Approved: March 2, 2006
Date

# MINUTES OF THE HOUSE HEALTH AND HUMAN SERVICES COMMITTEE

The meeting was called to order by Vice-Chair Peggy Mast at 1:30 P.M. on March 1, 2006, in Room 526-S of the Capitol.

All members were present except Representatives Watkins, Kelley, Kilpatrick, Morrison, Landwehr, and Kirk, all of whom were excused.

Committee staff present:
Melissa Calderwood, Kansas Legislative Research Department
Mary Galligan, Kansas Legislative Research Department
Renae Jefferies, Revisor of Statutes' Office
Gary Deeter, Committee Secretary

Conferees appearing before the committee:
David Searle, Director, Pharmacy Development, Pfizer
Carmen Catizone, Executive Director, National Association of Boards of Pharmacy
Debra Billingsley, Executive Secretary, Kansas State Board of Pharmacy
Kevin Nicholson, Vice President of Pharmacy Regulatory Affairs, National Association of Chain Drug Stores
David Gonzales, Director, State Government Affairs, Healthcare Distribution Management Association

Others attending:
See attached list (not available on electronic copy).

The Chair opened the hearing on **HB 2820** and noted a previous hearing on a similar bill, **HB 2397**, which hearing was on 2-7.

David Searle, Director, Pharmacy Development, Pfizer, testified as a proponent for the proposed legislation. (Attachment 1) He related the dangers of counterfeit drugs, noting the need to regulate the secondary market by defining normal distribution and creating a pedigree or footprint to trace each drug through the distribution system. He listed the advantages of the bill, saying that it safeguards the state's drug supply through the Kansas Board of Pharmacy, whose licensing and background checks will better protect Kansas citizens.

Carmen Catizone, Executive Director, National Association of Boards of Pharmacy, testified in favor of the bill, noting that the NABP is an independent, impartial association that assists state boards to develop and implement uniform standards. (Attachment 2) Noting that about 15 states have similar legislation, he cited evidence to show that the present tracking is inadequate, but that the present bill has safeguards to prevent Kansas from becoming a haven for unscrupulous wholesalers.

Patrick Hubbell, representing PhRMA, offered written testimony in support of the bill. (Attachment 3)

Debra Billingsley, Executive Secretary, Kansas State Board of Pharmacy, speaking as a neutral party, delineated various concerns expressed by the Board. (Attachment 4) She estimated each pharmacy would expend $10,000 to implement electronic tracking; she said some definitions are confusing or conflict with present statutes or regulations; she commented that the cost of background checks and inspections could be onerous if not passed on to distributors; and she said the mandates are unrealistic. She noted that the Board is in agreement with the theory of the bill, but is reluctant to implement it at the present time.

Kevin Nicholson, Vice President of Pharmacy Regulatory Affairs, National Association of Chain Drug Stores, spoke as opponent to the bill (Attachment 5) and suggested amendments that he said would make the bill more acceptable. (Attachment 6) He noted that the present bill contains various inaccuracies and that because of continued changes at the federal level and in a number of states, counterfeit drug cases in 2005 fell to nearly half the number in 2004. He explained that by 2010 an effective tracking system will become common—the RFID, or radio-frequency identification, an electronic chip that will provide a complete pedigree for each prescription bottle. He asked the committee to delay action on what he called a premature bill.

David Gonzales, Director, State Government Affairs, Healthcare Distribution Management Association, testified in opposition to the bill. He said his colleague, Dan Bellingham, gave testimony opposing a similar bill (**HB 2397**) on February 7, testimony which he said applied to this bill as well. He cited two problems with the bill: First, the licensing requirements are onerous, and, second, the pedigree requirements unnecessarily restrict a wholesaler's ability to serve its customers. Noting that the ideal pedigree will be RFID, he said 90% of drugs are easily tracked because they follow the normal distribution chain. However, 10% of drugs are purchased outside that chain when a wholesaler does not buy directly from a manufacturer; the bill makes tracking that 10% becomes unnecessarily restrictive.

A fiscal note was provided for committee members. (Attachment 7)

Members posed questions to conferees. Ms. Billingsley said the Federal Drug Administration (FDA) began but never completed a pedigree system. Mr. Catizone explained that the FDA does not have resources to oversee drug tracking, since licensing rests with the states, observing that if 1% of drugs were counterfeited, that would total 35 million prescriptions, a Herculean task to regulate. Ms. Billingsley said that the Board of Pharmacy regulates wholesalers intrastate and requests inspections from resident states for out-of-state wholesalers. Mr. Catizone said the patchwork of regulations is disappearing as more states impose stricter tracking statutes. Mr. Gonzales stated that his association has offered a federal model for licensing to the FDA. Mr. Catizone added that the tracking process can be implemented, but not yet at the unit level. A member commented that at present Kansas regulates puppy mills more stringently than it does prescription drugs. Mr. Catizone said Indiana has implemented an effective drug-tracking system paid for by manufacturer and wholesaler fees. A member expressed concern that wholesalers would simply pass on these fees to retailers.

The Chair closed the hearing.

The minutes for February 21, 2006, were approved.

Staff Mary Galligan briefed the committee on **HB 2813**. She said the bill repeals one section of the nurse practice act which allows a nurse to practice up to 120 days pending receipt of the results of his/her licensing examination.

Staff Melissa Calderwood explained two similar bills, **HB 2852** and **HB 2853**, both of which create new law requiring the State Board of Nursing to require fingerprinting and criminal history record checks before licensing nurses, practical nurses, and mental health technicians. She noted that in both bills there is no language directing the deposit of funds into the state treasury nor does the bill specify how the funds would be generated. The bill assumes but does not state that the Board will increase license fees for applicants.

The meeting was adjourned at 2:54 p.m. The next meeting is scheduled for Thursday, March 2, 2006.

## HOUSE HEALTH AND HUMAN SERVICES COMMITTEE
## GUEST LIST

**DATE:** MARCH 1 2006

| NAME | REPRESENTING |
|---|---|
| Debra Billingsley | Board of Pharmacy |
| Mal Hendrick | Member Board of R — D |
| Julie Hein | Hein Law Firm |
| Kevin Nicholson | NACDS |
| Jammie Capps | Schering Plough |
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Attachment 1
HHS 3-1-06

# HB 2820 - Wholesale Licensure and Prescription Medication Integrity Act

Hearing before the House Health and Human Services
Wednesday, March 1, 2006
1:30 PM

Testimony by David Searle, RPh
Director, Pharmacy Development, Pfizer Inc.

# Overview of Issue

- Three years ago fake Lipitor was sold in the U.S. including the Kansas City market because of a faulty distribution system.
- The top 3 wholesalers account for 90% of the drug distribution in the US. Yet there are thousands of registered wholesalers in the US, creating a secondary market.
- When we look at this secondary marketplace in light of the sharp rise in counterfeit cases in the US, it becomes increasingly clear that this large number of wholesalers requires increased regulatory oversight.
- HB 2820 includes modifications over previous versions made by multiple groups over the last year

# How Fake Lipitor was Sold

1-3

- Federal prosecutors arrested a twice-convicted cocaine dealer who manufactured and distributed a convincing copy of the medicine.
- Counterfeit product originated in Costa Rica
- Product repackaged by Med-Pro of Nebraska and distributed by a **secondary wholesaler** in Missouri

# How Fake Lipitor was Sold

- 200,000 bottles or 18 million tablets had to be recalled: 30 day supply for 600,000 people
- Costa Rica to Brazil to Florida to California to Maryland to Nebraska to Missouri to Kansas City
- One of the distributors charged is a Kansas citizen

# Pedigree Legislation: Ensuring the Safety of Medicine

## Most prescription drug distribution follows a simple path

**VAST MAJORITY OF Rx MEDICINES DISTRIBUTED BY THE BIG 3:**

Amerisource-Bergen, Cardinal Health Inc. and McKesson Corp.

- Some medicines are sold through smaller wholesalers known as regional or secondary wholesalers.
- Multiplicity of distribution points poses challenges for regulators
- There are more than **6,000** wholesalers in the U.S.
- Pfizer does business with 40

***To better ensure the safety and quality of pharmaceuticals, legislation should be passed that increases oversight on wholesalers, especially those operating outside of the usual distribution channels.***

**To stop counterfeiting, wholesale distributors must be required to:**

1. **Meet strict licensing requirements**
   - Wholesalers should pass criminal and business background checks.
   - Wholesalers should be sufficiently bonded.
2. **Create pedigrees or legitimate "trails" for every sale, trade or transfer of a drug that leaves the normal distribution chain**
   - Safety and quality of prescription drugs will be easier to verify if sales, trades and transfers are tracked.

# Combating Counterfeit Drugs: A Report of the Food and Drug Administration Annual Update



http://www.fda.gov/oc/initiatives/counterfeit/update2005.html

- **The comprehensive Report highlights several measures that can be taken to better protect Americans from counterfeit drugs.**

**These measures address six critical areas:**

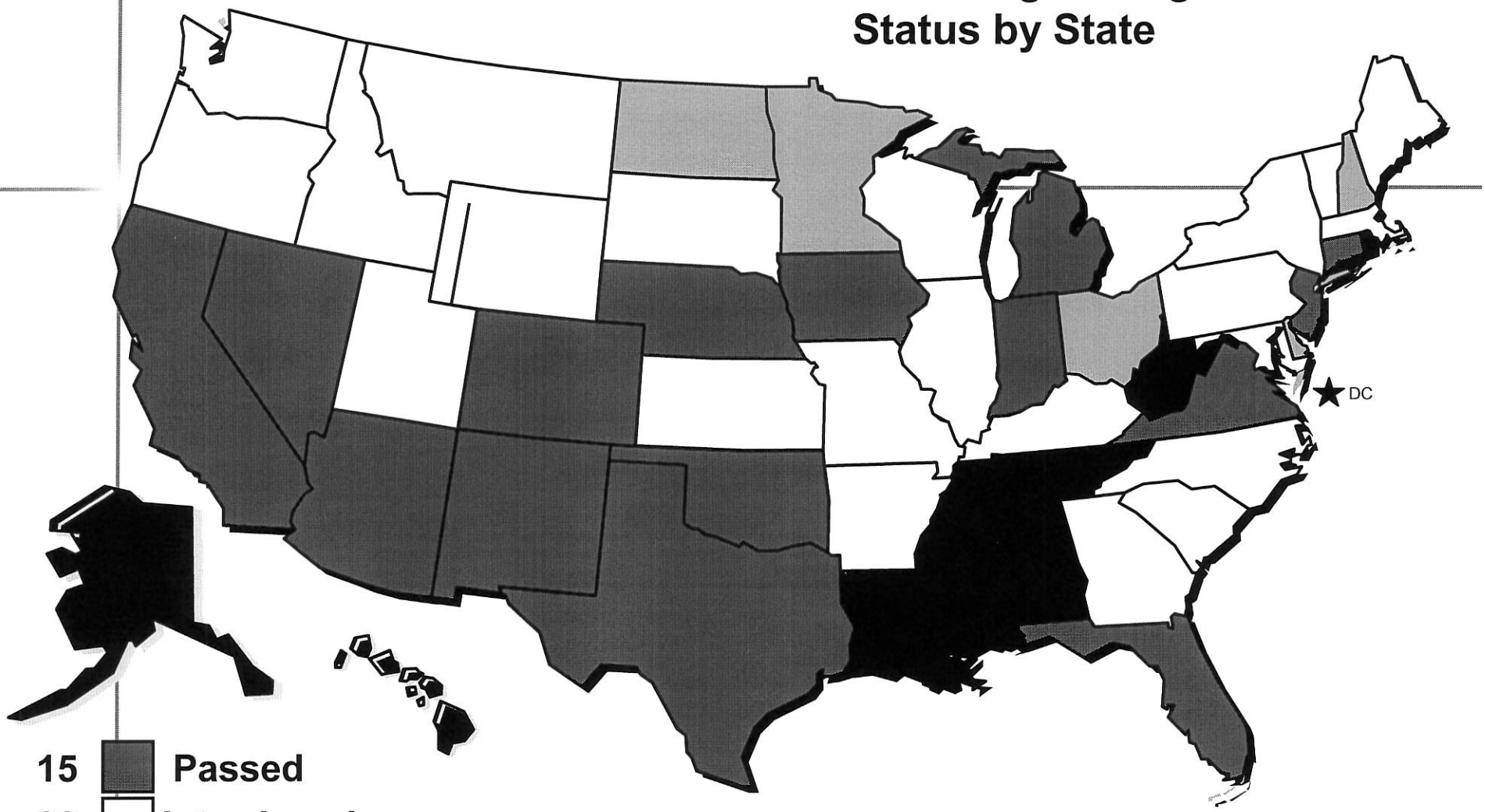
- **Securing the actual drug product and its packaging**
- **Securing the movement of the product as it travels through the U.S. drug distribution chain (Normal Distribution)**
- **Enhancing regulatory oversight and enforcement**
- **Increasing penalties for counterfeiters**
- **Heightening vigilance and awareness of counterfeit drugs**
- **Increasing international collaboration**

# Key Elements of the Legislation



- **Board of Pharmacy is responsible for Safeguarding the State's Drug Supply**
- **Licensure Process is Critical – it ensures that only those organizations that meet the predetermined standard of the state are allowed to provide medications to the state's citizens**
- **Background Checks Weed out Bad Players – such as process will allow for the identification of unscrupulous individuals that have a history of engaging in activities that are not only illegal but may be dangerous to patients.**
- **Kansas currently has around 700 wholesalers**

# Counterfeit / Pedigree Legislation Status by State




| | |
|---|---|
| 15 | Passed |
| 22 | Introduced |
| 5 | To be introduced |
| 8 | Not introduced |

Pfizer

January 17, 2006

# Legislation Has Evolved Over The Last Year

- Boards of Pharmacy, NABP, HDMA, Pharmacy Associations and other manufacturers– have all offered changes
- Based on these changes, HB 2820 was drafted
- QUESTIONS???

# Testimony Before the
# Kansas House Health and Human Services Subcommittee

## Challenges Facing the US Medication System

## Wholesale Distributor Licensing

## March 1, 2006

**Presented by:**

**Carmen A. Catizone, MS, RPh, DPh**
**Executive Director/Secretary**
**National Association of Boards of Pharmacy**

Attachment 2
HHS 3-1-06

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# Challenges Facing the US Medication System

Wholesale Distributor Licensing
March 1, 2006

National Association of Boards of Pharmacy

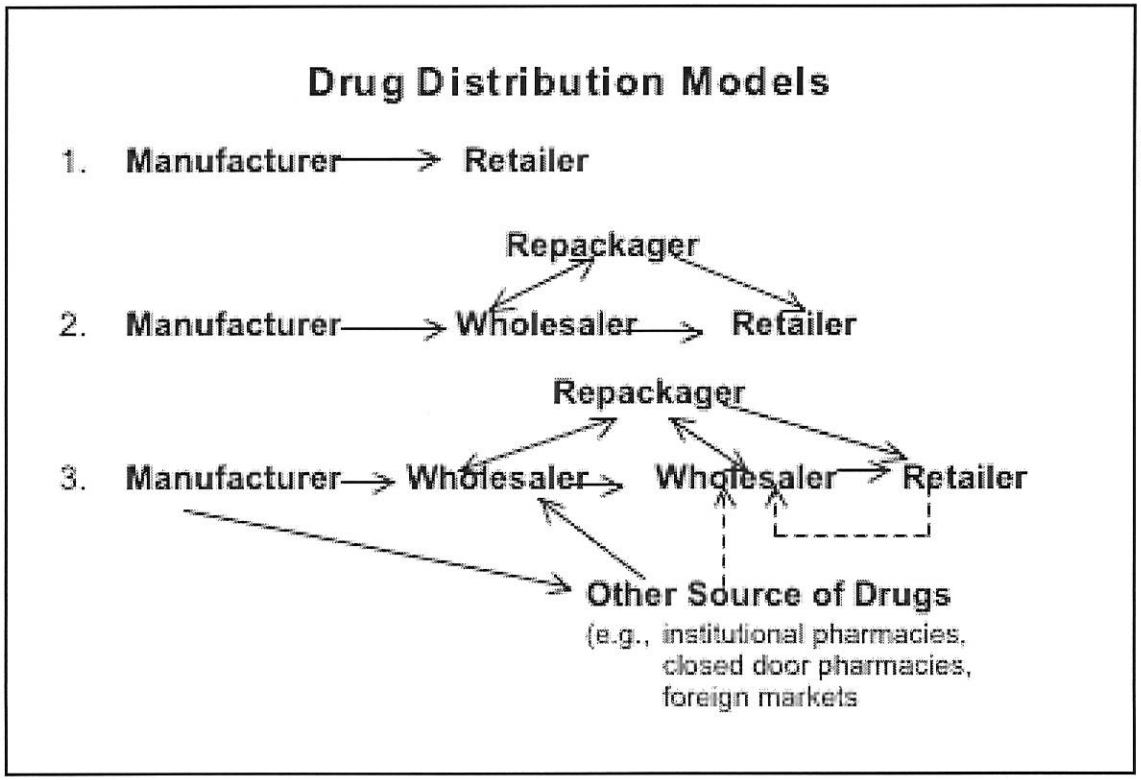
# NABP

- Founded in 1904
- Members include all state, provincial, and territorial jurisdictions that regulate the practice of pharmacy
  - All 50 state boards of pharmacy
  - District of Columbia, Guam, Puerto Rico, and the Virgin Islands
  - Eight Canadian provinces, two Australian States, New Zealand, and South Africa

# NABP

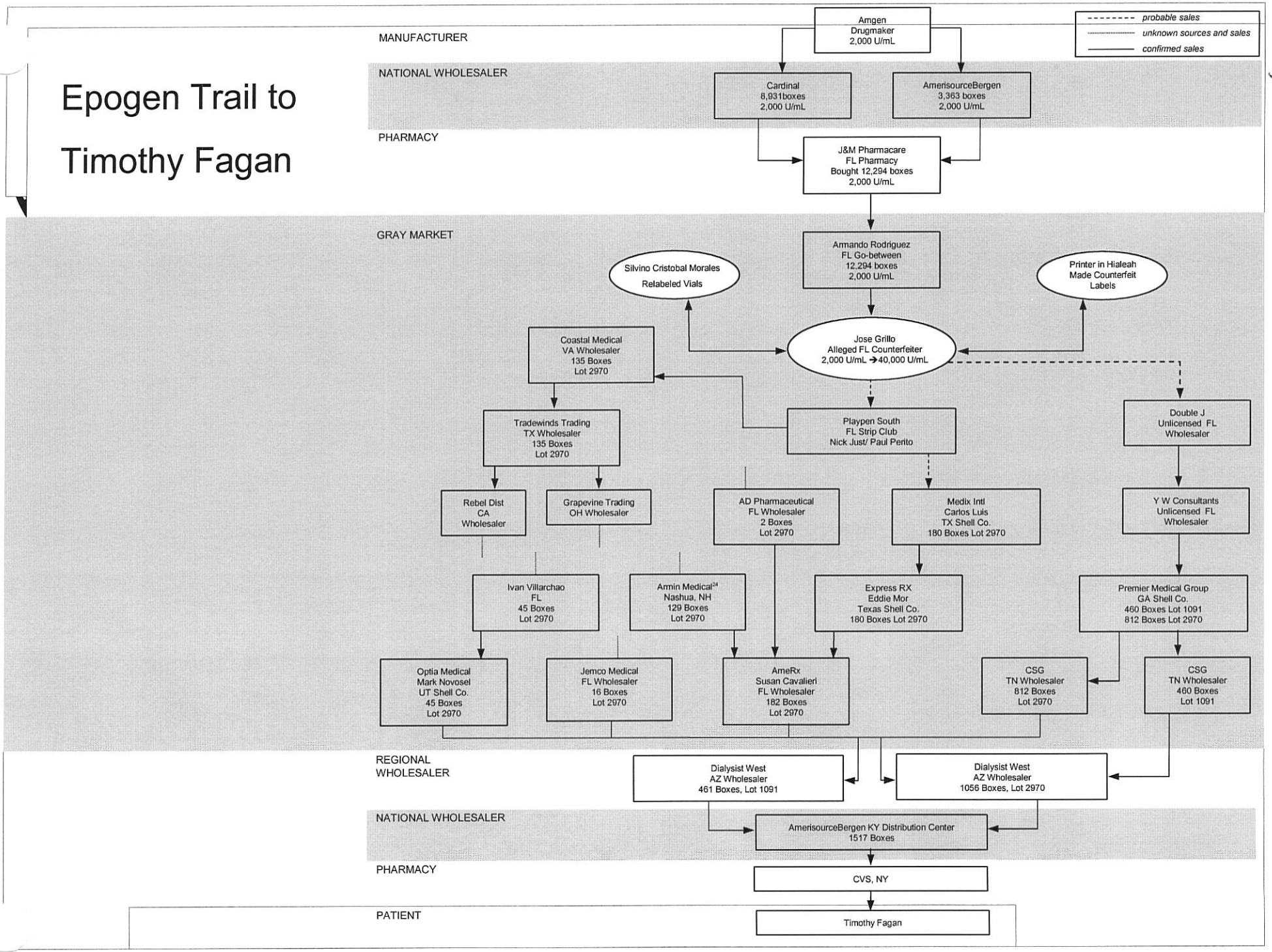
- **Mission**
  - **The National Association of Boards of Pharmacy is the independent, international, and impartial Association that assists its member boards and jurisdictions in developing, implementing, and enforcing uniform standards for the purpose of protecting the public health.**

# How are Counterfeit and Diverted Drugs Introduced into the Drug Distribution System?




FDA's Counterfeit Drug Task Force Interim Report, October 2003

# Epogen Trail to Timothy Fagan




2-6

# Federal Regulation of Wholesale Distributors

- Prescription Drug Marketing Act (PDMA) of 1987, Prescription Drug Amendments (PDA) of 1992
  - Banned the Sale of Drug Samples and Drug Coupons
  - Banned Reimportation (limited exceptions)
  - Set Requirements for Sample Distribution and Storage
  - Required State Licensing of Wholesale Distributors
  - Required Identity Statements for Sales (pedigrees) by Unauthorized Distributors of Record

# Federal Authorities Seize Prescription Drugs from Distributors

- April 28, 2005 - FDA/US Attorney District of Utah
- Series of indictments against multiple prescription drug distributors
  - PDRX (Pharma Discount) – Salt Lake City, UT
  - Empire Pharmaceuticals – Newberry Park, CA
  - DRX Medical (Defonte Trading) – Aberdeen, NJ
  - PRNY Enterprises/AC Global/AC Healthcare/Afro Caribbean Healthcare – Floral Park, NY
- Illegal distribution of the diverted drugs could affect the safety and efficacy of over 40 medications in over 80 pharmacies

# Wholesale Distributor Legislation
# State Activity

- Currently 12- 15 states are drafting legislation and/or regulations to address the counterfeit drug issue
- NABP's involvement at state level
  - Provides background and education to the boards
  - Reviews legislation/regulations and provides feedback
  - Testifies, upon request, before the board, at committee hearings, etc

# State Licensing of Wholesale Distributors

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

# FDA's Request to NABP to Combat Counterfeiting

- FDA Counterfeit Drug Task Force (July 2003)
- NABP Task Force on Counterfeit Drugs and Wholesale Distributors (October 2003)
- NABP Model Rules for the Licensure of Wholesale Distributors and National Specified List of Susceptible Products (February 2004; Revised in March 2005)

# NABP Task Force on Counterfeit Drugs and Wholesale Distributors

- Input from Industry Stakeholders, State and Federal Governmental Agencies
- Concerted Effort over the Course of Four Months
- Ultimate Goal: Obtaining Uniformity Among States

2-13

# NABP Task Force to Develop Recommendations on Electronic Pedigrees

- Primary Objective:
  - Gain consensus from state boards of pharmacy and other applicable state regulatory agencies regarding the necessary components for electronic pedigrees
- Recommendations:
  - Electronic pedigree records all transactions and distributions of a product beginning with manufacturer until final sale and distribution to the pharmacy
  - Implementation of electronic pedigrees by December 2007
  - Specified data elements of electronic pedigrees:
    - Drug name, amount of drug, dosage form, dosage strength, lot/control numbers, NDC (optional), name of manufacturer
    - Dates of transactions, sales invoice numbers
    - Name, address, telephone, number, e-mail address, VAWD #, state license number of each entity involved in the chain of custody
    - Certification that each recipient has authenticated the pedigree and information included within the pedigree is true
    - Name and address of each person certifying delivery or receipt of the drug

# VAWD Accreditation Process

- Application
  - Verification of licensure (Facility and Personnel)
  - Clearinghouse screening (Facility and Personnel)
- Policy and Procedure Evaluation
- Facility Inspection
  - Tour, staff interviews, documentation review
  - Periodic reviews and inspections
- Award Accreditation
  - Publish VAWD Accreditation

# VAWD Criteria

- Licensure
- Facility
- Personnel
- Recordkeeping
- Authentication and Verification
- Returned, Damaged and Outdated Products
- Policies and Procedures

# VAWD Criteria

- Licensure:
  - Validly licensed (Applicable State and Federal)
  - Compliance with Laws/Regulations (Applicable State and Federal)
  - Sufficient liability insurance/secured funds (surety bond)
- Facility:
  - Suitable construction
  - No operation from place of residence
  - Appropriate storage conditions
  - Controlled substances isolated from non-controlled substances
  - Designated quarantine area
  - Security (security & alarm systems, limited access)

# VAWD Criteria

- Personnel: Designated Representative
  - Two years verifiable managerial experience
  - Involved in the daily operations
  - Background check (criminal and financial)
  - Appropriate education and experience

- Personnel: Additional Key Personnel
  - DR's supervisor
  - Persons with a 10% or greater ownership interest if company not public
  - Others as applicable (if application evaluation reveals a question/issue)
  - Criminal/financial background checks

# VAWD Criteria

- Recordkeeping:
  - Inventories, invoices, pedigrees
  - Appropriate security of records
  - Inventory control to detect counterfeiting, diversion and theft
  - Readily available for inspection
- Authentication and Verification:
  - Verification of identity and legitimacy of purchasing and selling entities
  - Conducting For Cause Authentications
  - Inspection and examination of products received and shipped

# VAWD Criteria

- Returned, Damaged and Outdated Drugs:
  - Quarantine of products unfit for distribution
  - Quarantine and reporting of suspicious product (to the Board, FDA, Wholesale Distributor, Manufacturer within 3 business days)
- Policies and Procedures that Address:
  - Recalls and withdrawals
  - Crises that affect security, operation, in the event of strike, fire, flood, natural disaster, etc.
  - Disposition/destruction of outdated and expired drugs, containers and labeling
  - Inventory discrepancies
  - Reporting of criminal activities to appropriate authorities

# State Legislation - VAWD

- Indiana and Oklahoma specifically mention VAWD in their wholesale distributor legislation.
- Idaho - Although not explicitly stated in their legislation or regulations, Idaho endorses VAWD and requires nonresident wholesales who are not able to obtain an inspection from their state to be VAWD accredited.

# State Legislation - VAWD

- Nebraska has included language in their proposed legislation to allow for an inspection to be performed "by the department or a nationally recognized accreditation program approved by the board".
- Several other states that are working on wholesale distributor legislation that have expressed an interest in endorsing VAWD in their upcoming regulations and legislation.

# Statement PhRMA

**Statement in Support of HB 2820**
**February, 20 2006**

PhRMA member companies have a strong interest in ensuring that the drugs they discover and manufacture are safe, effective and of the highest quality. This interest extends beyond the factory gates all the way to the patient, since even the most innovative medicines cannot help the patients who need them if those medicines are compromised by breakdowns in the distribution system. PhRMA member companies are committed to doing their part to protect the integrity of the American drug supply. Critical to this enterprise is the ability to verify the authenticity and integrity of the original pharmaceutical packaging unit before drug product is dispensed to a patient.

Given the complexity of the drug distribution system in the United States, this is no easy task. It has been estimated that there are approximately 80,000 dispensing sites in the United States that are supplied by a shifting group of primary and secondary wholesalers. While three major drug distributors dominate the primary market, there are a much larger number of both licensed primary and secondary distributors. Secondary buying and selling of packaged pharmaceuticals is common as a normal part of inventory adjustment; however it is often the way in which counterfeit medicines have entered the U.S. distribution system. Personal importation of small amounts of pharmaceuticals has been documented with increasing frequency. In addition, numerous Internet sites offer consumers pharmaceuticals at deeply discounted prices even though these products are of dubious origin and quality. Repackaging of pharmaceuticals takes place at a variety of levels despite the fact the manufacturer's original container/closure system has been breached and product quality may suffer as a result. Collectively, all of the above practices may create opportunities for counterfeit or diverted drugs to enter the system, thus potentially compromising the public health of patients.

Pharmaceutical companies use a variety of counterfeit resistant technologies on drug packaging and labeling to help protect the integrity of the U.S. drug supply. These include overt and covert packaging and labeling features, such as color-shifting inks, holograms, and micro-printing, as well as chemical taggants embedded in the drug product itself. These technologies provide multiple layers of security that make drug products more difficult for counterfeiters to reproduce accurately. They also are useful for assessing the authenticity of drug products already identified as "questionable."

It is important to recognize, however, that counterfeit resistant technologies may not provide a mechanism for identifying counterfeit drugs in real time, particularly at the dispensing level. First, counterfeit resistant technologies can themselves be duplicated, often within 12-18 months, and thus need to be rotated on a regular basis. Second, neither pharmacists nor patients realistically can be expected to routinely check, or even be aware of, the wide variety of overt features used on the thousands of different drug products available through pharmacies, particularly if those features are rotated on a regular basis. Third, overt and covert packaging technologies are rendered useless if a drug product is repackaged, a practice that is common in the industry and subject to only minimal regulation. That is why the integrity of the drug supply chain needs to be protected through

*Pharmaceutical Research and Manufacturers of America*
1100 Fifteenth Street, NW Washington, DC 20005 (202) 835-3400

Attachment 3
HHS 3-1-06

safeguards throughout the distribution system to prevent the entry of counterfeit drugs into the US.

A pedigree statement is understood to be the mainstay protection against counterfeit, diverted, adulterated, and misbranded drugs. The increasing experience of many states is that the risks of diversion increase as lateral transfers occur among stakeholders in the distribution chain; that is why there is a growing consensus to limit exemptions from pedigree requirements. Pharmaceutical manufacturers, originators of the product, have an obligation to protect the integrity of their own products and therefore should be exempt from pedigree requirements.

At a time when many states are growing increasingly concerned about counterfeit or diverted drugs, some secondary wholesalers are seeking to relax pedigree requirements, so that there would not be verifiable documentation of each sale that occurs in the drug distribution chain. All of the necessary information for a pedigree is provided to the wholesaler on the initial purchase from the manufacturer. For this reason, secondary wholesalers, including those considered unauthorized distributors, should be held to the pedigree requirement. The distribution chain must be carefully maintained to avoid gaps in the protective pedigree paper safety net. To broaden a class of those exempted from the pedigree requirement (ie. a lateral transfer by the first authorized distributor to a second wholesaler) allows an unraveling of the purpose and safety protection of the pedigree paper.

This is precisely the wrong time to consider relaxing protections for the American drug distribution system. The states play a crucial role in assuring and preserving the integrity of the drug distribution system; state laws and regulations should preserve meaningful pedigree requirements. When drugs lose their pedigree, either by slipping out of the legitimate supply chain in the U.S., or leaving this country, there is no way to trace medicines back to the original manufacturer and assure their quality. That is why it is important for state authorities to enforce requirements that preserve the legitimate distribution chain, and keep suspect medicines out of circulation.

It is critical that a pharmaceutical chain of custody be preserved. PhRMA member companies put the safety of patients who need their medicines above all other considerations. The cornerstone of the development of safe and effective prescription medicines is the original manufacturer's full compliance with an FDA-approved New Drug Application (NDA) and total control of the process from the selection of raw materials, design of the manufacturing process, packaging of the final product, evaluation of the conditions for storage (including the establishment of an expiration date after which the medication should be discarded), and careful selection of the distribution pathway. American patients expect FDA and manufacturers to ensure that the medicines they receive will be of the highest quality.

The only way to assure that the highest quality pharmaceuticals reach the patient is to uphold the integrity of the distribution system through the use of pedigrees. Without a legal document assuring traceability back to the original manufacturer, there is no guarantee that the pharmaceutical product is not counterfeit. Furthermore, even in cases where drug product may have originated at the original manufacturer, there would not be any history of where the particular lot of pharmaceutical was stored. Exacting storage conditions identified in the NDA must be maintained to assure product quality. Thus, without a closed distribution system requiring pedigree papers for prescription drugs that leave the normal

distribution chain, American consumers could be placed at risk of receiving pharmaceuticals that are sub-potent or even have no activity, or are adulterated by dangerous by-products or other contaminants toxic to patients' health.

KANSAS

BOARD OF PHARMACY
DEBRA L. BILLINGSLEY, EXECUTIVE DIRECTOR

KATHLEEN SEBELIUS, GOVERNOR

**Testimony concerning HB 2820: Wholesale Licensure and Prescription Medication Integrity Act**
**House Health and Human Services Committee**
**Presented by Debra Billingsley**
**On Behalf of**
**The Kansas State Board of Pharmacy**
**March 1, 2006**

Mr. Chairman, Members of the Committee:

My name is Debra Billingsley and I am the Executive Secretary of the Kansas State Board of Pharmacy. Our Board is created by statute and is comprised of six members, each of whom are appointed by the Governor. The Board is responsible for regulating pharmacy professionals and pharmacy related entities. The Board currently licenses 720 prescription drug distributors.

Many of the distributors that are licensed are not sending "drugs" into Kansas. The definition of "drug" includes any article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals. This broad definition includes durable medical supplies that are issued pursuant to a prescription. It would also include oxygen or other medical gases. Therefore, the majority of prescription drug distributors in Kansas are not shipping in drugs as defined by this bill. HB 2820 would require an overview of the Kansas Pharmacy Act to correct deficiencies or conflict in statutes and regulations.

The Board of Pharmacy meets four times a year. During 2005 they discussed the pedigree requirement at several of their meetings. They also reviewed the other states laws that have been passed. The Board supports the theory behind pedigrees but they have some concerns regarding the bill that is before the committee. There are some flaws in the bill that would need to be corrected.

The Board would like to have the opportunity to regulate the distributors. We have the expertise to regulate distributors. However, this bill does not permit the Board to pass the costs of regulation onto the distributor. HB2820 requires the Board to consider the results of national criminal history background checks. The Board reviewed the language with the KBI and the FBI and it is acceptable to granting the Board authority. However, the KBI will charge $54 for searches on the FBI national database. The bill does not address whether the distributor bears the expense of this fee or whether the Board of Pharmacy will be responsible. Likewise, the Board has the ability to test and inspect these facilities

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Attachment 4
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but they would need to be able to pass these costs on to the distributors. Further, the Board would like the language to offer the option of contracting outside of the agency should that become necessary.

This bill also sets deadlines that are ambitious. Our neighboring states all have different laws and this is of concern to the Board. The Board would like to continue reviewing other states laws so that we could get the best language possible. They would also like to review current law in-depth so that any conflicts could be corrected. The Board believes that their should be a full blown review of current laws related to distributors so that we nothing is in conflict.

In closing, the Board is aware of the problems of counterfeit drugs and how it has affected major drug manufacturers. Therefore, the Board is in full agreement with this type of law in theory but it has not been fully tested in any state. Our discussions with Florida and California have indicated that they have continued to work out issues with the law. It is a new idea and has many areas of concern. We would like the opportunity to work with the industry to come up with a law that is suitable and permits the Board the ability to fully ensure the integrity of medication distributed in the state of Kansas. This bill is not entirely the vehicle necessary to do this.

Thank you very much for permitting me to testify, and I will be happy to yield to questions.

NACDS
NATIONAL ASSOCIATION OF
CHAIN DRUG STORES

**Testimony re: HB 2820**
**House Health and Human Services Committee**
**Presented by Kevin Nicholson**
**on behalf of**
**National Association of Chain Drug Stores**
**March 1, 2006**

Mr. Chairman and committee members, thank you for the opportunity for the National Association of Chain Drug Stores to share with you our perspectives on initiatives that will reduce the risk of counterfeit drugs reaching consumers. My name is Kevin Nicholson, Vice President of Pharmacy Regulatory Affairs for NACDS.

NACDS is opposed to House Bill 2820 unless it is amended to address concerns we have about numerous inaccuracies and conflicts regarding the bill's language. We can remove our opposition if the bill is amended as we have indicated in the attached document.

NACDS represents the nation's leading retail chain pharmacies and suppliers, helping them better meet the changing needs of their patients and customers. Our members operate more than 35,000 pharmacies, employ 108,000 pharmacists, fill more than 2.3 billion prescriptions yearly, and have annual sales of over $700 billion. Other members include almost 1,000 suppliers of products and services to the chain pharmacy industry.

413 North Lee Street
P.O. Box 1417-D49
Alexandria, Virginia
22313-1480

NACDS believes that the U.S. drug distribution system is among the safest and most secure in the world. We are proud of the systems and initiatives that our members have developed to improve the integrity of our drug supply.

I had the opportunity to testify before the Food and Drug Administration in Washington, DC on February 9 of this year, less than a month ago, on the very same topics that are being addressed by House Bill 2820, that is reducing the risk of counterfeit drugs reaching consumers, and using a pedigree system as a possible initiative to achieve that goal. Many of the points I made before the FDA will be the same as the points I will share with you today.

It is critical to the chain pharmacy industry that consumers have confidence in their pharmacists and the medications they dispense. It is equally important that physicians and pharmacists have confidence in the integrity of the medications they dispense and prescribe. It takes a concerted effort of all affected parties to make our drug distribution system among the safest and most secure in the world.

The community pharmacy industry consists of companies of varying sizes and technical capabilities. Our members range from the largest company in the world to others that have as few as four pharmacies and a little over $10 million in total annual sales. As we look for solutions that can be adopted, please recognize that not all companies have the financial, technical, or human resources to be at the leading edge of the technology curve. I urge you to consider that pharmacies have varying levels of resources, and that for a

(703) 549-3001
Fax (703) 836-4869
www.nacds.org

Attachment 5
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prescription drug pedigree system to work it must be standards-driven, proven, cost-efficient, and easy to implement.

Despite the increasing media attention on counterfeit drugs, the problem of counterfeit drugs being found in the legitimate drug distribution system is actually not increasing. In FDA's report *Combating Counterfeit Drugs: A Report of the Food and Drug Administration's Annual Update,* published on May 18, 2005, it was disclosed that while there were more counterfeit drug cases initiated in 2004 compared to 2003 most of the suspect cases were found in smaller quantities. In addition, "most of these drugs were destined for the black market or Internet distribution, rather than widespread distribution in the nation's drug supply chain."[1] At FDA's Anti-Counterfeiting Drug Initiative Workshop, we learned from FDA that the number of counterfeit drug cases in 2005 fell to almost half the number of cases in 2004. We believe that these results are directly attributable to the numerous changes that members of the legitimate drug supply chain have made in recent years.

While not discounting the possibilities that some of today's emerging technologies, such as Radio Frequency Identification (commonly known as "RFID") for electronic pedigrees, may provide future improvements to the drug supply chain integrity, these technologies remain unproven and significant time will be required to fully develop and understand their capabilities. In the meantime, there are practical and immediate initiatives that have been undertaken to improve the integrity of the drug supply chain.

**A. Community Pharmacy Initiatives**

Community pharmacy has taken a leadership role in adopting practical and immediate steps to further ensure the integrity of the products they dispense. Many pharmacies have made changes in their purchasing practices such as requiring their wholesale distributors to purchase their prescription drugs directly from manufacturers. Additionally, community pharmacy has steadfastly supported individual state efforts to strengthen existing wholesale licensing requirements. These stricter requirements have removed the unscrupulous wholesale distributors from operating within the legitimate drug supply chain.

**B. Wholesale Distributor Initiatives**

The wholesale distribution industry has also taken dramatic steps to further ensure the integrity of the products they distribute. Many wholesale distributors, including the nation's three largest wholesale distributors, have indicated they would no longer trade with secondary wholesalers. This practice was historically a potential entry point for counterfeit products and contributed heavily toward prescription drug diversion. The elimination of this practice creates a direct flow of product from the manufacturer to the wholesale distributor to the pharmacy, and finally to the patient.

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[1] *Combating Counterfeit Drugs: A Report of the Food and Drug Administration's Annual Update;* May 18, 2005; located at http://www.fda.gov/oc/initiatives/counterfeit/update2005.html.

Additionally, the wholesale industry has migrated towards a Fee-For-Service / Inventory Management Agreement relationship with manufacturers. This move has eliminated the speculative purchasing on the part of the wholesale distributors. Historically, this activity was an integral piece of the wholesale distributors' business model; it allowed them to capitalize on the incremental revenue that could be gained in advance of manufacturers' price increases. With the advent of these agreements, new relationships between wholesale distributors and manufacturers have been developed that have resulted in less excess inventory in the drug supply chain. Less excess inventory in the drug supply chain has helped to eliminate questionable entities from participating in the legitimate drug supply chain.

**C. Pharmaceutical Manufacturer Initiatives**

Pharmaceutical manufacturers have become more restrictive in their selling practices, ensuring that they sell their products only to legitimate operators within the drug supply chain. Manufacturers have also embraced the Fee-For-Service and Inventory Management Agreements with wholesale distributors as it allows them tighter control of the quantity of product in the drug supply chain at any point in time. Additionally, manufacturers are increasingly using overt counterfeit measures such as color shifting ink to make their products more difficult to counterfeit.

**D. State Initiatives**

Many states have adopted laws and regulations with more stringent requirements for licensure of wholesale drug distributors and drug distribution records intended to minimize the risk of counterfeit drugs appearing in their state. NACDS applauds the Kansas legislature for proposing legislation to do the same.

As in other states, the more stringent licensing state provisions have often caused questionable entities to close down, thus eliminating bad actors from participating in the wholesale distributor market.

While there appears to be uniformity in the states efforts to strengthen wholesale licensing requirements, no two states pedigree requirements are exactly the same. However, we do believe that many states have passed a workable solution; this is the "normal distribution channel" approach that requires pedigrees for only those prescription drugs that are distributed outside the defined normal distribution channel.

**E. Normal Distribution Channel**

The concept that pedigrees are required for wholesale distributions outside the normal distribution channel has been recognized and adopted by many states including Arizona,

Indiana, Oklahoma, and Texas, as well as embraced by the National Association of Boards of Pharmacy (NABP) and other stakeholders in the drug supply chain. Normal Distribution Channel has been defined as the: "chain of custody during distribution of prescription medication that goes from [1] the manufacturer to a wholesale distributor to a pharmacy or [2] the manufacturer to a wholesale distributor to a chain pharmacy distribution center to their intra-company pharmacy. Direct sales of prescription medication by a manufacturer to a pharmacy or chain pharmacy distribution center are also included within the normal distribution channel."

Under this concept, pedigrees are not required to be passed for prescription drugs that remain within the normal distribution channel. This approach treats each member of the drug supply chain equally so long as they are purchasing and distributing prescription medication within the defined normal distribution channel.

## F. Making Pedigrees Workable

### 1. *Paper* Pedigrees Are Unworkable

A *paper* pedigree system is not the answer to counterfeiting problems. Linking a piece of paper to the billions of prescription drugs that move through the drug supply chain is logistically impossible. Any attempt to do so would lead to astronomical costs being passed down to pharmacies, which have no ability to absorb these costs. Moreover, raising the cost of prescription drugs would make drug counterfeiting more profitable, so a paper pedigree requirement may inadvertently encourage additional drug counterfeiting and/or adulteration.

In addition to being costly, tracing a prescription drug pedigree on paper is subject to multiple record keeping failures and fraud. Worst of all, sophisticated drug counterfeiters would no doubt find it easier to counterfeit a paper pedigree than to counterfeit the drugs themselves.

### 2. *Electronic* Pedigrees Are a Better Solution

NACDS supports efforts to establish *electronic* pedigrees and to promote the promise of RFID track and trace technology. RFID track and trace technology promises to eventually eliminate the need for paper pedigrees.

The goal for using RFID track and trace technology for electronic pedigrees is that every manufacturer would place an RFID tag on every drug product they manufacture. This tag would emit a radio signal that uniquely identifies each distinct product with an electronic product code; an analogy can be drawn to each item having its own social security number that is transmitted by the radio tag. The tag would be read by a special radio frequency reader. This technology promises to allow each drug product to be individually tracked and traced from point of manufacture until it reaches the pharmacy or other dispenser.

RFID technology solutions are not yet ready for full implementation across the drug supply chain. We believe that any requirement for pedigrees before RFID track and trace technology is widely available and nationally standardized will cause stakeholders to incur incalculable costs resulting from a variety of temporary alternatives to RFID that ultimately will not succeed. This will cause them to invest time, effort and capital into other less beneficial e-pedigree technologies, thus taking resources away from implementing nationally standardized and operational RFID technology. Consequently, RFID technology implementation would be further delayed.

We expect that RFID track and trace technology solutions will not be ready for another five to ten years.

**G. Drug Importation and the Black Market**

No discussion about the problem of counterfeit drugs would be complete without addressing consumers' accessing prescription drugs from outside the legitimate drug supply chain, such as from foreign sources and through unscrupulous Internet-based vendors. FDA officials have stated that incidences of counterfeit drugs in the legitimate drug supply chain are rare, and that we can have no confidence in the safety or validity of a drug purchased outside the legitimate drug supply chain. Consumers rarely receive counterfeit drugs from their corner pharmacy, yet consumers receive counterfeit drugs every day from sources on the Internet and from foreign countries.

Importation of drugs for personal use from foreign countries poses a serious threat to the health and safety of Americans. Drug importation via unregulated Internet sites and/or "store fronts" in the United States offers a significant and growing avenue for counterfeit drugs to enter the country. The initiatives that Kansas adopts to strengthen our closed drug distribution system will be in vain if consumers are continuing to access drugs from these illegitimate sources. Greater licensing of wholesale distributors, drug pedigrees, and other proposals will not prevent counterfeiting if counterfeiters are allowed to mail their products directly to consumers from domestic operations and foreign countries.

We also urge the State of Kansas to continue to educate consumers about the threats to their own personal safety resulting from personal importation of drugs from other countries. In addition to being told that this practice is illegal, consumers may not be aware that this practice is also dangerous and potentially life-threatening.

**H. Necessary Edits to House Bill 2820**

NACDS requests various edits to House Bill 2820, to clarify definitions, to clarify its provisions to ensure better compliance, and to ensure that all entities that handle prescription drugs are subject to the requirements of the bill, including drug manufacturers. Under the current version of this bill, drug manufacturers are exempt from almost all requirements, and are exempt from any penalties for noncompliance. We seek to remedy these problems.

1. Problem: Inconsistency about who must pass a pedigree.
   Description: Section 5(a) requires a pedigree for prescription drugs that leave the normal distribution channel. However, Section 2(e) states that a pedigree is for a drug within the normal distribution channel. Sections 5(b) and (c) are unclear on this point.
   Remedy: Edit Sections 5(a), 5(b), 5(c), and 2(e) to clarify that a pedigree must be passed only for transactions outside the normal distribution channel.

2. Problem: Unclear definition of "chain pharmacy warehouse" under Section 2(b).
   Description: Definition may not allow for more than one chain pharmacy warehouse to be under common ownership or control. Definition would require chain pharmacy warehouses to be under common ownership *and* control. Our members have more than one chain pharmacy warehouse under their ownership or control. Also, there are situations where a business entity may consist of different corporations under common control.
   Remedy: Amend definition to fix problems identified.

3. Problem: Unclear definition of "normal distribution channel" under Section (2)(d), and definition does not include direct sales from a manufacturer to a pharmacy.
   Description: "Normal distribution channel" applies only to distribution transactions, and should include situations when a prescription drug is sold directly from a manufacturer to a pharmacy.
   Remedy: Amend definition to clarify that it applies only to distribution transactions, and that it includes situations when a prescription drug is sold directly from a manufacturer to a pharmacy.

4. Problem: Definition of "wholesale distribution" under Section 2(i) is unclear.
   Description: Definition of "wholesale distribution" not clear that:
   - it does not apply to sales to patients and consumers;
   - it does not apply to intra-company transfers;
   - it does not include sales of minimal quantities to other pharmacies, in addition to practitioners; and
   - it does not apply to drug returns from pharmacies.

   Remedy: Amend definition to fix problems identified.

5. Problem: Section 3(a) would grant manufacturers a blanket exemption from requirements to be licensed as wholesale distributors even if they engage in wholesale distribution.
   Description: Any entity that engages in wholesale distribution should be subject to all the requirements of a wholesale distributor. There is no reason to grant manufacturers a blanket exemption.
   Remedy: Delete manufacturer exemption under 3(a).

6. Problem: Under Section 3(d)(2)(C), the wholesale distributor's designated representative is required to pass an examination, and under Section 3(j) the designated representative would have to complete continuing education programs.
   Description: It will be extremely difficult for one designated representative to ensure compliance with multiple states' testing and continuing education requirements.
   Remedy: Delete requirements. The experiential and policy requirements should ensure that a designated representative is knowledgeable about his/her operations. The background checks for the designated representative should assure the state that the designated representative is trustworthy.

7. Problem: Under Section 3(f), wholesale distributors must post $100,000 bond for Kansas, even if they have already posted such a bond for another state.
   Description: Numerous states are passing legislation requiring wholesale distributors to post $100,000 bonds. It is unnecessarily costly, burdensome, and redundant to require $100,000 bond in every state.
   Remedy: Waive bond requirement if wholesale distributor has posted a comparable bond or other means of security for the purpose of licensure in another state where the wholesale distributor possesses a valid wholesale distributor license in good standing.

8. Problem: Under Section 3(f), wholesale distributors must post $100,000 bond even if they are a publicly-held company, or under common ownership or control with another entity that is already licensed by the board.
   Description: The purpose of posting a bond is to ensure that a company will be able to pay fines and other penalties or damages, should that become necessary. A publicly-held company is most likely going to be financially solvent enough to meet these financial responsibilities. They cannot pack up and disappear in the middle of the night. They are responsible to shareholders. An entity that is under common ownership or control with another entity that is already licensed by the board provides the board with another recourse should fining or penalties be necessary, such as fining or placing penalties on the pharmacy licensee.
   Remedy: Amend bond requirements to waive entities that are publicly-held companies or under common ownership or control with another entity that is already licensed by the board.

9. Problem: Under Section 4(a), it is not clear that drug returns from a pharmacy are not subject to all the requirements of Section 5.
   Description: Section 4(a) exempts drug returns from a pharmacy from the pedigree requirements of Section 5. Section 5 describes the requirements for pedigrees. It is not clear why the language specifically refers to the "pedigree" requirements of Section 5.
   Remedy: For clarity, exempt drug returns from a pharmacy from all the requirements of Section 5.

10. Problem: Section 4(e) would prohibit a manufacturer or wholesale distributor from accepting credit for the payment of prescription drugs unless certain individuals establish the account.
    Description: Chain pharmacy warehouses normally use credit to purchase prescription drugs from wholesalers in indirect purchasing arrangements. Under these arrangements, chain pharmacy warehouses use credit they have with a wholesale distributor to purchase prescription drugs directly from a manufacturer. The prescription drugs are delivered directly from the manufacturer to the chain pharmacy warehouse, but the financial transaction is brokered through the wholesale distributor. Section 4(e) would make such arrangements cumbersome and difficult to manage.
    Remedy: Exempt from the prohibition normal indirect purchasing practices between a chain pharmacy warehouse, a wholesale distributor, and a manufacturer.

11. Problem: Study requirements under Section 5(a)(2) are flawed.
    Description: As FDA has observed, RFID technology promises to eventually eliminate the need for paper pedigrees. Unfortunately, RFID technology solutions are not yet ready for full implementation across the drug supply chain. We believe that any requirement for pedigrees before RFID track and trace technology is widely available and nationally standardized will cause stakeholders to incur incalculable costs resulting from a variety of temporary alternatives to RFID that ultimately will not succeed. This will cause them to invest time, effort and capital into other less beneficial e-pedigree technologies, thus taking resources away from implementing nationally standardized and operational RFID technology. Consequently, RFID technology implementation would be further delayed. RFID technology will not be widely available across the drug distribution system for another five to ten years.
    Remedy: Extensive edits are necessary

12. Problem: The language under Section 5(a)(2) would require pedigrees for all participants in the drug supply chain.
    Description: Pedigrees are not necessary within the normal distribution channel.
    Remedy: Amend language not to require pedigrees within the normal distribution channel.

13. Problem: There is no requirement in the bill for manufacturers, wholesalers or repackagers to respond to requests to authenticate a pedigree.
    Description: One cannot authenticate a pedigree unless every member of the drug supply chain cooperates with such requests.
    Remedy: Add language under Sections 5(b) and 7(g) to require manufacturers, wholesalers and repackagers to comply with requests to authenticate a pedigree.

14. Problem: If a lot number for a drug is not available, need a substitute identifier.
    Description: Section 5(c)(2)(E) requires that a pedigree must include a drug's lot number, but provides no alternative if a lot number is unavailable.

Remedy: Allow for the use of a drug's control number if a drug's lot number is unavailable.

15. Problem: Section 5(d)(2) would require a business to provide all drug pedigree files within 2 business days. It may be difficult to access a drug pedigree within 2 business days.
    Description: If an inspector requests a large number of pedigree records, it may take more than 2 days to retrieve all requested records.
    Remedy: Allow up to seven business days to respond to a request for pedigree records.

16. Problem: Section 6 (a) would provide manufacturers with a blanket exemption from the requirements of the act.
    Description: There is no reason to grant manufacturers with a blanket exemption from the requirements of the act. They should comply to the extent that they engage in wholesale distribution, just like any other entity.
    Remedy: Delete manufacturers blanket exemption under Section 6(a).

17. Problem: Section 7(b) would prohibit purchasing or receiving prescription drugs from a pharmacy if the requirements of this act are not met.
    Description: The Pharmacy Practice Act and the Kansas board of pharmacy regulate under what conditions a pharmacy may dispense prescription drugs. This act cannot replace the Pharmacy Practice Act and the regulations of the board of pharmacy.
    Remedy: Delete Section 7(b).

18. Problem: Section 7(j) and 7(k) would exempt manufacturers from prohibitions on adulterating, misbranding or counterfeiting a prescription drug
    Description: Manufacturers, just like anyone else, must not be allowed to engage in these harmful activities.
    Remedy: Delete manufacturers' exemptions under Section 7(j) and 7(k).

## I. Conclusion

We very much appreciate the opportunity to provide our perspectives on the counterfeit drug problem 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 2820. 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 in approximately five to ten years.

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 must be determined and assessed.

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.

# KS HB 2820 NACDS Edit

AN ACT concerning distribution of certain prescription drugs; enacting the wholesale licensure and prescription medication integrity act.

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

Section 1. Sections 1 through 8, and amendments thereto, shall be known and may be cited as the ''wholesale licensure and prescription medication integrity act''.

Sec. 2. As used in the wholesale licensure and prescription medication integrity act:

(a) ''Authentication'' means to affirmatively verify before any wholesale distribution of a prescription drug occurs that each transaction listed on the pedigree has occurred.

(b) ''Chain pharmacy warehouse'' means a physical location for drugs or devices, or both, that acts as a central warehouse and performs intracompany sales or transfers of the drugs or devices to a group of chain pharmacies or other chain pharmacy warehouses that are under common ownership or control.

**Comment:** Clarification of definition of "chain pharmacy warehouse"

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(c) ''Facility'' means a facility of a wholesale distributor where prescription drugs are stored, handled, repackaged or offered for sale.

(d) ''Normal distribution channel'' means a chain of custody during distribution of a prescription medication that goes from a manufacturer to a wholesale distributor to a pharmacy to a patient or a chain of custody for a medication that goes from a manufacturer to a wholesale distributor to a chain pharmacy warehouse to their intracompany pharmacy to a patient. Direct sales of prescription medications by a manufacturer to a pharmacy or a chain pharmacy warehouse are within the normal distribution channel.

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**Comment:** Clarification of definition of "normal distribution channel." Includes direct sales from a manufacturer to a pharmacy

(e) ''Pedigree'' means a document or electronic file containing information that records each wholesale distribution of any given prescription drug that occurs outside the normal distribution channel.

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**Comment:** Clarifies that pedigree documents transactions outside the normal distribution channel.

(f) ''Prescription drug'' means any drug, including any biological product, except for blood and blood components intended for transfusion or biological products that are also medical devices, required by federal law, or federal regulation, to be dispensed only by a prescription, including finished dosage forms and bulk drug substances subject to section 503(b) of the federal food, drug and cosmetic act (FFDCA).

(g) ''Repackage'' means repackaging or otherwise changing the container, wrapper or labeling to further the distribution of a prescription drug excluding that completed by the pharmacists responsible for dispensing product to the patient.

(h) ''Repackager'' means a person who repackages.



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(i) ''Wholesale distributor'' means anyone engaged in the wholesale distribution of prescription drugs, including, but not limited to, repackagers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, and drug wholesalers or distributors; independent wholesale drug traders; retail pharmacies that conduct wholesale distribution; and chain pharmacy warehouses that conduct wholesale distribution.

(j) ''Wholesale distribution'' means distribution of prescription drugs to persons or entities other than a consumer or patient, but shall not include:

(1) Intracompany sales or transfers of prescription drugs, meaning any transaction or transfer between any division, subsidiary, parent or affiliated or related company under common ownership or control of an entity;
(2) the sale, purchase, distribution, trade or transfer of a prescription drug or offer to sell, purchase, distribute, trade or transfer a prescription drug for emergency medical reasons;
(3) the distribution of prescription drug samples by manufacturers' representatives;
(4) drug returns, when conducted by a hospital, health care entity or charitable institution in accordance with 21 C.F.R. § 203.23;
(5) the sale of minimal quantities of prescription drugs by retail pharmacies to other pharmacies or to licensed practitioners for office use;
(6) retail pharmacies' delivery of prescription drugs to a patient or patient's agent pursuant to the lawful order of a licensed practitioner;
(7) the sale, transfer, merger or consolidation of all or part of the business of a pharmacy or pharmacies from or with another pharmacy or pharmacies, whether accomplished as a purchase and sale of stock or business assets; or
(8) The sale or transfer from a retail pharmacy or chain pharmacy warehouse of expired, damaged, returned or recalled drugs to the original manufacturer or to a third party returns processor.

**Comment:** Clarification that "wholesale distribution" does not include sales to patients and consumers.

**Comment:** Clarification that "wholesale distribution" does not include intracompany transfers.

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**Comment:** Clarification that "wholesale distribution" does not include sales of minimal quantities to other pharmacies (in addition to practitioners.

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**Comment:** Clarification that "wholesale distribution" does not include drug returns.

(k) ''Wholesaler'' means a person engaged in the wholesale distribution of prescription drugs.

Sec. 3 (a) Each wholesale distributor who engages in the wholesale distribution of prescription drugs shall be licensed by the state board of pharmacy and every nonresident wholesale distributor shall be licensed in a state if it ships prescription drugs into that state, in accordance with this act before engaging in wholesale distributions of wholesale prescription drugs.
(b) The state board of pharmacy shall require the following minimum information from each wholesale distributor applying for a license under subsection (a) of this section:

(1) The name, full business address and telephone number of the licensee;
(2) all trade or business names used by the licensee;
(3) addresses, telephone numbers and the names of contact persons for all facilities used by the licensee for the storage, handling and distribution of prescription drugs;

**Comment:** Manufacturers should be licensed, just like anyone else, if they meet the requirements of this section.

**Deleted:** The state board of pharmacy shall exempt manufacturers from any licensing and other requirements of this section, to the extent not required by federal law or regulation, unless particular requirements are deemed necessary and appropriate following rulemaking.



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(4) the type of ownership or operation, including, but not limited to, partnership, corporation or sole proprietorship;
(5) the name or names of the owner or operator of the licensee, 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 state of incorporation; and

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

(6) a list of all licenses and permits issued to the applicant by any other state that authorizes the applicant to purchase or possess prescription drugs;

(7) the name of the applicant's designated representative for the facility, together with the personal information statement and fingerprints, required pursuant to subparagraph (8) of subsection (b) of this section for such person; and

(8) each person required by subparagraph (7) of subsection (c) of this section to provide a personal information statement and fingerprints shall provide the following information to the state:

(A) The person's places of residence for the past seven years;

(B) the person's date and place of birth;

(C) the person's occupations, positions of employment and offices held during the past seven years;

(D) the 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;

(E) whether the person has been, during the past seven years, the subject of any proceeding for the revocation of any license or any criminal violation and, if so, the nature of the proceeding and the disposition of the proceeding;

(F) whether, during the past seven years, the person 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 distribution of prescription drugs or criminal violations, together with details concerning any such event;

G) a 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, distributed or stored

pharmaceutical products and any lawsuits in which such businesses were named as a party;

(H) a description of any misdemeanor or felony criminal offense 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 that criminal offense, the applicant must, within 15 days after the disposition of the appeal, submit to the state board of pharmacy a copy of the final written order of disposition; and

(I) a photograph of the person taken in the previous 30 days.

(c) The information required pursuant to subsection (b) of this section shall be provided under oath.

(d) The state shall not issue a wholesale distributor license of an applicant, unless the state:

(1) Conducts a physical inspection of the facility at the address provided by the applicant as required in subsection (b) of section 3 of this section; and

(2) determines that the designated representative meets the following qualifications:

(A) Is at least 21 years of age;

(B) has been employed full time for at least three years in a pharmacy or with a wholesale distributor in a capacity related to the dispensing and distribution of and recordkeeping relating to prescription drugs;

(C) is employed by the applicant full time in a managerial level position;

(D) is actively involved in and aware of the actual daily operation of the wholesale distributor;

(E) is physically present at the facility of the applicant during regular business hours, except when the absence of the designated representative is authorized, including, but not limited to, sick leave and vacation leave;

(F) is serving in the capacity of a designated representative for only one applicant at a time;

**Comment:** It will be extremely difficult for a single designated representative to ensure compliance with multiple states' testing and continuing education requirements.

**Deleted:** has received a score of 75% or more on an examination given by the state board of pharmacy regarding federal and state laws governing wholesale distribution of prescription drugs. ¶ (D)

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(G) does not have any convictions under any federal, state or local laws relating to wholesale or retail prescription drug distribution or distribution of controlled substances; and

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(H) does not have any felony convictions under federal, state or local laws.

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(e) The state shall submit the fingerprints provided by a person with a license application for a statewide criminal record check and for forwarding to the federal bureau of investigation to conduct a national criminal record check of the person.

(f) The state board of pharmacy shall require every wholesale distributor applying for a license to submit a bond of at least $100,000, or other equivalent means of security acceptable to the state, such as an irrevocable letter of credit or a deposit in a trust account or financial institution, payable to a fund established by the state, pursuant to subsection (g) of this section. The purpose of the bond is to secure payment of any fines or penalties imposed by the state and any fees and costs incurred by the state regarding such license, which are authorized under state law and which the licensee fails to pay 30 days after the fines, penalties or costs become final. The state may make a claim against such bond or security until one year after the licensee's license ceases to be valid. The bond shall cover all facilities operated by the applicant in the state. The bond requirement may be waived if the wholesale distributor has in place a comparable bond or other equivalent means of security for the purpose of licensure in another state where the wholesale distributor possesses a valid wholesale distributor license in good standing. The surety bond requirement shall be waived if the wholesale distributor (1) is a chain pharmacy warehouse, (2) is or is owned or controlled by, a publicly-held company, or (3) is under common ownership or control with an entity that has been licensed by the state board of pharmacy.

**Comment:** Avoid unnecessary, redundant bond requirements if already posted a bond.

**Comment:** These entities are already regulated by the state or share common ownership with an entity that is already regulated by the state; and are generally considered financially solvent and trustworthy businesses.

(g) There is hereby created in the state treasury the drug wholesaler trust fund. The executive secretary of the state board of pharmacy shall administer the fund. Proceeds from the bond prescribed by subsection (f) of this section shall be remitted to the state treasurer in accordance with the provisions of K.S.A. 75-4215, and amendments thereto. Upon receipt of each such remittance the state treasurer shall deposit the entire amount in the state treasury to the credit of the drug wholesaler trust fund. Moneys in the drug wholesaler trust fund may be expended for the purposes prescribed in subsection (f) of this section. All expenditures from the drug wholesaler trust fund shall be made in accordance with appropriation acts upon warrants of the director of accounts and reports issued pursuant to vouchers approved by the executive secretary of the state board of pharmacy.

(h) If a wholesale distributor distributes prescription drugs from more than one facility, the wholesale distributor shall obtain a license for each facility.

(i) Every calendar year, the state board of pharmacy shall send to each wholesale distributor licensed under this section a form setting forth the information that the

wholesale distributor provided pursuant to subsection (b) of this section. Within 30 days of receiving such form, the wholesale distributor must identify and state under oath to the state board of pharmacy all changes or corrections to the information that were provided pursuant to subsection (b) of this section. Changes in, or corrections to, any information in subsection (b) of this section shall be submitted to the state board of pharmacy as required by such board. The state board of pharmacy may suspend or revoke the license of a wholesale distributor if such board determines that the wholesale distributor no longer qualifies for the license issued under this section.

(j) Information provided under this section of this act shall not be disclosed to any person or entity other than a state board of pharmacy, government board or government agency provided such board or other state or federal agency needs such information for licensing or monitoring purposes.

Sec. 4. (a) A wholesale distributor shall receive prescription drug returns or exchanges from a pharmacy or chain pharmacy warehouse pursuant to the terms and conditions of the agreement between the wholesale distributor and the pharmacy or chain pharmacy warehouse, or both, including the returns of expired, damaged and recalled pharmaceutical product to either the original manufacturer or a third party returns processor, and such returns or exchanges shall not be subject to the requirements prescribed by section 5 of this act. Wholesale distributors shall be held accountable for policing their returns process and insuring that such returns are of products manufactured by their operations, are secure and do not permit the entry of adulterated and counterfeit product.

(b) A manufacturer or wholesale distributor shall furnish prescription drugs only to a person licensed by the state board of pharmacy. Before furnishing prescription drugs to a person not known to the manufacturer or wholesale distributor, the manufacturer or wholesale distributor shall affirmatively verify that the person is legally authorized to receive the prescription drugs by contacting the state board of pharmacy.

(c) Prescription drugs furnished by a manufacturer or wholesale distributor shall be delivered only to the premises listed on the license, except that the manufacturer or wholesale distributor may furnish prescription drugs to an authorized person or agent of that person at the premises of the manufacturer or wholesale distributor if:

(1) The identity and authorization of the recipient is properly established; and

(2) this method of receipt is employed only to meet the immediate needs of a particular patient of the authorized person.

(d) Prescription drugs may be furnished to a hospital pharmacy receiving area provided that a pharmacist or authorized receiving personnel signs, at the time of delivery, a receipt showing the type and quantity of the prescription drug so received.

**Comment:** The designated representative identified pursuant to subsection (b)(7) of section 3 of this act must complete continuing education programs as required by the state board of pharmacy regarding federal and state laws governing wholesale distribution of prescription drugs.

**Deleted:** The designated representative identified pursuant to subsection (b)(7) of section 3 of this act must complete continuing education programs as required by the state board of pharmacy regarding federal and state laws governing wholesale distribution of prescription drugs.

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(k)

**Comment:** Clarification that returns are not subject to all requirements of Section 5, not just pedigree requirements.

**Deleted:** pedigree

Any discrepancy between receipt and the type and quantity of the prescription drug actually received shall be reported to the delivering manufacturer or wholesale distributor on or before the next business day after the delivery to the pharmacy receiving area.

(e) A manufacturer or wholesale distributor shall not accept payment for, or allow the use of, a person or entity's credit to establish an account for the purchase of prescription drugs from any person other than the owner or owners of record, the chief executive officer or the chief financial officer listed on the license of a person or entity legally authorized to receive prescription drugs. Any account established for the purchase of prescription drugs must bear the name of the licensee. This paragraph (e) shall not apply to normal indirect purchasing practices between a chain pharmacy warehouse, a wholesale distributor and a manufacturer.

Sec. 5. (a) Each person who is engaged in the wholesale distribution of prescription drugs shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of the prescription drugs. These records shall include pedigrees for wholesale distributions of all prescription drugs that occur outside the normal distribution channel.

(1) A retail pharmacy or chain pharmacy warehouse shall comply with the requirements of this section only if the pharmacy or chain pharmacy warehouse engages in wholesale distribution of prescription drugs outside the normal distribution channel.

(2) Prior to imposing a requirement for electronic tracking and tracing of prescription drugs , the state board of pharmacy shall conduct and publish a study of the feasibility and costs of a large scale electronic product identification tracking system implementation across the pharmaceutical supply chain, to be completed on or before January 1, 2007. Such report shall include consultation with manufacturers, wholesale distributors and pharmacies responsible for the sale and distribution of prescription drug products in the state. The study shall determine whether electronic technologies such as radio frequency identification may have a negative impact on the safety, efficacy or price of prescription drugs. Based on the results of the study the state board of pharmacy shall determine a mandated implementation date for electronic pedigrees for wholesale distribution that occurs outside the normal distribution channel. The implementation date for any mandated electronic pedigree shall be no sooner than December 31, 2010, and may occur only after adoption and implementation of national standards for use of an electronic pedigree system that can and will be used by the entire pharmaceutical distribution supply chain.

(b) Each person who is engaged in the wholesale distribution of a prescription drug, including repackagers, outside the normal distribution channel who is in possession of a pedigree for a prescription drug and who intends to engage in further wholesale distribution of that prescription drug, shall affirmatively verify before any wholesale distribution of a prescription drug occurs that each transaction listed on the pedigree has

**Comment:** Chain pharmacy warehouses often uses credit to purchase prescription drugs in indirect purchasing arrangements with manufacturers and wholesalers.

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**Comment:** Clarification that pedigrees are for transactions outside the normal distribution channel.

**Deleted:** The state board of pharmacy

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**Comment:** With respect to the study:
•need a report published from the study so we can see the results
•need clarification on the goal and intent of the study. The study should address RFID and look at the overall impact on safety, efficacy and price of prescription drugs.. expensive and delicate products, especially bio-engineered products. The board may (not shall) mandate an electronic pedigree system for distributions outside the normal distribution chain (no need for trusted entities within the normal distribution chain to have to pass pedigrees). A compliance date of 2007 is too soon, no one is close to ready for electronic pedigrees, 2010 is more reasonable... but even then there must be standards in place... we have no standards at this time. Every link in the supply chain may be using different technologies for an electronic pedigree.. unless there are standards they cannot communicate with each other.

**Deleted:** , but excluding the original manufacturer of the finished form of the prescription drug

**Deleted:** attempts

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occurred. All manufacturers, wholesale distributors and repackagers have an affirmative duty to promptly, accurately and fully respond to requests for authentication with information sufficient to allow the requesting party to authenticate the pedigree.

**Comment:** Would require manufacturers, wholesalers, and repackagers to respond to authentication requests. We cannot authenticate a pedigree without their cooperation.

(c) The pedigree shall:

(1) Include all necessary identifying information concerning each sale in the chain of wholesale distribution of the product from the manufacturer, through acquisition and sale by any wholesale distributor or repackager, until final sale to a wholesale distributor or chain pharmacy warehouse. At minimum, the necessary chain of distribution information shall include:

**Deleted:** pharmacy

**Deleted:** other person dispensing or administering the drug. ¶

**Comment:** Clarify that the pedigree applies only to transactions outside the normal distribution channel.

(A) Name, address, telephone number and if available, the e-mail address, of each owner of the prescription drug, and each wholesale distributor of the prescription drug;

(B) the name and address of each location from which the product was shipped, if different from the owner's;

(C) transaction dates; and

(D) certification that each recipient has authenticated the pedigree.

(2) At minimum, the pedigree shall also include:

(A) Name of the prescription drug;

(B) dosage form and strength of the prescription drug;

(C) size of the container;

(D) number of containers;

(E) lot or control number of the prescription drug; and

**Comment:** Need a control number if lot number is not available.

(F) name of the manufacturer of the finished dosage form.

(d) Each pedigree or electronic file shall be:

(1) Maintained by the purchaser and the wholesale distributor for three years from the date of sale or transfer; and

(2) available for inspection or use within seven business days upon a request of an authorized officer of the law.

**Comment:** Would prefer 7 business days to respond to an inspection request for electronic pedigrees.

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(e) The state board of pharmacy shall adopt rules and a form relating to the requirements of this subsection no later than 120 days after the effective date of this act.

Sec. 6. (a) If the state finds that there is a reasonable probability that:

(1) A wholesale distributor has:
(A) Violated a provision in this act; or
(B) falsified a pedigree, or sold, distributed, transferred, manufactured, repackaged, handled or held a counterfeit prescription drug intended for human use.
(2) The prescription drug at issue as a result of a violation of paragraph (1) of subsection (a) of this section could cause serious, adverse health consequences or death; and
(3) other procedures would result in unreasonable delay, the state shall issue an order requiring the appropriate person, including the distributors or retailers of the drug to immediately cease distribution of the drug within that state.
(b) An order issued under subsection (a) of this section shall provide the person subject to the order with an opportunity for an informal hearing, to be held no later than 10 days after the date of the issuance of the order, on the actions required by the order. If, after providing an opportunity for such a hearing, the state determines that inadequate grounds exist to support the actions required by the order, the state shall vacate the order.

Sec. 7. It shall be unlawful for a person to perform or cause the performance of or aid and abet any of the following acts in this state:

(a) Failure to obtain a license in accordance with this act, or operating without a valid license when a license is required by this act;
(b) the sale, distribution, or transfer of a prescription drug to a person that is not authorized under the law of the jurisdiction in which the person receives the prescription drug to receive the prescription drug, in violation of subsection (b) of section 4 of this act;
(c) failure to deliver prescription drugs to specified premises, as prescribed by subsection (c) of section 4 of this act;

(d) accepting payment or credit for the sale of prescription drugs in violation of subsection (e) of section 4 of this act;
(e) failure to maintain or provide pedigrees as required by this act;

(f) failure to obtain, pass or authenticate a pedigree, as required by this act;

(g) Failure to provide information to a purchaser or seller of prescription drugs that is necessary to create, obtain, pass, or authenticate a pedigree;

(h) providing the state or any of its representatives or any federal official with false or fraudulent records or making false or fraudulent statements regarding any matter within the provisions of this act;

(i) obtaining or attempting to obtain a prescription drug by fraud, deceit, misrepresentation or engaging in misrepresentation or fraud in the distribution of a prescription drug;
(j) the manufacture, repacking, sale, transfer, delivery, holding or offering for sale any prescription drug that is adulterated, misbranded, counterfeit, suspected of being counterfeit or has otherwise been rendered unfit for distribution;

**Comment:** There is no reason that manufacturers should have a blanket exemption from complying with this Act.

**Deleted:** , other than a manufacturer,

**Comment:** Deletes a prohibition on purchasing or receiving a prescription drug from a pharmacy if the requirements of this Act are not met. We cannot be sure that this Act covers all circumstances in which a person may purchase or receive a drug from a pharmacy. For example, pharmacies provide drugs to nursing homes for administration to patients.

**Deleted:** (b) purchasing or otherwise receiving a prescription drug from a pharmacy, unless the requirements prescribed by subsection (a) of section 3 of this act are met; ¶

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**Comment:** Would require manufacturers and wholesalers to provide information that is necessary to create, obtain, pass, or authenticate a pedigree.

**Comment:** Would delete manufacturers' attempt to exclude themselves from violations.

**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 United States food and drug administration,



6-9

(k) the adulteration, misbranding or counterfeiting of any prescription drug;

(l) the receipt of any prescription drug that is adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit or suspected of being counterfeit and the delivery or proffered delivery of such drug for pay or otherwise;

(m) the alteration, mutilation, destruction, obliteration or removal of the whole or any part of the labeling of a prescription drug or the commission of any other act with respect to a prescription drug that results in the prescription drug being misbranded; and

(n) such prohibited acts shall not include a prescription drug manufacturer or agent of a prescription drug manufacturer, obtaining or attempting to obtain a prescription drug for the sole purpose of testing the prescription drug for authenticity.

Sec. 8. (a) A person convicted of violating section 7, and amendments thereto, shall be guilty of a drug severity level 1 felony.
(b) This section shall be part of and supplemental to the uniform controlled substances act.

Sec. 9. This act shall take effect and be in force from and after its publication in the statute book, but shall not be enforced by the state until one year after the date of final promulgation of all rules necessary to implement this act.

**Comment:** Would delete manufacturers' attempt to exclude themselves from violations.

**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 United States food and drug administration,

**Comment:** Affected parties should be given time to comply with rules promulgated pursuant to this act.



6-10

February 28, 2006

The Honorable Jim Morrison, Chairperson
House Committee on Health and Human Services
Statehouse, Room 143-N
Topeka, Kansas 66612

Dear Representative Morrison:

SUBJECT: Fiscal Note for HB 2820 by House Committee on Appropriations

In accordance with KSA 75-3715a, the following fiscal note concerning HB 2820 is respectfully submitted to your committee.

HB 2820 would expand the requirements that a wholesale drug distributor must meet in order to be eligible for licensure in Kansas. The bill would require criminal history background checks for wholesale drug distributor licensure. The bill would require the Board of Pharmacy to perform physical inspections of out-of-state manufacturers. HB 2820 would also require the Board to give an exam to a designated representative of the distributor to determine whether he or she meets state requirements. Each licensee would have to provide a $100,000 bond or other security deposit. The distributors would have to keep and authenticate routinely legend drug or device pedigrees. The pedigree is a statement, kept in written or electronic form, which records each distribution of a legend drug or device from the original sale by the manufacturer through the acquisition and sale by each wholesale drug distributor. The bill would require the Board, in consultation with the industry, to determine a date to mandate electronic pedigrees. This date could not be sooner than December 31, 2007.

HB 2820 would provide for administrative penalties, such as suspension or revocation of licenses or issuance of cease and desist orders, for distributors who do not meet the licensure requirements. The bill would create a criminal penalty, a drug severity level 1 felony, for not complying with certain licensure requirements.

Attachment 7
HHS 3-1-06

The Kansas Board of Pharmacy states that passage of HB 2820 would increase inspections, legal proceedings, background checks, and other clerical duties. The Board would require an additional 1.00 FTE Inspector position and a 0.50 FTE Administrative Assistant position. The salary expenditures for the inspector would be approximately $62,000 and the wage expenditures for the administrative assistant would be approximately $8,000. The background checks from the Kansas Bureau of Investigation cost $54 each. The Board cannot estimate the number that would be required each year. There is also no way to estimate the additional costs for travel, proceedings, and other operating expenses. Although it is not specifically provided for in HB 2820, the Board assumes that it can pass on these additional costs in the form of licensing fees for distributors.

The Kansas Sentencing Commission states that passage of HB 2820 would result in an additional one to three prison admissions per year, beginning in FY 2007. There would therefore be the need for one to three additional prison beds in FY 2007 growing to a need of an additional 10 to 30 prison beds by FY 2016. Any fiscal effect associated with HB 2820 is not included in *The FY 2007 Governor's Budget Report.*

Sincerely,

Duane A. Goossen
Director of the Budget

cc: Debra Billingsley, Board of Pharmacy
Patti Biggs, Sentencing Commission