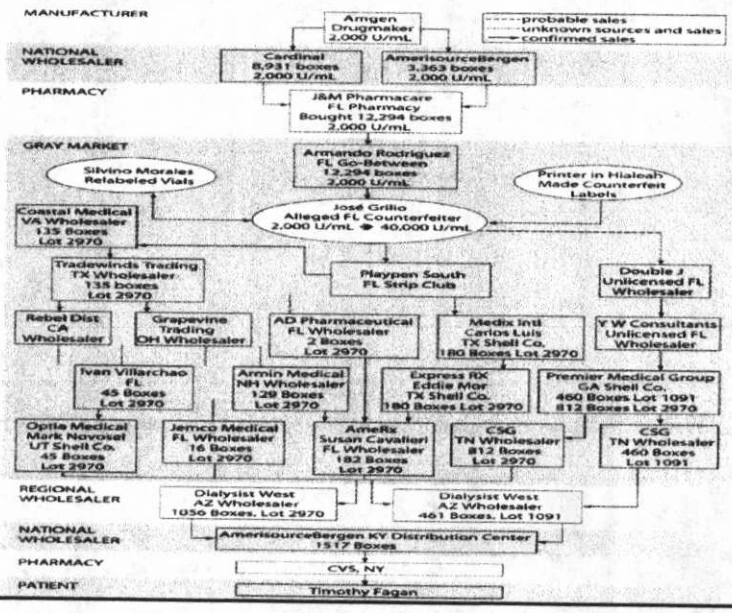




Dangerous DOSES

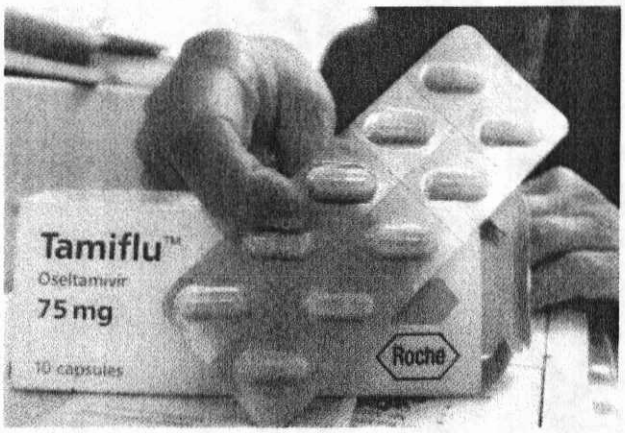
How Counterfeiters Are Contaminating America's Drug Supply
Katherine Eban • May 2005 • Harcourt, Inc

THE EPOGEN TRAIL TO TIMOTHY FAGAN



Example 3: Tamiflu

Fighting Fake Flu Pills



What can be done?

- Federal Regulation of Wholesale Distributors:

  Prescription Drug Marketing Act (PDMA) of 1987, Prescription Drug Amendments (PDA) of 1992

  - Banned the Sale of Drug Samples and Drug Coupons
  - Banned Reimportation (limited exceptions)
  - Set Requirements for Sample Distribution and Storage
  - Required State Licensing of Wholesale Distributors
  - Required Identity Statements for Sales (pedigree) by Unauthorized Distributors of Record

What can be done?

- State Licensing of Wholesale Distributors:
  - State Boards of Pharmacy
  - Renewal Schedule: One to Two years
  - Out-of-State Wholesale Distributors
  - Regulatory Challenges
    - Limited Board of Pharmacy Resources
    - Lack of Uniformity of States' Regulation
    - Lack of Communication Between Regulators

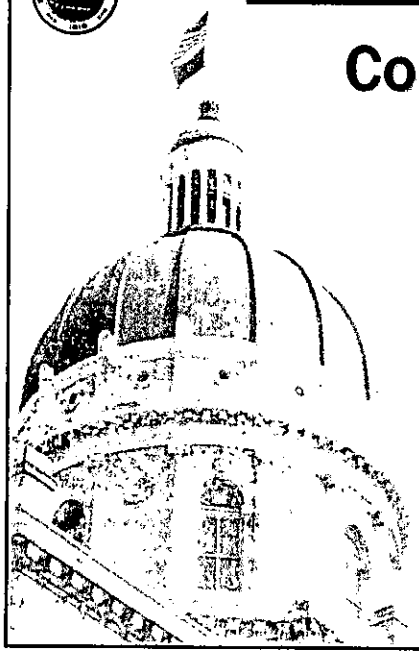
Indiana's New WDD Law

- Increases penalties for counterfeiting Rx drugs and distributing contraband drugs
- Creates rigorous licensing requirements including mandatory accreditation for all wholesalers
- Determines a "Normal Chain of Distribution" (NCOD)
- Requires pedigree for all drugs distributed outside of NCOD

Indiana's New WDD Law

Mandatory National Accreditation

- VAWD® or other Board Approved Accreditation
- Accreditation will ensure compliance with relevant state and federal laws
- Newly issued licensees must obtain Accreditation prior to issuance
- Existing license holders must obtain prior to next license renewal (9/30/06)
- Negligible fiscal and operational impact on state



Counterfeit Drugs:

A CLEAR AND PRESENT DANGER

State Senator Marvin Riegsecker, R.Ph.

#4

Daniel Bellingham, Associate Director, State Government Affairs
Healthcare Distribution Management Association (HDMA)
Testimony Regarding H.B. 1455
North Dakota Senate Human Services Committee
March 13, 2007

Madame Chair and members of the Committee, my name is Daniel Bellingham, Associate Director, State Government Affairs with the Healthcare Distribution Management Association (HDMA). I appreciate the opportunity to provide testimony regarding H.B. 1455. HDMA is the trade association representing the nation's primary, full-service healthcare distributors. Ten of these members serve the State of North Dakota, including Dakota Drug with facilities in Minot and Fargo.

Each and every day, HDMA member companies safely and efficiently deliver nine million healthcare products to more than 144,000 pharmacies, hospitals, nursing homes, physician offices and clinics in every state in the nation. In fact, nearly 80% of all prescription medicines in this country go through an HDMA member distribution facility on the way from the manufacturer to the pharmacy setting. This essential public health function is provided with tremendous efficiency, saving the nation's healthcare system $10.5 billion each year.

HDMA and its member companies work actively with legislators and regulators, both at the state and federal levels, to identify additional steps to further secure the medicine supply from counterfeit drugs. These steps include:

1. Strengthen the licensure requirements for pharmaceutical distributors.
2. Increase criminal penalties for those who counterfeit medicines or knowingly distribute compromised products.
3. Promote and work toward the development and adoption of current and emerging technologies, such as Radio Frequency Identification (RFID), which can track, trace and authenticate individual prescription medicines as they travel through the supply chain.

While we support the goal of H.B. 1455, we respectfully request that the Committee consider the following amendments:

SECTION 2 [43-15.3-03 (1)] Wholesale drug distributor licensing requirement – Minimum requirements for licensure (page 8)

As currently written, this section exempts manufacturers who distribute drugs from new requirements for licensure in the bill. While HDMA recognizes the critical role of the manufacturer in the supply chain, we do not advocate for an exemption for manufacturers from new stronger state requirements aimed at protecting the public. The manufacturer community is as diverse as any other and they collectively play an important role in protecting prescription drug consumers. When a manufacturer is functioning in the capacity of a wholesale distributor (e.g., warehousing and shipping drugs), there is no logical reason to regulate the manufacturer any differently than a wholesale distributor. Manufacturers have argued that they are already subject to the FDA's Good Manufacturing Practice (GMP) regulations and, therefore, they are already highly regulated. The reality is that the GMP regulations focus on manufacturing practices and not to any significant extent on distribution practices. In addition, the penalties included in the GMP regulations are relatively weak (three years for similar violations) compared to recent state legislation. If a manufacturer is engaging in business in a state, and if they are engaging in

wholesale distribution activities, their facilities should be subject to the same scrutiny as other members of the supply chain.

SECTION 2 [43-15.3-04 (1) Requirements to Distribute Prescription Drugs (pages 12-13):

While we are pleased that the committee is interested in strengthening its licensure standards for pharmaceutical distributors, we are deeply concerned about the possibility of making accreditation a requirement for distributors doing business in North Dakota. HDMA members fully support the need for facility inspections as a mechanism to ensure that distributors are meeting licensure standards, however, we want to discourage the Board of Pharmacy from relinquishing its inspection authority over in-state distributors, and hope to ensure that a degree of choice is maintained for out-of state licensees in order to preserve the safe and efficient supply of prescription drugs to North Dakota patients.

HDMA fully recognizes the necessity for strong regulation of the distribution industry, conducted by appropriate governmental authorities operating under validly enacted laws and regulations. As you know, the inspection of pharmaceutical distribution facilities is a complex undertaking that requires the use of trained and experienced staff, familiarity with the industry, knowledge of applicable laws, and established procedures to ensure the commercial interests of license applicants are lawfully protected. Oftentimes, VAWD inspectors have never been inside a distribution center until the day of the VAWD inspection. It has been our experience that they do not have any previous experience with pharmaceutical distribution.

Further, HDMA encourages the committee to allow the Board of Pharmacy to consider alternatives for out-of-state distributors. We are not opposed to an accreditation program as one *option*, however, our members' experience suggests that there is a need for other routes to meet the conditions of licensure. While we strongly encourage the North Dakota Board of Pharmacy to continue to perform inspections of distributors domiciled in the state of North Dakota, if there is a concern about the lack of resources available to carry out this task, we would like to work with you to find a solution.

For North Dakota distributor-licensees located outside the state, we support reciprocity for those distributors licensed in good standing in their resident states. Another alternative would be to accept Board of Pharmacy-approved individual distributor internal audit inspections or audits by approved contract inspection services. Individual distributor internal audits usually consist of, but are not limited to reviews of: safety and security standards; sanitation and product storage rotation practices; inventory management controls and loss prevention controls; narcotic and hazardous material reviews; and, transportation protocols. This method has been adopted in some states, such as California, where distributors' designated representatives are required to conduct a yearly internal audit and submit it, with their certification, to the Board. Additionally, there are several industry contract inspection consultants that have expertise in the distribution industry. While they may not yet have organized "accreditation" programs, we believe there are several existing companies equipped to perform thorough and effective inspections of distribution facilities.

Without necessary alternatives, HDMA is concerned about the continuity of the pharmaceutical supply chain. Our top priority is ensuring that pharmacies, hospitals, nursing homes, and physicians continue to efficiently and safely receive life-saving medicines for their patients.

SECTION 2 [43-15.3-06 (1)] - Pedigree (page 14-15)

HDMA advocates for development of a track and trace system that supports pedigree and tracks the path of a drug from its creation through the supply chain until it is ultimately dispensed to the patient. This type of system is under development but may not be widely available for several years. In the interim HDMA supports additional regulatory controls such as stronger licensure laws, increased penalties, and use of pedigree as a safety mechanism in those instances where drugs are at the highest risk – outside the normal or primary distribution channel.

We believe that tracking technologies such as RFID have the most promise for use in this way by the supply channel. However, any such tracking mechanism must originate at the manufacturer – at the product's inception - in order to ensure that there are no gaps in the chain that might invite counterfeiters or diverters of prescription medicines.

HDMA language clarifies that electronic pedigree would not be utilized until readily available across the entire industry. Such a system would start with the manufacturer and be used at the item level for all drugs, not just those outside of "normal distribution".

Thank you for considering these amendments to this important piece of legislation. HDMA commends you for addressing this issue and we look forward to working with you and other industry stakeholders on this important issue.

ATTACHMENT A

H.B. 1455 HDMA recommended language:

SECTION 2 [43-15.3-03 (1)] Wholesale drug distributor licensing requirement – Minimum requirements for licensure (page 8)

1. A wholesale distributor that engages in the wholesale distribution of prescription drugs must be licensed by the board under this chapter and must be properly licensed in any other state in which the wholesale distributor engages in the distribution of prescription drugs before engaging in wholesale distributions of wholesale prescription drugs in this state. ~~However, information and qualification requirements for licensure beyond that required by federal law or regulation do not apply to manufacturers distributing their own United States food and drug administration approved drugs, unless particular requirements are deemed necessary and appropriate following rulemaking.~~

SECTION 2 [43-15.3-04 (1)] Requirements to Distribute Prescription Drugs (pages 12-13):

1. A person may not engage in wholesale distributions of prescription drugs without, after December 31, 2007, obtaining and maintaining accreditation or certification from ~~the national association of boards of pharmacy's verified accredited wholesale distributor or~~ an accreditation body approved by the board under subsection 4 or obtaining and maintaining a license issued by the board, and paying any reasonable fee required by the board. By action of the board, the deadline may be extended through December 31, 2008.

2. The board may not issue or renew the license of a wholesale drug distributor that does not comply with this chapter. The board shall require a separate license for each facility or location where wholesale distribution operations are conducted. An agent or employee of any licensed wholesale drug distributor does not need a license and may lawfully posses pharmaceutical drugs when acting in the usual course of business or employment. The issuance of a license under this chapter does not affect tax liability imposed by the tax department on any wholesale drug distributor.

3. The board may adopt rules that permit out-of-state wholesale drug distributors to obtain a license on the basis of reciprocity if an out-of-state wholesale drug distributor possesses a valid license granted by another state and the legal standards for licensure in the other state are comparable to the standards under this chapter and the other state extends reciprocity to wholesale drug distributors licensed in this state. However, if the requirements for licensure under this chapter are more restrictive than the standards of the other state, the out-of-state wholesale drug distributor must comply with the additional requirements of this chapter to obtain a license under this chapter. The board may also license by reciprocity, a wholesale distributor that is licensed under the laws of another state, if the applicant is inspected or accredited by a third party recognized and

approved by the board; or the applicant has completed an internal audit and review, according to standards approved by the Board.

4. The board may adopt rules to approve an accreditation body to evaluate a wholesale drug distributor's operations to determine compliance with professional standards, this chapter and any other applicable law, and perform inspections of each facility and location where wholesale distribution operations are conducted by the wholesale drug distributor. Any applicant denied licensure by the state shall have the right of timely review and appeal by the state regulatory authority.

5. The Board shall develop and implement an approval process for third party inspectors/accrediting organizations that meet criteria and standards developed by an advisory group consisting of representatives of the Board, distributors, manufacturers, pharmacies and other stakeholders. Such criteria and standards shall include guidelines and training processes for third party/accreditation inspectors, and safeguards for protecting the confidentiality of proprietary information obtained during the inspection/accreditation process.

6. Individual third party personnel/inspectors must demonstrate to the Board that they have received training and/or demonstrate familiarity with the inspection standards. Evidence such as a letter of certification from a training program, notice from the inspector's employing third party organization, or other means recognized by the Board shall be accepted as meeting the requirement.

SECTION 2 [43-15.3-06 (1) subsection (b)
Substitute the current subsection with the following language (page 15):

(b) Effective at a date established by the Board, pedigrees may be implemented through an approved and readily available system that electronically tracks and traces the wholesale distribution of each prescription drug starting with the sale by a manufacturer through acquisition and sale by any wholesale distributor, until final sale to a pharmacy or other authorized person administering or dispensing the prescription drug. This electronic tracking system will be deemed to be readily available only upon there being available a standardized system originating at the manufacturer and capable of being used on a wide scale across the entire pharmaceutical supply chain which includes manufacturers, wholesale distributors, and pharmacies. Also, consideration must be given, however, to the large-scale implementation of this technology across the supply chain and the technology must be proven to have no negative impact on the safety and efficacy of the pharmaceutical product. "Track and trace" means the ability to locate a product in the supply chain and determine its outbound distribution path.

#5

Legislation To Strengthen Protections For North Dakota Consumers
Against The Threat Of Counterfeit Drugs

House Bill No. 1455
Senate Human Services Committee
March 13, 2007

Comments of PhRMA regarding
Written Testimony Submitted by HDMA

At today's hearing on HB 1455, Madam Chairman provided written comments that had been sent by Daniel Bellingham, on behalf of HDMA (the Healthcare Distribution Management Association). The comments consist of HDMA's request that the Senate Human Services Committee consider three amendments, each of which had previously been proposed to, and rejected by, the House Health Committee prior to House adoption of the Engrossed HB 1455. PhRMA respectfully requests that the Senate Human Services Committee likewise decline to adopt any of the following HDMA amendments.

1. To subject Manufacturers to all of the additional licensing qualification requirements of conventional wholesalers. As detailed in testimony to the Committee today by Matt Van Hook, the horror stories regarding the intrusion of counterfeit and adulterated drugs in to the U.S. distribution system have been wholly associated with risky behavior by conventional wholesalers, and not manufacturers distributing their own FDA-licensed drugs. This is detailed, for example, in both the 2003 Florida Statewide Grand Jury Report, and the book Dangerous Doses (see footnote 5 of Van Hook written testimony, and related text). Accordingly, it makes no sense to subject manufacturers distributing their own FDA-licensed drugs from more that the basic licensing requirements they are currently subject to under both U.S. and North Dakota law, and this approach is shared in related state legislative initiatives (e.g. South Dakota), and in related model vehicles (e.g., that of the National Association of Boards of Pharmacy). This HDMA amendment deserves to be rejected.

2. To eliminate the requirement in 43-15.3-04(1) that wholesale licensees obtain accreditation by VAWD (or another accreditation body approved by the Board of Pharmacy). HDMA proposes a range of inspection alternatives (in addition to the existing exemption for manufacturer facilities registered with FDA; 43-15.3-03(4)(a), p. 10 lines 24-27). The North Dakota Board of Pharmacy rejected this suggestion in the House, and unless the Board wishes to revisit the matter, PhRMA does not see the merit in this amendment at this time.

3. To amend the existing provision regarding electronic track and trace technology, 43-15.3-06(1)(b), page 15 lines 12-23, to include specific details of how that technology must look once research and development efforts now underway are finished. Everyone involved in drug distribution, from FDA to State regulatory authorities and manufacturers to wholesalers and pharmacies agree that electronic track and trace pedigree technology has great promise for improving on the existing pedigree system. But, as evidenced by

FDA's mistaken expectation that such technology could be in place and operational this year, there is as yet no reliable crystal ball to foresee the details. PhRMA is convinced it would be a mistake to put any more details of how this technology will look or operate into HB 1455, particularly since the Board is given full authority to implement the technology when it becomes available. This amendment deserves to be rejected.

Matt Van Hook (Lobbyist No. 593)
On behalf of PhRMA

#2

BOARD OF PHARMACY
State of North Dakota

John Hoeven, Governor

OFFICE OF THE EXECUTIVE DIRECTOR
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Hettinger, Senior Member
Dewey Schlittenhard, MBA, R.Ph.
Bismarck
Rick L. Detwiller, R.Ph.
Bismarck
Laurel Haroldson, R.Ph.
Jamestown
William J. Grosz, Sc.D., R.Ph.
Wahpeton, Treasurer

HOUSE BILL No. 1455 – Pedigree for Wholesale Drugs
Senate Human Services Committee
8:30 AM - Tuesday – March 13th, 2007 Red River Room

Chairman Lee and members of the Senate Human Services Committee, for the record I am Howard C. Anderson Jr., R.Ph, Executive Director of the North Dakota State Board of Pharmacy. Thank you for the opportunity to speak with you today.

The Board of Pharmacy is testifying in favor of this legislation, because we feel that a pedigree is important. However, we did not feel it was necessary to introduce the bill in this session, but, some of our Senators and Representatives felt we did, so we are not going to oppose that idea.

The Board of Pharmacy currently has 718 licensed under our Wholesale Licensing Statute, which is NDCC 43-15.1 and NDAC 61-10.

I was on the Executive Board of the National Association of Boards of Pharmacy (NABP) when we first adopted the Wholesale Licensing Model Act pertaining to pedigrees.

The amendments that were worked out on the House side with Mr. Joel Gilbertson, addressed the concerns that we initially had with this bill. Manufacturers are no longer exempted from licensure, though we have exempted them from the bonding, finger print and pedigree requirements. Though at this time, I do not believe it necessary, eventually I do believe the manufacturers will need to be included in the pedigree. Since, if we are going to have a pedigree on a drug, we would need to start that with the manufacturer. Just as with a dog, horse or bull, you need to be able to go back to the beginning if you are going to have a verifiable pedigree language.

Of the 718 Wholesalers currently licensed 52 of them are located in North Dakota. For your information, I have provided you a list of the wholesalers, both in and out of state.

As you can see from the provided list, many of our North Dakota licensed wholesalers are medical gas suppliers and off site intravenous solution storage facilities for our hospitals. We do want to license these facilities, so that we can keep track of them and so that they can receive drugs from the other wholesalers and manufacturers, but we need to have the flexibility to exempt them from the bonding requirements.

If I had my druthers, I would have liked to have included legend devices in this bill as well, as we are increasingly getting requests from manufacturers, suppliers, wholesalers and end users about the security and integrity of the distribution channel for legend devices. Many of our legend devices are beginning to include drugs, such as drug eluting stints, pre-filled syringes, respiratory therapy products and many others, which should be controlled under the wholesale licensing statute, as they are just as important to the care and mitigation of disease as are the drugs themselves. We can bring those things to you next session.

I have communicated the engrossed version of the bill to the National Association of Board's of Pharmacy (NABP) operational people, for the Verified Accredited Wholesale Distributor (VAWD) Program. They have informed me our time-table within the bill, should be reasonable for them to meet. The Board of Pharmacy does have the authority in the engrossed version to extend the requirement for the VAWD certification, for an additional year, for those wholesalers in specific instances, where we deem it appropriate.

Thank for your time and attention.

COMPANY IN North Dakota	ADDRESS_LINE_1	ADDRESS_LINE_2	CITY	STATE_A	ZIP
Agriceutical Resources LLC	709 River Bend Road		Oxbow	ND	58047
Airgas North Central Inc	2808 Gateway Drive		Grand Forks	ND	58203
Altru Renal Unit at Mercy Hospital	1031 7th Street		Devils Lake	ND	-58301
Amercian Welding Supplies Inc	2900 Burdick Expressway E		Minot	ND	58701
American Welding Supplies & Fire Equip	1800 East Main Ave.		West Fargo	ND	58078-0613
American Welding Supplies Inc	2320 Memorial Highway		Mandan	ND	58554
Blood Systems dba United Blood Services	3231 S. 11th Street		Fargo	ND	58104
Clinical Supplies Management Inc	4733 Amber Valley Parkway		Fargo	ND	-58104
DMS Health Technologies Inc.	2131 16th Street North		Fargo	ND	58102
Dakota Clinic Pharmacy	1702 S University Dr		Fargo	ND	-58103
Dakota Drug Inc	4121 12th Ave NW		Fargo	ND	58102
Dakota Drug Inc.	P O Box 5009	28 N Main Street	Minot	ND	58702-5009
Dakota Pharmaceutical Packaging, LLC	4733 Amber Valley Parkway		Fargo	ND	58104
Grafton Pharmaceutical Distribution LLC	508 Hill Ave	P O Box 545	Grafton	ND	58237-0545
H. E. Everson Company of Grafton Inc	106 East 12th Street		Grafton	ND	58237
H. E. Everson Company of Rugby Inc	703 1st St N Box 166		Rugby	ND	58368-0166
H.E. Everson Company of Cando Inc	512 Main		Cando	ND	58324
H.E. Everson Company of Cooperstown Inc	806 Burrel Ave SW - Box 688		Cooperstown	ND	58425
H.E. Everson Company of Devils Lake	211 College Drive South		Devils Lake	ND	58301
Hubbard Feeds Inc.	1503 Yegen Road	PO Box 1877	Bismarck	ND	58502-1877
Lincare, Inc	521 Dakota Ave		Wahpeton	ND	58075-4414
Lincare, Inc	2100 S Columbia Road		Grand Forks	ND	58201
Lincare, Inc.	1535 S University Drive		Fargo	ND	58103
MedCenterOne, Inc. (Warehouse)	1112 S 12th Street		Bismarck	ND	58504-000
MedEquip One, LLC	626 6th Street North		Bismarck	ND	58501
MeritCare Enterprises, Inc	501 N 4th Street		Fargo	ND	-58102
MeritCare Hospital-South University	1720 S University Drive		Fargo	ND	58103
Meritcare Healthcare Accessories LLC	1023 10th St SE		Jamestown	ND	58401
Meritcare Healthcare Accessories LLC	116 1st Street SW		Minot	ND	58701
Meritcare Healthcare Accessories LLC	3223 32nd Ave SW		Fargo	ND	-58103

Meritcare Healthcare Accessories LLC	121 E Century Ave		Bismarck	ND	58503
Midland Hospital Supply Inc.	2011 Great Northern Drive	P O Box 2685	Fargo	ND	58102
North Central Healthcare Alliance	1300 Industrial Drive #2		Bismarck	ND	58501
Northwest Respiratory Services LLC	4445 2nd Ave SW		Fargo	ND	58103
PSI Health Care, Inc/dbaArrowhealth Medical S	4025 4th Ave SW		Fargo	ND	-58103
Patterson Dental Supply Inc.	3321 4th Ave SW		Fargo	ND	58103
Praxair Distribution Inc	820 E Front Ave		Bismarck	ND	58504
Praxair Distribution Inc	521 19th Street N		Fargo	ND	58102
Praxair Distribution Inc	2205 N Washington Street		Grand Forks	ND	58202
Praxair Distribution Inc	602 20th SW	P o Box 2134	Jamestown	ND	58402-2134
Praxair Distribution Inc	2912 2nd Ave West	P O Box 1654	Williston	ND	58802-1654
Praxair Distribution Inc	677 26th Ave E		Dickinson	ND	58601
Praxair Distribution Inc #422	2816 S Broadway		Minot	ND	-58701
Praxair Healthcare Services Inc.	2816 South Broadway		Minot	ND	58701
Rummel's Auto Wrecking & Welding Supplies	1132 West Villard		Dickinson	ND	58601-5453
St Alexius Medical Center	1300 Industrial Drive		Bismarck	ND	-58501
TWL Billing Service & Supplies Inc	Warehouse	1600 Basin Ave #2	Bismarck	ND	58504
Trinity Health	3100 4th Ave SE		Minot	ND	-58701
United Blood Services	517 South 7th St.	PO Box 2052	Bismarck	ND	58502-2052
Universal Hospital Services, Inc.	918 Page Drive		Fargo	ND	-58103
White Drug #61	708C 38th Street NW		Fargo	ND	58102
Wholesale Supply Co Inc.	3500 Burdick Expressway	P O Box 1948	Minot	ND	58702-1948

COMPANY	CITY	STAT	ZIP	LICENSE	Wholesaler Type
A + Z Pharmaceutical LLC	Pittsburgh	PA	15220	842	DIST
A.F. Hauser Inc	Valparaiso	IN	46383	854	DIST
Abbott Laboratories Inc / Crown	Rocky Mount	NC	27804	769	DIST
Abbott Laboratories Inc / Kuehne & Na	Dallas	TX	75212	771	DIST
Abbott Laboratories Inc / Exel Logistics	Ontario	CA	91761	770	DIST
Abbott Laboratories, Inc.	Abbott Park	IL	60064-3500	3	DIST
Abrika Pharmaceuticals, Inc.	Sunrise	FL	33325	712	DIST
Accredo Health Group Inc	Memphis	TN	38134-0180	247	DIST
Accredo Health Group, Inc	Warrendale	PA	-15086	212	DIST
Actavis Elizabeth LLC	Elizabeth	NJ	-7207	242	DIST
Actavis Mid Atlantic LLC	Columbia	MD	-21046	789	DIST
Adams Respiratory Operations Inc	Fort Worth	TX	-76155	494	DIST
Adolor Corporation	Exton	PA	19341	600	DIST
Advantage Logistics	Oglesby	IL	61348	763	DIST
Airgas North Central Inc	Grand Forks	ND	58203	687	DIST
Akorn, Inc.	Buffalo Grove	IL	-60089	342	DIST
Alamo Pharmaceuticals, Div. Avanir Pl	Beverly Hills	CA	90211	721	DIST
Alexion Pharmaceuticals Inc.	Cheshire	CT	6410	861	DIST
Allscripts LLC	Libertyville	IL	-60048	8	DIST
Amercian Welding Supplies Inc	Minot	ND	58701	847	DIST
Ameri Source Bergen Drug Corp	Eden Prairie	MN	-55344	20	DIST
American Drug Stores/Osco Distributic	Elk Grove Village	IL	-60007	217	DIST
American Medical Distributors, Inc	N Amityville	NY	-11701	446	DIST
American Medical Distributors, Inc	Brea	CA	92621	27	DIST
American Welding Supplies & Fire Equ	West Fargo	ND	58078-0613	17	DIST
American Welding Supplies Inc	Mandan	ND	58554	849	DIST
Ameridose LLC	Farmingham	MA	1702	282	DIST
AmerisourceBergen Drug Co	Lockbourne	OH	43137	764	DIST
AmerisourceBergen Drug Corporation	Kansas City	MO	64153	471	DIST
Amgen Inc	Thousand Oaks	CA	91320-1799	14	DIST
Anda , Inc.	Weston	FL	-33331	357	DIST
Anda Pharmaceuticals, Inc.	Groveport	OH	43125	959	DIST
Andrx Pharmaceuticals, Inc.	Davie	FL	33314	663	DIST
ANIP Acquisition daba ANI Pharmaceu	Gulfport	MS	39501	822	DIST
APL Logistics WMS	Suwanee	GA	30024	127	DIST
AR Scientific Inc	Philadelphia	PA	19111	336	DIST
Armstrong Pharmaceuticals Inc	Canton	MA	2021	334	DIST
Artes Medical Inc	San Diego	CA	92121	798	DIST
Ascend Therapeutics Inc	LaVergne	TN	37086	444	DIST
ASD Specialty Healthcare Inc	Brooks	KY	40109	325	DIST
ASD Specialty Healthcare Inc	Reno	NV	89502	501	DIST
Astellas Pharma Manufacturing Inc	Grand Island	NY	14072	271	DIST
AstraZeneca Pharmaceuticals In	Newark	DE	19714-4250	314	DIST
AstraZeneca, L P	Westborough	MA	-1581	353	DIST
Atlantic Biologicals Corp	Tucson	AZ	85705	817	DIST
Atlantic Biologicals Corp	Miami	FL	33179	818	DIST
Atlantic Biologicals Corp	Goodlettsville	TN	37072	819	DIST
Aton Pharma Inc	Lawrenceville	NJ	8648	225	DIST
Atrion Medical Products Inc	Arab	AL	-35016	484	DIST
Auriga Laboratories Inc	Norcross	GA	30092	799	DIST
Aurobindo Pharma USA Inc	Cranbury	NJ	8512	758	DIST
Auxilium Pharmaceuticals Inc	Malvern	PA	19355	96	DIST
Avanir Pharmaceuticals	San Diego	CA	92121	561	DIST
B. Braun Medical Inc	Breinigsville	PA	18031	701	DIST
Ballard Medical Products	Draper	UT	84020-9414	823	DIST
Barr Laboratories Inc.	Forest	VA	-24551	36	DIST
Barrier Therapeutics Inc	Princeton	NJ	8540	226	DIST

Bausch & Lomb Incorporated	Greenville	SC	-29615	467	DIST
Bausch & Lomb Incorporated	Lynchburg	VA	-24502	386	DIST
Baxter Healthcare Corporation	Los Angeles	CA	90039	39	DIST
Baxter Healthcare Corporation	Memphis	TN	38118	40	DIST
Baxter Healthcare Corporation	Ontario	CA	91761	459	DIST
Baxter Healthcare Corporation	Thousand Oaks	CA	91320-2530	385	DIST
Baxter Healthcare Corporation	Memphis	TN	38141	682	DIST
Baxter Healthcare Corporation	Morrow	GA	30260	807	DIST
Baxter Healthcare Corporation	Fife	WA	98424	816	DIST
Bayer Healthcare LLC	Berkeley	CA	94710-1986	41	DIST
Bayer Healthcare LLC Animal Health D	Shawnee Mission	KS	66201-0390	389	DIST
BD Distribution Center	Swedesboro	NJ	8085	826	DIST
BD Distribution Center	Plainfield	IN	46168	827	DIST
BD Distribution Center	Redlnads	CA	92374	828	DIST
Ben Venue Labs dba Bedford Laborat	Walton Hills	OH	-44146	46	DIST
Benco Dental Supply Co	Fort Wayne	IN	46808	787	DIST
Biomed Plus Inc	Miami	FL	33143	672	DIST
Bioscrip Pharmacy Services	Columbus	OH	43228	208	DIST
Biovail Pharmaceuticals Inc.	Memphis	TN	38141	361	DIST
Blood Diagnostics Inc	Temecula	CA	92590	251	DIST
Blood Systems dba United Blood Servi	Fargo	ND	58104	373	DIST
Body Dynamics dba BDI Marketing	Carmel	IN	-46032	55	DIST
Boehringer Ingelheim Pharmaceuticals	Ridgefield	CT	6877	802	DIST
Boehringer Ingelheim Roxane, Inc	Reno	NV	89502	803	DIST
Boehringer Ingelheim Roxane, Inc	Columbus	OH	43228-9396	804	DIST
Boehringer Ingelheim Roxane, Inc.	Columbus	OH	43228	248	DIST
Bound Tree Medical LLC	South Haven	MS	38671	645	DIST
Bound Tree Medical LLC	Tempe	AZ	85282	87	DIST
Bradley Pharmaceuticals	Fairfield	NJ	07004-2402	688	DIST
Brighton Pharmaceuticals Inc	Cary	NC	27518-8696	760	DIST
Bristol-Myers Squibb Medical Imaging	N. Billerica	MA	01862-0272	98	DIST
Butler Animal Health Supply LLC	Columbus	OH	43204	681	DIST
Butler Animal Health Supply LLC	Des Moines	IA	50313	759	DIST
Cardinal Health	Champlin	MN	-55316	6	DIST
Cardinal Health	Hudson	WI	54016	59	DIST
Cardinal Health	La Vergne	TN	37086	205	DIST
Cardinal Health	Anoka	MN	-55303	327	DIST
Cardinal Health	Waukegan	IL	60085	776	DIST
Cardinal Health / Specialty Pharmaceu	Lavergne	TN	-37086	85	DIST
Cardinal Health dba Specialty Pharma	LaVergne	TN	37086	424	DIST
Cedardale Distributors LLC	Carlstadt	NJ	7072	736	DIST
Central Admixture Pharmacy Services	Houston	TX	-77054	70	DIST
Centric Health Resources, Inc.	Chesterfield	MO	63005	522	DIST
Centrix Pharmaceutical Inc	Birmingham	AL	35242	244	DIST
Chapin Drug Company	Annaheim Hills	CA	92807	72	DIST
Chiron Corporation	Emeryville	CA	-94608	74	DIST
Cobalt Laboratories Inc	Bonita Springs	FL	34134	780	DIST
Colgate Oral Pharmaceuticals Inc	Carrollton	TX	75006-5410	78	DIST
Colgate-Palmolive Company	Piscataway	NJ	08855-1343	346	DIST
Connetics Corporation	Palo Alto	CA	943034	82	DIST
Cook Medical Incorporated	Bloomington	IN	47402-4195	77	DIST
Coram Alternate Site Services Inc	Malvern	PA	19355	181	DIST
Corepharma LLC	Middlesex	NJ	8846	806	DIST
Corporate Mailings Inc	West Caldwell	NJ	7006	66	DIST
Critical Therapeutics Inc	Lexington	MA	2421	159	DIST
CSC High Plains LTD	Sioux Falls	SD	-57104	463	DIST
CSL Behring LLC	Bradley	IL	60915	779	DIST
CuraScript SD Specialty Distribution	Grove City	OH	-43123	378	DIST

CuraScript SD Specialty Distribution	Groveport	OH	43125	671	DIST
CVS Indiana LLC	Indianapolis	IN	46219	784	DIST
Cytogen Corporation	Princeton	NJ	8540	832	DIST
Dakota Drug Inc	Fargo	ND	58102	717	DIST
Dakota Drug Inc.	Minot	ND	58702-5009	88	DIST
Darby Dental Supply LLC	Memphis	TN	38118	814	DIST
Darby Dental Supply, LLC	Reno	NV	89502	829	DIST
Darby Group Companies Inc	Memphis	TN	-38117	448	DIST
DDN/Obergfel LLC	Ontario	CA	-91761	91	DIST
DDN/Obergfel LLC	Memphis	TN	-38141	92	DIST
Dendrite Interactive Marketing LLC	Totowa	NJ	7512	692	DIST
DEPOMED INC	Menlo Park	CA	94025-1436	808	DIST
Dey, L.P.	Allen	TX	-75013	436	DIST
Dik Drug Company	Burr Ridge	IL	60527-5720	862	DIST
Dispensing Solutions Inc	Santa Ana	CA	92704	95	DIST
Dispensing Solutions Inc	Santa Ana	CA	92704	840	DIST
Distribution Solutions dba Priority Solu	Memphis	TN	38141-8210	696	DIST
DIT Healthcare Distribution Inc	West Chester	OH	45246	358	DIST
Diversified Healthcare Services Inc	Roswell	GA	30076	865	DIST
Dixon-Shane LLC d/b/a R & S Northea	Philadelphia	PA	19115	598	DIST
Drogueria De La Villa, Inc	Arecibo Puerto Rico		612	870	DIST
DSM Pharmaceuticals Inc	Greenville	NC	27834	157	DIST
Dubin Medical Inc	San Diego	CA	92109	565	DIST
Duramed Pharmaceuticals Inc	Cincinnati	OH	45213	511	DIST
DVM Resources / Walco International	Spencer	IA	51301	231	DIST
E.R. Squibb & Sons, LLC	Mt Vernon	IN	47620	362	DIST
Eastman Kodak Company	Whittier	CA	90606	543	DIST
Ebewe Parenta Pharmaceuticals Inc	West Columbia	SC	29169	835	DIST
Edwards Lifesciences Research Medic	Midvale	UT	84047	662	DIST
Elan Pharmaceuticals	Memphis	TN	38141	634	DIST
Eli Lilly and Company	Enfield	CT	6082	106	DIST
Eli Lilly and Company	Indianapolis	IN	-46285	108	DIST
Eli Lilly and Company (CA)	Fresno	CA	-93725	105	DIST
Emergency Medical Products Inc	Waukesha	WI	-53186	495	DIST
Encysive Pharmaceuticals	Houston	TX	77081	781	DIST
Enzon Pharmaceuticals	Indianaplis	IN	46268	475	DIST
ENZON Pharmaceuticals Inc.	S Plainfield	NJ	-7080	426	DIST
Eon Labs Inc dba SANDOZ	Wilson	NC	27893	713	DIST
Ethex Corporation	Bridgeton	MO	-63044	110	DIST
Exel Inc	Middletown	PA	-17057	115	DIST
Exel Inc	Mechanicsburg	PA	17050	566	DIST
Exel Inc	New Kingstown	PA	17072	604	DIST
Express Scripts Specialty Distribution	Maryland Heights	MO	-63043	500	DIST
F M Howell & Company	Elmira	NY	14902-0286	744	DIST
Factor Health Management LLC	Boca Raton	FL	33487	573	DIST
Fairview Health Services	Minneapolis	MN	55455	100	DIST
FamilyMeds Inc dba FamilyMeds Medi	Farmington	CT	6032	836	DIST
FFF Enterprises Inc.	Temecula	CA	92591	349	DIST
Fisher Clinical Services Inc	Allentown	PA	18106	820	DIST
FMC Distributors Inc	Ponce	PR	00716-2007	626	DIST
Forest Pharmaceuticals Inc.	St. Louis	MO	-63045	125	DIST
Fort Dodge Animal Health	Wilmington	OH	45177	337	DIST
Fort Dodge Laboratories, Inc.	Fort Dodge	IA	50501	264	DIST
Forum Products dba SourcePharma	Southampton	NY	11968	162	DIST
Fresenius Medical Care North America	Pleasant Prairie	WI	53158	738	DIST
Fresenius Medical Care North America	Ogden	UT	84404	857	DIST
Galderma Laboratories L.P.	Fort Worth	TX	-76177	126	DIST
Gebauer Company	Cleveland	OH	44128	128	DIST

Genentech Inc	Louisville	KY	40258	772	DIST
Genpharm, L.P. % Dey LP	Allen	TX	75013	624	DIST
Genta Incorporated	Berkeley Heights	NJ	7922	509	DIST
Genzyme Corporation	Framingham	MA	1701	579	DIST
GlaxoSmithKline	Knoxville	TN	37921	641	DIST
Glenmark Pharmacetuicals Inc, USA	Mahwah	NJ	7430	449	DIST
Global Pharmaceutical Sourcing	Bethesda	MD	20814	443	DIST
Grafton Pharmaceutical Distribution LL	Grafton	ND	58237-0545	833	DIST
Gtx Inc	Memphis	TN	38163	539	DIST
Guardian Laboratories Div	Hauppauge	NY	-11788	135	DIST
Gulf South Medical Supply, Inc	Omaha	NE	68138	38	DIST
H.E. Everson Company of Cando Inc	Cando	ND	58324	711	DIST
H.E. Everson Company of Cooperstow	Cooperstown	ND	58425	693	DIST
Health Coalition Inc.	Miami	FL	33122	343	DIST
Healthcare & Diagnostic Solutions Inc	Loxley	AL	36551	809	DIST
HealthCare Logistics LLC d/b/a Pharm	Somerset	NJ	8873	597	DIST
Heartland Repack Services LLC	Toledo	OH	43615	964	DIST
Heartland Repack Services LLC	Maumee	OH	43537	708	DIST
Henry Schein Inc	Jacksonville	FL	32219	90	DIST
Henry Schein Inc	Sparks	NV	89434	141	DIST
Henry Schein Inc	Sparks	NV	89434	667	DIST
Henry Schein Inc.	Denver	PA	-17517	328	DIST
Henry Schein Inc.	Grapevine	TX	-76051	356	DIST
Henry Schein Inc.	Indianapolis	IN	-46268	140	DIST
Hoffmann La Roche Inc.	Joppa	MD	-21085	145	DIST
Hospira Worldwide Inc	Santa Fe Springs	CA	90670	706	DIST
Hospira Worldwide Inc	Pleasant Prairie	WI	53158	364	DIST
Hospira Worldwide Inc	Stone Mountain	GA	30083	703	DIST
Hospira Worldwide Inc	Farmers Branch	TX	75244	704	DIST
Hospira Worldwide Inc	King of Prussia	PA	19406	705	DIST
Hospira Worldwide, Inc	Morgan Hill	CA	95037	755	DIST
Hubbard Feeds Inc.	Bismarck	ND	58502-1877	139	DIST
Hygen Pharmaceuticals Inc	Bellevue	WA	98005	866	DIST
Idenix Pharmaceuticals Inc	Cambridge	MA	2139	830	DIST
IDEXX Operations Inc	Memphis	TN	-38141	461	DIST
Indevus Pharmaceuticals Inc	Lexington	MA	2421	777	DIST
Insource Inc.	Bastian	VA	-24314	148	DIST
Integrated Rx Solutions, Inc.	Longwood	FL	32750	730	DIST
InterMune Inc.	Brisbane	CA	-94005	393	DIST
InterPharm Inc.	Hauppauge	NY	11788-3605	150	DIST
Intervet Inc	Millsboro	DE	19966-0318	339	DIST
Intervet Inc	DeSoto	KS	66018	677	DIST
IVAX Pharmaceuticals, Inc.	Walton	KY	-41094	315	DIST
Ivers-Lee Corp dba Sharp Corporation	Fairfield	NJ	7004	197	DIST
J. Knipper and Company Inc	Lakewood	NJ	8701	867	DIST
J. Knipper and Company, Inc.	Lakewood	NJ	-8701	156	DIST
JACE Pharmaceuticals Inc	Paramus	NJ	7652	213	DIST
Jacobson Warehouse Company	Delano	PA	18220	810	DIST
Jacobson Warehouse Company, Inc	Ankeny	IA	50021	563	DIST
Jacobson Warehouse Company, Inc	Memphis	TN	38118	694	DIST
Jazz Pharmaceuticals Inc	Palo Alto	CA	94304	844	DIST
JMI Daniels Pharmaceuticals, Inc	St Petersburg	FL	-33713	477	DIST
JOM Pharmaceutical div of Ortho-McN	Bridgewater	NJ	8807	596	DIST
JOM Pharmaceutical Services Div of C	Somerset	NJ	8873	589	DIST
Kenco Durham	Durham	NC	27713	380	DIST
KENCO VPI	Chattanooga	TN	37419	308	DIST
King Pharmaceuticals, Inc.	Bristol	TN	-37620	158	DIST
KVK-TECH, Inc	Newtown	PA	18940	831	DIST

L. Perrigo Company	Allegan	MI	-49010	169	DIST
Lee Pharmaceuticals, Inc.	South El Monte	CA	-91733	164	DIST
Leitner Pharmaceuticals LLC	Piney Flats	TN	37686	608	DIST
Life Science Logistics LLC	Louisville	KY	40258	845	DIST
Lil' Drug Store Products, Inc.	Cedar Rapids	IA	52402	168	DIST
Lincare, Inc	Wahpeton	ND	58075-4414	313	DIST
Lincare, Inc	Grand Forks	ND	58201	312	DIST
Lincare, Inc.	Fargo	ND	58103	311	DIST
Logistics Health Incorporated	La Crosse	WI	54601	863	DIST
Martec USA, LLC	Kansas City	MO	-64120	176	DIST
Masters Pharmaceutical Inc.	Cincinnati	OH	45240	648	DIST
Matthews Book Company	Maryland Heights	MO	63043	482	DIST
Mayne Pharma (USA) Inc	Paramus	NJ	7652	395	DIST
McGuff Company	Santa Anna	CA	92704	359	DIST
McKesson Corporation	Aberdeen	SD	57402-1240	678	DIST
McKesson Corporation	Salt Lake City	UT	-84104	423	DIST
McKesson Corporation	Memphis	TN	38141	365	DIST
McKesson Corporation	Livonia	MI	-48150	412	DIST
McKesson Corporation	Wilsonville	OR	97070	602	DIST
McKesson Corporation/Drug Company	West Sacramento	CA	95691-3472	434	DIST
McKesson Drug Co.	Everett	WA	-98204	402	DIST
McKesson Drug Co.	Little Canada	MN	-55117	178	DIST
McKesson Drug Company	Carol Stream	IL	60188	123	DIST
McKesson Medical Surgical Inc.	Kansas City	MO	64120	583	DIST
McKesson Medical-Surgical Inc	Grapevine	TX	76051	137	DIST
McKesson Medical-Surgical MN Suppl	Maple Grove	MN	-55369	384	DIST
McKesson R D C	Memphis	TN	-38141	323	DIST
McKesson Specialty Distribution LLC	Memphis	TN	-38141	372	DIST
McKesson Specialty Distribution LLC	Washington Court	OH	43160	767	DIST
McKesson Trading Company	Aurora	CO	80011	281	DIST
MedCenterOne, Inc. (Warehouse)	Bismarck	ND	58504-000	468	DIST
Medco Supply Company, Inc.	Tonawanda	NY	14150	236	DIST
MedEquip One, LLC	Bismarck	ND	58501	606	DIST
Medical Specialties Distributors LLC	City of Industry	CA	91748	627	DIST
Medical Specialties Distributors LLC	Smyrna	GA	30080	628	DIST
Medical Specialties Distributors LLC	Streetsboro	OH	44241	629	DIST
Medical Specialties Distributors LLC	Stoughton	MA	02072-4707	630	DIST
Medical Specialties Distributors LLC	Irving	TX	75063	631	DIST
Medi-Physics Inc dba GE Healthcare	West Milwaukee	WI	-53215	548	DIST
Medisca Inc.	Plattsburgh	NY	-12901	189	DIST
MedSource Direct	Woods Cross	UT	84087	689	DIST
MedVantx, Inc.	San Diego	CA	92121	664	DIST
Merck & Co, Inc	West Point	PA	19486	303	DIST
Merck & Co., Inc	Duluth	GA	-30097	536	DIST
Merck & Co., Inc.	Reno	NV	-89502	367	DIST
Merial Limited	Athens	GA	-30601	191	DIST
Meritcare Healthcare Accessories LLC	Jamestown	ND	58401	450	DIST
Meritcare Healthcare Accessories LLC	Minot	ND	58701	451	DIST
Meritcare Healthcare Accessories LLC	Fargo	ND	-58103	138	DIST
Meritcare Healthcare Accessories LLC	Bismarck	ND	58503	415	DIST
Merridian Medical Technologies	St Louis	MO	63146	584	DIST
Merridian Medical Technologies	St Louis	MO	63144	581	DIST
Methapharm, Inc.	Coral Springs	FL	-33065	572	DIST
Metro Medical Supply, Inc.	Nashville	TN	37228	599	DIST
MGI Pharma Inc	Baltimore	MD	-21224	514	DIST
MGI PHARMA, INC.	Bloomington	MN	55437-3174	194	DIST
Midland Healthcare LLC	Kansas City	KS	66103	109	DIST
Midland Hospital Supply Inc.	Fargo	ND	58102	344	DIST

Midlothian Laboratories LLC	Montgomery	AL	36116-5125	117	DIST
Midwest Drug Supply LLC	Jackson	MI	49202-3925	335	DIST
Midwest Veterinary Supply Inc	Burnsville	MN	-55337	195	DIST
Mutual Pharmaceutical Company Inc	Philadelphia	PA	19111	723	DIST
MWI Veterinary Supply Co	Nampa	ID	-83687	202	DIST
MWI Veterinary Supply Co	Aurora	CO	80011	455	DIST
MWI Veterinary Supply Co	Clear Lake	WI	54005	821	DIST
MWI Veterinary Supply Company	Grand Prairie	TX	75050	610	DIST
Mylan Pharmaceuticals, Inc.	Morgantown	WV	26505-2730	320	DIST
Nabi Biopharmaceuticals	Boca Raton	FL	33487	203	DIST
New River Pharmaceuticals Inc	Radford	VA	24141	868	DIST
Niftus LLC	Wytheville	VA	24382	284	DIST
NitroMed Inc	Lexington	MA	02421-7801	643	DIST
Northwest Respiratory Services LLC	Fargo	ND	58103	86	DIST
Novartis Consumer Health Inc	Lincoln	NE	68501-3288	813	DIST
Novartis Pharmaceuticals Corp	E Hanover	NJ	-7936	210	DIST
Novis Pharmaceutical LLC	Plymouth Meeting	PA	19462	843	DIST
Novis Pharmaceuticals LLC	Elk Grove Village	IL	60007	864	DIST
Ocusoft Inc	Rosenberg	TX	77471	146	DIST
Odyssey Pharmaceuticals Inc	East Hanover	NJ	7936	496	DIST
Oncology Supply	Dothan	AL	36303-1038	329	DIST
Onset Therapeutics LLC	Cumberland	RI	02864-1788	811	DIST
OraPharma Inc	Warminster	PA	-18974	528	DIST
Oscient Pharmaceuticals Corporation	Waltham	MA	2451	499	DIST
OTN Paret Corp dba Oncology Therap	LaVergne	TN	37086	745	DIST
Par Pharmaceutical Inc.	Montebello	NY	10901	219	DIST
Parenta Pharmaceuticals Inc	West Columbia	SC	29169	618	DIST
Parmed Pharmaceuticals Inc.	Niagara Falls	NY	-14305	221	DIST
Patterson Logistics Services Inc	Boone	IA	50036	859	DIST
PDA Services instaCare Corp	Westlake Village	CA	91361	464	DIST
PDI Enterprises Inc.	Valencia	CA	-91355	223	DIST
PDL BioPharma Inc c/o SPS Cardinal I	LaVergne	TN	37086	785	DIST
Perrigo of SC / Perrigo Pharmaceutica	Greenville	SC	29607	355	DIST
Pfizer Inc	Lincoln	NE	-68521	518	DIST
Pfizer Inc	Parsippany	NJ	7054	575	DIST
Pfizer Inc	Guilderand Center	NY	-12085	519	DIST
Pfizer Inc	South Bend	IN	-46628	516	DIST
Pfizer Inc	Reno	NV	89521	574	DIST
Pfizer Inc	Lee's Summit	MO	-64081	517	DIST
Pfizer Inc.	Marietta	GA	-30062	515	DIST
Pfizer Inc.	Fort Worth	TX	-76140	521	DIST
Pfizer Inc.	Memphis	TN	-38134	228	DIST
PharmaCare Pharmacy #2921	Pittsburgh	PA	15235	84	DIST
Phoenix Marketing Group LLC	Towaco	NJ	7082	586	DIST
Phoenix Marketing Group LLC	Lincoln Park	NJ	-7035	585	DIST
Pierre Fabre Pharmaceuticals	Parsippany	NJ	7054	619	DIST
Prasco Laboratories	Cincinnati	OH	45249	160	DIST
Praxair Distribution Inc	Bismarck	ND	58504	969	DIST
Praxair Distribution Inc	Fargo	ND	58102	970	DIST
Praxair Distribution Inc	Grand Forks	ND	58202	971	DIST
Praxair Distribution Inc	Jamestown	ND	58402-2134	972	DIST
Praxair Distribution Inc	Williston	ND	58802-1654	973	DIST
Praxair Distribution Inc	Dickinson	ND	58601	846	DIST
Praxair Distribution Inc #422	Minot	ND	-58701	234	DIST
Praxair Healthcare Services Inc.	Minot	ND	58701	614	DIST
Praxair Inc	Inver Grove Heigh	MN	55075	773	DIST
Precision Dose Inc	South Beloit	IL	61080	617	DIST
Priority Air Express dba Priority Solutio	Swedesboro	NJ	8085	855	DIST

Priority dba CuraScript SD Specialty D	Sparks	NV	89431	790	DIST
Procter & Gamble Pharmaceuticals	Cincinnati	OH	-45249	569	DIST
Professional Veterinary Prodcuts dba F	Omaha	NE	68138	795	DIST
Professional Veterinary Prodcuts dba F	York	PA	17402	796	DIST
PromoTech Research Associates	Louisville	CO	-80027	466	DIST
PSI Health Care, Inc/dbaArrowhealth M	Fargo	ND	-58103	456	DIST
Purdue Pharmaceuticals LP	Wilson	NC	27893	306	DIST
Putney Inc	Portland	OR	4101	858	DIST
Q Logistics Inc	Florham Park	NJ	7932	834	DIST
QK Healthcare Inc.	Ronkonkoma	NY	-11779	245	DIST
QOL Medical LLC	Kirkland	WA	98033	635	DIST
Qualitest Pharmaceuticals Inc.	Huntsville	AL	-35811	243	DIST
Quality Assured Services Inc	Orlando	FL	32804-6103	526	DIST
Questcor Pharmaceuticals Inc	Union City	CA	94587	841	DIST
Quinnova Pharmaceutical Inc	Newtown	PA	18940	856	DIST
R & S Sales LLC	Fountain Run	KY	-42133	249	DIST
Ranbaxy Pharmaceuticals	Jacksonville	FL	32257-3644	534	DIST
Rebel Distributors Corp	Thousand Oaks	CA	91320	625	DIST
Reckitt Benckiser Pharmaceuticals Inc	Richmond	VA	23235	783	DIST
RedPharm Drug	Eden Prairie	MN	55344	848	DIST
Reliance Pharmaceuticals dba Med-Se	Ft Lauderdale	FL	33309	407	DIST
Reliance Wholesale Inc	Cordova	TN	38018	786	DIST
Resolve MSS US Inc	Norristown	PA	19403	860	DIST
Richie Pharmacal Company LLC	Glasgow	KY	42141	188	DIST
Rising Pharmaceuticals Inc	Allendale	NJ	7401	838	DIST
Roxane Laboratories, Inc	Columbus	OH	43228	805	DIST
Rummel's Auto Wrecking & Welding S	Dickinson	ND	58601-5453	839	DIST
Rx C Acquisitions dba Rx Crossroads	Louisville	KY	-40218	568	DIST
Saddle River Marketing Concepts Inc	Paramus	NJ	7652	613	DIST
SAJ Distributors	Pine Bluff	AR	71603	852	DIST
Sandoz Inc.	Broomfield	CO	80038-0446	131	DIST
Sanofi Pasteur Inc - Kansas City Distril	Kansas City	MO	64120	23	DIST
Sanofi Pasteur Inc - Scranton Distribut	Taylor	PA	18517	25	DIST
Sanofi Pasteur Inc. - Sparks Distributic	Sparks	NV	89434	24	DIST
sanofi-aventis U.S. Inc.	Des Plaines	IL	60018	322	DIST
sanofi-aventis U.S. LLC	Kansas City	MO	64132	144	DIST
sanofi-aventis U.S. LLC	Portage	IN	46368	326	DIST
sanofi-aventis U.S. LLC	Forest Park	GA	30297	966	DIST
sanofi-aventis U.S. LLC	Sparks	NV	89431	967	DIST
Santarus Inc	San Diego	CA	92130	473	DIST
Schering Corporation	Reno	NV	89506-1600	255	DIST
Schering Corporation	Branchburg	NJ	8876	590	DIST
Schering Corporation	Suwanee	GA	30024	591	DIST
Schering Plough Animal Health Corp	Omaha	NE	68127	743	DIST
Sciele Pharma Sales Inc	Atlanta	GA	30328	797	DIST
Sciele Pharma, Inc.	Alpheretta	GA	30005	399	DIST
Seacoast Pharmaceutical Inc	Omaha	NE	68138	549	DIST
Seton Pharmaceuticals LLC	Sea Girt	NJ	8750	824	DIST
Shire LLC	Florence	KY	41042	638	DIST
Sirius Laboratories Inc	Vernon Hills	IL	-60061	559	DIST
SkinMedica Inc.	Carlsbad	CA	92010	657	DIST
SkyePharma Inc	San Diego	CA	92121	288	DIST
Smart-Fill	Austin	MN	55912	391	DIST
Smith Drug Company	Paragould	AR	72450	623	DIST
Smith Drug Company	Spartanburg	SC	29301	656	DIST
Somerset Pharmaceuticals Inc.	Tampa	FL	-33607	265	DIST
Southern Anesthesia & Surgical	West Columbia	SC	-29169	661	DIST
Southwood Pharmaceuticals Inc	Lake Forkest	CA	92630	538	DIST

Spear Dermatology	Louisville	KY	40218	437	DIST
STAT Pharmaceuticals Inc.	Santee	CA	92071	577	DIST
Stiefel Laboratories Inc.	Oak Hill	NY	12460	272	DIST
Stiefel Laboratories, Inc	Suwanee	GA	30024	587	DIST
Sun Belt Medical / Emergi-Source	Hilton Head Island	SC	29926	58	DIST
Sunset Pharmaceuticals Inc	San Diego	CA	92117	801	DIST
Synthon Pharmaceuticals Inc	Research Triangle	NC	27709	741	DIST
Takeda Pharmaceuticals America	Deerfield	IL	60015	408	DIST
Talecris Biotherapeutics Inc	Clayton	NC	27520	540	DIST
Targacept Inc	Winston Salem	NC	27101	452	DIST
Tercica Inc	Brisbaine	CA	94005	552	DIST
TEVA Pharmaceuticals USA	North Wales	PA	19454-1090	279	DIST
TEVA Pharmaceuticals USA Inc	Chalfont	PA	18914	825	DIST
The Harvard Drug Group / Major Pharr	Indianapolis	IN	-46268	851	DIST
The Harvard Drug Group / RSV Veteri	Livonia	MI	-48150	850	DIST
The P.F. Laboratories Inc.	Totowa	NJ	-7512	352	DIST
The Red Horse LLC	Norwood	NJ	7648	715	DIST
Ther-Rx Corporation	Bridgeton	MO	-63044	396	DIST
Thrifty Drug Stores Inc	Maple Grove	MN	-55369	285	DIST
Torrent Pharma Inc	Kalamazoo	MI	49009	869	DIST
Total Health Rewards Inc	New York	NY	10001	490	DIST
Tower Laboratories Ltd	Centerbrook	CT	6409	316	DIST
Triax Pharmaceuticals LLC	Cranford	NJ	7016	639	DIST
Trinity Health	Minot	ND	-58701	523	DIST
Triplefin LLC	Cincinnati	OH	-45242	143	DIST
TWL Billing Service & Supplies Inc	Bismarck	ND	58504	812	DIST
Tyco Healthcare Group LP	Joliet	IL	-60431	370	DIST
UCB Pharma Inc.	Birmingham	AL	-35244	289	DIST
United Blood Services	Bismarck	ND	58502-2052	291	DIST
United Research Laboratories Inc	Philadelphia	PA	19111	725	DIST
Universal Footcare Products Inc	Northbrook	IL	60062	698	DIST
Universal Hospital Services, Inc.	Fargo	ND	-58103	560	DIST
UPS Supply Chain Solutions Inc	Harrisburg	PA	17112	487	DIST
UPS Supply Chain Solutions Inc	Decatur	GA	-30034	376	DIST
UPS Supply Chain Solutions Inc	Memphis	TN	-38114	413	DIST
UPS Supply Chain Solutions Inc	Rancho Cucamon	CA	-91730	170	DIST
UPS Supply Chain Solutions Inc	Louisville	KY	40219	180	DIST
UPS Supply Chain Solutions Inc	Stead	NV	89506	555	DIST
UPS Supply Chain Solutions Inc	Ft. Worth	TX	-76177	491	DIST
UPS Supply Chain Solutions Inc	Louisville	KY	40219	791	DIST
UPS Supply Chain Solutions, Inc	Newark	DE	-19702	171	DIST
Upsher-Smith Laboratories Inc	Maple Grove	MN	55369-6026	294	DIST
Upsher-Smith Laboratories Inc	Minneapolis	MN	55447-4709	293	DIST
US Oncology Specialty, LP	Fort Worth	TX	76177-3237	647	DIST
Valeant Puerto Rico LLC	Humacao	PR	00791-9731	369	DIST
Valley Apothecary Wholesale	Salem	VA	24153	837	DIST
Valmed Pharmaceutical Inc d/b/ VIP	Grand Island	NY	-14072	295	DIST
Vernalis Pharmaceuticals Inc	Morristown	NJ	7960	774	DIST
Verus Pharmaceuticals Inc	San Diego	CA	92130	607	DIST
Vet Pharm Inc.	Sioux Center	IA	-51250	481	DIST
Victory Pharma Inc	San Diego	CA	92130	520	DIST
VWR International Inc	Batavia	IL	-60510	298	DIST
Walgreen Co	Perrysburg	OH	43551	853	DIST
Walgreens Co	Windsor	WI	-53598	299	DIST
Warner-Lambert Company	Lititz	PA	-17543	368	DIST
Warrick Pharmaceuticals Corporation	Reno	NV	89506-1600	302	DIST
Warrick Pharmaceuticals Corporation	Branchburg	NJ	8876	594	DIST
Warrick Pharmaceuticals Corporation	Suwanee	GA	30024	595	DIST

Watson Pharma Inc	Gurnee	IL	-60031	360	DIST
Webster Veterinary Supply Inc.	Sterling	MA	1564	695	DIST
WellSpring Pharmaceutical Corporatio	Bradenton	FL	34202	778	DIST
Wholesale Supply Co Inc.	Minot	ND	58702-1948	278	DIST
Wyeth Pharmaceuticals Div of Wyeth	Sparks	NV	-89434	310	DIST
Xanodyne Pharmaceuticals Inc	LaVergne	TN	37086	800	DIST
Zydus Pharmaceuticals USA Inc	Princeton	NJ	8540	542	DIST
3M Pharmaceuticals	Northridge	CA	91324	1	MAN
Abraxis BioScience Inc	Schaumburg	IL	60173	375	MAN
Actavis Totowa LLC	Totowa	NJ	7512	782	MAN
Akorn d/b/a Taylor Pharmaceuticals	Decatur	IL	-62522	277	MAN
ALK-Abello, Inc.	Port Washington	NY	-11050	68	MAN
Altana Inc.	Melville	NY	11747-2006	11	MAN
Alza Corporation	Mountain View	CA	94043	12	MAN
American Regent, Inc.	Shirley	NY	-11967	16	MAN
Ameripharm Inc	Sioux Falls	SD	57104	644	MAN
AmeriSource Health Service/dba Amer	Columbus	OH	-43217	21	MAN
Amphastar Pharmaceuticals Inc.	Rancho Cucamon	CA	91730	965	MAN
Andrx Therapeutics Inc.	Weston	FL	33331	257	MAN
Armstrong Pharmaceuticals Inc	West Roxbury	MA	2132	754	MAN
B.F. Ascher & Company, Inc.	Lenexa	KS	-66219	31	MAN
Bausch & Lomb Incorporated	Tampa	FL	-33637	37	MAN
Bayer Pharmaceuticals Corporation	West Haven	CT	66216	42	MAN
Beach Products dba Pharmaceutical A	Greenville	SC	-29605	45	MAN
Biogen Idec U.S. Corporation	Cambridge	MA	-2142	53	MAN
Braintree Laboratories Inc.	Braintree	MA	02185-0929	57	MAN
Butler Animal Health Supply LLC	Fort Worth	TX	76155	562	MAN
Centocor Inc.	Malvern	PA	19355	69	MAN
Church & Dwight Co Inc	Princeton	NJ	8543	233	MAN
CollaGenex Pharmaceuticals, Inc.	Newtown	PA	18940	603	MAN
Combe Incorporated	White Plains	NY	10604-3597	80	MAN
CooperSurgical Inc.	Trumbull	CT	6611	83	MAN
Cubist Pharmaceuticals Inc	Lexington	MA	2421	716	MAN
Cumberland Pharmaceuticals Inc.	Nashville	TN	37203	660	MAN
Daiichi Sankyo Inc	Parsippany	NJ	-7054	489	MAN
Dey LP	Napa	CA	-94558	93	MAN
DPT Laboratories Ltd.	San Antonio	TX	-78215	363	MAN
Eon Labs Inc dba Sandoz	Laurelton	NY	-11413	388	MAN
Exel Inc	Fontana	CA	92335	111	MAN
Exel Inc	Mechanicsburg	PA	17050	112	MAN
Exel Inc	Olive Branch	MS	-38654	113	MAN
Ferndale Laboratories Inc.	Ferndale	MI	-48220	119	MAN
Fleming & Company Pharmaceuticals	Fenton	MO	-63026	120	MAN
Fort Dodge Laboratories, Inc.	Fort Dodge	IA	50501	304	MAN
G & W Laboratories Inc.	S Plainfield	NJ	-7080	124	MAN
Genetco Inc.	Ronkonkoma	NY	-11779	122	MAN
Genzyme Corporation	Allston	MA	2134	578	MAN
Gilead Sciences Inc	San Dimas	CA	-91773	341	MAN
GlaxoSmithKline	Philadelphia	PA	19101	133	MAN
GlaxoSmithKline	Durham	NC	-27713	486	MAN
GlaxoSmithKline	Research Triangle	NC	27709	611	MAN
Glenwood LLC	Englewood	NJ	7631	134	MAN
Halocarbon Products Corporation	River Edge	NJ	-7661	136	MAN
Hawkins Inc	Minneapolis	MN	55413	183	MAN
Healthpoint Ltd.	Fort Worth	TX	76107-7253	379	MAN
Hill Dermaceuticals Inc.	Sanford	FL	-32773	142	MAN
Hill-Rom, Inc.	Charleston	SC	29405	697	MAN
Humco Holding Group Inc.	Texarkana	TX	75501-0282	333	MAN

INO Therapeutics Inc	Port Allen	LA	-70767	151	MAN
International Medication Systems Ltd	South El Monte	CA	-91733	149	MAN
Inwood Laboratories, Inc.	Commack	NY	-11725	152	MAN
ISTA Pharmaceuticals Inc	Irvine	CA	92618	753	MAN
Leiner Health Products, LLC	Fort Mill	SC	29708	734	MAN
Ligand Pharmaceuticals Inc	San Diego	CA	92121	580	MAN
Lincare Inc	Miles City	MT	59301	765	MAN
Lincare Inc	Sidney	MT	59270	766	MAN
LTS Lohmann Therapy Systems Corp	West Caldwell	NJ	7006	398	MAN
Mallinckrodt Inc.	St. Louis	MO	-63134	173	MAN
Mallinckrodt Inc	Maryland Heights	MO	-63043	172	MAN
Mallinckrodt-Webster Groves Technic	St Louis	MO	63119	167	MAN
Medicis Pharmaceutical Corp.	Scottsdale	AZ	-85258	184	MAN
MedImmune Distribution LLC	Shepherdsville	KY	40165	425	MAN
MedImmune, Inc	Gaithersburg	MD	-20878	556	MAN
Medi-Physics Inc dba GE Healthcare	South Plainfield	NJ	-7080	551	MAN
Medi-Physics Inc dba GE Healthcare	Arlington Heights	IL	-60004	550	MAN
MedPointe Healthcare Inc.	Decatur	IL	62523-1125	65	MAN
Medtronic USA, Inc.	Columbia Heights	MN	-55421	190	MAN
Monsanto Company (Manufacturer)	St. Louis	MO	-63167	428	MAN
Morton Grove Pharmaceuticals Inc.	Morton Grove	IL	-60053	199	MAN
Mutual Pharmaceutical Company Inc	Philadelphia	PA	-19124	201	MAN
Novartis Animal Health US Inc	Greensboro	NC	-27408	209	MAN
Novartis Pharmaceuticals Corp	Suffern	NY	10901	506	MAN
Organon USA Inc	Allentown	PA	-18103	215	MAN
OSG Norwich Pharmaceuticals	North Norwich	NY	-13814	218	MAN
Par Pharmaceutical Inc	Spring Valley	NY	10977	260	MAN
PD-Rx Pharmaceuticals Inc.	Oklahoma City	OK	-73127	462	MAN
Pfeiffer Pharmaceuticals Inc.	Atlanta	GA	30315	227	MAN
PharMedium Services LLC	Edison	NJ	-8817	720	MAN
PharMedium Services LLC	Sugar Land	TX	77478	397	MAN
PharMedium Services LLC	Cleveland	MS	38732	719	MAN
Pharmion Corporation	La Vergne	TN	37086	621	MAN
PharmPak Inc.	San Rafael	CA	-94901	232	MAN
PLIVA Inc.	East Hanover	NJ	-7936	262	MAN
Professional Dental Technologies The	Batesville	AR	72501	633	MAN
PSS World Medical Inc.	Rogers	MN	55374	241	MAN
Salix Pharmaceuticals Inc.	Morrisville	NC	27560	535	MAN
Sanofi Pasteur Inc	Swiftwater	PA	18370	81	MAN
Schwarz Pharma Manufacturing Inc	Seymour	IN	47274-0328	256	MAN
Sicor Pharmaceuticals Inc.	Irvine	CA	92618-1902	132	MAN
Smiths Medical ASD Inc	Keene	NH	-3431	263	MAN
Solvay Pharmaceuticals Inc.	Marietta	GA	-30062	266	MAN
Specialty Pharmaceutical Services	LaVergne	TN	37086	530	MAN
Spectrum Laboratory Products Inc	Gardena	CA	90248-2027	239	MAN
UCB Manufacturing Inc.	Rochester	NY	-14623	182	MAN
Valera Pharmaceuticals Inc	Cranbury	NJ	08512-3617	541	MAN
ViroPharma Incorporated	Exton	PA	19341	747	MAN
Vivus Inc.	Mountain View	CA	-94040	297	MAN
Warner Chilcott Inc.	Rockaway	NJ	-7866	300	MAN
Warner-Lambert Company	Elk Grove Village	IL	-60007	301	MAN
West-Ward Pharmaceutical Corp	Eatontown	NJ	7724	525	MAN
Wyeth Pharmaceutical Div of Wyeth H	Pearl River	NY	-10965	165	MAN
Advancis Pharmaceutical Corporation	Germantown	MD	20876	229	REV
Akyma Pharmaceuticals LLC	Fountain Run	KY	42133	615	REV
AmerisourceBergen Drug Corporation	Denver	CO	80216	659	REV
Capital Returns Inc.	Milwaukee	WI	-53218	61	REV
Clinical Supplies Management Inc	Fargo	ND	-58104	76	REV

Dakota Pharmaceutical Packaging, LL	Fargo	ND	58104	558	REV
EXP Pharmaceutical Services Corp	Fremont	CA	94539	377	REV
Guaranteed Returns Midwest Division	St Charles	MO	63367	103	REV
Heritage Labs	Olathe	KS	66061	727	REV
ImaRx Therapeutics Inc	Tucson	AZ	85719	410	REV
Med-Turn Inc	Westfield	IN	46074	729	REV
Med-Turn, Inc.	Ft Worth	TX	76155	544	REV
National Pharmaceutical Returns	Des Moines	IA	50322-7929	204	REV
Obagi Medical Products Inc	Carson	CA	90810	483	REV
Pharmaceutical Returns	Northfield	MN	-55057	381	REV
PharmaLink, Inc	Largo	FL	33773	345	REV
Sage Products Inc	Cary	IL	60013	762	REV
Siemens Medical Solutions Diagnostic	Los Angeles	CA	-90045	351	REV
Stericycle Inc	Boynton Beach	FL	33426	371	REV
Stericycle, Inc.	Indianapolis	IN	46241	330	REV
Stericycle, Inc.	Conyers	GA	-30013	406	REV
Superior Medical Supply Inc	Broomfield	CO	80021	531	REV
Taro Pharmaceuticals USA, INC	Canbury	NJ	8512	290	REV
Altru Renal Unit at Mercy Hospital	Devils Lake	ND	-58301	414	WARE
Apotex Corp	Indianapolis	IN	-46268	524	WARE
Cardinal Health Inc.	McGaw Park	IL	60085	653	WARE
MeritCare Enterprises, Inc	Fargo	ND	-58102	478	WARE
Metro Park Warehouses, Inc.	Kansas City	MO	-66110	440	WARE
St Alexius Medical Center	Bismarck	ND	-58501	400	WARE
Walgreen Co	Woodland	CA	-95776	441	WARE
Agriceutical Resources LLC	Oxbow	ND	58047	710	WHOLE
Allergan Sales , LLC	Irvine	CA	92623-9534	7	WHOLE
Amgen USA Inc.	Louisville	KY	-40299	15	WHOLE
Auburn Pharmaceutical Company	Troy	MI	48083-2512	29	WHOLE
B. Braun Medical Inc	Santa Ana	CA	92704	793	WHOLE
B. Braun Medical Inc	DFW Airport	TX	75261-2506	794	WHOLE
Banyan International Corporation	Abilene	TX	-79604	34	WHOLE
Baxter Healthcare Corporation	Catano		962	508	WHOLE
Baxter Healthcare Corporation	Grand Prairie	TX	75052	505	WHOLE
Baxter Healthcare Corporation	Montgomery	NY	12549	493	WHOLE
Baxter Healthcare Corporation	Marion	NC	28752	792	WHOLE
Bellco Drug Corp	N Amityville	NY	-11701	447	WHOLE
BioRx LLC	Cincinnati	OH	45242	305	WHOLE
Block Drug Company Inc.	Memphis	TN	38181-0709	331	WHOLE
Bristol Myers Squibb	Mt Vernon	IN	-47620	547	WHOLE
C T International	San Luis Obispo	CA	93401	654	WHOLE
Caraco Pharmaceutical Laboratories L	Detroit	MI	-48202	63	WHOLE
Cardinal Health	St Paul	MN	-55114	567	WHOLE
Cardinal Health	Moorhead	MN	-56560	545	WHOLE
Caremark Inc.	Redlands	CA	-92374	60	WHOLE
Certified Business Supply dba Purity M	Placentia	CA	92870	722	WHOLE
Chester Valley Pharmaceuticals Inc	LaVergne	TN	37086	67	WHOLE
Creekwood Pharmaceutical Inc	Birmingham	AL	35242	655	WHOLE
Cura Pharmaceutical Company Inc	Eatontown	NJ	7724	616	WHOLE
Dakota Clinic Pharmacy	Fargo	ND	-58103	89	WHOLE
DAVA Pharmaceuticals	Fort Lee	NJ	7024	751	WHOLE
Eastman Kodak Company	Rochester	NY	14652-0130	332	WHOLE
Eli Lilly and Company	Plainfield	IN	46168	107	WHOLE
Expert-Med Inc	Greenville	SC	29607	652	WHOLE
E-Z-EM Inc	Westbury	NY	11590-5021	718	WHOLE
Fisher Scientific Company LLC	Somerville	NJ	8876	636	WHOLE
FMC Distributors of Nevada Inc	Las Vegas	NV	89118	768	WHOLE
Fresenius Medical Care NA & Nephror	Charlotte	NC	-28273	485	WHOLE

Genentech Inc.	South San Francis	CA	94080-4990	121	WHOLE
General Injectables & Vaccines Inc.	Bastian	VA	-24314	130	WHOLE
GeneraMedix Inc	Liberty Corner	NJ	7938	185	WHOLE
GFCO,Inc.	Hazelwood	MO	63042	675	WHOLE
Global Pharmaceutical Sourcing	Nashville	TN	37211	683	WHOLE
Golden State Medical Supply Inc	Ventura	CA	93003	492	WHOLE
H.D. Smith Wholesale Drug Co	Wood Dale	IL	-60191	504	WHOLE
Harte - Hanks Direct Marketing	Shawnee	KS	66214-1407	417	WHOLE
Hikma Pharmaceuticals USA Inc	Eatontown	NJ	7724	460	WHOLE
HPS Rx Enterprises Inc	Roanoke	VA	-24018	512	WHOLE
Independent Pharmacy Cooperative	Sun Prairie	WI	-53590	147	WHOLE
INO Therapeutics LLC	Woodridge	IL	60517	665	WHOLE
Integrated Commercial Solutions/ I.C.S	Brooks	KY	-40109	401	WHOLE
Intendis Inc	Pine Brook	NJ	07058-1000	761	WHOLE
Jacobus Pharmaceutical Company	Princeton	NJ	-8540	153	WHOLE
Kenco Knoxville	Knoxville	TN	37921	750	WHOLE
Kuehne + Nagel	Memphis	TN	-38141	472	WHOLE
Kuehne + Nagel	Reno	NV	-89502	470	WHOLE
Lehigh Valley Technologies Inc	Allentown	PA	18102	366	WHOLE
Lincare Pharmacy Services, Inc.	Clearwater	FL	33762	962	WHOLE
Mallinckrodt Inc.	Hobart	NY	13788-0416	174	WHOLE
McKesson Corp dba McKesson Drug	Santa Fe Springs	CA	-90670	420	WHOLE
McKesson Corporation	Washington Court	OH	-43160	179	WHOLE
McKesson Corporation	New Castle	PA	-16101	497	WHOLE
McKesson Corporation	Aurora	CO	-80011	421	WHOLE
Meretek Diagnostics, Inc.	Lafayette	CO	80026	570	WHOLE
Merit Pharmaceutical	Los Angeles	CA	90065	609	WHOLE
MeritCare Hospital-South University	Fargo	ND	58103	601	WHOLE
Merz Pharmaceuticals, LLC	Greensboro	NC	27410	668	WHOLE
Millennium Pharmaceuticals	LaVergne	TN	37086	669	WHOLE
Moore Medical LLC	New Britain	CT	-6051	700	WHOLE
Nationwide Medical / Surgical Inc.	Van Nuys	CA	91405	637	WHOLE
Nelson Laboratories Limited Partners	Sioux Falls	SD	-57104	206	WHOLE
Perrigo Pharmaceuticals Company	Allegan	MI	49010	390	WHOLE
ProEthic Pharmaceuticals Inc	Montgomery	AL	36117	749	WHOLE
Professional Compounding Ctrs of Am	Houston	TX	77099-5132	240	WHOLE
Smith & Nephew Inc	Largo	FL	33773	469	WHOLE
South Pointe Wholesale Inc.	Glasgow	KY	42141	593	WHOLE
St Mary's Medical Park Pharmacy	Oro Valley	AZ	-85737	270	WHOLE
TheraCom Inc	Rockville	MD	20850	280	WHOLE
Top Rx, Inc	Bartlett	TN	-38133	340	WHOLE
Triple i	Carlstadt	NJ	7072	286	WHOLE
VaxServe Inc / Taylor Distribution Cent	Taylor	PA	18517	658	WHOLE
VaxServe Inc/Sparks Dist Ctr	Sparks	NV	89431	679	WHOLE
Watson Laboratories Inc	Salt Lake City	UT	84108	775	WHOLE
Watson Pharma Inc.	Brewster	NY	-10509	253	WHOLE
Watson Pharma, Inc	Corona	CA	92880	732	WHOLE
White Drug #61	Fargo	ND	58102	348	WHOLE
Williams Medical Company	Placentia	CA	-92670	307	WHOLE
Wyeth Pharmaceuticals Div of Wyeth	Vonore	TN	-37885	427	WHOLE
Zila Pharmaceuticals Inc.	Phoenix	AZ	85040-1939	317	WHOLE
Alcon Manufacturing, Ltd.	Fort Worth	TX	76134-2099	5	
Axcan Scandipharm, Inc.	Birmingham	AL	-35242	252	
B. Braun Medical Inc	Bridgeview	IL	60455	699	
Berlex Inc.	Wayne	NJ	-7470	48	
Blood Diagnostics Inc.	Irmo	SC	-29063	382	
Cardinal Health Inc	Englewood	CO	80112	383	
Columbia Laboratories Inc	Livingston	NJ	7039	674	

DMS Health Technologies Inc.	Fargo	ND	58102	94
Guerbet LLC	Bloomington	IN	47403	622
H. E. Everson Company of Grafton Inc	Grafton	ND	58237	702
H. E. Everson Company of Rugby Inc	Rugby	ND	58368-0166	685
H.E. Everson Company of Devils Lake	Devils Lake	ND	58301	691
Hollister-Stier Laboratories LLC	Spokane	WA	-99207	409
IVPCare Inc	Frisco	TX	75034	739
MD Logistics, Inc.	Plainfield	IN	46168	192
Midwest Med Specialties Inc.	Loogootee	IN	47553	646
Mylan Pharmaceutical Distribut	Greensboro	NC	-27406	347
North Central Healthcare Alliance	Bismarck	ND	58501	432
Patterson Dental Supply Inc	Boone	IA	50036	735
Patterson Dental Supply Inc.	Fargo	ND	58103	222
Pedinol Pharmacal Inc.	Farmingdale	NY	-11735	224
Premium Health Services Inc	Columbia	MD	21045	724
Redi-Mail Direct Marketing	Fairfield	NJ	7004	642
Septodont Inc.	New Castle	DE	-19720	258
Sigma-Tau Pharmaceuticals Inc	Frederick	MD	-21703	261
SourceOne Healthcare Technologies	St Paul	MN	55114	961
SuperGen Inc.	Dublin	CA	-94568	273
United Research Laboratoires Inc	Philadelphia	PA	-19124	503
UpState Pharma LLC	Rochester	NY	14623	620
VaxServe Inc/Kansas City Distribution	Kansas City	MO	64120	680

#3

Legislation To Strengthen Protections For North Dakota Consumers Against The Threat Of Counterfeit Drugs

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State of North Dakota

House Bill No 1455

Senate Human Services Committee

March 13, 2007

Testimony Of Matt Van Hook, Engel & Novitt
On Behalf Of PhRMA

Madam Chairman and members of the committee, thank you for the opportunity to appear before you today, and provide input on this important legislation. I am a partner with a small Washington, D.C. law firm that focuses on Food & Drug matters, particularly drug development, and issues related to the drug distribution system. I am appearing here today on behalf of the Pharmaceutical Research and Manufacturers of America. PhRMA represents the country's leading pharmaceutical research and biotechnology companies, which in 2006 invested over $43 billion in discovering and developing new medicines. PhRMA companies are the source of nearly all new drugs discovered and marketed throughout the world, and they are subject to very heavy regulatory oversight by the U.S. FDA in terms of what drugs may be marketed, and where and how they are produced. PhRMA is keenly interested in helping to assure the integrity of the distribution system for these medicines, so that for example when you go to your local pharmacy here in Bismarck, you can be assured you are dispensed exactly what your doctor ordered.

PhRMA supports Engrossed House Bill No. 1455 in the form that it passed the House, because it would establish important improvements in consumer protections here in North Dakota for the drug distribution system, in some respects reflecting recent reforms in Federal law, and in other respects providing important supplemental protections designed to close loopholes in Federal law. In summary, HB 1455 would achieve these increased levels of protection by: (1) strengthening requirements regarding the licensing of wholesale distributors; and (2) assuring that the chain of custody from Manufacturer to Pharmacy is documented ("pedigreed") to the extent consistent with good public policy and the best available technology. These reforms build on, and are consistent with, both the existing Federal scheme, and similar reforms now being implemented by your sister States.

I would like to first briefly outline the key provisions of HB 1455, and then show how they help respond to the increasing challenge of counterfeit drugs. Both wholesaler licensing and pedigree requirements have their roots in consumer protections first put in place at the Federal level nearly 20 years ago, as a result of a series of oversight hearings that documented how counterfeits

were threatening the U.S. Unfortunately, those threats have grown; however, we can thank vigilant law enforcement authorities at both the State and Federal level for keeping counterfeiters at bay even as we develop new compliance tools, and we can also look toward promising new technology that is expected to increase the integrity of our drug distribution system significantly.

Key Anti-Counterfeit Reforms In HB 1455

Tightened Licensing Of Wholesale Distributors

- Section 2, 43-15.3-03(1) (page 8, line 13) would require every person engaged in wholesale distribution in North Dakota to be licensed by the Board (ND state board of pharmacy).
- In addition to the minimum requirements of Federal law (see, e.g., 21 CFR Part 205), this generally would include identification of a Designated Representative, and detailed criminal background, and submission of a bond (see Sections 43-15.3-03(2)(f-h), and (4-11) pages 9-12).
- As with Federal law, manufacturers engaged in wholesale distribution would be subject to licensing. However, because manufacturers have not been associated with the concerns that have led FDA and other states to tighten oversight, manufacturers distributing their own FDA-approved drugs would be exempted from the more stringent qualifications required for licensing. See 43-15.3-03(1), page 8 lines 17-21.

Pedigree Requirements

- HB 1455 conforms to the minimum requirements of Federal law by requiring pedigrees for any transactions by wholesalers that are not either the Manufacturer, or an Authorized Distributor of Record (ADR), and also closes the Federal ADR loophole by requiring pedigrees even for ADRs for any drugs that leave, or have ever left, the Normal Distribution Channel (see Pedigree requirement, 43-15.3-06(1), page 15 line 4; NDC definition, 43-15.3-01(10), page 5, line 19). This limitation of distributions which may be non-pedigreed reflects the concerns of state legislatures and pharmacy boards in states such as Nevada and Florida, which have responded to an influx of counterfeit activity with extended pedigree requirements as well as greater licensing scrutiny.
- The bill also contemplates the advent of electronic track & trace pedigree technology, by authorizing the Board of Pharmacy to determine when such e-pedigree technology is available across the entire pharmaceutical supply chain (with implementation no sooner than July 1, 2010, and extendable by the board in one-year increments). See 43-15.3-06(1)(b), page 15 lines 12-23.

Unlawful Acts and Enforcement

- 43-15.3-08(1) on pages 17-18 lists 13 specific acts that would be made unlawful, including failing to obtain a license (p. 17 line 21), unauthorized sales or distributions (p. 17 line 26), failing to maintain, provide, obtain,

pass, or authenticate a pedigree (p. 18 lines 3-5), and adulteration or misbranding (except with regard to manufacturers pursuant to FDA approval; see p. 18 lines 12-21).

- Sanctions for committing these prohibited acts range from a civil penalty up to $10,000 per violation (43-15.3-09(1)(b), page 19 line 8), to a Class A misdemeanor for knowingly purchasing from an unlicensed source (43-15.3-09(4), page 19 line 27), to a Class A felony for knowingly engaging in wholesale distribution in violation of pedigree requirements (43-15.3-09(6), page 20 lines 10-21).

Counterfeiting Abuses Justify Passage Of HB 1455

The concerns driving the need for this legislation were first widely documented during a series of Congressional hearings in the mid-1980's, which led to passage of the federal Prescription Drug Marketing Act (PDMA). Congress found that so-called "secondary wholesalers," rather than distributors with whom the manufacturer had established an "ongoing relationship" to distribute its drugs, were the source of counterfeit and adulterated drugs.[1] In response, two key consumer protections were added to the Federal Food, Drug, and Cosmetic Act:

(1) *Pedigree*: a requirement that unauthorized distributors provide before each wholesale distribution a "statement . . . identifying each prior sale, purchase or trade of such drug."
(2) *Wholesaler Licensing*: a prohibition on engaging in wholesale distribution in interstate commerce "unless such person is licensed by the State" in accordance with minimum standards and guidelines issued by FDA.[2]

FDA has established several useful websites, documenting the challenge of counterfeit drugs,[3] and providing a range of PDMA- and pedigree-related

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[1] "The Oversight Subcommittee's investigation found that most of the drugs that were counterfeits, stolen, expired, or obtained through fraud were handled by secondary wholesalers, who were not authorized to distribute that manufacturer's product." H.R. Rep. No. 76, 100th Cong., 1st Sess. 17 (1987). See also *Dangerous Medicine: The Risk to American Consumers From Prescription Drug Diversion and Counterfeiting*, 99th Cong., 2nd Sess., (Committee Print 99-Z 1986) (Report by the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, Hon. John D. Dingell, Chairman). Among the oversight findings: "The realities of the wholesale marketplace have combined to create a system in which a large amount of attractively priced pharmaceuticals are constantly available, some of which are not safe or effective. The physical movement, conditions of storage, and, in some cases, even the origins of much of this merchandise is unknown to the first, second, or third level buyer, who in effect plays a form of Russian roulette. This situation cannot be allowed to continue." *Dangerous Medicine*, p. 20.

[2] The pedigree requirement is codified at 21 U.S.C. §353(e)(1), FD&C Act §503(e)(1). Implementing regulations are in 21 CFR §203.50. Requirements regarding state licensing of wholesalers are codified at 21 U.S.C. §353(e)(2), FD&C §503(e)(2), with implementing regulations in 21 CFR Part 205.

[3] FDA Counterfeit Drugs website:

resources and references. ***FDA's PDMA/Pedigree site includes detailed explanations of the decision to let the pedigree regulations go into effect as of December 1, 2006 (driven by the recognition that electronic track & trace technology is not imminently available), and the agency's views regarding the implications of pedigree-related litigation now pending in the E.D.N.Y.***[4]

In recent years, state authorities have confronted increasingly alarming counterfeiting situations, leading Florida for example to pass its pioneering wholesaler reform law in 2003. The experience of Florida with wholesaler practices of concern was documented in a 2003 Statewide Grand Jury Report by Florida's Attorney General, and also in the book Dangerous Doses,[5] both of which illustrate the need for every state, ***including North Dakota***, to tighten wholesaler licensing and pedigree requirements. As documented in the Grand Jury Report:

- Florida investigators reported "shocking and disturbing" evidence of counterfeiting, with "potential profits" for corrupt wholesalers "rival[ing] those found in narcotics trafficking." (p. 4)

- *Methodology:* counterfeiters relabel drugs "to hide the fact that they have expired, been previously dispensed, or illegally imported; to falsely overstate their strength (sometimes by as much as 2000%); or to pass off some other substance as a genuine pharmaceutical." (p. 3)

- *Wholesaler missteps show up in pharmacies:* "One case concerned a father who repeatedly injected his son [with 'growth hormone' that turned out to be insulin]. He did not buy that medication out of a car trunk or a back alley. Those drugs were traced to a legitimate pharmacy in Orlando, Florida, but it is obvious this mislabeled, adulterated product was brought into the stream of commerce by some counterfeiter. **Had the wholesaler bothered to check the pedigree by verifying the transactions, it would have discovered that the drugs could not be traced to the manufacturer.**" (p. 22)

- *Federal ADR loophole a concern:* "Wholesalers state that, in their interpretation, if they meet the definition of an Authorized Distributor of Record (ADR) for a particular manufacturer, then they are exempt from

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http://www.fda.gov/oc/initiatives/counterfeit/default.htm

[4] **FDA PDMA/Pedigree website:**
http://www.fda.gov/cder/regulatory/PDMA/default.htm

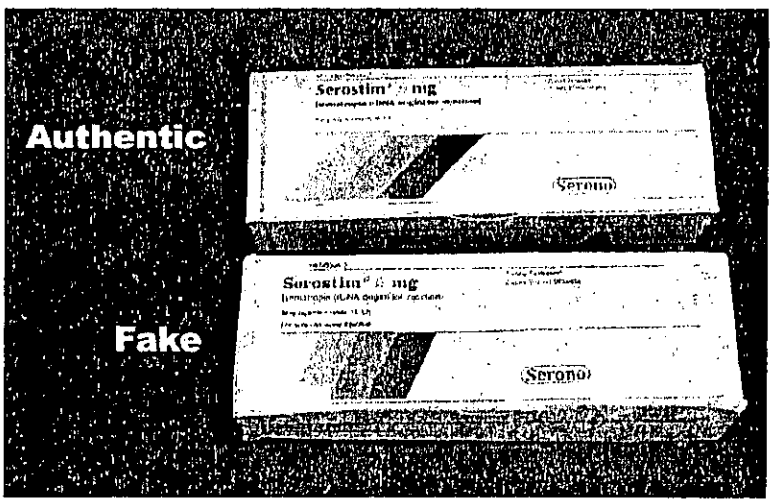
[5] **Florida Attorney General – Statewide Grand Jury Report re Rx Wholesalers**
http://myfloridalegal.com/pages.nsf/4492D797DC0BD92F85256CB80055FB97/09558F82389E020785256CDA006DB01A?OpenDocument
Dangerous Doses – "A True Story of Cops, Counterfeiters, and the Contamination of America's Drug Supply," Katherine Eban (Harcourt, Inc., ©2005).

the requirements to provide a pedigree paper . . . regardless of where the wholesaler acquired the drugs being sold. **That is, even if a wholesaler purchases Procrit [for treatment of anemia in cancer/kidney patients] out of a car trunk, they believe that they are not obligated to provide a pedigree paper . . . .**" (p. 12)

There is a reason why Congress exempts manufacturers from passing a pedigree, and why states have found no reason to subject manufacturers engaged in distributing their own drugs from additional qualifications for wholesale licensure beyond the minimum requirements in federal law: manufacturers have not engaged in the kind of "gray market" activity that some wholesalers have engaged in, which has resulted in the introduction of counterfeited drugs into the U.S. distribution system, and even onto the shelves of some U.S. pharmacies. Yes, many manufacturers do engage in distributing their own drugs, and when they do may properly be subject to licensing as 'wholesalers.' But unlike manufacturers, those whose primary business is wholesaling not only engage in distributing drugs – they also necessarily must BUY drugs, and that is why it is good public policy to subject such wholesalers (and not manufacturers) to stricter licensing requirements to help assure the integrity of the drug distribution system.

Here is an example of counterfeit human growth hormone, from FDA's counterfeit drug web page:[6]

Counterfeit duplication of the packaging for an injectable drug.

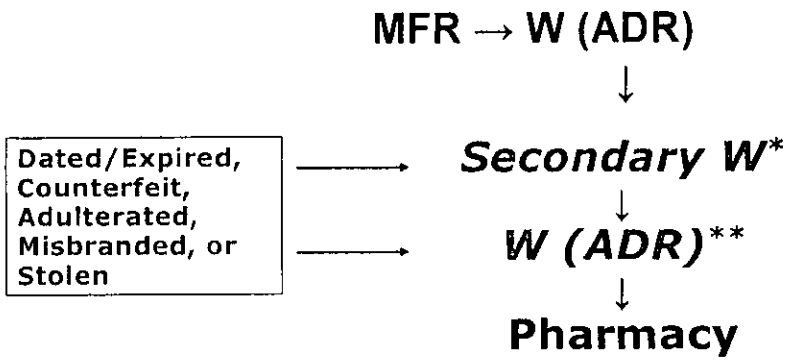


[6] http://www.fda.gov/oc/initiatives/counterfeit/default.htm

That very drug is considered by Florida officials to be one of the top counterfeit drugs, and it was found by Florida officials to have been the subject, in one instance of counterfeiting that was uncovered, of at least 8 wholesaler-to-wholesaler resales (so-called lateral transactions), including from a New York wholesaler (listed as an ADR), to a Texas wholesaler, to a Missouri wholesaler, to three Florida wholesalers in Boca Raton and Miami. A state pharmacy bureau official, in relating this actual distribution scenario, asked rhetorically "What's wrong with this picture?".[7] What's wrong is that such secondary, or "gray market" transactions make little if any economic sense, yet they provide an entry point for counterfeit, stolen, outdated, and illegally diverted drugs to enter the U.S. drug distribution system, and ultimately to end up on the shelves of American pharmacies.[8]

The figure below shows how alternative distribution scenarios, involving both wholesalers that are ADRs and those that are not, can increase the opportunity for counterfeit and adulterated drugs to be purchased from illegitimate sources and enter into the U.S. drug distribution system:

Multiple Transactions Increase Risks Of Counterfeit Entering Drug Distribution



* Federal pedigree required, if W is not ADR

** No federal pedigree required, regardless of source of drug (federal ADR loophole), if W = ADR

This distribution scenario shows where counterfeit drugs have entered the distribution channels, as documented by both Congress, and the Florida Grand Jury report. Pedigree papers are not perfect, but they at least provide state and federal compliance officials with an excellent enforcement tool; a falsified or

[7] Presentation by Susan Stovall, Florida Bureau of Statewide Pharmaceutical Services, to a counterfeit drug conference sponsored by the Food and Drug Law Institute, Chicago, Illinois, May 4, 2004, slide #18.

[8] See Stovall presentation, slides 3 & 4.

missing pedigree can provide a "smoking gun" for prosecutors. More importantly, reform measures like HB 1455 can improve on the existing system by closing the "federal ADR loophole," demonstrated in the above scenario where, under federal law, the second ADR Wholesaler would not be required to pass a pedigree. ***Under the proposed North Dakota law, each of the listed wholesalers after the first ADR would be required to pass a pedigree, whether they had ADR status or not, because of the fact the drug had left, or ever left, the normal distribution channel.*** (See Bill Section 2, 43-15.3-06(1), page 15 lines 4-8).

In conclusion, thank you for your attention to this complex, but significant area of legislative concern. HB 1455 provides timely and important consumer protection measures, and on behalf of PhRMA I would like to support its passage.

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