Approved: Mar. 20, 2007
Date

MINUTES OF THE HOUSE HEALTH AND HUMAN SERVICES COMMITTEE

The meeting was called to order by Chair Brenda Landwehr at 1:30 P.M. on February 14, 2007 in Room 526-S of the Capitol.

All members were present.

Committee staff present:
Norman Furse, Revisor's Office
Melissa Calderwood, Legislative Research
Mary Galligan, Legislative Research
Patti Magathan, Committee Assistant

Conferees appearing before the committee:
Senator Mike Peterson
Nancy Zogleman, Pfizer Corporation
Jack Geisser, Director of State Policy for Pharmaceutical Research Manufacturers of America
Debra Billingsley, KS State Board of Pharmacy
Julie Hein, National Association of Chain Drug Stores
Dan Bellingham, Health Care Distribution Management Association
Brian Caswell, Pharmacist
Donovan Pepper

Others Attending:
See Attached List.

Chair Landwehr opened the floor on hearings for **HB2392**- Registration requirements of pharmacy for wholesale distribution of drugs.

Senator Mike Peterson, Proponent, stated that this bill is important due to the rapidly growing problem of counterfeit drugs and the potential of a terrorist attack to our pharmaceutical supply. It is important to consumers to have confidence in the drugs prescribed to them as well as doctors having the confidence that medications are have their intended healing effect. More than two dozen states have enacted or are considering new and tougher documentation requirements of drugs being sold in their borders. (Attachment 1)

Nancy Zogleman, Pfizer Corporation, discussed, risks saying that this is a patient safety issue. This is the third year a similar bill has been introduced to the legislature. Ms. Zogleman showed a slide show which depicted counterfeit drugs alongside the real drugs, illustrating that there is little or no difference based on a physical comparison. This is a global problem that is escalating, with a 92% increase in counterfeit medications predicted from 2005 to 2010. **HB2392** is the work product of a study group made up of all interested parties and addresses the desire of the legislature to have recommendations for licensing and wholesale distribution legislation. (Attachment 2)

Jack Geisser, Director of State Policy for the Pharmaceutical Research and Manufacturers of America, said that his organization supports **HB2392**, however they would like to suggest amendments to comply with the Federal Prescription Drug Act regarding prohibited acts, definitions and licensing of wholesale distributors, electronic track and trace pedigree technology, reporting of suspicious/counterfeit activity and enforcement/penalties. (Attachment 3)

Brian Caswell, Pharmacist, Chairman of the Governmental Affairs Committee of the Kansas Pharmacists Association, and representative of the Kansas Pharmacy Coalition, stated that he is in opposition to **HB2392**. Pharmacists want a safe and legal means of delivering medications to their patients and support any means that helps to protect and safeguard against any threat to our nation's medication supply. **HB2392** may inadvertently create an environment that produces hurdles, slows down delivery to properly authorized and legal agents, and may actually fall far short of attaining its ultimate goal. The Kansas Pharmacists Association would like to recommend that the two key components of the bill be reexamined separately. Licensure of Wholesale distributors should be the first step in maintaining a safe and secure drug distribution system. The pedigree piece has many potential shortfalls and is reliant upon a futuristic

model that has yet to be determined. (Attachment 4)

Opponent **Dan Bellingham**, Associate Director of State Government Affairs with Healthcare Distribution Management Association, fully supports stronger licensure requirements, increased criminal penalties, and effective and efficient pedigree requirements to secure the supply chain. He stated that, with all due respect, this 28-page bill should be addressed at the Board of Pharmacy. The language mirrors the N.A.B.P. Model Rules not the four page N.A.B.P. Model Bill. Those who were present at the November 2006 Board Stakeholders meeting agreed that the legislature should address a much shorter version, leaving the details to be worked out in rule making. Their concerns are 1.) Clarification that electronic pedigrees must start with the manufacturer. 2.) Language regarding "unknowingly" penalties language. 3.) More specifics on the use of third party accreditation programs. 4.) An explanation regarding the manufacturers exemption from stronger licensing requirements. (Attachment 5)

Opponent **Debra Billingsley**, Executive Director of the Kansas State Board of Pharmacy stated that the Board of Pharmacy has the responsibility for safeguarding the state's drug supply and regulating those involved in the distribution of medications. She informed the committee that the 2006 legislature mandated that the Board conduct a task forced to study the issue of counterfeit drugs, including pedigrees, penalty for violation of requirements, and registration requirements for wholesalers. The Board met on numerous occasions. Meetings were facilitated by an associate of the National Association of Boards of Pharmacy, with at least twenty different entities being represented at the meetings.

The Task Force determined that the first step in combating counterfeit drugs was to set high standards for registration of all distributors shipping into Kansas. They also agreed that penalties should be increased for those in violation of any provision of the Pharmacy Act. The Board of Pharmacy supports efforts to accomplish this goal.

The task force did not come to an agreement regarding the provision related to pedigree for the following reasons: 1.) No consensus on beginning point for pedigree being with the Manufacturer or with the Distributor, 2.) Availability of emerging technologies such as radio frequency identification is not commonly available, and paper pedigrees are of little value, 3.) The FDA has mandated pedigrees in the Prescription Drug Marketing Act, however there is pending litigation with the likelihood that the regulations are unconstitutional.

The Board of Pharmacy would submit that there needs to be more stringent requirements for registration of wholesale distributors, whether or not there is pedigree. We are providing a copy of bill language that would provide additional requirements and safeguards to the drug distribution channels. (Attachment 6)

Opponent **Julie Hein**, representing the National Association of Chain Drug Stores said that this is a technical issue and provided the written testimony of Kevin Nicholson, who is snowed in and unable to be here today. The Association provided an edited version of the bill that addresses several of their concerns (Attachment 7).

Mr. Donovan Pepper with Walgreens Corporation, provided some impromptu remarks. Wholesale pharmacy is not opposed to wholesale provisions and/or pedigree, and we are concerned about counterfeit drugs and adulterated products. There are provisions in this bill that need to be addressed. We hope that the Kansas legislature would consider federal legislation and legislation passed in other states when considering statute changes.

Chair Landwehr closed hearings on **HB 2392** and adjourned the meeting at 3:05 P.M. Next meeting will be February 15 at 1:30 P.M.

HOUSE HEALTH AND HUMAN SERVICES COMMITTEE GUEST LIST

DATE: February 14, 2007

NAME	REPRESENTING
Ron Gaches	KPSC
Brad Smoot	Pfizer
MIKE PETERSEN	SENATE 28TH
Dan Bellingham	HDMA

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(785) 296-7355
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SENATOR MIKE PETERSEN

COMMITTEES
ELECTIONS & LOCAL GOVERNMENT
TRANSPORTATION
UTILITIES

JT. COMMITTEE ON
INFORMATION TECHNOLOGY

Testimony Before the Kansas House Health and Human Services Committee
Presented on Wednesday, February 14th, 2007
in Support of House Bill 2392

Chairperson Brenda Landwehr and Members of the Committee, I want to thank you for the opportunity to testify in support of HB 2392. I believe the drugs available in the U.S. today are among the safest in the world. While attending a CSG and Midwestern States conference this summer, I was made aware of the rapidly growing problem of counterfeit drugs and the potential of a terrorist attack to our pharmaceutical supply. Attached to my testimony you will find a press release from the National Association of Boards of Pharmacy dated Jan. 11, 2007. It warns about the continued dangers of counterfeit drugs and provides examples of some of the problems that have been encountered, noting that 19 people were indicted in Detroit, MI for importing and distributing counterfeit products. According to reports, portions of the proceeds were used to fund the terrorist organization Hezbollah. The potential of a terrorist organization introducing a small amount of poison that would have an adverse affect over a long period of time into our supply chain is rapidly becoming a real concern. On the press release attached to my testimony, is a NABP website with information on the dangers of counterfeit drugs.

It is important to consumers in our state that they have confidence in the drugs prescribed to them as well as doctors having the confidence that their medications are having their intended healing effect. More than two dozen states have enacted or are considering new and tougher documentation requirements on drugs being sold in their borders. Please give your full consideration to the safety of the complex process of pharmaceutical distribution.

Respectfully submitted,

Mike Petersen

Mike Petersen
Senate, District 28

House Health and Human Services

DATE: 2-14-07

ATTACHMENT 1-1

FOR IMMEDIATE RELEASE:

Contact: Gertrude Levine
847-391-4497

The National Association of Boards of Pharmacy Warns About the Continued Dangers of Counterfeit Prescription Drugs

2006 Unprecedented Year of Increased Fake Drug Production, Introduction into U.S. Drug Supply

Washington, D.C., January 11, 2007 – Amid increased concern over the growing epidemic of counterfeit drugs, the National Association of Boards of Pharmacy (NABP) issued the following information concerning worldwide counterfeiting activity. Much of this increased activity is aimed a pharmacy outlets in the United States. According to a 2006 World Health Organization report, the current prevalence of counterfeit medicines can range to over 10 percent of the drug supply globally.

NABP notes that in 2006:

- **United States**
  Nineteen people were indicted in Detroit, Michigan, for importing and distributing counterfeit products, to include pharmaceuticals. A portion of the proceeds were used to fund the terrorist organization Hezbollah.

  Eleven people in Georgia, North Carolina, South Dakota and the Central American nation of Belize were indicted on charges of selling counterfeit prescription drugs over the Internet. Investigators believe many of the drugs had little or no medicinal value, and that those behind the scam netted more than $19 million.

- **Canada**
  One of Canada's largest Internet pharmacies is selling counterfeit versions of Lipitor, Crestor, Celebrex and seven other drugs, according to the Food and Drug Administration (FDA). These counterfeits were seized en route to American patients.

- **Mexico**
  Eleven tons of counterfeit, expired, stolen, or illegally imported medicines were reported seized by Mexican authorities in Mexico City, Guadalajara, Jalisco, and Morelia in November 2006. Six individuals were arrested and fourteen more are under investigation according to Mexican news sources.

- **South America**
  It is reported that in underdeveloped countries such as Argentina, Colombia, and Mexico, up to 40 percent of manufactured pharmaceuticals are believed to be counterfeit.

- **United Kingdom**
  In July 2005, 70 packs of counterfeit Lipitor, marked with genuine batch numbers, were found in two separate licensed wholesalers in the UK. Dutch customs intercepted a consignment of counterfeit Lipitor bound for Canada and found 10,000 packs in UK packaging. The British Medicines and Healthcare Products Regulatory Agency (MHRA) recalled the suspect batch numbers and more than half the 520 packs returned were found to be counterfeit. Around 2,500 counterfeit packs had already been consumed or discarded by the National Health Service patients. Days after that incident came to light a second batch of counterfeit Lipitor was found.

- **China**
  In China, authorities believe that for some drugs, the estimated average of counterfeit copies can be as high as 50 percent. Chinese police dealt with more than 4,600 cases involving counterfeit and inferior goods from January to November 2006, according to the Ministry of Public Security. One of the most serious cases was the use of tainted drugs manufactured by Qiqihar No. 2 Pharmaceutical Co., which left 11 people dead.

- **India**
  20% of medicines sold across India are fake or counterfeit, according to the Associated Chambers of Commerce of India. Of the 20% fake medicines, 60% are without active ingredients, 19% have wrong ingredients while 16% have harmful and inappropriate ingredients, such as talcum powder.

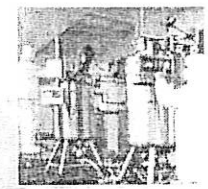
Legislation to curb the instances of counterfeit drugs entering the U.S. supply has been introduced in 2006 on both the federal and state levels. This includes legislation requiring everyone in the drug-supply chain to adopt more secure business practices and instituting tougher criminal penalties those found manufacturing and distributing counterfeits.

"Individuals who depend on medications should have the peace of mind that what they are taking to make them better is in fact doing so, and not endangering their health." said Carmen Catizone MS, RPh, DPh, executive director/secretary of the NABP. "We will continue to work with state and federal governments to ensure prescription drug safety for the future and hope that the safety of America's drug supply remains a priority in Washington."

Also in 2006, NABP introduced a web site to help educate the public about the dangers of counterfeits and steps they can take to protect themselves. For more information, visit www.dangerouspill.com.

The National Association of Boards of Pharmacy (NABP) was founded in 1904 and represents all of the pharmacy regulatory and licensing jurisdictions in the United States, the District of Columbia, Puerto Rico, Guam, the Virgin Islands, eight provinces of Canada, two Australian States, New Zealand, and South Africa. Its purpose is to serve as the independent, international, and impartial Association that assists its member boards and jurisdictions in developing, implementing, and enforcing uniform standards for the purpose of protecting the public health.

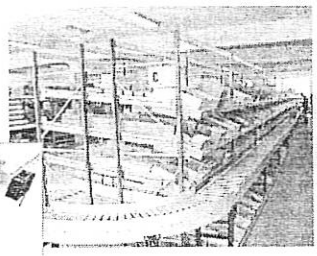
How Counterfeit Drugs are Entering the Supply Chain



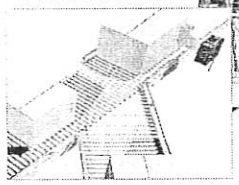
Pharmaceutical Manufacturers

Drugs are shipped in bulk from drug manufacturers to wholesalers.

Wholesalers repackage the drugs into smaller boxes and resell the medicine to retailers such as pharmacies & hospitals, where they can be safely prescribed to patients.



Wholesalers



Counterfeiters get drugs from wholesalers, add their own phony drugs, and sell the mixed up boxes back to the wholesalers & retailers — where they may be inadvertently dispensed to patients.

Pharmacies

Hospitals

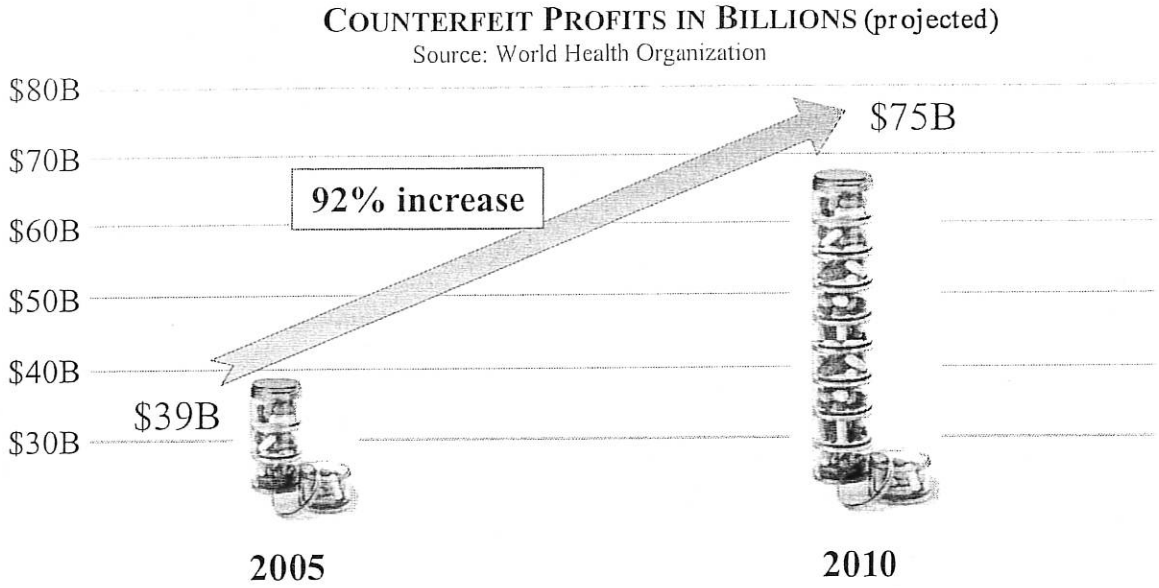
The Solution

Fueled by growing fears over the safety and efficacy of the nation's drug supply and by a number of highly publicized cases involving tainted or counterfeit drugs, **more than two dozen states have enacted or are considering new and far tougher documentation requirements on every drug sold or distributed in their jurisdictions.** And some of those states are demanding not just an electronic record, but a paper trail, as well.

Counterfeit Drugs are a Problem.

"The criminals are very savvy business people and they see an opportunity. They sell counterfeit drugs, because that is where the money is."

-Peter Pitts, director of CMPI and the FDA's former associate commissioner for external relations.



Counterfeit Drugs More Lucrative Than Heroin

The main reason for the sudden rash of counterfeit drugs is, in a word, money. Criminals are getting wise to the fact that there are enormous profits to be made in fake pharmaceuticals. Americans spent $203 billion on prescription drugs in 2003, according to statistics from the National Association of Chain Drug Stores. Any counterfeiter who manages to nab a tiny sliver of the pie can make a fortune.

"Some of the experts are telling us it's more lucrative to sell a counterfeit drug than it is a narcotic such as heroin," William Hubbard, FDA's associate commissioner for policy and planning, tells WebMD. Nor is counterfeiting limited to small-time hustlers looking to turn a quick buck. "We're seeing **organized criminal elements** getting involved."

-WebMD

"Sales of counterfeit prescription medicines are forecast to reach $75 billion by the end of the decade, nearly doubling current levels and outgrowing the annual growth rate of legitimate pharmaceutical sales."

-Health Business Week, December 30, 2005

"No country is immune to the threat of counterfeit drugs." according to Tom Kubic, executive director, Pharmaceutical Security Institute, a member of the Partnership for Safe Medicines.

-Med Ad News, October 1, 2005

"The Internet is facilitating the globalization of counterfeit drugs. I don't think the primary reason is even pricing, because Africa and Asia and Europe are suffering from the same problems that North America is."

-Washington Drug Letter, September 26, 2005

Omaha World-Herald

Fake drug's packager says it's not his fault Med-Pro's owner says the tablets being recalled looked exactly like the real drug.

By Virgil Larson, Omaha World Herald, May 28, 2003

The owner of a Lexington, Neb., company said Tuesday that while his company packaged 100,000 bottles that the FDA says contained counterfeit Lipitor, his company has no responsibility for whether the pills were the real thing.

Rick Rounsborg issued a statement saying the tablets that Med-Pro Inc. repackaged for a Kansas City, Mo., distributor were the same shape, size and color and had the "exact same markings" as Lipitor samples. Lipitor is a cholesterol-fighting drug.

Med-Pro got the tablets in bulk and repackaged them in accordance with Food and Drug Administration regulations, the statement said. The company said it then shipped them to various places as directed by Albers Medical Distributors Inc., the Kansas City firm.

"It's not a recall of anything we did," Rounsborg said in an interview.

Albers voluntarily recalled the tablets, the FDA announced Friday as it warned that the counterfeit Lipitor poses a health risk to users.

The 90-tablet bottles that were recalled carry the notation "Repackaged by: Med-Pro, Inc. Lexington, Neb." on the label. The lot numbers recalled are 20722V and 16942V, both with an expiration date of September 2004, and 04132V, expiring in January 2004.

People should not use the tablets, and the pills should be returned to pharmacies, the FDA said.

Med-Pro said the original labeling on the tablets it received for repackaging for Albers showed that the product was made by Warner-Lambert Export Ltd. in Dublin, Ireland. It said the bulk product was in what Med-Pro believes to be the manufacturer's original packaging.

Pfizer acquired Warner-Lambert and Lipitor.

Rounsborg referred questions to Albers, which referred questions to the FDA. Spokeswoman Indya Mungo said the FDA was continuing an investigation into counterfeit Lipitor that the agency disclosed Friday when it announced the recall. Mungo said she had no new information.

The FDA has not said what is dangerous about the pills.

Lipitor is the world's largest-selling pharmaceutical. Pfizer sells $ 8 billion worth a year.

Pfizer spokespeople could not be reached Tuesday.

Rounsborg said he bought Med-Pro, which was started in 1985, in 1999. The company had

Th PHARMACIST
Vol. 4 No. 9
www.therph.com | SEPTEMBER 2006

TERROR in a BOTTLE

ALSO
Working and Living in Alaska

1-7

HB 2392 – Wholesale Distribution of Drugs

Hearing before the House
Health and Human Services
Wednesday, February 14, 2007

Testimony by Nancy Zogleman
Pfizer, Inc.

1

The Problem Defined

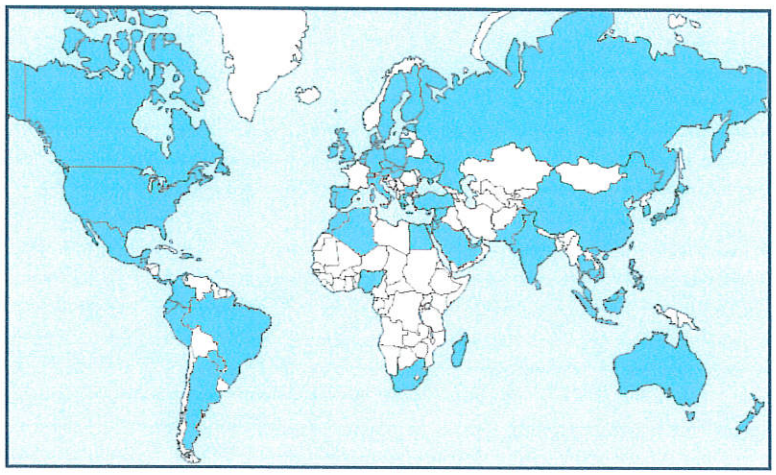
What is a Counterfeit?

Pfizer defines a counterfeit pharmaceutical product as any non-authentic Pfizer tablet, capsule and/or packaging that appears the same as an authentic Pfizer product. A counterfeit product may or may not contain the same active pharmaceutical ingredient (API) as the authentic product.

2

House Health and Human Services
DATE: 2-14-07
ATTACHMENT 2-1

Counterfeit Pharmaceuticals: Global Problem

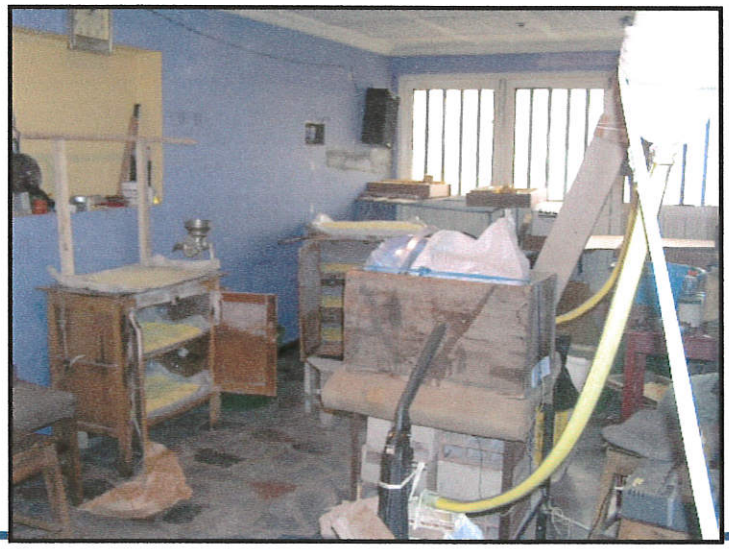


A Growing Problem

"Trade in counterfeits is extremely lucrative, thus making it more attractive to criminal networks. A report released by the Centre for Medicines in the Public Interest, in the United States, projects counterfeit drug sales to reach US$ 75 billion in 2010, a 92 % increase from 2005."

WHO Counterfeit medicines: the silent epidemic press release, February 2006

Counterfeit Lab in Ponstan, Colombia



Tableting Machine in Latin America

Drying Oven In Latin American

Counterfeit Viagra in Egypt

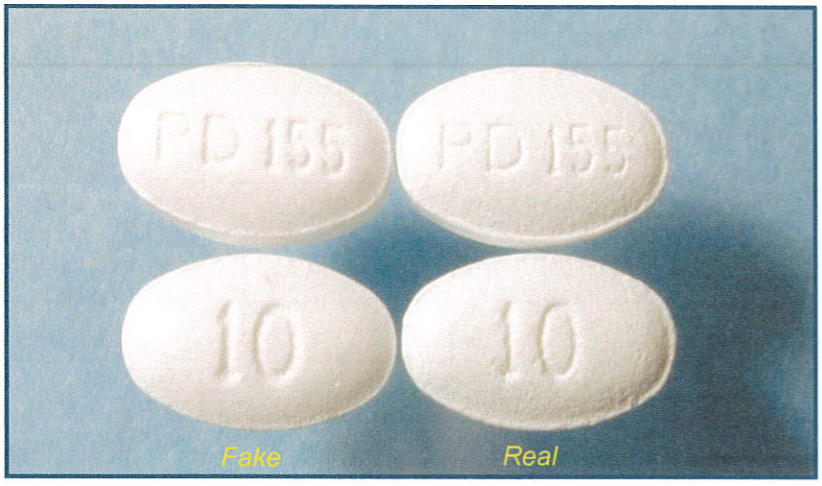
"What happened to us?"

One Case Study:

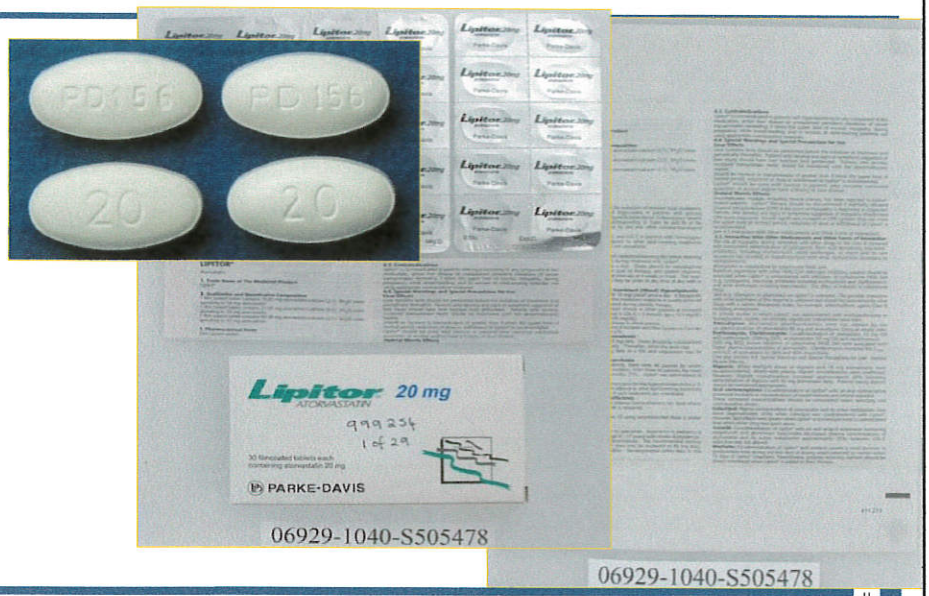
COUNTERFEIT LIPITOR® IN U.S. SUPPLYCHAIN

In 2003, Pfizer assisted federal law enforcement in the investigation of five U.S. firms involved in the distribution of counterfeit Lipitor tablets. The most significant of those investigations concerned counterfeit Lipitor tablets repackaged by a company in Nebraska, and distributed primarily by another company in Missouri.

Lipitor (lowers high cholesterol)



Suspect Lipitor Looked Convincing



11

"What happened to us?"

- Lipitor is the most prescribed pharmaceutical product for the reduction of cholesterol in the world.
- During 2003, for example, 68,958,000 prescriptions for Lipitor were written in the U.S. alone.
- To put this case into perspective, more than 600,000 U.S. residents -- after visiting their local pharmacy, or placing an order by phone, mail or internet --may have received a thirty day supply of Lipitor that contained counterfeit tablets.
- We know of 160,000... . .
- FDA recalled more than 18,000,000 counterfeit and repackaged "Lipitor" tablets.
- Scarier still is the fact that this happened in the Kansas City market with one of the persons indicted being from Kansas

12

We are not alone…This is an article from Time Magazine last winter.

N O T E B O O K

FIGHTING FAKE FLU PILLS

AVIAN FLU CLAIMED more lives last week. In eastern Turkey, initial tests showed at least two of the three deceased siblings from the Kocyigit family had succumbed to the virus' dreaded H5N1 strain, becoming its first human victims outside East Asia. As fears of a pandemic continue to grow, customs and health officials are struggling to halt a burgeoning trade in counterfeit forms of Tamiflu, the only drug approved to treat the disease. U.S. Customs and Border Protection (CBP) officials tell TIME that last week their officers seized 250 separate parcels of suspect Tamiflu at the airmail facility in New York City—the biggest interception to date—and one package in Chicago. The New York shipments came from the island of Mauritius and were probably destined for American consumers wanting to stock up in case of a pandemic.

Officials expect more—and bigger—seizures of fake Tamiflu. "We believe they will continue to go up dramatically," says CBP's William Hellfeld. If past experience is any guide, the pills will contain no more than trace elements of Tamiflu's active ingredient. Less than a month ago, authorities in San Francisco announced the confiscation of 51 packages of phony Tamiflu ordered through the Internet and shipped from Asia. Tests on those pills found only harmless ingredients, but experts worry that in an outbreak, people might take such pills and consider themselves protected.

The World Health Organization, which has recorded 76 human deaths from H5N1 since 2003, discourages individuals from hoarding Tamiflu since there is a global shortage and those who can afford it are unlikely to be most vulnerable. Tamiflu's manufacturer, Roche, has promised to increase production tenfold from its 2004 level, to 300 million 10-pill courses by the end of 2007. A rush order of 100,000 courses was sent last week to Turkey, where 20 people with symptoms of bird flu remained hospitalized, including the last surviving sibling in the Kocyigit family. —*By Amanda Bower. With reporting by Andrea Gerlin*

A health worker disinfects a chicken coop in eastern Turkey

VERBATIM

"He was dividing God's land. And I would say, 'Woe unto any Prime Minister of Israel who takes a similar course to appease the E.U., the United Nations or the United States of America.' God says, 'This land belongs to me. You better leave it alone.'"
PAT ROBERTSON, *televangelist, suggesting that Israeli Premier Ariel Sharon's massive stroke last week was divine punishment*

"Today you will all have heard—and I hope that this is final—that the criminal of Sabra and Shatila has rejoined his ancestors. God willing, the others will join him soon."
MAHMOUD AHMADINEJAD, *President of Iran, making a premature announcement of the ailing Sharon's death*

"It wasn't bad/ just went to sleep."
MARTIN TOLER JR., *one of 12 miners who died last week after an explosion at West Virginia's Sago coal mine, in a scrawled note found with his body assuring his family that his final hours were painless*

"I believe they are capable of making a deal with the devil himself so that they can be represented widely in the coming government."
SALEH AL-MUTLAQ, *Sunni Arab politician, criticizing the Iraqi Accordance Front—the Sunni Arabs' major political party—for planning to join with Kurds and Shi'ites to form a coalition government*

"Killing one educated person is as effective as killing dozens of ordinary people."
MULLAH NAQIBULLAH, *Afghan tribal elder, warning of the dangers of the Taliban—who last week beheaded a high school teacher—and its efforts to undermine trust in the government*

"There is a sort of an unwritten code in Washington among the underworld and the hustlers and these other guys, that I am their friend . . . I was a little hurt."
MARION BARRY, *Washington council member and former mayor, after two young men robbed him at gunpoint while helping him carry groceries into his home*

13

Legislation – HB 2392

- Needless to say – this is a complicated topic
- Kansas Legislature looked at this issue extensively last session
- SB 51 passed last session which addressed the criminal activity and directed the Board of Pharmacy to study this issue and bring "recommendations for licensing and pedigree legislation to the legislature no later than January 15, 2007."
- Study Group made up of all interested parties – Wholesalers, Pharmacists, Manufacturers, Chain Drug Stores, Board members – assisted by staff from National Association of Boards of Pharmacies worked through the summer and fall.
- HB 2392 is the work product of that group and addresses the desire of the legislature to have recommendations for <u>licensing and wholesale distribution legislation.</u>

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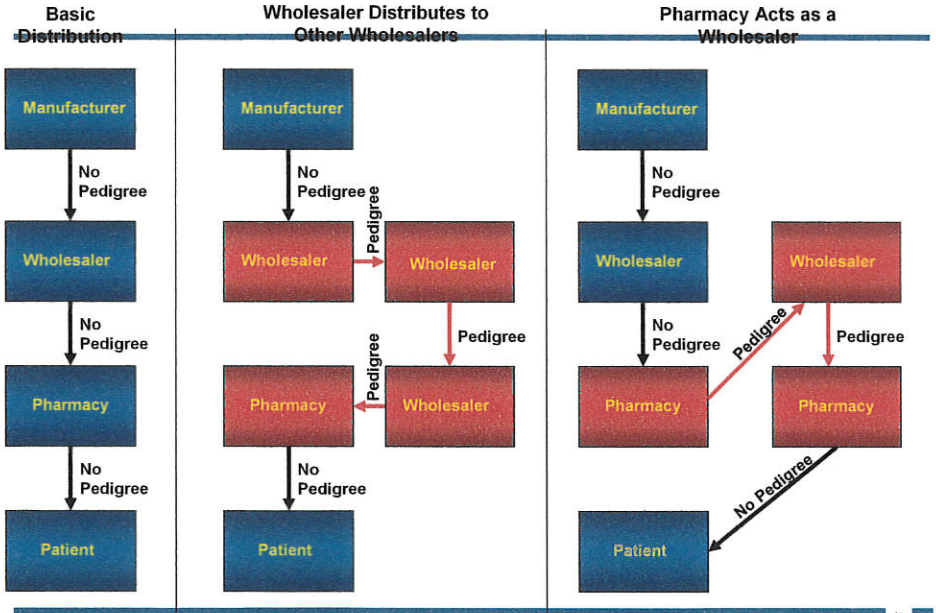
Understanding HB 2392

- Essentially three parts to the Legislation.
  - Licensure / Accreditation
  - **Distribution**
  - Penalties

15

A BRIEF Look at the Distribution World:
Basic Normal Distribution v. Outside Normal Distribution



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Pedigree Required for ALL Future Distribution System Points Once Drug Leaves Normal Distributions

Passed Full Pedigree

- Arizona
- California
- Colorado
- Florida
- Indiana
- Iowa
- Nebraska
- Nevada
- New Jersey
- Oregon (IN BOP Regs)
- Texas
- Vermont
- Virginia

Legislation Introduced in 2007

* Introduced in 2006 but died – will be reintroduced

- Alabama
- Alaska
- Arkansas
- Connecticut*
- Delaware
- Georgia*
- Idaho
- Illinois
- Kansas
- Kentucky
- Maryland
- Maine
- Massachusetts
- Minnesota
- Missouri*
- Montana
- New York*
- North Dakota
- Ohio
- Pennsylvania
- South Dakota
- Tennessee
- Utah
- Washington
- Wisconsin*
- Wyoming

Statement PhRMA

Testimony Before the House Health and Human Services Committee Supporting HB 2392 Regarding Wholesale Licensure and Prescription Drug Pedigree Requirements (Written Statement)

February 14, 2007

Good afternoon, Madam Chairman, Members of the Committee, my name is Jack Geisser, Director of State Policy for the Pharmaceutical Research and Manufacturers of America (PhRMA). Thank you for allowing me to testify before your committee this afternoon in general support of HB 2392. We commend you, Madam Chairman, and the entire Committee for your work on this important legislation. While PhRMA supports this consensus legislation, we do have some reservations about the language and believe both technical and substantial amendments are necessary. The U.S. drug distribution system faces increasing challenges from the threat of counterfeit and adulterated drugs. In 1988, the federal Prescription Drug Marketing Act (PDMA) was enacted with provisions intended to address the threat of counterfeit drugs. These provisions included key elements related to state licensing of wholesalers and a requirement that certain wholesalers pass a "statement" (pedigree) identifying each prior sale and related information:

- **Wholesaler Licensure:** Minimum federal standards for state licensure of wholesale distributors: see 21 U.S.C. §353(e)(2) and federal regulations at 21 CFR Part 205.
- **Pedigree:** Federal requirement for certain wholesalers (those who are not the manufacturer, or not a manufacturer-designated "authorized distributor of record") to provide a pedigree before each wholesale distribution: see 21 U.S.C. §353(e)(1) and federal regulations at 21 CFR Part 203 Subpart E – Wholesale Distribution (in particular, 21 CFR §203.50, which went into effect December 1, 2006). FDA has recently established a website, with various pertinent PDMA-related resources and guidances at http://www.fda.gov/cder/regulatory/PDMA/default.htm. On that website, FDA also addresses its policy regarding the RxUSA case currently before the Federal District Court, EDNY; as explained in an Addendum to its Guidance on Pedigree Requirements, FDA is exercising its enforcement discretion nationwide until that litigation is resolved, in applying the still-applicable federal statutory pedigree requirement, in a manner that only requires a pedigree to document transactions back to the manufacturer or the last ADR.

In recent years, the challenge to the integrity of the U.S. drug distribution system from counterfeit drugs has grown and many states like Kansas are responding with renewed attention to both wholesaler licensing and pedigree requirements. The bill, now under consideration in Kansas addresses the wholesale distribution of prescription drugs, including longstanding requirements for the licensing of Wholesale Drug Distributors. The proposed legislation would build on the existing Kansas regulatory framework, with enhanced requirements for wholesale licensure, and a new section devoted to pedigree which assures compliance with minimum federal standards and also closes some federal pedigree loopholes. The overall approach in HB 2392 reflects consensus legislation reached by the Kansas Board of Pharmacy, the National Association of Boards of Pharmacy (NABP), PhRMA, retail pharmacies, as well as the wholesalers. HB 2392 is consistent in some key respects with recommendations of model legislation advocated by the NABP and PhRMA. While PhRMA has concerns with some provisions, we hope those

differences can be resolved through the legislative process.

Following is a summary of the sections of this bill that would amend Kansas statute.

Section 65-1643 – Prohibited Acts

- This provision lists specific acts which are made unlawful, among them: failing to pass or authenticate a pedigree as required by this Act (65-1643 (z)); and, except for manufacturers of drugs delivered into commerce pursuant to FDA authority, the making or selling of adulterated, misbranded, or counterfeit drugs (Section 65-1643 (m) and (n)).

Section 2. 65-1655 – Definitions and Licensing of Wholesale Distributors

- These are key to both the licensing and pedigree provisions discussed below; rather than summarize all individual terms here, most are discussed below in the context of the operative provisions. However, Section 65-1655(33)(b) requires every person engaged in wholesale distribution in Kansas to be licensed by the Board of Pharmacy, including non-resident distributors (who also must be licensed in their state of residence).
- Requirements for licensure include all of the minimum requirements under federal law relating to information about the applicant and its qualifications. Manufacturers engaged in wholesale distribution must get a license pursuant to federal law, but are subject only to these federal minimum requirements, and are exempt from additional licensing requirements. The rationale being that manufacturers are heavily regulated by FDA and have not been associated with problems related to the introduction of counterfeit drugs that have occasioned the tightened licensing requirements.
- The tightened licensing requirements in this section include the identification of a "designated representative" in the state, detailed criminal background including the submission of fingerprints, and submission of a bond of at least $100,000.

Pedigree Requirement; Electronic Track And Trace Pedigree Technology

- Consistent with both PhRMA and NABP model legislation, this bill would require a pedigree (with minimum information outlined in Section 4(c)) for any distribution of a prescription drug that has left the "normal distribution channel." This conforms to federal law, by requiring a pedigree for any distributor that is neither the manufacturer nor an "authorized distributor of record." By requiring a pedigree for any drug that leaves or has ever left the normal distribution channel, the provision closes a significant loophole in federal law that can allow an authorized distributor of record (ADR) to further distribute without pedigree even if the drug was obtained from a source other than the manufacturer or another ADR. The definition of "normal distribution channel," which lists specific distribution pathways, also limits non-pedigreed transactions more strictly than federal law, by effectively precluding non-pedigreed lateral distributions among ADRs, with limited exceptions (such as in the case of distributions from a manufacturer's third-party logistics provider/ADR, or manufacturer's exclusive distributor/ADR, to another wholesale distributor/ADR). Pharmacies are only required to pedigree when they engage in wholesale distribution.
- The intent of this "normal distribution channel" approach is to shorten the non-pedigreed distribution channel; other states such as Nevada and Florida have shortened their non-pedigreed distribution channels with the aim of further protecting the distribution system against opportunities for the introduction of counterfeit or adulterated drugs. It should be emphasized that this does not preclude distribution by non-ADRs, or ADRs seeking to make additional lateral distributions; however, such distributions would be required to be

pedigreed.

- The validity of the pedigree is further assured by requiring that each person receiving a pedigreed distribution affirmatively verify the pedigree before engaging in any further distribution.
- Federal and state regulatory authorities agree that the drug distribution system will be optimally protected once electronic track and trace technology becomes feasible and available. There are differences among interested stakeholders as to how that goal should be achieved. One common agreement is that the date is far off in the future and that the technology should be *universally* available amongst all stakeholders in the pharmaceutical supply chain. PhRMA believes the language should make this clear instead of saying specifically the pedigree should originate with the manufacturer. The manufacturer authenticates its ownership in a pedigree as well as supplies the information for a pedigree to start. We are ready and willing to do our part, including participating in the necessary technology, but the realities of the pedigree system must also be understood. A pedigree is a record of a transaction/distribution. If a manufacturer begins a transaction, it cannot be recorded until after the sale has been completed at the receiving wholesaler thus recorded by the receiver.
- The Board of Pharmacy should be directed to determine a targeted implementation date for such electronic track and trace pedigree technology, based on consultation with various stakeholders (manufacturers, distributors, and pharmacies). The implementation date could be extendable by the Board at one-year increments if it appears the technology is not *universally* available across the entire prescription drug supply chain. However, it should not be stated in legislative terms that the manufacturer "starts" the pedigree.

Reporting of Suspicious/Counterfeit Activity

- This provision requires wholesalers to maintain a system for handling recalls and withdrawals of prescription drugs and devices. PhRMA supports its current voluntary policy of "identifying, investigating, and reporting significant discrepancies" in drug inventory and notifying the FDA within 5-days. The FDA is currently supportive of this policy as well. This legislation requires "notifying the board or appropriate federal or state agency" within 10-days upon discovery of such discrepancy.

Section 3– Enforcement/Penalties

This provision provides for a finding of a Class C felony or a fine of up to $500,000 for a violation of the act.

Thank you for the opportunity to testify before the committee today. We ask you to support HB 2392 with modification.

House Health and Human Services Committee
Testimony Re: HB 2392
Presented By Brian Caswell
February 14, 2007

Madam Chair, and members of the Committee:

My name is Brian Caswell, I am a Pharmacist from Baxter Springs, KS who operates Wolkar Drug, and I am Chairman of the Governmental Affairs Committee of the Kansas Pharmacists Association along with being a representative of the Kansas Pharmacy Coalition.

I come today in opposition of HB 2392. Pharmacists across the country each year graduate from their respective schools with a license in one hand and the other clasping an oath to maintain the highest principles in moral, ethical, and legal conduct. Also, to maintain a professional conduct to assist in positive patient outcomes. Pharmacists want a safe and legal means of delivering medications to their patients in order to fulfill that promise of their oath. We support any means that helps to protect and safeguard against any threat to our nations medication supply and delivery of the tools that we so desperately need in order to assist our patients in their medication management.

HB 2392 in its attempt to safeguard our medication supply may inadvertently create an environment that produces hurdles, slows down delivery to properly authorized and legal agents, and may actually fall far short of attaining its ultimate goal.

First of all the Kansas Pharmacists Association would like to recommend that the two key components of this bill, be reexamined separately. KPhA fully supports the licensure of Wholesale distributors. KPhA feels that it is critical that Wholesale licensure be the first step in maintaining a safe and secure drug distribution system. In doing so, it should be possible to track and investigate any suspicion of illegal activity and create a standard for which all purchasers could easily and readily utilize in obtaining safe and legal medications. The pedigree piece has many potential shortfalls and is reliant upon a futuristic model that has yet to be determined how efficient, how costly, and who will create a standardized electronic system.

KPhA would like to ensure that the normal distribution channel not be impeded with the delivery or return of a product to its previous seller.

In order to maintain the highest standard of security, KPhA would request that all pedigrees begin with the drug manufacturer. It is important that the final user of a medication be able to track completely back to the manufacturer of origin and the channel for which a said product had been distributed.

The Kansas Pharmacists Association wishes to support a secure drug distribution system. Pharmacy has always been on the forefront of technology, and would like to pursue an

electronic means of ensuring the safety of our system. However, until readily available and cost affordable electronic technology is present, we feel that we can monitor and regulate through the State Board of Pharmacy a system that would hold properly licensed agents fully accountable for the security and authenticity of the medications for which they distribute.

I thank the committee for the opportunity to present our concerns on such an important matter. I would be available for any questions that the committee may have.

Brian Caswell

Kansas Pharmacists Association
1020 SW Fairlawn Rd
Topeka, KS 66604

HDMA HB 2392 TESTIMONY
KANSAS HOUSE HEALTH AND HUMAN SERVICES COMMITTEE
FEBRUARY 14, 2007

Madam Chairman and Committee Members:

Thank you for this opportunity to testify today. My name is Dan Bellingham, Associate Director of State Government Affairs with HDMA (Healthcare Distribution Management Association). HDMA is the national trade organization for full-service, primary distributors. We have 40 full-service, primary distributor members nationwide, including 10 who do business in Kansas.

HDMA staff has worked with legislators and regulators in over 25 states in their efforts to strengthen the prescription drug supply chain. This includes participating in stakeholder meetings organized by the Kansas Board of Pharmacy and testifying before the legislature last year.

HDMA and its members fully support stronger licensure requirements, increased criminal penalties, and effective and efficient pedigree requirements to secure the supply chain.

With all do respect, this 28 page bill should be addressed at the Board of Pharmacy. The language mirrors the NABP Model Rules not the four page NABP Model Bill. Those who were present at the November 2006 Board Stakeholders meeting agreed that the legislature should address a much shorter version, leaving the details to be worked out in rulemaking.

We were discouraged to see that the longer version was introduced. The most important stakeholder in all of this is the Board of Pharmacy. We don't see the logic in moving forward with a proposal that the state regulatory authority may not be fully supportive of.

Time permitting, our specific concerns include, but are not limited to, the following issues:

-- Clarification that electronic pedigrees must start with the manufacturer.

-- Language regarding "unknowingly" penalties language.

-- More specifics on the use of third party accreditation programs.

-- An explanation regarding the manufacturers exemption from stronger licensing requirements.

Thank you for this opportunity to testify today and I would be happy to take any questions.

House Health and Human Services
DATE: 2-14-07
ATTACHMENT 5

KANSAS

BOARD OF PHARMACY
DEBRA L. BILLINGSLEY, EXECUTIVE DIRECTOR

KATHLEEN SEBELIUS, GOVERNOR

Testimony re: HB 2392
House Health and Human Services
Presented by Debra L. Billingsley
February 14, 2007

Chairperson Landwehr and Members of the Committee:

My name is Debra Billingsley, and I am the Executive Director of the Kansas State Board of Pharmacy. The Board of Pharmacy has the responsibility for safeguarding the state's drug supply and regulating those involved in the distribution of medications.

In 2006 the legislature mandated that the Board of Pharmacy conduct a task force to study the issue of counterfeit drugs, pedigrees for prescription drugs, penalty aspects for violation of pedigree requirements, and registration requirements of wholesale distributors. The Board met on numerous occasions and the meetings were facilitated by an associate of the National Association of Boards of Pharmacy. There were at least twenty different entities represented at the meetings including the Board of Pharmacy, the Kansas Legislature, Kansas Pharmacy Association, animal health distributors, manufacturers, mail order pharmacy, distributors, community pharmacy, chain pharmacy, and hospital pharmacy.

After an extensive review of the issues the Board determined that there was a need for changes in the wholesale distribution process. First, they determined that increased requirements for registration was critical to make sure that entities met the minimum standards. This was a noncontroversial item and everyone agreed that the Board's registration and accreditation standards needed to be increased. Everyone agreed that the Board needed to provide a more in-depth application process and establish standards for surety bonds; registration and periodic inspections; certification of a designated representative; designation of a registered agent; storage of drugs and devices; handling, transportation, and shipment of all drugs and devices; security; examination of drugs and devices and treatment of those found to be unacceptable as defined by the Board; due diligence regarding the wholesale distribution; and creation and maintenance of records, including transaction records, and procedures for operation. Therefore, it was determined that the first step in combating counterfeit drugs was to set high standards for registration of all distributors shipping into Kansas. The task force also agreed that there should be increased penalties against those entities that violated any provision of the Pharmacy Act.

The task force did not come to agreement regarding the provision related to pedigree. This was based on several factors. First, there was not a consensus on when the pedigree

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should begin. The manufacturers wanted the pedigree to begin with the distributor while every other entity in the group felt that it should begin with the manufacturer. Individuals responsible for wholesale manufacturing facilities have a responsibility to prevent counterfeiting and it should begin at their level. The bill does not address this responsibility and is a major stumbling block in opposing pedigree.

Secondly, the availability of today's emerging technologies, such as radio frequency identification for electronic pedigrees is not commonly available. The task force and the Board agreed that paper pedigrees are of little value. They can be forged so they do nothing to combat against counterfeiting. The electronic pedigree will definitely provide future improvements to the integrity of the drug supply chain. However, those capabilities are not available at this time. The states that have legislated electronic pedigrees have pushed their implementation date back every year because there is no efficient or effective uniform system readily available. Further, no one knows the costs regarding these efforts.

Lastly, the FDA implemented regulations in the Prescription Drug Marketing Act (PDMA) which mandated pedigrees. The task force considered the regulations and worked on efforts to fill any areas that the PDMA did not address. However, in December of 2006 a group of independent pharmaceutical companies sued the FDA in Federal Court seeking an injunction that would prohibit the regulations from becoming effective. On December 11, 2006, the Federal District Court in the Eastern District of New York issued a preliminary injunction finding that the pharmaceutical companies had shown a substantial likelihood of success on their claim that the regulations were unconstitutional. With the federal scheme being potentially declared illegal, this does not seem a good time to try to devise a state system for pedigree.

The Board of Pharmacy would submit that there needs to be more stringent requirements for registration of wholesale distributors. The Board believes that increasing the registration requirements is needed regardless of whether there is pedigree. We are providing a copy of bill language that would provide additional requirements and safeguards to the drug distribution channels. This will minimize the risks of counterfeit drugs. The Board believes that the pedigree issue needs further study. It is not critical that pedigree be made law at this time since it is not available in any state electronically.

Debra Billingsley
Executive Secretary

65-1626. Definitions. For the purposes of this act:

(a) "Administer" means the direct application of a drug, whether by injection, inhalation, ingestion or any other means, to the body of a patient or research subject by:

(1) A practitioner or pursuant to the lawful direction of a practitioner;

(2) the patient or research subject at the direction and in the presence of the practitioner; or

(3) a pharmacist as authorized in K.S.A. 65-1635a and amendments thereto.

(b) "Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor or dispenser but shall not include a common carrier, public warehouseman or employee of the carrier or warehouseman when acting in the usual and lawful course of the carrier's or warehouseman's business.

(c) "Board" means the state board of pharmacy created by K.S.A. 74-1603 and amendments thereto.

(d) "Brand exchange" means the dispensing of a different drug product of the same dosage form and strength and of the same generic name than the brand name drug product prescribed.

(e) "Brand name" means the registered trademark name given to a drug product by its manufacturer, labeler or distributor.

(f) "Deliver" or "delivery" means the actual, constructive or attempted transfer from one person to another of any drug whether or not an agency relationship exists.

(g) "Direct supervision" means the process by which the responsible pharmacist shall observe and direct the activities of a pharmacy student or pharmacy technician to a sufficient degree to assure that all such activities are performed accurately, safely and without risk or harm to patients, and complete the final check before dispensing.

(h) "Dispense" means to deliver prescription medication to the ultimate user or research subject by or pursuant to the lawful order of a practitioner or pursuant to the prescription of a mid-level practitioner.

(i) "Dispenser" means a practitioner or pharmacist who dispenses prescription medication.

(j) "Distribute" means to deliver, other than by administering or dispensing, any drug.

(k) "Distributor" means a person who distributes a drug.

(l) "Drug" means: (1) Articles recognized in the official United States pharmacopoeia, or other such official compendiums of the United States, or official national formulary, or any supplement of any of them; (2) articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals; (3) articles, other than food, intended to affect the structure or any function of the body of man or other animals; and (4) articles intended for use as a component of any articles specified in clause (1), (2) or (3) of this subsection; but does not include devices or their components, parts or accessories, except that the term "drug" shall not include amygdalin (laetrile) or any livestock remedy, if such livestock remedy had been registered in accordance with the provisions of article 5 of chapter 47 of the Kansas Statutes Annotated prior to its repeal.

(m)"Durable Medical Equipment" means technologically sophisticated medical devices that may be used in a residence, including the following: (1) Oxygen and oxygen delivery system; (2) Ventilators; (3) Respiratory disease management devices; (4) Continuous positive airway pressure (CPAP) devices; (5) Electronic and computerized wheelchairs and seating systems; (6) Apnea monitors; (7) Transcutaneous electrical nerve stimulator (TENS) units; (8) Low air loss cutaneous pressure management devices; (9) Sequential compression devices; (10) Feeding pumps; (11) Home phototherapy devices; (12) Infusion delivery devices; (13) Distribution of medical gases to end users for human consumption; (14) Hospital beds; (15) Nebulizers; (16) Other similar equipment determined by the Board in rules and regulations adopted by the Board.

(n) "Electronic transmission" means transmission of information in electronic form or the transmission of the exact visual image of a document by way of electronic equipment.

(o) "Generic name" means the established chemical name or official name of a drug or drug product.

(p) (1) "Institutional drug room" means any location where prescription-only drugs are stored and from which prescription-only drugs are administered or dispensed and which is maintained or operated for the purpose of providing the drug needs of:

(A) Inmates of a jail or correctional institution or facility;

(B) residents of a juvenile detention facility, as defined by the Kansas code for care of children and the Kansas juvenile justice code;

(C) students of a public or private university or college, a community college or any other institution of higher learning which is located in Kansas;

(D) employees of a business or other employer; or

(E) persons receiving inpatient hospice services.

(2) "Institutional drug room" does not include:

(A) Any registered pharmacy;

(B) any office of a practitioner; or

(C) a location where no prescription-only drugs are dispensed and no prescription-only drugs other than individual prescriptions are stored or administered.

(q) "Medical care facility" shall have the meaning provided in K.S.A. 65-425 and amendments thereto, except that the term shall also include facilities licensed under the provisions of K.S.A. 75-3307b and amendments thereto except community mental health centers and facilities for the mentally retarded.

(r) "Manufacture" means the production, preparation, propagation, compounding, conversion or processing of a drug either directly or indirectly by extraction from substances of natural origin, independently by means of chemical synthesis or by a combination of extraction and chemical synthesis and includes any packaging or repackaging of the drug or labeling or relabeling of its container, except that this term shall not include the preparation or compounding of a drug by an individual for the individual's own use or the preparation, compounding, packaging or labeling of a drug by: (1) A practitioner or a practitioner's authorized agent incident to such practitioner's administering or dispensing of a drug in the course of the practitioner's professional practice; (2) a practitioner, by a practitioner's authorized agent or under a practitioner's supervision for the purpose of, or as an incident to, research, teaching or chemical analysis and not for sale; or (3) a pharmacist or the pharmacist's authorized agent acting under the direct supervision of the pharmacist for the purpose of, or incident to, the dispensing of a drug by the pharmacist.

(s) "Person" means individual, corporation, government, governmental subdivision or agency, partnership, association or any other legal entity.

(t) "Pharmacist" means any natural person licensed under this act to practice pharmacy.

(u) "Pharmacist in charge" means the pharmacist who is responsible to the board for a registered establishment's compliance with the laws and regulations of this state pertaining to the practice of pharmacy, manufacturing of drugs and the distribution of drugs. The pharmacist in charge shall supervise such establishment on a full-time or a part-time basis and perform such other duties relating to supervision of a registered establishment as may be prescribed by the board by rules and regulations. Nothing in this definition shall relieve other pharmacists or persons from their responsibility to comply with state and federal laws and regulations.

(v) "Pharmacy," "drug store" or "apothecary" means premises, laboratory, area or other place: (1) Where drugs are offered for sale where the profession of pharmacy is practiced and where prescriptions are compounded and dispensed; or (2) which has displayed upon it or within it the words "pharmacist," "pharmaceutical chemist," "pharmacy," "apothecary," "drugstore," "druggist," "drugs," "drug sundries" or any of these words or

combinations of these words or words of similar import either in English or any sign containing any of these words; or (3) where the characteristic symbols of pharmacy or the characteristic prescription sign "Rx" may be exhibited. As used in this subsection, premises refers only to the portion of any building or structure leased, used or controlled by the licensee in the conduct of the business registered by the board at the address for which the registration was issued.

(w) "Pharmacy student" means an individual, registered with the board of pharmacy, enrolled in an accredited school of pharmacy.

(x) "Pharmacy technician" means an individual who, under the direct supervision and control of a pharmacist, may perform packaging, manipulative, repetitive or other nondiscretionary tasks related to the processing of a prescription or medication order and who assists the pharmacist in the performance of pharmacy related duties, but who does not perform duties restricted to a pharmacist.

(y) "Practitioner" means a person licensed to practice medicine and surgery, dentist, podiatrist, veterinarian, optometrist licensed under the optometry law as a therapeutic licensee or diagnostic and therapeutic licensee, or scientific investigator or other person authorized by law to use a prescription-only drug in teaching or chemical analysis or to conduct research with respect to a prescription-only drug.

(z) "Preceptor" means a licensed pharmacist who possesses at least two years' experience as a pharmacist and who supervises students obtaining the pharmaceutical experience required by law as a condition to taking the examination for licensure as a pharmacist.

(aa) "Prescription" means, according to the context, either a prescription order or a prescription medication.

(bb) "Prescription medication" means any drug, including label and container according to context, which is dispensed pursuant to a prescription order.

(cc) "Prescription-only drug" means any drug whether intended for use by man or animal, required by federal or state law (including 21 United States Code section 353, as amended) to be dispensed only pursuant to a written or oral prescription or order of a practitioner or is restricted to use by practitioners only.

(dd) "Prescription order" means: (1) An order to be filled by a pharmacist for prescription medication issued and signed by a practitioner or a mid-level practitioner in the authorized course of professional practice; or (2) an order transmitted to a pharmacist through word of mouth, note, telephone or other means of communication directed by such practitioner or mid-level practitioner.

(ee) "Probation" means the practice or operation under a temporary license, registration or permit or a conditional license, registration or permit of a business or profession for which a license, registration or permit is granted by the board under the provisions of the

pharmacy act of the state of Kansas requiring certain actions to be accomplished or certain actions not to occur before a regular license, registration or permit is issued.

(ff) "Professional incompetency" means:

(1) One or more instances involving failure to adhere to the applicable standard of pharmaceutical care to a degree which constitutes gross negligence, as determined by the board;

(2) repeated instances involving failure to adhere to the applicable standard of pharmaceutical care to a degree which constitutes ordinary negligence, as determined by the board; or

(3) a pattern of pharmacy practice or other behavior which demonstrates a manifest incapacity or incompetence to practice pharmacy.

(gg) "Retail dealer" means a person selling at retail nonprescription drugs which are prepackaged, fully prepared by the manufacturer or distributor for use by the consumer and labeled in accordance with the requirements of the state and federal food, drug and cosmetic acts. Such nonprescription drugs shall not include: (1) A controlled substance; (2) a prescription-only drug; or (3) a drug intended for human use by hypodermic injection.

(hh) "Secretary" means the executive secretary of the board.

(ii) "Unprofessional conduct" means:

(1) Fraud in securing a registration or permit;

(2) intentional adulteration or mislabeling of any drug, medicine, chemical or poison;

(3) causing any drug, medicine, chemical or poison to be adulterated or mislabeled, knowing the same to be adulterated or mislabeled;

(4) intentionally falsifying or altering records or prescriptions;

(5) unlawful possession of drugs and unlawful diversion of drugs to others;

(6) willful betrayal of confidential information under K.S.A. 65-1654 and amendments thereto;

(7) conduct likely to deceive, defraud or harm the public;

(8) making a false or misleading statement regarding the licensee's professional practice or the efficacy or value of a drug;

(9) commission of any act of sexual abuse, misconduct or exploitation related to the licensee's professional practice; or

(10) performing unnecessary tests, examinations or services which have no legitimate pharmaceutical purpose.

(jj) "Mid-level practitioner" means an advanced registered nurse practitioner issued a certificate of qualification pursuant to K.S.A. 65-1131 and amendments thereto who has authority to prescribe drugs pursuant to a written protocol with a responsible physician under K.S.A. 65-1130 and amendments thereto or a physician assistant licensed pursuant to the physician assistant licensure act who has authority to prescribe drugs pursuant to a written protocol with a responsible physician under K.S.A. 65-28a08 and amendments thereto.

(kk) "Vaccination protocol" means a written protocol, agreed to by a pharmacist and a person licensed to practice medicine and surgery by the state board of healing arts, which establishes procedures and recordkeeping and reporting requirements for administering a vaccine by the pharmacist for a period of time specified therein, not to exceed two years.

(ll) "Veterinary medical teaching hospital pharmacy" means any location where prescription-only drugs are stored as part of an accredited college of veterinary medicine and from which prescription-only drugs are distributed for use in treatment of or administration to a non-human.

History: L. 1953, ch. 290, § 3; L. 1975, ch. 319, § 2; L. 1977, ch. 217, § 1; L. 1978, ch. 242, § 1; L. 1978, ch. 243, § 1; L. 1979, ch. 193, § 1; L. 1982, ch. 182, § 138; L. 1986, ch. 235, § 1; L. 1986, ch. 231, § 9; L. 1986, ch. 236, § 1; L. 1987, ch. 235, § 5; L. 1987, ch. 236, § 1; L. 1988, ch. 297, § 2; L. 1989, ch. 193, § 1; L. 1989, ch. 192, § 2; L. 1989, ch. 192, § 3; L. 1991, ch. 272, § 10; L. 1996, ch. 229, § 118; L. 1997, ch. 112, § 1; L. 1999, ch. 38, § 1; L. 1999, ch. 149, § 6; L. 2000, ch. 89, § 1; L. 2000, ch. 159, § 10; L. 2001, ch. 31, § 1; L. 2002, ch. 25, § 2; L. 2003, ch. 124, § 8; July 1.

65-1627. Grounds for revocation, suspension, placement in probationary status, denial, temporary suspension or temporary limitation of license for pharmacist, permit for retail dealer or registration for pharmacy or manufacturer or distributor; procedure. (a) The board may revoke, suspend, place in a probationary status or deny a renewal of any license of any pharmacist upon a finding that:

(1) The license was obtained by fraudulent means;

(2) the licensee has been convicted of a felony and the licensee fails to show that the licensee has been sufficiently rehabilitated to warrant the public trust;

(3) the licensee is found by the board to be guilty of unprofessional conduct or professional incompetency;

(4) the licensee is addicted to the liquor or drug habit to such a degree as to render the licensee unfit to practice the profession of pharmacy;

(5) the licensee has violated a provision of the federal or state food, drug and cosmetic act, the uniform controlled substances act of the state of Kansas, or any rule and regulation adopted under any such act;

(6) the licensee is found by the board to have filled a prescription not in strict accordance with the directions of the practitioner or a mid-level practitioner;

(7) the licensee is found to be mentally or physically incapacitated to such a degree as to render the licensee unfit to practice the profession of pharmacy;

(8) the licensee has violated any of the provisions of the pharmacy act of the state of Kansas or any rule and regulation adopted by the board pursuant to the provisions of such pharmacy act;

(9) the licensee has failed to comply with the requirements of the board relating to the continuing education of pharmacists;

(10) the licensee as a pharmacist in charge or consultant pharmacist under the provisions of subsection (c) or (d) of K.S.A. 65-1648 and amendments thereto has failed to comply with the requirements of subsection (c) or (d) of K.S.A. 65-1648 and amendments thereto;

(11) the licensee has knowingly submitted a misleading, deceptive, untrue or fraudulent misrepresentation on a claim form, bill or statement;

(12) the licensee has had a license to practice pharmacy revoked, suspended or limited, has been censured or has had other disciplinary action taken, or voluntarily surrendered the license after formal proceedings have been commenced, or has had an application for license denied, by the proper licensing authority of another state, territory, District of

Columbia or other country, a certified copy of the record of the action of the other jurisdiction being conclusive evidence thereof;

(13) the licensee has self-administered any controlled substance without a practitioner's prescription order or a mid-level practitioner's prescription order; or

(14) the licensee has assisted suicide in violation of K.S.A. 21-3406 and amendments thereto as established by any of the following:

(A) A copy of the record of criminal conviction or plea of guilty for a felony in violation of K.S.A. 21-3406 and amendments thereto.

(B) A copy of the record of a judgment of contempt of court for violating an injunction issued under K.S.A. 2002 Supp. 60-4404 and amendments thereto.

(C) A copy of the record of a judgment assessing damages under K.S.A. 2002 Supp. 60-4405 and amendments thereto; or

(15) the licensee has failed to furnish the board, its investigators or its representatives any information legally requested by the board.

(b) In determining whether or not the licensee has violated subsection (a)(3), (a)(4), (a)(7) or (a)(13), the board upon reasonable suspicion of such violation has authority to compel a licensee to submit to mental or physical examination or drug screen, or any combination thereof, by such persons as the board may designate. To determine whether reasonable suspicion of such violation exists, the investigative information shall be presented to the board as a whole. Information submitted to the board as a whole and all reports, findings and other records shall be confidential and not subject to discovery by or release to any person or entity. The licensee shall submit to the board a release of information authorizing the board to obtain a report of such examination or drug screen, or both. A person affected by this subsection shall be offered, at reasonable intervals, an opportunity to demonstrate that such person can resume the competent practice of pharmacy with reasonable skill and safety to patients. For the purpose of this subsection, every person licensed to practice pharmacy and who shall accept the privilege to practice pharmacy in this state by so practicing or by the making and filing of a renewal application to practice pharmacy in this state shall be deemed to have consented to submit to a mental or physical examination or a drug screen, or any combination thereof, when directed in writing by the board and further to have waived all objections to the admissibility of the testimony, drug screen or examination report of the person conducting such examination or drug screen, or both, at any proceeding or hearing before the board on the ground that such testimony or examination or drug screen report constitutes a privileged communication. In any proceeding by the board pursuant to the provisions of this subsection, the record of such board proceedings involving the mental and physical examination or drug screen, or any combination thereof, shall not be used in any other administrative or judicial proceeding.

(c) The board may temporarily suspend or temporarily limit the license of any licensee in accordance with the emergency adjudicative proceedings under the Kansas administrative procedure act if the board determines that there is cause to believe that grounds exist for disciplinary action under subsection (a) against the licensee and that the licensee's continuation in practice would constitute an imminent danger to the public health and safety.

(d) The board may suspend, revoke, place in a probationary status or deny a renewal of any retail dealer's permit issued by the board when information in possession of the board discloses that such operations for which the permit was issued are not being conducted according to law or the rules and regulations of the board.

(e) The board may revoke, suspend, place in a probationary status or deny a renewal of the registration of a pharmacy upon a finding that: (1) Such pharmacy has been operated in such manner that violations of the provisions of the pharmacy act of the state of Kansas or of the rules and regulations of the board have occurred in connection therewith; (2) the owner or any pharmacist employed at such pharmacy is convicted, subsequent to such owner's acquisition of or such employee's employment at such pharmacy, of a violation of the pharmacy act or uniform controlled substances act of the state of Kansas, or the federal or state food, drug and cosmetic act; (3) the owner or any pharmacist employed by such pharmacy has fraudulently claimed money for pharmaceutical services; or (4) the registrant has had a registration revoked, suspended or limited, has been censured or has had other disciplinary action taken, or an application for registration denied, by the proper registering authority of another state, territory, District of Columbia or other country, a certified copy of the record of the action of the other jurisdiction being conclusive evidence thereof.

(f) A registration to manufacture~~, or~~ to distribute at wholesale a drug, *or to sell durable medical equipment* or a registration for the place of business where any such operation is conducted may be suspended, revoked, placed in a probationary status or the renewal of such registration may be denied by the board upon a finding that the registrant or the registrant's agent: (1) Has materially falsified any application filed pursuant to or required by the pharmacy act of the state of Kansas; (2) has been convicted of a felony under any federal or state law relating to the manufacture or distribution of drugs; (3) has had any federal registration for the manufacture or distribution of drugs suspended or revoked; (4) has refused to permit the board or its duly authorized agents to inspect the registrant's establishment in accordance with the provisions of K.S.A. 65-1629 and amendments thereto; (5) has failed to keep, or has failed to file with the board or has falsified records required to be kept or filed by the provisions of the pharmacy act of the state of Kansas or by the board's rules and regulations; or (6) has violated the pharmacy act of the state of Kansas or rules and regulations adopted by the state board of pharmacy under the pharmacy act of the state of Kansas or has violated the uniform controlled substances act or rules and regulations adopted by the state board of pharmacy under the uniform controlled substances act.

(g) Orders under this section, and proceedings thereon, shall be subject to the provisions of the Kansas administrative procedure act.

History: L. 1953, ch. 290, § 13; L. 1965, ch. 369, § 5; L. 1972, ch. 231, § 5; L. 1975, ch. 319, § 3; L. 1982, ch. 262, § 1; L. 1984, ch. 313, § 106; L. 1986, ch. 235, § 2; L. 1986, ch. 231, § 10; L. 1986, ch. 234, § 3; L. 1988, ch. 356, § 195; L. 1989, ch. 193, § 2; L. 1991, ch. 187, § 1; L. 1994, ch. 118, § 2; L. 1995, ch. 106, § 1; L. 1998, ch. 98, § 1; L. 1999, ch. 38, § 3; L. 1999, ch. 149, § 7; April 1, 2000.

65-1643. Registration or permit required; pharmacies, manufacturers, wholesalers, auctions, sales, distribution or dispensing of samples, retailers, institutional drug rooms, pharmacy students, veterinary medical teaching hospital pharmacies; certain acts declared unlawful. It shall be unlawful:

(a) For any person to operate, maintain, open or establish any pharmacy within this state without first having obtained a registration from the board. Each application for registration of a pharmacy shall indicate the person or persons desiring the registration, including the pharmacist in charge, as well as the location, including the street name and number, and such other information as may be required by the board to establish the identity and exact location of the pharmacy. The issuance of a registration for any pharmacy shall also have the effect of permitting such pharmacy to operate as a retail dealer without requiring such pharmacy to obtain a retail dealer's permit. On evidence satisfactory to the board: (1) That the pharmacy for which the registration is sought will be conducted in full compliance with the law and the rules and regulations of the board; (2) that the location and appointments of the pharmacy are such that it can be operated and maintained without endangering the public health or safety; (3) that the pharmacy will be under the supervision of a pharmacist, a registration shall be issued to such persons as the board shall deem qualified to conduct such a pharmacy.

(b) For any person to manufacture within this state any drugs except under the personal and immediate supervision of a pharmacist or such other person or persons as may be approved by the board after an investigation and a determination by the board that such person or persons is qualified by scientific or technical training or experience to perform such duties of supervision as may be necessary to protect the public health and safety; and no person shall manufacture any such drugs without first obtaining a registration so to do from the board. Such registration shall be subject to such rules and regulations with respect to requirements, sanitation and equipment, as the board may from time to time adopt for the protection of public health and safety.

(c) For any person to distribute at wholesale any drugs without first obtaining a registration so to do from the board.

(d) For any person to sell or offer for sale at public auction or private sale in a place where public auctions are conducted, any drugs without first having obtained a registration from the board so to do, and it shall be necessary to obtain the permission of the board in every instance where any of the products covered by this section are to be sold or offered for sale.

(e) For any person to in any manner distribute or dispense samples of any drugs without first having obtained a permit from the board so to do, and it shall be necessary to obtain permission from the board in every instance where the samples are to be distributed or dispensed. Nothing in this subsection shall be held to regulate or in any manner interfere with the furnishing of samples of drugs to duly licensed practitioners, to mid-level practitioners, to pharmacists or to medical care facilities.

(f) Except as otherwise provided in this subsection (f), for any person operating a store or place of business to sell, offer for sale or distribute any drugs to the public without first having obtained a registration or permit from the board authorizing such person so to do. No retail dealer who sells 12 or fewer different nonprescription drug products shall be required to obtain a retail dealer's permit under the pharmacy act of the state of Kansas or to pay a retail dealer new permit or permit renewal fee under such act. It shall be lawful for a retail dealer who is the holder of a valid retail dealer's permit issued by the board or for a retail dealer who sells 12 or fewer different nonprescription drug products to sell and distribute nonprescription drugs which are prepackaged, fully prepared by the manufacturer or distributor for use by the consumer and labeled in accordance with the requirements of the state and federal food, drug and cosmetic acts. Such nonprescription drugs shall not include: (1) A controlled substance; (2) a prescription-only drug; or (3) a drug product intended for human use by hypodermic injection; but such a retail dealer shall not be authorized to display any of the words listed in subsection (u) of K.S.A. 65-1626 and amendments thereto, for the designation of a pharmacy or drugstore.

(g) For any person to sell any drugs manufactured and sold only in the state of Kansas, unless the label and directions on such drugs shall first have been approved by the board.

(h) For any person to operate an institutional drug room without first having obtained a registration to do so from the board. Such registration shall be subject to the provisions of K.S.A. 65-1637a and amendments thereto and any rules and regulations adopted pursuant thereto.

(i) For any person to be a pharmacy student without first obtaining a registration to do so from the board, in accordance with rules and regulations adopted by the board, and paying a pharmacy student registration fee of $25 to the board.

(j) For any person to operate a veterinary medical teaching hospital pharmacy without first having obtained a registration to do so from the board. Such registration shall be subject to the provisions of K.S.A. 65-1662 and amendments thereto and any rules and regulations adopted pursuant thereto.

(k) For any person to sell or distribute in a pharmacy a controlled substance designated in subsection (e) or (f) of K.S.A. 65-4113, and amendments thereto, unless:

(A) Such controlled substances is sold or distributed by a licensed pharmacist, a registered pharmacy technician or a pharmacy intern or clerk supervised by a licensed pharmacist; and

(B) any person purchasing, receiving or otherwise acquiring any such controlled substances produces a photo identification showing the date of birth of the person and signs a log. The log or database required by the board shall be available for inspection during regular business hours to the board of pharmacy and any law enforcement officer; or

(l) For any person to sell or distribute in a pharmacy four or more packages or containers of any controlled substance designated in subsection (e) or (f) of K.S.A. 65-4113, and amendments thereto, to a specific customer within any seven-day period.

(m) *For any person to sell or offer for sale durable medical equipment without first obtaining a registration from the Board.*

History: L. 1953, ch. 290, § 29; L. 1967, ch. 342, § 3; L. 1975, ch. 319, § 29; L. 1979, ch. 193, § 3; L. 1982, ch. 263, § 7; L. 1983, ch. 210, § 2; L. 1986, ch. 231, § 29; L. 1997, ch. 112, § 3; L. 1997, ch. 184, § 2; L. 1999, ch. 38, § 5; L. 1999, ch. 149, § 8; L. 2000, ch. 89, § 2; Apr. 27.

65-1626. Definitions. For the purposes of this act:

(a) "Administer" means the direct application of a drug, whether by injection, inhalation, ingestion or any other means, to the body of a patient or research subject by:

(1) A practitioner or pursuant to the lawful direction of a practitioner;

(2) the patient or research subject at the direction and in the presence of the practitioner; or

(3) a pharmacist as authorized in K.S.A. 65-1635a and amendments thereto.

(b) "Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor or dispenser but shall not include a common carrier, public warehouseman or employee of the carrier or warehouseman when acting in the usual and lawful course of the carrier's or warehouseman's business.

(c) "Board" means the state board of pharmacy created by K.S.A. 74-1603 and amendments thereto.

(d) "Brand exchange" means the dispensing of a different drug product of the same dosage form and strength and of the same generic name than the brand name drug product prescribed.

(e) "Brand name" means the registered trademark name given to a drug product by its manufacturer, labeler or distributor.

(f) *"Chain Pharmacy Warehouse" means a permanent physical location for Drugs and/or devices that act as a cen tral warehouse and performs intracompany sales and transfers of Prescription Drugs or Devices to chain Pharmacies, which are members of the same affiliated group, under common ownership and control. Chain Pharmacy Warehouses must be licensed as Wholesale Distributors.*

(g) *"Co-licensee" means a pharmaceutical manufacturer that has entered into an agreement with another pharmaceutical manufacturers to engage in a business activity or occupation related to the manufacture or distribution of a Prescription Drug and the National Drug Code on the drug productlabel shall be used to determine the identity of the drug manufacturer.*

(h) "Deliver" or "delivery" means the actual, constructive or attempted transfer from one person to another of any drug whether or not an agency relationship exists.

(i) "Direct supervision" means the process by which the responsible pharmacist shall observe and direct the activities of a pharmacy student or pharmacy technician to a

sufficient degree to assure that all such activities are performed accurately, safely and without risk or harm to patients, and complete the final check before dispensing.

(j) "Dispense" means to deliver prescription medication to the ultimate user or research subject by or pursuant to the lawful order of a practitioner or pursuant to the prescription of a mid-level practitioner.

(k) "Dispenser" means a practitioner or pharmacist who dispenses prescription medication.

(l) "Distribute" means to deliver, other than by administering or dispensing, any drug.

(m) "Distributor" means a person who distributes a drug.

(n) "Drug" means: (1) Articles recognized in the official United States pharmacopoeia, or other such official compendiums of the United States, or official national formulary, or any supplement of any of them; (2) articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals; (3) articles, other than food, intended to affect the structure or any function of the body of man or other animals; and (4) articles intended for use as a component of any articles specified in clause (1), (2) or (3) of this subsection; but does not include devices or their components, parts or accessories, except that the term "drug" shall not include amygdalin (laetrile) or any livestock remedy, if such livestock remedy had been registered in accordance with the provisions of article 5 of chapter 47 of the Kansas Statutes Annotated prior to its repeal.

(o) *"Exclusive Distributor" means any entity that:*

(A) Contracts with a Manufacturer to provide or coordinate warehousing, Wholesale Distribution, or other services on behalf of a Manufacturer and who takes title to that Manufacturer's Prescription Drug, but who does not have general responsibility to direct the sale or disposition of the Manufacturer's Prescription Drug;

(B) Is licensed as a Wholesale Distributor under this chapter; and

© To be considered part of the National Distribution Channel, must be an Authorized Distributor of Record.

(o) "Electronic transmission" means transmission of information in electronic form or the transmission of the exact visual image of a document by way of electronic equipment.

(p) "Generic name" means the established chemical name or official name of a drug or drug product.

(q) (1) "Institutional drug room" means any location where prescription-only drugs are stored and from which prescription-only drugs are administered or dispensed and which is maintained or operated for the purpose of providing the drug needs of:

(A) Inmates of a jail or correctional institution or facility;

(B) residents of a juvenile detention facility, as defined by the Kansas code for care of children and the Kansas juvenile justice code;

(C) students of a public or private university or college, a community college or any other institution of higher learning which is located in Kansas;

(D) employees of a business or other employer; or

(E) persons receiving inpatient hospice services.

(2) "Institutional drug room" does not include:

(A) Any registered pharmacy;

(B) any office of a practitioner; or

(C) a location where no prescription-only drugs are dispensed and no prescription-only drugs other than individual prescriptions are stored or administered.

(r) "Medical care facility" shall have the meaning provided in K.S.A. 65-425 and amendments thereto, except that the term shall also include facilities licensed under the provisions of K.S.A. 75-3307b and amendments thereto except community mental health centers and facilities for the mentally retarded.

(s) "Manufacture" means the production, preparation, propagation, compounding, conversion or processing of a drug either directly or indirectly by extraction from substances of natural origin, independently by means of chemical synthesis or by a combination of extraction and chemical synthesis and includes any packaging or repackaging of the drug or labeling or relabeling of its container, except that this term shall not include the preparation or compounding of a drug by an individual for the individual's own use or the preparation, compounding, packaging or labeling of a drug by: (1) A practitioner or a practitioner's authorized agent incident to such practitioner's administering or dispensing of a drug in the course of the practitioner's professional practice; (2) a practitioner, by a practitioner's authorized agent or under a practitioner's supervision for the purpose of, or as an incident to, research, teaching or chemical analysis and not for sale; or (3) a pharmacist or the pharmacist's authorized agent acting under the direct supervision of the pharmacist for the purpose of, or incident to, the dispensing of a drug by the pharmacist.

(t) "Person" means individual, corporation, government, governmental subdivision or agency, partnership, association or any other legal entity.

(u) "Pharmacist" means any natural person licensed under this act to practice pharmacy.

(v) "Pharmacist in charge" means the pharmacist who is responsible to the board for a registered establishment's compliance with the laws and regulations of this state pertaining to the practice of pharmacy, manufacturing of drugs and the distribution of drugs. The pharmacist in charge shall supervise such establishment on a full-time or a part-time basis and perform such other duties relating to supervision of a registered establishment as may be prescribed by the board by rules and regulations. Nothing in this definition shall relieve other pharmacists or persons from their responsibility to comply with state and federal laws and regulations.

(w) "Pharmacy," "drug store" or "apothecary" means premises, laboratory, area or other place: (1) Where drugs are offered for sale where the profession of pharmacy is practiced and where prescriptions are compounded and dispensed; or (2) which has displayed upon it or within it the words "pharmacist," "pharmaceutical chemist," "pharmacy," "apothecary," "drugstore," "druggist," "drugs," "drug sundries" or any of these words or combinations of these words or words of similar import either in English or any sign containing any of these words; or (3) where the characteristic symbols of pharmacy or the characteristic prescription sign "Rx" may be exhibited. As used in this subsection, premises refers only to the portion of any building or structure leased, used or controlled by the licensee in the conduct of the business registered by the board at the address for which the registration was issued.

(x) "Pharmacy student" means an individual, registered with the board of pharmacy, enrolled in an accredited school of pharmacy.

(y) "Pharmacy technician" means an individual who, under the direct supervision and control of a pharmacist, may perform packaging, manipulative, repetitive or other nondiscretionary tasks related to the processing of a prescription or medication order and who assists the pharmacist in the performance of pharmacy related duties, but who does not perform duties restricted to a pharmacist.

(z) "Practitioner" means a person licensed to practice medicine and surgery, dentist, podiatrist, veterinarian, optometrist licensed under the optometry law as a therapeutic licensee or diagnostic and therapeutic licensee, or scientific investigator or other person authorized by law to use a prescription-only drug in teaching or chemical analysis or to conduct research with respect to a prescription-only drug.

(aa) "Preceptor" means a licensed pharmacist who possesses at least two years' experience as a pharmacist and who supervises students obtaining the pharmaceutical experience required by law as a condition to taking the examination for licensure as a pharmacist.

(bb) "Prescription" means, according to the context, either a prescription order or a prescription medication.

(cc) "Prescription medication" means any drug, including label and container according to context, which is dispensed pursuant to a prescription order.

(dd) "Prescription-only drug" means any drug whether intended for use by man or animal, required by federal or state law (including 21 United States Code section 353, as amended) to be dispensed only pursuant to a written or oral prescription or order of a practitioner or is restricted to use by practitioners only.

(ee) "Prescription order" means: (1) An order to be filled by a pharmacist for prescription medication issued and signed by a practitioner or a mid-level practitioner in the authorized course of professional practice; or (2) an order transmitted to a pharmacist through word of mouth, note, telephone or other means of communication directed by such practitioner or mid-level practitioner.

(ff) "Probation" means the practice or operation under a temporary license, registration or permit or a conditional license, registration or permit of a business or profession for which a license, registration or permit is granted by the board under the provisions of the pharmacy act of the state of Kansas requiring certain actions to be accomplished or certain actions not to occur before a regular license, registration or permit is issued.

(gg) "Professional incompetency" means:

(1) One or more instances involving failure to adhere to the applicable standard of pharmaceutical care to a degree which constitutes gross negligence, as determined by the board;

(2) repeated instances involving failure to adhere to the applicable standard of pharmaceutical care to a degree which constitutes ordinary negligence, as determined by the board; or

(3) a pattern of pharmacy practice or other behavior which demonstrates a manifest incapacity or incompetence to practice pharmacy.

(hh) "Retail dealer" means a person selling at retail nonprescription drugs which are prepackaged, fully prepared by the manufacturer or distributor for use by the consumer and labeled in accordance with the requirements of the state and federal food, drug and cosmetic acts. Such nonprescription drugs shall not include: (1) A controlled substance; (2) a prescription-only drug; or (3) a drug intended for human use by hypodermic injection.

(ii) "Secretary" means the executive secretary of the board.

(jj) "Third Party Logistics Provider" means an entity that:

(A) Provides or coordinates warehouseing, Distribution, or other services on behalf of a Manufacturer, but does not take title to the Prescription Drug or have general responsibility to direct the prescription drug's sale or disposition;

(B) Is licensed as a Wholesale Distributor under this chapter; and

© To be considered part of the Normal Distribution Channel, must also be anAuthorized Distributor of Record.

(kk) "Unprofessional conduct" means:

(1) Fraud in securing a registration or permit;

(2) intentional adulteration or mislabeling of any drug, medicine, chemical or poison;

(3) causing any drug, medicine, chemical or poison to be adulterated or mislabeled, knowing the same to be adulterated or mislabeled;

(4) intentionally falsifying or altering records or prescriptions;

(5) unlawful possession of drugs and unlawful diversion of drugs to others;

(6) willful betrayal of confidential information under K.S.A. 65-1654 and amendments thereto;

(7) conduct likely to deceive, defraud or harm the public;

(8) making a false or misleading statement regarding the licensee's professional practice or the efficacy or value of a drug;

(9) commission of any act of sexual abuse, misconduct or exploitation related to the licensee's professional practice; or

(10) performing unnecessary tests, examinations or services which have no legitimate pharmaceutical purpose.

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(ll) "Mid-level practitioner" means an advanced registered nurse practitioner issued a certificate of qualification pursuant to K.S.A. 65-1131 and amendments thereto who has authority to prescribe drugs pursuant to a written protocol with a responsible physician under K.S.A. 65-1130 and amendments thereto or a physician assistant licensed pursuant to the physician assistant licensure act who has authority to prescribe drugs pursuant to a

written protocol with a responsible physician under K.S.A. 65-28a08 and amendments thereto.

(mm) "Vaccination protocol" means a written protocol, agreed to by a pharmacist and a person licensed to practice medicine and surgery by the state board of healing arts, which establishes procedures and recordkeeping and reporting requirements for administering a vaccine by the pharmacist for a period of time specified therein, not to exceed two years.

(nn) "Veterinary medical teaching hospital pharmacy" means any location where prescription-only drugs are stored as part of an accredited college of veterinary medicine and from which prescription-only drugs are distributed for use in treatment of or administration to a non-human.

(oo) "Wholesale Distributor" means any person engaged in Wholesale Distribution of Prescription Drugs or Devices in or into the State, including but not limited to Manufacturers, Repackagers, own-label distributors, private-label distributors, jobbers, brokers, warehouses, including Manufacturers' and Distributors' warehouses, Co-Licensees, Exclusive Distributors, Third Party Logistics Providers, Chain Pharmacy Warehouses, and Wholesale Drug warehouses, independent Wholesale Drug traders, and retail Pharmacies that conduct Wholesale Distributions.

(pp) "Wholesale Distribution" means the Distribution of Prescription Drugs or Devices by Wholesale Distributors to Persons other than consumers or patients, and includes the transfer of Prescription Drugs by a Pharmacy to another Pharmacy if the value of the goods transferred exceeds five percent (5%) of total Prescription Drug sales revenue of either the transferor or transferee Pharmacy during any consecutive twelve (12)-month period. Wholesale Distribution does not include:

- *(A) The sale, purchase, or trade of a Prescription Drug or Device, an offer to sell, purchase or trade a prescription drug or device, or the dispensing of a prescription drug or device pursuant to a prescription;*
- *(B) The sale, purchase, or trade of a prescription drug or device or an offer to sell, purchase, or trade a prescription drug or device for emergency medical reasons;*
- *(C) Intracompany Transactions, unless in violation of own use provisions;*
- *(D) The sale, purchase, or trade of a prescription drug or device or an offer to sell, purchase, or trade a prescription drug or device amoung hospitals, chain pharmacy warehouses, pharmacies, or other healdh care entitites that are under common control;*
- *(E) The sale, purchase, or trade of a prescription drug or device or the offer to sell, purchase, or trade a prescription drug or device by a charitable organization described in 503©(3) of the Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;*

(F) The purchase or other acquisition by a hospital or other similar health care entity that is a member of a group purchasing organization of a prescription drug or device for its own use from the group purchasing organization or from other hospitals or similar health care entities that are members of these organizations.

(G) The transfer of prescription drugs or devices between pharmacies pursuant to a centralized prescription processing agreement;

(H) The sale, purchase, or trade of blood and blood components intended for transfusion;

(I) The return of recalled, expired, damaged, or otherwise non-salable prescription drugs, when conducted by a hospital, health care entity, pharmacy, chain pharmacy warehouse, or charitable institutution in accordance with the Board's regulations; or

(J) The sale, transfer, merger, or consolidation of all or part of the business of a retail pharmacy or pharmacies from or with another retail pharmacy or pharmacies, whether accomplished as a purchase and sale of stock or business assets, in accordance with the Board's regulations.

(K) The distribution of drug samples by manufacturers' and authorized distributors' representatives;

the sale of minimal quantities of drugs by retail pharmacies to licensed practitioners for office use.

History: L. 1953, ch. 290, § 3; L. 1975, ch. 319, § 2; L. 1977, ch. 217, § 1; L. 1978, ch. 242, § 1; L. 1978, ch. 243, § 1; L. 1979, ch. 193, § 1; L. 1982, ch. 182, § 138; L. 1986, ch. 235, § 1; L. 1986, ch. 231, § 9; L. 1986, ch. 236, § 1; L. 1987, ch. 235, § 5; L. 1987, ch. 236, § 1; L. 1988, ch. 297, § 2; L. 1989, ch. 193, § 1; L. 1989, ch. 192, § 2; L. 1989, ch. 192, § 3; L. 1991, ch. 272, § 10; L. 1996, ch. 229, § 118; L. 1997, ch. 112, § 1; L. 1999, ch. 38, § 1; L. 1999, ch. 149, § 6; L. 2000, ch. 89, § 1; L. 2000, ch. 159, § 10; L. 2001, ch. 31, § 1; L. 2002, ch. 25, § 2; L. 2003, ch. 124, § 8; July 1.

K.S.A. 65-1655 is hereby amended to read as follows: 65-1655. (a) The board shall require an applicant for registration to distribute at wholesale any drugs under K.S.A. 65-1643 and amendments thereto, or an applicant for renewal of such a registration, to provide the following information:

(1) The name, full business address and telephone number of the applicant;

(2) all trade or business names used by the applicant;

(3) addresses, telephone numbers, and the names of contact persons for all facilities used by the applicant for the storage, handling and distribution of prescription drugs;

(4) the type of ownership or operation of the applicant;

(5) the name of the owner or operator, or both, of the applicant, including:

(A) If a person, the name of the person;

(B) if a partnership, the name of each partner, and the name of the partnership;

(C) if a corporation, the name and title of each corporate officer and director, the corporate names and the name of the state of incorporation;

(D) if a sole proprietorship, the full name of the sole proprietor and the name of the business entity; and

(6) such other information as the board deems appropriate. Changes in any information in this subsection (a) shall be submitted to the board as required by such board.

(b) In reviewing the qualifications for applicants for initial registration or renewal of registration to distribute at wholesale any drugs, the board shall consider the following factors:

(1) Any convictions of the applicant under any federal, state or local laws relating to drug samples, wholesale or retail drug distribution or distribution of controlled substances;

(2) any felony convictions of the applicant under federal or state laws;

(3) the applicant's past experience in the manufacture or distribution of prescription drugs, including controlled substances;

(4) the furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;

(5) suspension or revocation by federal, state or local government of any license or registration currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;

(6) compliance with registration requirements under previously granted registrations, if any;

(7) compliance with requirements to maintain or make available to the board or to federal state or local law enforcement officials those records required by federal food, drug and cosmetic act, and rules and regulations adopted pursuant thereto; and

(8) any other factors or qualifications the board considers relevant to and consistent with the public health and safety.

(c) After consideration of the qualifications for applicants for registration to distribute at wholesale any drugs, the board may deny an initial application for registration or application for renewal of a registration if the board determines that the granting of such ~~r~~egistration would not be in the public interest. The authority of the board under this subsection to deny a registration to distribute at wholesale any drugs shall be in addition to the authority of the board under subsection (e) of K.S.A. 65-1627 and amendments thereto or subsection (e) of K.S.A. 65-1645 and amendments thereto.

(d) The board by rules and regulations shall require that personnel employed by persons registered to distribute at wholesale any drugs have appropriate education or experience, or both, to assume responsibility for positions related to compliance with state registration requirements.

e) The board by rules and regulations may implement this section to conform to any requirements of the federal prescription drug marketing act of 1987 (21 U.S.C. 321 et seq.) in effect on the effective date of this act.

(f) *Each facility that engages in wholesale distribution must undergo an inspection by the Board or a third party recognized by the Board to inspect and accredit wholesale distributors for the purpose of inspecting the wholesale distribution operations prior to initial licensure and periodically thereafter in accordance with a schedule to be determined by the Board but not less than once every three (3) years. .The Board shall have the authority to waive licensing requirements for wholesale distributors that are accredited by an accrediting agency approved by the Board*

(g) A person licensed or approved by the FDA to engage in the manufacture of drugs or devices engaged in Wholesale distribution need only satisfy the minimum federal requirements for licensure provided in FDA regulations 21 CFR Part 205 to provide wholesale distribution services.

(h) *The Board by rule and regulation shall establish standards and requirements for the issuance and maintenance of a wholesale distributor license, including but not limited to requirements regarding the following:*

(1) an application and renewal fee

(2) a surety bond

(3) licensing and periodic inspections

(4) certification of a Designated Representative

(5) Designation of a Registered Agent

(6)Storage of drugs and devices

(7) Handling, transportation and shipment of drugs and devices

(8) security

(9) Examination of drugs and devices and treatment of those found to be unacceptable as defined by the Board;

(10) due diligence regarding other wholesale distributors

(11) creation and maintenance of records, including transaction records;

(12) procedures for operation.

((i) This section shall be part of and supplemental to the pharmacy act of the state of Kansas.

History: L. 1991, ch. 189, § 1; L. 1995, ch. 106, § 4; Apr. 13.

NACDS
NATIONAL ASSOCIATION OF
CHAIN DRUG STORES

Presented by Julie Hein

Testimony re: House Bill 2392
Kevin N. Nicholson, R.Ph., JD
Vice President, Pharmacy Regulatory Affairs
National Association of Chain Drug Stores (NACDS)
Before the Kansas House Health and Human Services Committee
February 14, 2007

Ms. Chairman and members of the Committee, I am Kevin Nicholson, Vice President of Pharmacy Regulatory Affairs for the National Association of Chain Drug Stores (NACDS). NACDS represents the nation's leading retail chain pharmacies and suppliers, helping them better meet the changing needs of their patients and customers. NACDS' members operate more than 37,000 pharmacies, employ 114,000 pharmacists, fill more than 2.3 billion prescriptions yearly, and have annual sales of nearly $700 billion.

Our 15 members in Kansas operate 310 pharmacies, employ almost 27,000 Kansans, and contribute over $403 million in tax revenue to the state of Kansas every year.

On behalf of our members, I appreciate the opportunity to provide testimony on House Bill 2392.

NACDS believes that the U.S. prescription drug distribution system is one of the safest and most secure in the world. We are proud of the systems and initiatives that our members have developed with other industry stakeholders to improve the integrity of the U.S. drug supply chain. There have been a number of initiatives over the past few years by community pharmacy, wholesale distributors and manufacturers, as well as state-level legislation to enhance the licensure requirements for wholesale drug distributors that represent practical and immediate actions that have had immeasurable positive impact on the drug supply chain's integrity. We support these activities and continuing efforts to work with the supply chain stakeholders to enhance the security and safety of the drug distribution system. It is critical to the chain pharmacy industry that consumers have confidence in their pharmacies, pharmacists, and the prescription drugs they dispense. It is equally important that physicians and pharmacists have confidence in the integrity of the drugs they prescribe and dispense. The concerted partnership of all parties in the prescription drug supply chain works to maintain the U.S. drug distribution system among the safest and most secure in the world. NACDS works closely with other industry associations to develop workable means to enhance the integrity of the drug supply chain.

While we fully support efforts to promote the security and integrity of the U.S. drug distribution system and the goal of House Bill 2392, we have identified a number of concerns with the bill that we believe need to be addressed and respectfully request consideration of our concerns.

ATTACHMENT 7-1

Our concerns can be summarized into the following six categories:

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House Health and Human Services
DATE: 2-14-07

1. **Pedigrees are necessary only outside the "normal distribution channel"**
2. **Requirements for entities engaged in wholesale distribution**
3. **Wholesalers shouldn't be required to perform duties that are the responsibility of the board of pharmacy**
4. **Unnecessary impact on operations that can be easily addressed**
5. **Manufacturers should not be exempt from the bill's requirements**
6. **Clarification of the existing language**

1. **Normal Distribution Channel**
   See attachment, comments: NACDS22, NACDS23, NACDS26, NACDS34

House Bill 2392 recognizes the distribution of prescription drugs through a secure channel, that is the "normal distribution channel." This is a distribution of prescription drugs that occurs, generally, from manufacturer to wholesaler to pharmacy. Pedigrees are redundant in this channel because each member knows exactly where the prescription drug has been. Only when a prescription drug moves outside this secure channel does a pedigree become necessary.

This bill would require pedigrees ***outside*** the normal distribution channel at a time to be determined by the board of pharmacy. We ask that that language be deleted from the bill. The vast majority of states with pedigree laws require pedigrees only outside the normal distribution channel.

The only way that pedigrees could be feasible across the whole supply chain would be by the use of some sort of track and trace technology, such as radio frequency identification (RFID). Although emerging electronic drug tracking technologies, such as radio frequency identification (RFID) to track and trace the distribution of prescription drugs, have promise as a future safeguard, 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. Although considerable efforts are underway through various pilot programs, these technologies have not yet had sufficient time, evaluation, and testing for wide-spread use across the drug supply chain, and the need to reach consensus on many issues needs to be reached. Further evaluation, testing, and more extensive pilots are also needed to understand the capabilities and accuracy, to measure their operational reliability and scalability for all stakeholders across the drug supply chain, and to determine and resolve any problems related to their use and widespread adoption.

Since these technologies are not yet mature, and we don't know when they will be ready for use across the various industries in the prescription drug supply chain, and since a system wide pedigree is not necessary to protect citizens from counterfeit drugs, we ask that the requirements for a system-wide pedigree be deleted.

States that have legislated system-wide pedigrees have continuously delayed their implementation dates because there is no way to comply with these requirements.

2. **Requirements for entities engaged in wholesale distribution**
See attachment, comments: NACDS17

One of the goals of House Bill 2392 is to strengthen the licensing requirements for entities that engage in wholesale distribution, to make sure that rogue entities are not issued a license. Caught up in this legislation are chain pharmacy warehouses. These are entities that essentially serve as an offsite storage location of prescription drugs for a chain pharmacy company. The chain pharmacy company uses the chain pharmacy warehouse as a distribution center for delivering prescription drugs to its own pharmacies. Although this practice is not defined as "wholesale distribution," chain pharmacy warehouses have traditionally been licensed as wholesale distributors.

We are not concerned that chain pharmacy warehouses will have increased requirements in order to be licensed, however, we do feel that the posting of a $100,000 bond should apply only to those entities that actually engage in wholesale distribution, as the intent of the bond requirement is to ensure that the board will be able to take recourse against an entity engaged in wholesale distribution. Chain pharmacy warehouses that do not engage in wholesale distribution should not be required to post such bond. Moreover, chain pharmacy warehouses are owned by pharmacies; the board may pursue action against the pharmacies in addition to the chain pharmacy warehouse should it be necessary.

3. **Wholesalers shouldn't be required to perform duties that are the responsibility of the board of pharmacy**
See attachment, comments: NACDS27, NACDS28, NACDS29, NACDS30, NACDS31, NACDS32, NACDS33

House Bill 2392 contains numerous provisions that would require a wholesale distributor to ensure that other wholesale distributors are properly licensed, to inspect other wholesale distributors, to conduct background checks of other wholesale distributors, and to perform related duties that should be the responsibility of the board of pharmacy. We oppose these requirements as they would require a wholesaler to access confidential and

proprietary information from their competitors. These actions are the responsibility of the board of pharmacy, and we ask that they remain there.

4. **Unnecessary impact on operations that can be easily addressed**
   See attachment, comments NACDS8, NACDS10, NACDS11, NACDS13, NACDS14, NACDS15, NACDS16, NACDS18, NACDS19, NACDS21, NACDS25

There are numerous provisions of House Bill 2392 that would cause unnecessary burdens to wholesale distributors, chain pharmacy warehouses, and pharmacies. We request minor edits to these provisions to lessen the impact on the regulated entities without reducing the effect of the bill.

5. **Manufacturers should not be exempt from the bill's requirements**
   See attachment, comments: NACDS1, NACDS2
6. **Clarification of the existing language**
   See attachment, comments: NACDS3, NACDS4, NACDS5, NACDS6, NACDS7, NACDS9, NACDS12, NACDS20, NACDS24

There are numerous provisions in the bill from which manufacturers are exempt; we see no reason to exempt them. Finally, there are numerous provisions in the bill that we feel require clarification; the clarifications we ask for merely clarify what we believe is vague or unclear language and do not change the intent of the bill.

Conclusion

We very much appreciate the opportunity to provide our perspectives and to recommend solutions to deterring the introduction of counterfeit drugs into the legitimate drug supply chain. We look forward to continuing to work with the Kansas legislature, Kansas board of pharmacy, and our drug supply chain partners in assuring the safety and integrity of our drug distribution system.

We ask the Kansas legislature to consider the edits that we seek to HB 2392. The bill as currently written presents numerous problems for the chain pharmacy industry and for the drug supply chain as a whole. The language currently has many inconsistencies that must be addressed so that affected businesses can comply.

We ask the Kansas legislature to clearly state that pedigrees are not required for distributions within the normal distribution channel, and to recognize that a pedigree

system for prescription drugs will not be available across the entire drug supply chain until RFID track and trace technology is widely available.

RFID track and trace technology provides the best promise for such a pedigree system, but RFID technology is still relatively new and unproven. Much still remains to be learned and decided. Standards must be adopted. Business issues must be resolved. Obstacles must be overcome. Costs are still unknown.

If the legislature mandates a pedigree system too soon, then it would cause stakeholders to incur incalculable costs resulting from a variety of temporary alternatives to RFID that ultimately will not succeed. This will cause the stakeholders to invest time, effort and capital into other less beneficial electronic pedigree technologies, thus taking resources away from implementing nationally standardized and operational RFID track and trace technology. Consequently, implementation of RFID track and trace technology would be further delayed.

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"ATTACHMENT"

KS HB 2392 NACDS Edits

Session of 2007

HOUSE BILL No. 2392

By Committee on Health and Human Services

2-5

AN ACT concerning registration requirements of pharmacy and wholesale distribution of drugs; amending K.S.A. 65-1655 and K.S.A. 2006 Supp. 65-1643 and repealing the existing sections.

Be it enacted by the Legislature of the State of Kansas:

Section 1. K.S.A. 2006 Supp. 65-1643 is hereby amended to read as follows: 65-1643. It shall be unlawful:

(a) For any person to operate, maintain, open or establish any pharmacy within this state without first having obtained a registration from the board. Each application for registration of a pharmacy shall indicate the person or persons desiring the registration, including the pharmacist in charge, as well as the location, including the street name and number, and such other information as may be required by the board to establish the identity and exact location of the pharmacy. The issuance of a registration for any pharmacy shall also have the effect of permitting such pharmacy to operate as a retail dealer without requiring such pharmacy to obtain a retail dealer's permit. On evidence satisfactory to the board: (1) That the pharmacy for which the registration is sought will be conducted in full compliance with the law and the rules and regulations of the board; (2) that the location and appointments of the pharmacy are such that it can be operated

and maintained without endangering the public health or safety; (3) that the pharmacy will be under the supervision of a pharmacist, a registration shall be issued to such persons as the board shall deem qualified to conduct such a pharmacy.

(b) For any person to manufacture within this state any drugs except under the personal and immediate supervision of a pharmacist or such other person or persons as may be approved by the board after an investigation and a determination by the board that such person or persons is qualified by scientific or technical training or experience to perform such duties of supervision as may be necessary to protect the public health and safety; and no person shall manufacture any such drugs without first obtaining a registration so to do from the board. Such registration shall be subject to such rules and regulations with respect to requirements, sanitation and equipment, as the board may from time to time adopt for the protection of public health and safety.

(c) For any person to distribute at wholesale any drugs without first obtaining a registration so to do from the board.

(d) For any person to sell or offer for sale at public auction or private sale in a place where public auctions are conducted, any drugs without first having obtained a registration from the board so to do, and it shall be necessary to obtain the permission of the board in every instance where any of the products covered by this section are to be sold or offered for sale.

(e) For any person to in any manner distribute or dispense samples of any drugs without first having obtained a permit from the board so to do, and it shall be necessary to obtain permission from the board in every instance where the samples are to be distributed or dispensed. Nothing in this subsection shall be held to regulate or in any manner interfere with the furnishing of samples of drugs to duly licensed practitioners, to mid-level practitioners, to pharmacists or to medical care facilities.

(f) Except as otherwise provided in this subsection (f), for any person operating a store or place of business to sell, offer for sale or distribute any drugs to the public without first having obtained a registration or permit from the board authorizing such person so to do. No retail dealer who sells 12 or fewer different nonprescription drug products shall be required to obtain a retail dealer's permit under the pharmacy act of the state of Kansas or to pay a retail dealer new permit or permit renewal fee under such act. It shall be lawful for a retail dealer who is the holder of a valid retail dealer's permit issued by the board or for a retail dealer who sells 12 or fewer different nonprescription drug products to sell and distribute nonprescription drugs which are prepackaged, fully prepared by the manufacturer or distributor for use by the consumer and labeled in accordance with the requirements of the state and federal food, drug and cosmetic acts. Such nonprescription drugs shall not include: (1) A controlled substance; (2) a prescription-only drug; or (3) a

drug product intended for human use by hypodermic injection; but such a retail dealer shall not be authorized to display any of the words listed in subsection (u) of K.S.A. 65-1626 and amendments thereto, for the designation of a pharmacy or drugstore.

(g) For any person to sell any drugs manufactured and sold only in the state of Kansas, unless the label and directions on such drugs shall first have been approved by the board.

(h) For any person to operate an institutional drug room without first having obtained a registration to do so from the board. Such registration shall be subject to the provisions of K.S.A. 65-1637a and amendments thereto and any rules and regulations adopted pursuant thereto.

(i) For any person to be a pharmacy student without first obtaining a registration to do so from the board, in accordance with rules and regulations adopted by the board, and paying a pharmacy student registration fee of $25 to the board.

(j) For any person to operate a veterinary medical teaching hospital pharmacy without first having obtained a registration to do so from the board. Such registration shall be subject to the provisions of K.S.A. 65-1662 and amendments thereto and any rules and regulations adopted pursuant thereto.

(k) For any person to sell or distribute in a pharmacy a controlled substance designated in subsection (e) or (f) of K.S.A. 65-4113, and amendments thereto, unless:

(1) (A) Such controlled substance is sold or distributed by a licensed pharmacist, a registered pharmacy technician or a pharmacy intern or clerk supervised by a licensed pharmacist; and

(B) any person purchasing, receiving or otherwise acquiring any such controlled substance produces a photo identification showing the date of birth of the person and signs a log. The log or database required by the board shall be available for inspection during regular business hours to the board of pharmacy and any law enforcement officer; or

(2) there is a lawful prescription.

(l) For any person to sell or distribute in a pharmacy four or more packages or containers of any controlled substance designated in subsection (e) or (f) of K.S.A. 65-4113, and amendments thereto, to a specific customer within any seven-day period.

(m) for any person to engage in the manufacture, repackaging, sale, delivery or holding or offering for sale any prescription drug or device that is adulterated,

Comment [NACDS1]: Manufacturers should not be exempt

Deleted: Except for the wholesale distribution by manufacturers of a prescription drug that has been delivered into commerce pursuant to an application approved under federal law by the food and drug administration,

misbranded, counterfeit, suspected of being counterfeit or has otherwise been rendered unfit for distribution or wholesale distribution;

(n) for any person to engage in the adulteration, misbranding or counterfeiting of any prescription drug or device;

(o) For any person to receive any prescription drug or device that is adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit, or suspected of being counterfeit, or the delivery or proffered delivery of such prescription drug or device for pay or otherwise;

(p) For any person to engage in the alteration, mutilation, destruction, obliteration or removal of the whole or any part of the product labeling of a prescription drug or device or the commission of any other act with respect to a prescription drug or device that results in the prescription drug or device being misbranded;

(q) For any person to engage in the forging, counterfeiting, simulating or falsely representing of any prescription drug or device without the authority of the manufacturer,

(r) For any person to purchase or receive a prescription drug or device from a person that is not licensed to wholesale distribute prescription drugs or devices to that purchaser or recipient;

(s) For any person to sell or transfer a prescription drug or device to a person who is not legally authorized to receive a prescription drug or device;

(t) For any person to fail to maintain or provide records as required by this act and rules and regulations adopted thereunder;

(u) For any person to provide the board or any of its representatives or any state or federal official with false or fraudulent records or making false or fraudulent statements regarding any matter within the provisions of this act and rules and regulations adopted thereunder;

(v) For any person to engage in the wholesale distribution of any prescription drug or device that was:

(1) Purchased by a public or private hospital or other health care entity;

(2) donated or supplied at a reduced price to a charitable organization; or

(3) stolen or obtained by fraud or deceit.

Comment [NACDS2]: Manufacturers should not be exempt.

Deleted: Except for the wholesale distribution by manufacturers of a prescription drug that has been delivered into commerce pursuant to an application approved under federal law by the food and drug administration,

Comment [NACDS3]: Vague, could mean that a pharmacist cannot put a prescription label on a bottle

Deleted: or using any mark, stamp, tag, label or other identification device without the authorization of the manufacturer;

(w) For any person to fail to obtain a license or operating without a valid license when a license is required;

(x) For any person to obtain or attempt to obtain a prescription drug or device by fraud, deceit, misrepresentation or engaging in misrepresentation or fraud in the distribution or wholesale distribution of a prescription drug or device;

(y) For any person to distribute a prescription drug or device to the patient without a prescription or prescription order from a practitioner licensed by law to use or prescribe the prescription drug or device;

(z) For any person to fail to obtain, authenticate or pass on a pedigree when required under these rules and regulations adopted thereunder;

(aa) For any person to receive a prescription drug or device pursuant to a wholesale distribution without first receiving a pedigree, when required, that was attested to as accurate and complete by the wholesale distributor;

(bb) For any person to distribute or distribute by wholesale a prescription drug or device that was previously dispensed by a pharmacy or distributed by a practitioner;

(cc) For any person to fail to report any prohibited act as listed in these rules and regulations adopted thereunder; or

(dd) For any person to fail to exercise due diligence as provided in K.S.A. 65-1655(i), and amendments thereto, (due diligence) of these regulations.

Sec. 2. K.S.A. 65-1655 is hereby amended to read as follows: 65-1655. (a) For the purposes of this act:

(1) "Adulterated" means: a drug or device shall be deemed to be adulterated:

(A) If:

(i) It consists in whole or in part of any filthy, putrid, or decomposed substance; or

(ii) it has been produced, prepared, packed, or held under unsanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or if the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practices to assure that the

drug or device meets the requirements of this paragraph as to safety and has the identity and strength, and meets the quality and purity characteristics that it purports or is represented to possess; or

(iii) its container is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health; or

(iv) it bears or contains, for purposes of coloring only, a color additive that is unsafe within the meaning of the federal food, drug and cosmetic act (federal act); or it is a color additive, the intended use of which is for purposes of coloring only, and is unsafe within the meaning of the federal act;

(B) if it purports to be or is represented as a drug, the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in the compendium. Such a determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in the compendium, or in the absence of or inadequacy of these tests or methods of assay, those prescribed under authority of the federal act. No drug defined in an official compendium shall be deemed to be adulterated under this paragraph because it differs from the standard of strength, quality, or purity therefore set forth in the compendium, if its difference in strength, quality, or purity from that standard is plainly stated on its label. Whenever a drug is recognized in both the United States pharmacopeia (USP) and the homeopathic pharmacopoeia of the United States it shall be subject to the requirements of the USP unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the homeopathic pharmacopoeia of the United States and not those of the USP;

(C) if it is not subject to paragraph (2) and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess; or

Comment [NACDS4]: This doesn't make sense. Paragraph 2 of what?

(D) if it is a drug and any substance has been mixed or packed therewith so as to reduce its quality or strength; or substituted wholly or in part therefore.

(2) "Authenticate" means to affirmatively verify before any wholesale distribution that each transaction listed on the pedigree and any other accompanying documentation has occurred, in accordance with the rules of the board.

(3) "Authorized distributor of record" means a wholesale distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's prescription drug. An ongoing relationship is deemed to exist between such wholesale distributor and a manufacturer when the wholesale distributor, including any affiliated group of the wholesale distributor, as defined in section 1504 of the internal revenue

code, complies with any one of the following: (1) The wholesale distributor has a written agreement currently in effect with the manufacturer evidencing such ongoing relationship; and (2) the wholesale distributor is listed on the manufacturer's current list of authorized distributors of record, which is updated by the manufacturer on no less than a monthly basis.

(4) "Centralized prescription processing" means the processing by a pharmacy of a request from another pharmacy to fill or refill a prescription drug order or to perform processing functions such as dispensing, drug regimen review (DRR), claims adjudication, refill authorizations, and therapeutic interventions.

(5) "Closed pharmacy" means a pharmacy that purchases drugs or devices for a limited patient population and is not open for dispensing to the general patient population and cannot operate or be licensed as a wholesale distributor.

(6) "Chain pharmacy warehouse" means a permanent physical location for prescription drugs and devices that acts as a central warehouse and performs intracompany sales or transfers of prescription drugs or devices to chain pharmacies that have the same common ownership or control. Chain pharmacy warehouses must be licensed as wholesale distributors.

(7) "Co-licensee" means a pharmaceutical manufacturer that has entered into an agreement with another pharmaceutical manufacturer to engage in a business activity or occupation related to the manufacture or distribution of a prescription drug and the national drug code on the drug product label shall be used to determine the identity of the drug manufacturer.

(8) "Contraband drug" means a drug which is counterfeit, stolen, misbranded, obtained by fraud, purchased by a nonprofit institution for its own use and placed in commerce in violation of the own use agreement for that drug, or for which a pedigree (if required) does not exist, or for which the pedigree in existence has been forged, counterfeited, falsely created, or contains any altered, false, or misrepresented information.

(9) "Counterfeit drug" means a drug which, or the container, shipping container, seal, or product labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, distributed, or wholesale distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed, distributed, or wholesale distributed by, such other manufacturer, processor, packer, or distributor.

Comment [NACDS5]: Clarification that this applies only to prescription drugs.

Comment [NACDS6]: This doesn't make sense. What is an "affiliated group"?

Deleted: and

Deleted: , which are members of the same affiliated group, under

Deleted: and

(10) "Designated representative" means an individual designated by the wholesale distributor who will serve as the responsible individual of the wholesale distributor with the board who is actively involved in and aware of the actual daily operation of the wholesale distributor.

(11) "Distribute" or "distribution" means to sell, offer to sell, deliver, offer to deliver, broker, give away, or transfer a drug, whether by passage of title, physical movement, or both. The term does not include:

(A) To dispense or administer;

(B) delivering or offering to deliver a drug by a common carrier in the usual course of business as a common carrier; or

(C) providing a drug sample to a patient by a practitioner licensed to prescribe such drug; a health care professional acting at the direction and under the supervision of a practitioner; or the pharmacy of a hospital or of another health care entity that is acting at the direction of such a practitioner and that received such sample in accordance with the act and regulations to administer or dispense.

(12) "Drop shipment" means the sale, by a manufacturer, that manufacturer's co-licensee, that manufacturer's third party logistics provider, or that manufacturer's exclusive distributor, of the manufacturer's prescription drug, to a wholesale distributor whereby the wholesale distributor takes title but not possession of such prescription drug and the wholesale distributor invoices the pharmacy, the chain pharmacy warehouse, or other designated person authorized by law to dispense or administer such prescription drug, and the pharmacy, the chain pharmacy warehouse, or other designated person authorized by law to dispense or administer such prescription drug receives delivery of the prescription drug directly from the manufacturer, that manufacturer's co-licensee, that manufacturer's third party logistics provider, or that manufacturer's exclusive distributor, of such prescription drug. Drop shipments shall be part of the "normal distribution channel".

(13) "Emergency medical reasons" include, but are not limited to, transfers of a prescription drug between a wholesale distributor or pharmacy to alleviate a temporary shortage of a prescription drug arising from delays in or interruption of regular distribution schedules; sales to nearby emergency medical services, such as ambulance companies and firefighting organizations in the same state or same marketing or service area, or nearby licensed practitioners of prescription drugs for use in the treatment of acutely ill or injured persons; provision of minimal emergency supplies of prescription drugs to nearby nursing homes for use in emergencies or during hours of the day when

necessary prescription drugs cannot be obtained; and transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage.

(14) "Exclusive distributor" means an entity that:

(A) Contracts with a manufacturer to provide or coordinate warehousing, wholesale distribution, or other services on behalf of a manufacturer and who takes title to that manufacturer's prescription drug, but who does not have general responsibility to direct the sale or disposition of the manufacturer's prescription drug;

(B) is licensed as a wholesale distributor under this act; and

(C) to be considered part of the normal distribution channel, must also be an authorized distributor of record.

(15) "FDA" means food and drug administration, a federal agency within the United States department of health and human services, established to set safety and quality standards for drugs, food, cosmetics, and other consumer products.

(16) "Federal act" means the federal food, drug, and cosmetic act.

(17) "Health care entity" means any person that provides diagnostic, medical, surgical, dental treatment, or rehabilitative care but does not include any retail pharmacy or wholesale distributor.

(18) "Immediate container" means a container and does not include package liners.

(19) "Intracompany transaction" means any transaction, or transfer between a division, subsidiary, parent, or affiliated or related company under the common ownership and control of a corporate entity.

(20) "Label" means a display of written, printed, or graphic matter upon the immediate container of any drug or device.

(21) "Manufacturer" means a person licensed or approved by the FDA to engage in the manufacture of drugs and devices.

(22) "Misbranded" means a drug or device shall be deemed to be misbranded if the label is false or misleading in any particular; or the label does not bear the name and address of the manufacturer, packer, or distributor and does not have an accurate statement of the quantities of the active ingredients in the case of a drug; or the label does not show an accurate monograph for prescription drugs.

(23) "Normal distribution channel" means a chain of custody for a prescription drug, including drop shipments, that goes from a manufacturer of the prescription drug, the manufacturer's co-licensee, the manufacturer's third-party logistics provider, or the manufacturer's exclusive distributor to:

Comment [NACDS7]: Clarification

(A) a wholesale distributor, to a pharmacy to a patient or other designated persons authorized by law to dispense or administer such prescription drug to a patient; or

(B) a wholesale distributor, to a chain pharmacy warehouse to that chain pharmacy warehouse's intracompany pharmacy to a patient or other designated persons authorized by law to dispense or administer such prescription drug to a patient; or

(C) a chain pharmacy warehouse to that chain pharmacy warehouse's intracompany pharmacy to a patient or other designated persons authorized by law to dispense or administer such prescription drug to a patient; or

(D) a pharmacy to a patient;

(E) other designated persons authorized by law to dispense or administer such prescription drug to a patient;

(F) as prescribed by the board's regulations.

(24) "Pedigree" means a statement or record in a written form or electronic form, approved by the board, that records each wholesale distribution of any given prescription drug, excluding veterinary prescription drugs, which leaves the normal distribution channel. The pedigree shall minimally include the following information for each transaction:

(A) The source of the prescription drug, including the name and principal address of the seller;

(B) the proprietary and established name of the prescription drug, the amount of the prescription drug, the national drug code number, its dosage form and dosage strength, the date of the purchase, the sales invoice number, container size, number of containers, expiration date, and lot number or control number of the prescription drug;

(C) the business name and address of each owner of the prescription drug and its shipping information, including the name and address of the facility of each person certifying delivery or receipt of the prescription drug;

(D) information that states that the wholesale distributor has conducted due diligence of the wholesale distributor from which the wholesale distributor purchased; and

(E) a certification from the designated representative of the wholesale distributor that the information contained therein is true and accurate under penalty of perjury.

(F) other items as prescribed by the board's regulations.

(25) "Prescription drug" or "legend drug" means a drug which is required under federal law to be labeled with either of the following statements prior to being dispensed or delivered: (A) "Rx Only"; or (B) "Caution: Federal law restricts this drug to use by, or on the order of, a licensed veterinarian"; or (C) a drug which is required by any applicable federal or state law or rule to be dispensed pursuant only to a prescription drug order or is restricted to use by practitioners only.

(26) "Product labeling" means all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers, or accompanying such article.

(27) "Repackage" means changing the container, wrapper, quantity, or product labeling of a drug or device to further the distribution of the drug or device.

(28) "Repackager" means a person who repackages.

(29) "Sales unit" means the unit of measure the manufacturer uses to invoice its customer for the particular product.

(30) "Third party logistics provider" means an entity that:

(A) Provides or coordinates warehousing, distribution, or other services on behalf of a manufacturer, but does not take title to the prescription drug or have general responsibility to direct the prescription drug's sale or disposition;

(B) is licensed as a wholesale distributor under this chapter; and

(C) to be considered part of the normal distribution channel, must also be an authorized distributor of record.

(31) "USP standards" means standards published in the current official United States pharmacopeia or national formulary.

(32) "Wholesale distribution" means the distribution of prescription drugs or devices by wholesale distributors to persons other than consumers or patients, and includes the

transfer of prescription drugs by a pharmacy to another pharmacy if ***the total number of units transferred during a twelve (12) month period does not exceed five percent (5%) of the total number of all units dispensed by the pharmacy during the immediate twelve (12) month period.*** Wholesale distribution does not include:

(A) The sale, purchase or trade of a prescription drug or device, an offer to sell, purchase, or trade a prescription drug or device or the dispensing of a prescription drug or device pursuant to a prescription;

(B) the sale, purchase or trade of a prescription drug or device or an offer to sell, purchase, or trade a prescription drug or device for emergency medical reasons;

(C) intracompany transactions, meaning any transaction or transfer between any division, subsidiary, parent or affiliated or related company under common ownership and control of a corporate entity, or any transaction or transfer between co-licensees of a co-licensed product;

(D) the sale, purchase or trade of a prescription drug or device or an offer to sell, purchase or trade a prescription drug or device among hospitals, chain pharmacy warehouses, pharmacies or other health care entities that are under common control;

(E) the sale, purchase or trade of a prescription drug or device or the offer to sell, purchase or trade a prescription drug or device by a charitable organization described in 503(c)(3) of the internal revenue code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(F) the purchase or other acquisition by a hospital or other similar health care entity that is a member of a group purchasing organization of a prescription drug or device for its own use from the group purchasing organization or from other hospitals or similar health care entities that are members of these organizations;

(G) the transfer of prescription drugs or devices between pharmacies pursuant to a centralized prescription processing agreement;

(H) the sale, purchase or trade of blood and blood components intended for transfusion;

(I) the return of recalled, expired, damaged or otherwise non-salable prescription drugs, when conducted by a hospital, health care entity, pharmacy or charitable institution in accordance with the board's regulations; or

(J) the sale, transfer, merger or consolidation of all or part of the business of a retail

Comment [NACDS8]: Because of the extremely wide price range of prescription drugs, the number of units transferred is a better guideline than the value.

Deleted: if the value of the goods transferred exceeds 5% of total prescription drug sales revenue of either the transferor or transferee pharmacy during any consecutive 12-month period

Comment [NACDS9]: Clarification

Deleted: unless in violation of own use provisions

pharmacy or pharmacies from or with another retail pharmacy or pharmacies, whether accomplished as a purchase and sale of stock or business assets, in accordance with the board's regulations.

(K) the distribution of drug samples by manufacturers' and authorized distributors' representatives;

(L) the sale of minimal quantities of drugs by retail pharmacies to licensed practitioners for office use.

(M) The sale, purchase, distribution, trade, or transfer of a prescription drug from one authorized distributor of record to one additional authorized distributor of record when the manufacturer has stated in writing to the receiving authorized distributor of record that the manufacturer is unable to supply such prescription drug and the supplying authorized distributor of record states in writing that the prescription drug being supplied had until that time been exclusively in the normal distribution channel.

Comment [NACDS10]: Allows for distribution by one additional wholesaler when a manufacturer is not able to supply a prescription drug.

(N) 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.

Comment [NACDS11]: Allows for returns of saleable products.

(33) "Wholesale distributor" means any person engaged in wholesale distribution of prescription drugs or devices in or into the state, including but not limited to, manufacturers, repackagers, own-label distributors, private-label distributors, jobbers, brokers, warehouses, including manufacturers' and distributors' warehouses, co-licensees, exclusive distributors, third party logistics providers, chain pharmacy warehouses that conduct wholesale distributions, and wholesale drug warehouses, independent wholesale drug traders, and retail pharmacies that conduct wholesale distributions. To be considered part of the normal distribution channel, such wholesale distributor except for chain pharmacy warehouses must also be an authorized distributor of record.

Comment [NACDS12]: Clarification s

(b) Wholesale distributors that provide services within this state, whether the wholesale distributor is located within this state or outside this state, shall be licensed by the board and shall renew their license with the board using an application provided by the board. Wholesale distributors cannot operate from a place of residence. Where wholesale distribution operations are conducted at more than one location, each such location shall be licensed by the board of pharmacy. Manufacturers engaged in wholesale distribution need only satisfy the minimum federal requirements for licensure provided in FDA regulations 21 CFR part 205, and need not demonstrate or submit the following for licensure to provide wholesale distribution services: social security numbers or dates of birth (section (b)(1)(E)); designation of a designated representative (section (b)(1)(C)); a listing of any state licenses, registrations or permits (section (b)(1)(G)); and a copy of the

deed, information regarding product liability insurance and a description of import and export activities (section (b)(1)(J, K and L)). The board shall require an applicant for registration to distribute at wholesale any prescription drugs under K.S.A. 65-1643 and amendments thereto, or an applicant for renewal of such a registration, to provide the following information:

(1) The name, full business address and telephone number of the applicant;

(2) all trade or business names used by the applicant which cannot be identical to the name used by another unrelated wholesale distributor licensed to purchase prescription drugs or devices in the state ;

(3) addresses, telephone numbers, and the names of ~~contact persons for all facilities used by the applicant for the storage, handling and~~ a person(s) to serve as the designated representative for each facility of the wholesale distributor used for the wholesale distribution of prescription drugs;

(4) the type of ownership or operation of the applicant;

(5) the name of the owner or operator, or both, of the applicant, including:

(A) If a person, the name of the person , business address, social security number and date of birth ;

(B) if a partnership, the name , business address, social security number and date of birth of each partner, and the name of the partnership and the federal employer identification number ;

(C) if a corporation, the name , business address, social security number, date of birth and title of key each corporate officer and director who has direct responsibility for drug distribution, the corporate names and the name of the state of incorporation federal employer identification number and the name of the parent company, if any; the name, business address, and social security number of each shareholder owning 10% or more of the voting stock of the corporation, including over-the-counter (OTC) stock, unless the stock is traded on a major stock exchange and not OTC ;

Comment [NACDS13]: These edits bring this requirement in line with the requirements of (c)(2) below.

(D) if a sole proprietorship, the full name of the sole proprietor ~~and the name of the business entity; and~~ , business address, social security number and date of birth of the sole proprietor and the name and federal employer identification number of the business entity; and

(E) if a limited liability company, the name of the limited liability company and

federal employer identification number and the name of the state in which the limited liability company was organized.

~~(6)~~ (F) such other information as the board deems appropriate. Changes in any information in this ~~subsection (a)~~ section shall be submitted to the board as required by such board.

(G) a list of all state and federal licenses, registrations or permits, including the license, registration or permit numbers issued to the wholesale distributor by any other state and federal authority that authorizes the wholesale distributor to purchase, possess and wholesale distribute prescription drugs;

(H) a list of all disciplinary actions by state and federal agencies relating to wholesale distribution against the wholesale distributor as well as any such actions against principals, owners, directors or officers;

(I) a full description of each facility and warehouse, including all locations utilized for prescription drug storage or wholesale distribution, or both. The description should include the following:

(i) Square footage;

(ii) Statement that the facility has a security and alarm system ;

(iii) terms of lease or ownership;

(iv) address; and

(v) temperature and humidity controls.

(J) A copy of the deed for the property on which the wholesale distributor's establishment is located, if the property is owned by the wholesale distributor or a copy of the wholesale distributor's lease for the property on which the establishment is located that has an original term of not less than one calendar year, if the establishment is not owned by the wholesale distributor; lease terms that are considered proprietary, such as lease amount, may be redacted;

(K) information regarding general and product liability insurance, including copies of relevant policies;

(L) a description of the wholesale distributor's drug import and export activities; and

Comment [NACDS14]: We are concerned about providing information about security systems. Would prefer a statement that an appropriate security system is in use.

Deleted: descriptions

Comment [NACDS15]: We would like to redact proprietary information that is not necessary to be submitted

(M) a statement certifying that the wholesale distributor has written policies and procedures as required in KSA 65-1655 (l), and amendments thereto, available for inspection.

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Comment [NACDS16]: Polices and procedures are proprietary and confidential. Also, they can be quite extensive… many large three-ring binders. We would prefer a statement certifying that policies and procedures are available for inspection.

(N) The information collected pursuant to subparagraphs (I) and (M) shall be made available only to the board, a third party recognized by the board, and to state and federal law enforcement officials. The board shall make provisions for protecting the confidentiality of the information collected under this section.

(2) A "surety" bond of not less than $100,000, or other equivalent means of security acceptable to the board or a third party recognized by the board such as insurance, an irrevocable letter of credit or funds deposited in a trust account or financial institution, to secure payment of any administrative penalties imposed by the board and any fees or costs incurred by the board regarding that licensee when those penalties, fees or costs are authorized under state law and the licensee fails to pay 30 days after the penalty, fee or costs becomes final. A separate surety bond or other equivalent means of security is not required for each company's separate locations or for affiliated companies or groups when such separate locations or affiliated companies or groups are required to apply for or renew their wholesale distributor license with the board. The board may make a claim against such bond or other equivalent means of security until one year after the wholesale distributor's license ceases to be valid or until 60 days after any administrative or legal proceeding before or on behalf of the board that involves the wholesale distributor is concluded, including any appeal, whichever occurs later. Chain pharmacy warehouses that are not engaged in wholesale distribution and manufacturers shall be exempt from securing a "surety" bond or other equivalent means of security acceptable to the board or a third party recognized by the board. The board may waive the bond requirement, if the wholesale distributor has previously obtained a comparable surety bond or other equivalent means of security for the purpose of licensure in another state, where the wholesale distributor possesses a valid license in good standing.

Comment [NACDS17]: Bond requirement should apply only to entities engaged in wholesale distribution.

Deleted: M

(3) Every wholesale distributor who engages in wholesale distribution shall submit a reasonable fee to be determined by the board.

(4) Each facility that engages in wholesale distribution must undergo an inspection by the board or a third party recognized by the board for the purpose of inspecting the wholesale distribution operations prior to initial licensure and periodically thereafter in accordance with a schedule to be determined by the board but not less than once every three years. Manufacturing facilities are exempt from inspection by the board if the manufacturing facilities are currently registered with the food and drug administration in accordance with section 510 of the federal act.

(5) All wholesale distributors must publicly display or have readily available all

licenses and the most recent inspection report administered by the board.

(6) Changes in any information in this section shall be submitted to the board, or to a third party recognized by the board, within 30 days of such change, unless otherwise noted.

(7) Information submitted by the wholesale distributor to the board or a third party recognized by the board that is considered trade secret or proprietary information, as defined under this state's privacy and trade secret or proprietary statutes, shall be maintained by the board or a third party recognized by the board as private or trade secret or proprietary information and be exempt from public disclosure.

~~(b)~~ (c) (1) In reviewing the qualifications for applicants for initial registration or renewal of registration to distribute at wholesale any drugs, the board shall consider the following factors:

~~(1)~~ (A) Any convictions of the applicant under any federal, state or local laws relating to drug samples, wholesale or retail drug distribution or distribution of controlled substances;

~~(2)~~ (B) any felony convictions of the applicant under federal or state laws;

~~(3)~~ (C) the applicant's past experience in the manufacture or distribution of prescription drugs, including controlled substances;

~~(4)~~ (D) the furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;

~~(5)~~ (E) suspension or revocation by federal, state or local government of any license or registration currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;

~~(6)~~ (F) compliance with registration requirements under previously granted registrations, if any;

~~(7)~~ (G) compliance with requirements to maintain or make available to the board or to federal state or local law enforcement officials those records required by federal food, drug and cosmetic act, and rules and regulations adopted pursuant thereto; and

~~(8)~~ (H) any other factors or qualifications the board considers relevant to and consistent with the public health and safety.

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(2) The board shall consider the results of a criminal and financial background check of the applicant, including but not limited to all key personnel involved in the operations of the wholesale distributor, including the most senior person responsible for facility operations, purchasing, and inventory control and the person or persons they report to; and all company officers, key management, principals, and owners with 10% or greater ownership interest in the company, applying to non-publicly held companies only, to determine if an applicant or others associated with the ownership, management, or operations of the wholesale distributor have committed criminal acts that would constitute grounds for denial of licensure. The background check will be conducted in compliance with any applicable state and federal laws, at the applicant's expense, and will be sufficient to include all states of residence since the person has been an adult. Manufacturers shall be exempt from criminal and financial background checks.

(3) The applicant shall provide, and attest to, a statement providing a complete disclosure of any past criminal convictions and violations of the state and federal laws regarding drugs or devices or an affirmation and attestation that the applicant has not been involved in, or convicted of, any criminal or prohibited acts.

~~(c)~~ (4) After consideration of the qualifications for applicants for registration to distribute at wholesale any drugs, the board may deny an initial application for registration or application for renewal of a registration if the board determines that the granting of such registration would not be in the public interest. The authority of the board under this subsection to deny a registration to distribute at wholesale any drugs shall be in addition to the authority of the board under subsection (e) of K.S.A. 65-1627 and amendments thereto or subsection (e) of K.S.A. 65-1645 and amendments thereto.

(d) Each person that is issued an initial or renewal license as a wholesale distributor, whether in state or out of state, must designate in writing on a form required by the board a person for each facility to serve as the designated representative of the wholesale distributor. A wholesale distributor must report a change in designated representative for the facility to the board or a third party recognized by the board within 30 days of such change.

(1) To be certified as a designated representative, a person must:

(A) Submit an application on a form furnished by the board and provide information that includes, but is not limited to:

(i) Information required to complete the criminal and financial background checks required under subsection (c)(2);

(ii) date and place of birth;

(iii) occupations, positions of employment, and offices held during the past seven years;

(iv) principal business and address of any business corporation, or other organization in which each such office of the person was held or in which each such occupation or position of employment was carried on;

(v) whether the person, during the past seven years, has been enjoined, either temporarily or permanently, by a court of competent jurisdiction from violating any federal or state law regulating the possession, control or wholesale distribution of prescription drugs or devices, together with details of such events;

(vi) description of any involvement by the person with any business, including any investments, other than the ownership of stock in a publicly traded company or mutual fund, during the past seven years, which manufactured, administered, prescribed, wholesale distributed, or stored prescription drugs and devices in which such businesses were named as a party in a lawsuit;

(vii) description of any criminal offense, not including minor traffic violations, of which the person, as an adult, was found guilty, regardless of whether adjudication of guilt was withheld or whether the person pled guilty or nolo contendere. If the person indicates that a criminal conviction is under appeal and submits a copy of the notice of appeal of the criminal offense, the applicant must, within 15 days after the disposition of the appeal, submit to the board a copy of the final written order of disposition;

(viii) photograph of the person taken within the previous 180 days under procedures as specified by the board;

(x) any other information the board requires by rulemaking.

(B) have a minimum of two years of verifiable full-time managerial or supervisory experience in a pharmacy or wholesale distributor licensed in this state or another state, where the person's responsibilities included but were not limited to recordkeeping, storage, and shipment of prescription drugs or devices;

(C) may serve as the designated representative for only one wholesale distributor at any one time, except where more than one licensed wholesale distributor is co-located in the same facility and such wholesale distributors are members of an affiliated group, as defined in section 1504 of the internal revenue code;

Comment [NACDS18]: A large company begins the licensing process weeks to months ahead of time. Logistically, it would be difficult to make sure the photograph is not more than 30 days old. We believe 6 months is a more reasonable requirement.

Deleted: 30

Comment [NACDS19]: Requiring this family information is outrageously intrusive.

Deleted: (ix) name, address, occupation, and date and place of birth for each member of the person's immediate family, unless the person is employed by a wholesale distributor that is a publicly held company. As used in this subparagraph, the term "member of the immediate family" includes the person's spouse, children, parents, siblings, the spouses of the person's children, and the spouses of the person's siblings; and

Comment [NACDS20]: Additional requirements should be subject to the rulemaking process.

Deleted: deems relevant

(D) be actively involved in and aware of the actual daily operations of the wholesale distributor:

(i) Employed full-time in a managerial position by the wholesale distributor;

(ii) physically present at the wholesale distributor during normal business hours, except for time periods when absent due to illness, family illness or death, scheduled vacation or other authorized absence; and

(iii) aware of, and knowledgeable about, all policies and procedures pertaining to the operations of the wholesale distributor.

(2) The information collected pursuant to subsection (d)(1) shall be made available only to the board, a third party recognized by the board, and to state and federal law enforcement officials. The board and a third party recognized by the board shall make provisions for protecting the confidentiality of the information collected under this section.

(3) Each licensed wholesale distributor located outside of this state that wholesale distributes prescription drugs or devices in this state shall designate a registered agent in this state for service of process. Any licensed wholesale distributor that does not so designate a registered agent shall be deemed to have designated the secretary of state of this state to be its true and lawful attorney, upon who may be served all legal processes in any action or proceeding against such licensed wholesale distributor growing out of or arising from such wholesale distribution. A copy of any such service of process shall be mailed to such wholesale distributor by the board by certified mail, return receipt requested, postage prepaid, at the address such licensed wholesale distributor has designated on its application for licensure in this state. If any such wholesale distributor is not licensed in this state, service on the secretary of state only shall be sufficient service.

(4) A designated representative must complete:

(A) training programs that address applicable federal and state laws and are provided by qualified in-house specialists, outside counsel or consulting specialists with capabilities to help ensure compliance.

(e) The following are required for the storage, handling, transport and shipment of prescription drugs or devices and for the establishment and maintenance of wholesale distribution records by wholesale distributors and their officers, agents, representatives and employees.

Comment [NACDS21]: It would be impossible for one person to meet the continuing education requirements of 50 states.

Deleted: Continuing education programs specified by the board regarding federal and state laws in regard to the wholesale distribution, handling and storage of prescription drugs or devices; or

(B) if no formal continuing education is specified by the board,

(1) All facilities at which prescription drugs and devices are received, stored, warehoused, handled, held, offered, marketed, displayed or transported from shall:

(A) Be of suitable construction to ensure that all prescription drugs and devices in the facilities are maintained in accordance with the product labeling of such prescription drugs and devices, or in compliance with official compendium standards such as the United States pharmacopeia USP/NF;

(B) be of suitable size and construction to facilitate cleaning, maintenance and proper wholesale distribution operations;

(C) have adequate storage areas to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment and security conditions;

(D) have a quarantine area for storage of prescription drugs and devices that are outdated, damaged, deteriorated, misbranded or adulterated, counterfeit or suspected of being counterfeit, otherwise unfit for distribution or wholesale distribution or that are in immediate or sealed secondary containers that have been opened;

(E) be maintained in a clean and orderly condition;

(F) be free from infestation of any kind;

(G) be a commercial location and not a personal dwelling or residence;

(H) provide for the secure and confidential storage of information with restricted access and policies and procedures to protect the integrity and confidentiality of the information;

(I) provide and maintain appropriate inventory controls in order to detect and document any theft, counterfeiting or diversion of prescription drugs or devices; and

(J) provide to another wholesale distributor or pharmacy pedigrees for prescription drugs that leave the normal distribution channel before wholesale distribution to such other wholesale distributor or pharmacy in accordance with subsection (k). Effective at a date set by the board but not before July 1, 2010, pedigrees shall electronically record, for all prescription drugs, each wholesale distribution outside the normal distribution channel. The date 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. 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. Nevertheless,

Comment [NACDS22]: Date agreed to with PhRMA.

Deleted: 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

Comment [NACDS23]: Pedigrees are necessary only outside the normal distribution channel.

implementation should not be unnecessarily delayed. Until such date set by the board, manufacturers are exempt from this section, unless the manufacturer is performing the manufacturing operation of repackaging prescription drugs. The board's determination of the date shall be based on consultation with manufacturers, distributors, and pharmacies responsible for the sale and distribution of prescription drug products in Kansas. After consultation with interested stakeholders and prior to implementation of the electronic pedigree requirement, the Board shall determine that the technology is universally available across the entire prescription pharmaceutical supply chain, and that national standards have been adopted for the use of an electronic pedigree system that can be used across the entire pharmaceutical distribution system.

Comment [NACDS24]: Clarification

(2) Wholesale distributors involved in the wholesale distribution of controlled substances shall be duly registered with drug enforcement administration (DEA) and appropriate state controlled substance agency and in compliance with all applicable laws and rules for the storage, handling, transport, shipment and wholesale distribution of controlled substances.

(f) (1) All facilities used for wholesale distribution shall be secure from unauthorized entry:

(A) access from outside the premises shall be kept to a minimum and be well-controlled;

(B) the outside perimeter of the premises shall be well-lighted; and

(C) entry into areas where prescription drugs or devices are held shall be limited to authorized personnel; all facilities shall be equipped with an alarm system to detect entry after hours.

(2) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(3) All facilities shall be equipped with inventory management and control systems that protect against, detect, and document any instances of theft, diversion or counterfeiting.

(4) All facilities shall be equipped with security systems to protect the integrity and confidentiality of data and documents and make such data and documents readily available to the board and other state and federal law enforcement officials.

(5) Authentication of pedigrees:

(A) Wholesale distributors that acquire prescription drugs from other wholesale distributors outside the normal distribution channel shall authenticate the pedigrees of at least 10% of all such prescription drugs, unless an electronic pedigree and track and trace system or other acceptable means, which documents each transaction, is in place; and

(B) wholesale distributors and manufacturers from whom wholesale distributors have acquired prescription drugs shall cooperate with pedigree authentication efforts and provide the requested information in a timely manner. The board shall provide authentication standards and procedures.

(C) Each wholesale distributor that has distributed a prescription drug for which an acquiring wholesale distributor is conducting a pedigree authentication, shall provide to the acquiring wholesale distributor, upon request, detailed information regarding its acquisition of the prescription drug, including:

(i) Date of acquisition;

(ii) national drug code number and lot number or control number;

(iii) acquisition invoice number; and

(iv) name, address, telephone number and e-mail address, if available, of the manufacturer or wholesale distributor from which the prescription drug was acquired.

(D) If the wholesale distributor attempting to authenticate the pedigree of the prescription drug is unable to authenticate the pedigree, the wholesale distributor shall quarantine the prescription drug and file a report with the board and FDA within three business days after completing the attempted authentication; and

(E) if the wholesale distributor attempting to authenticate the pedigree of the prescription drug is able to authenticate the pedigree, the wholesale distributor shall maintain records of the authentication for three years, and shall produce them to the board upon request.

(g) All prescription drugs and devices shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the product labeling of such prescription drugs and devices, or with requirements in the current edition of an official compendium such as the USP-NF.

(1) If no storage requirements are established for a prescription drug, the prescription

drug may be held at "controlled" room temperature, as defined in an official compendium such as USP-NF, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(2)

(3) Packaging of the prescription drugs and devices should be in accordance with an official compendium such as USP-NF and identify any compromise in the integrity of the prescription drugs or devices due to tampering or adverse storage conditions.

(4) Controlled substance drugs should be isolated from non-controlled substance drugs and stored in a secure area in accordance with DEA security requirements and standards.

(5) The recordkeeping requirements in subsection (k) shall be followed for the wholesale distribution of all prescription drugs and devices.

(h) (1) Upon receipt, each shipping container shall be visually examined for identity and to determine if it may contain contaminated, contraband, counterfeit, suspected of being counterfeit or contraband, or damaged prescription drugs or devices, or prescription drugs or devices that are otherwise unfit for wholesale distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination, adulteration, misbranding, counterfeiting, contraband, suspected of being counterfeit or contraband or other damage to the contents.

(2) The prescription drugs or devices found to be unacceptable under paragraph 1 should be quarantined from the rest of stock until the examination and determination that the prescription drugs and devices are not outdated, damaged, deteriorated, misbranded, counterfeited, contraband or adulterated and the determination that they are fit for human use.

(3) Each outgoing shipment shall be carefully inspected for identity of the prescription drugs or devices and to ensure that there is no delivery of prescription drugs or devices that have been damaged in storage or held under improper conditions.

(4) Upon receipt, a wholesale distributor must review records for the acquisition of prescription drugs or devices for accuracy and completeness, considering the total facts and circumstances surrounding the transactions and the wholesale distributors involved.

(5) The recordkeeping requirements in subsection (k) shall be followed for all incoming and outgoing prescription drugs and devices.

(i) (1) Appropriate documentation shall be completed and any necessary notations

Comment [NACDS25]: This exceeds the USP requirement. Recording equipment or logs are an unnecessary burden.

Deleted: Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment or logs shall be utilized to document proper storage of prescription drugs and devices.

made to the return document as required under the terms of the agreement with the manufacturer or wholesale distributor, if any prescription drug that was ordered in excess of need by the wholesale distributor, if identified as such, and which the integrity has been maintained, that is returned to the manufacturer or wholesale distributor from which it was acquired, and a pedigree shall not be required.

Deleted: pedigree

Comment [NACDS26]: Pedigrees are not necessary within the normal distribution channel, whether for distributions or for returns.

Deleted: .

(2) Any prescription drug or device that is outdated, damaged, deteriorated, misbranded, counterfeited, contraband, suspected of being counterfeited or contraband, adulterated, or otherwise deemed unfit for human consumption shall be quarantined and physically separated from other prescription drugs and devices until it is destroyed or returned to either the manufacturer or wholesale distributor from which it was acquired. When prescription drugs and devices are adulterated, counterfeited, contraband, misbranded, or suspected of being adulterated, counterfeit, contraband, or misbranded, notice of the adulteration, counterfeiting, contrabandage, misbranding, or suspected adulteration, counterfeiting, contrabandage, or misbranding shall be provided within three business days of that determination to the board, FDA, and manufacturer or wholesale distributor from which they were acquired. Any prescription drug or device returned to a manufacturer or wholesale distributor shall be kept under proper conditions for storage, handling, transport, shipment, and documentation showing that proper conditions were maintained and shall be provided to the manufacturer or wholesale distributor to which the prescription drugs or devices are returned.

(3) Any prescription drug or device whose immediate or sealed outer or secondary containers or product labeling are adulterated, misbranded, counterfeited, contraband, or suspect of being counterfeit or contraband shall be quarantined and physically separated from other prescription drugs or devices until it is destroyed or returned to either the manufacturer or wholesale distributor from which it was acquired. When the immediate or sealed outer or secondary containers or product labeling of any prescription drug or device are adulterated, misbranded, counterfeited, contraband, or suspect of being counterfeit or contraband, notice of the adulteration, misbranding, counterfeiting, contrabandage, or suspected counterfeiting or contrabandage shall be provided within three business days of that determination to the board, FDA, and manufacturer or wholesale distributor from which it was acquired.

(4) Any prescription drug or device that has been opened or used, but is not adulterated, misbranded, counterfeited, contraband, or suspect of being counterfeit or contraband, shall be identified as such, and shall be quarantined and physically separated from other prescription drugs or devices until it is destroyed or returned to the manufacturer or wholesale distributor from which acquired.

(5) If the conditions under which a prescription drug or device has been returned cast doubt on the prescription drug's or device's safety, identity, strength, quality, or purity,

then the prescription drug or device shall be destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the prescription drug or device meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a prescription drug or device has been returned cast doubt on the prescription drug's or device's safety, identity, strength, quality, or purity, the wholesale drug distributor shall consider, among other things, the conditions under which the prescription drug or device has been held, stored, or shipped before or during its return and the condition of the prescription drug and its container, carton, or product labeling as a result of storage or shipping.

(6) Contraband, counterfeit, or suspected to be counterfeit or contraband drugs and devices, other evidence of criminal activity, and accompanying documentation shall be retained and not destroyed until its disposition is authorized by the board and FDA.

(7) The shipping, immediate, or sealed outer or secondary container or product labeling, and accompanying documentation, suspected of or determined to be counterfeit, contraband or otherwise fraudulent shall not be destroyed until its disposition is authorized by the board and FDA.

(8) The recordkeeping requirements in subsection (k) of this act shall be followed for all outdated, damaged, deteriorated, counterfeit, contraband, misbranded, or adulterated prescription drugs.

(j) If a wholesale distributor is licensed in accordance with this act or provides documentation that the due diligence procedures are in place and monitored by the board or a third party recognized by the board, then the following due diligence requirements shall be waived by the board. If a wholesale distributor licensed in accord with this Act does not provide documentation that due diligence procedures are in place, then the following are required:

Deleted: may

Comment [NACDS27]: Would prefer requiring the BoP to waive requirements below if the wholesaler engages in due diligence procedures.

(1) Prior to the initial wholesale distribution or acquisition of prescription drugs to or from any wholesale distributor or prior to any wholesale distribution to a wholesale distributor by a manufacturer, the distributing wholesale distributor or manufacturer shall provide the following information to the acquiring wholesale distributor:

(A) A list of states in which the wholesale distributor is licensed, and into which it ships prescription drugs;

(B) copies of all state and federal regulatory licenses and registrations;

(C) the wholesale distributor's most recent facility inspection reports;

(D) information regarding general and product liability insurance, including copies of relevant policies;

(E) a list of other names under which the wholesale distributor is doing business, or was formerly known;

(L) a description of the wholesale distributor's policies and procedures to comply with this act; and

(2) prior to the initial wholesale distribution or acquisition of prescription drugs to or from any wholesale distributor, the distributing or acquiring wholesale distributor shall:

(B) verify that the wholesale distributor has been accredited by a third party recognized by the board or is licensed in good standing in all states where the wholesale distributor is required to hold a license.

(3) If a wholesale distributor's facility has not been inspected by the board or a third party recognized by the board within three years of the contemplated transaction, any wholesale distributor choosing to do business with that facility shall contact the appropriate board or boards to request that the board or boards conduct an inspection of the former wholesale distributor's facility prior to the first transaction to ensure compliance with applicable laws and regulations relating to the storage and handling of prescription drugs or devices. A third party may be engaged to conduct the site inspection on behalf of the board or boards. If the wholesale distributor's facility has been inspected by the board or a third party recognized by the board, within a three-year time period, the inspection report is sufficient to meet the requirements of this subsection.

(4) At least annually, a wholesale distributor that wholesale distributes or acquires prescription drugs to or from another wholesale distributor shall update the information set forth in subsection (k).

(6) Wholesale distributors are exempt from inspecting and obtaining the information from manufacturers of prescription drugs as required in subsection (b)(4) (due diligence) when the manufacturer is registered with FDA in accordance with section 510 of the federal act.

(k) (1) Wholesale distributors shall establish and maintain inventories and records of all transactions regarding the receipt and wholesale distribution or other disposition of prescription drugs and devices. These records shall include:

Comment [NACDS28]: This information is proprietary and we would not want to share with another wholesale distributor.

Deleted: (F) a list of corporate officers;

(G) a list of managerial employees directly involved in the day-to-day operations of wholesale distribution;

(H) a list of all owners of the wholesale distributor that own more than 10% of the wholesale distributor, unless the wholesale distributor is publicly traded;

(I) a list of all disciplinary actions by state and federal agencies;

(J) a description, including the address, dimensions, and other relevant information, of each facility or warehouse used for prescription drug storage and wholesale distribution;

(K) a description of prescription drug import and export activities of the wholesale distributor;

Comment [NACDS29]: We should be able to rely that the board has done this as part of the licensing process.

Deleted: (A) Conduct a criminal background check of all of the wholesale distributor's personnel, shareholders, and owners involved in operations and management as specified in subsection (c)(2) (minimum qualifications); or

Comment [NACDS30]: Do not want to mandate the use of third party accrediting body.

Comment [NACDS31]: We should be able to rely on the board to do this as part of the licensing process.

Comment [NACDS32]: We should be able to rely on the board to do this as part of the licensing process.

Deleted: latter wholesale distributor

Comment [NACDS33]: We should be able to rely on the board to do this as part of the licensing process.

Deleted: (5) At least once every three years, a wholesale distributor that wholesale distributes or acquires prescription drugs to or from another wholesale distributor shall inspect or engage a third party to inspect, the premises of the facility or facilities of the [1]

(A) Dates of receipt and wholesale distribution or other disposition of the prescription drugs and devices;

(B) pedigrees for all prescription drugs that are wholesale distributed outside the normal distribution channel; and

(2) Such records shall include the inventories and records and shall be made available for inspection and photocopying by any authorized official of any state, federal or local governmental agency for a period of three years following their creation date.

(3) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two working days of a request by an authorized official of any state or federal governmental agency charged with enforcement of these rules.

(4) Wholesale distributors and manufacturers shall maintain an ongoing list of persons with whom they do business.

(5) All facilities shall establish and maintain procedures for reporting counterfeit and contraband or suspected counterfeit and contraband drugs or devices or counterfeiting and contraband or suspected counterfeiting and contraband activities to the board and FDA.

(6) Wholesale distributors shall maintain a system for the mandatory reporting of significant shortages or losses of prescription drugs and devices where it is known or suspected that diversion is occurring to the board and FDA, and, where applicable, to DEA.

(l) Wholesale distributors shall establish, maintain and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, transport and shipping and wholesale distribution of prescription drugs, including policies and procedures for identifying, recording and reporting losses or thefts, for correcting all errors and inaccuracies in inventories. Wholesale distributors shall include in their written policies and procedures the following:

(1) A procedure to be followed for handling recalls and withdrawals of prescription drugs and devices. Such procedure shall be adequate to deal with recalls and withdrawals due to:

Comment [NACDS34]: We believe that requiring pedigrees outside the normal distribution channel will provide the necessary protections from counterfeit drugs. Requiring pedigrees within the normal distribution channel is unnecessarily redundant, as entities within the normal distribution channel will know that a prescription drug has been distributed through a secure supply chain. When a wholesaler or pharmacy receives a prescription drug with a pedigree this will place them on notice that the drug has been outside the normal distribution channel and that the pedigree should be carefully reviewed. The vast majority of states with pedigree laws require pedigrees only outside the normal distribution channel.

Deleted: (C) effective at date set by the board, that shall be no sooner than July 1, 2009, pedigrees shall be maintained for each wholesale distribution of a 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. Pedigrees may be implemented through an approved and readily available system that electronically tracks and traces 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 healthcare industry 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. Nevertheless, implementation should not be unnecessarily delayed.

Deleted: .

(A) Any action initiated at the request of FDA or any other federal, state, or local law enforcement or other government agency, including the board of pharmacy; or

(B) any volunteer action by the manufacturer to remove defective or potentially defective prescription drugs or devices from the market.

(2) A procedure to ensure that wholesale distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of a strike, fire, flood or other natural disaster or other situations of local, state, or national emergency.

(3) A procedure to ensure that any outdated prescription drugs shall be segregated from other prescription drugs and either returned to the manufacturer or destroyed in accordance with federal and state laws, including all necessary documentation and the appropriate witnessing. This procedure shall provide for written documentation of the disposition of outdated prescription drugs. This documentation shall be maintained for two years after disposition of the outdated prescription drugs.

(4) A procedure for the destruction of outdated prescription drugs in accordance with federal and state laws, including all necessary documentation, maintained for a minimum of three years and the appropriate witnessing of the destruction of outdated prescription drugs in accordance with all applicable federal and state requirements.

(5) A procedure for the disposing and destruction of containers, labels and packaging to ensure that the containers, labels and packaging cannot be used in counterfeiting activities, including all necessary documentation, maintained for a minimum of three years, and the appropriate witnessing of the destruction of any labels, packaging, immediate containers, or containers in accordance with all applicable federal and state requirements.

(6) A procedure for identifying, investigating and reporting significant prescription drug inventory discrepancies involving counterfeit, suspect of being counterfeit, contraband, or suspect of being contraband, in the inventory and reporting of such discrepancies within 10 business days to the board or appropriate federal or state agency upon discovery of such discrepancies.

(7) A procedure for reporting criminal or suspected criminal activities involving the inventory of prescription drugs and devices to the board, FDA, and, if applicable, DEA, within the three business days.

(8) A procedure for conducting authentication of pedigrees in accordance with

subsection (f) and standards adopted by the board.

(m) Wholesale distributors shall be subject to the provisions of any applicable federal, state or local laws or rules that relate to prescription drug product salvaging or reprocessing, including chapter 21, parts 207, 210, and 211k of the code of federal regulations.

(n) The board shall have the authority to recognize a third party to inspect and accredit wholesale distributors.

(1) The board may license by reciprocity, a wholesale distributor that is licensed under the laws of another state, if:

(A) The requirements of that state are deemed by the board to be substantially equivalent; or

(B) the applicant is accredited by a third party recognized by the board.

(2) Any applicant that is denied accreditation described under paragraph (a), shall have the right of review of the accreditation body's decision, by:

(A) The accreditation body; and

(B) the board.

(3) The board recognized accreditation body shall ensure that the proprietary information obtained during the accreditation process remains confidential and privileged.

(4) The board may waive requirements of this act, by rule and regulation, for wholesale distributors that have obtained and maintain a board-approved accreditation.

~~(d)~~ (o) The board by rules and regulations shall require that personnel employed by persons registered to distribute at wholesale any drugs have appropriate education or experience, or both, to assume responsibility for positions related to compliance with state registration requirements.

~~(e)~~ (p) The board by rules and regulations may implement this section to conform to any requirements of the federal prescription drug marketing act of 1987 (21 U.S.C. 321 et seq.) in effect on the effective date of this act.

~~(f)~~ (q) This section shall be part of and supplemental to the pharmacy act of the state

of Kansas.

New Sec. 3. (a) If a person engages in the wholesale distribution of prescription drugs in violation of this act, the person may be imprisoned for not more than 15 years or fined not more than $50,000, or both.

(b) If a person knowingly engages in wholesale distribution of prescription drugs in violation of this act, the person shall be imprisoned for not more than 20 years or fined not more than $500,000, or both.

New Sec. 4. The 2007 amendments to K.S.A. 65-1655, and amendments thereto, and K.S.A. 2006 Supp. 65-1643, and amendments thereto, shall be known and may be cited as the Kansas pharmaceutical integrity act.

Sec. 5. K.S.A. 65-1655 and K.S.A. 2006 Supp. 65-1643 are hereby repealed.

Sec. 6. This act shall take effect and be in force from and after its publication in the statute book.

(5) At least once every three years, a wholesale distributor that wholesale distributes or acquires prescription drugs to or from another wholesale distributor shall inspect or engage a third party to inspect, the premises of the facility or facilities of the wholesale distributor to or from whom it is distributing or acquiring prescription drugs. If the distributing or acquiring wholesale distributor's facility has been inspected by the board or a third party recognized by the board within the three-year time period, the inspection report is sufficient to meet the requirements of this subsection.