Approved: March 20, 2007
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 5, 2007 in Room 526-S of the Capitol.

All members were present except:
Clark Shultz- excused
Ed Trimmer- excused
Jeff Colyer- excused
Jim Ward- excused
Mike Kigerl- excused

Committee staff present:
Justin Thompson, Revisor's Office
Renae Jefferies, Revisor's Office
Melissa Calderwood, Legislative Research
Mary Galligan, Legislative Research
Tatiana Lin, Legislative Research
Patti Magathan, Committee Assistant

Conferees appearing before the committee:
Debra Billingsley, Executive Director Kansas State Board of Pharmacy
Julie Hein, Representing the Kansas Pharmacy Coalition

Others Attending:
See Attached List.

Vice-Chair Mast opened hearing on **HB2531** - Pharmacy act amendments concerning durable medical equipment and wholesale drug distribution regulation.

Debra Billingsley, Executive Director of the Kansas State Board of Pharmacy, explained that a task force had been mandated by the 2006 legislature to study the issue of counterfeit drugs, pedigrees for prescription drugs, penalty aspects for violation of pedigree requirements, and registration requirements of wholesale distributors. This bill is a result of the task force recommendations. This bill helps by setting high standard for registration for all distributors shipping into Kansas. There are also increased penalties against those entities that violate any provision of the Pharmacy Act. There are some definitions and technical issues regarding the language that has been proposed. The Board is willing to work with interested parties and arrive at a mutually agreeable amendment to this bill. (Attachment 1)

Julie Hein, speaking on behalf of the Kansas Pharmacy Coalition (K.P.C.) Said that this bill will create additional safeguards and increases the requirements for wholesale licensure of prescription drugs. K.P.C. requests several amendments to clarify definitions. These amendments do not change the intent of **HB2531**, they merely provide clarification and address the return of saleable prescription drugs. (Attachment 2)

Written testimony was provided by Daniel Bellingham, Associate Director of State Government Affairs with Healthcare Distribution Management Association, proponent. (Attachment 3) In addition a newspaper article from the February 18, 2007 issue of the Kansas City Star, Parade, was provided for Committee perusal. (Attachment 4)

Chair Landwehr closed hearings on HB2531 and adjourned the meeting at 1:42. Next meeting is March 6, 2007 at 1:30 P.M.

HOUSE HEALTH AND HUMAN SERVICES COMMITTEE GUEST LIST

DATE: March 5, 2007

NAME	REPRESENTING
Bill Sneed	MERCK
Pat Hubbell	PHRMA
Julie Hein	KS Pharmacy Coalition
MARK P. MARTZ	VIA CHRISTI HEALTH SYSTEM
Ron Gaches	KDHA
Debra Billingsley	KBOP
[illegible]	KPOP Member [illegible]

KANSAS

BOARD OF PHARMACY
DEBRA L. BILLINGSLEY, EXECUTIVE DIRECTOR

KATHLEEN SEBELIUS, GOVERNOR

Testimony re: HB 2531
House Health and Human Services
Presented by Debra L. Billingsley
March 5, 2007

Chairperson Landwehr and Members of the Committee:

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

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

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

House Health and Human Services
DATE: 3-5-07
ATTACHMENT 1-1

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The Board of Pharmacy would submit that there needs to be more stringent requirements for registration of wholesale distributors. The Board believes that increasing the registration requirements is needed regardless of whether there is pedigree. This will minimize the risks of counterfeit drugs.

The Board is aware that there are some definitions and technical issues regarding the language that has been proposed. The Board is not in opposition to most of the changes but we would like to sit down with interested parties and prepare a balloon for next week. We think that most of the language can be worked out among the parties and then can be presented for approval to the Committee.

Thank you for permitting me to testify today.

Debra Billingsley
Executive Secretary

HEIN LAW FIRM, CHARTERED

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Ronald R. Hein
Attorney-at-Law
Email: rhein@heinlaw.com

Testimony re: HB 2531
House Health and Human Services Committee
Presented by Julie J. Hein
on behalf of
Kansas Pharmacy Coalition
March 3, 2007

Madam Chair and Members of the Committee:

My name is Julie Hein and I am speaking on behalf of the Kansas Pharmacy Coalition (KPC). The Kansas Pharmacy Coalition is an ad hoc coalition comprised of the Kansas Pharmacists Association and the Kansas Association of Chain Pharmacies.

KPC supports HB 2531.

HB 2531is the final work product of the Board of Pharmacy after interim study of the Wholesale Licensure and Pedigree issues. This bill will create additional safe guards and increases the requirements for wholesale licensure of prescription drugs.

We are requesting the following amendments. These amendments have been suggested by National Association of Chain Drug Stores (NACDS). NACDS has communicated with the Board of Pharmacy and has explained that their amendments are primarily clarifications to definitions. Briefly, the amendments do the following:

KSA 65-1626(f), the definition of "chain pharmacy warehouse" should be amended to reflect that intracompany sales are different transactions from transfers so the language should read "or" instead of "and". Further reference to "affiliated group" would not be the best legal term for the relationship between a CPW and it's corporate owner. We request language be amended to read "same ownership or control".

KSA 65-1626(qq), the definition of "wholesale distributor" identifies those entities that conduct wholesale distribution. We recommend inserting "that conduct wholesale distribution" to clarify that only CPWs that actually conduct wholesale distribution would be considered wholesale distributors, similar to the existing definition for pharmacies, only pharmacies that conduct wholesale distribution are considered wholesale distributors. This does not change requirements that all CPWs must be licensed by the Board.

House Health and Human Services
DATE: 3-5-07
ATTACHMENT 2-1

KSA 65-1626(rr), would establish the legal threshold for determining whether an entity is engaging wholesale distribution as a percentage sales figure. This is misleading and confusing, due to the extremely wide range of prices for prescription drugs. One entity could distribute a very large percentage of low price drugs and not reach the threshold, while another entity would reach the threshold by distributing a very small number of very expensive drugs. We recommend that "the number of units transferred" is a better value reference than the proposed 5% of sales.

KSA 65-1626(rr)(3) defines "intracompany transaction," which is not otherwise defined.

KSA 65-1626(rr)(13) includes a necessary exemption to the term "wholesale distribution." This language is needed for all pharmacies and chain pharmacy warehouses to be able to return saleable drug products. (9) above allows for the return on non-saleable products. Pharmacies and chain pharmacy warehouses commonly return overstock to the manufacturer or to the wholesale distributor from where they purchased it. This is allowed under federal FDA regulations. Unless this language is added, no pharmacy could return saleable drugs to the manufacturer or to their wholesaler without being considered a wholesale distributor. Also, this language would allow pharmacies to transfer non-saleable drugs to drug returns processors without being considered wholesale distributors.

KSA 65-1655(f) would allow the board to license out of state wholesale distributors by reciprocity if the board should deem it appropriate.

These amendments do not change the intent of HB2531. They merely provide clarification and address the return of saleable prescription drugs.

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

2007 KS H 2531 – NACDS Edits

AUTHOR: House Committee on Appropriations
VERSION: Introduced
VERSION DATE: 02/15/2007

Session of 2007

HOUSE BILL No. 2531

By Committee on Appropriations

2-15

AN ACT concerning the pharmacy act of the state of Kansas; amending K.S.A. 65-1627 and 65-1655 and K.S.A. 2006 Supp. 65-1626 and 65-1643 and repealing the existing sections.

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

Section 1. K.S.A. 2006 Supp. 65-1626 is hereby amended to read as follows: 65-1626. For the purposes of this act:

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

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

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

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

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

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

(d) "Brand exchange" means the dispensing of a different drug product of the same

dosage form and strength and of the same generic name than the brand name drug product prescribed.

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

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

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

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

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

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

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

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

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

~~(l)~~ (n) "Drug" means: (1) Articles recognized in the official United States pharmacopoeia, or other such official compendiums of the United States, or official national formulary, or any supplement of any of them; (2) articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals; (3) articles, other than food, intended to affect the structure or any function of the body of man or other animals; and (4) articles intended for use as a component of any articles specified in clause (1), (2) or (3) of this subsection; but does not include devices or their components, parts or accessories, except that the term "drug" shall not include amygdalin

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Comment [NACDS1]: Clarifying language

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(laetrile) or any livestock remedy, if such livestock remedy had been registered in accordance with the provisions of article 5 of chapter 47 of the Kansas Statutes Annotated prior to its repeal.

(o) "Durable medical equipment" means technologically sophisticated medical devices that may be used in a residence, including the following: (1) Oxygen and oxygen delivery system; (2) ventilators; (3) respiratory disease management devices; (4) continuous positive airway pressure (CPAP) devices; (5) electronic and computerized wheelchairs and seating systems; (6) apnea monitors; (7) transcutaneous electrical nerve stimulator (TENS) units; (8) low air loss cutaneous pressure management devices; (9) sequential compression devices; (10) feeding pumps; (11) home phototherapy devices; (12) infusion delivery devices; (13) distribution of medical gases to end users for human consumption; (14) hospital beds; (15) nebulizers; (16) other similar equipment determined by the board in rules and regulations adopted by the board.

(p) "Exclusive distributor" means any entity that: (1) Contracts with a manufacturer to provide or coordinate warehousing, wholesale distribution or other services on behalf of a manufacturer and who takes title to that manufacturer's prescription drug, but who does not have general responsibility to direct the sale or disposition of the manufacturer's prescription drug; (2) is licensed as a wholesale distributor under the pharmacy act of the state of Kansas; and (3) to be considered part of the national distribution channel, must be an authorized distributor of record.

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

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

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

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

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

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

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

(E) persons receiving inpatient hospice services.

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

(A) Any registered pharmacy;

(B) any office of a practitioner; or

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

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

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

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

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

~~(t)~~ (x) "Pharmacist in charge" means the pharmacist who is responsible to the board for a registered establishment's compliance with the laws and regulations of this state pertaining to the practice of pharmacy, manufacturing of drugs and the distribution of drugs. The pharmacist in charge shall supervise such establishment on a full-time or a part-time basis and perform such other duties relating to supervision of a registered establishment as may be prescribed by the board by rules and regulations. Nothing in this definition shall relieve other pharmacists or persons from their responsibility to comply with state and federal laws and regulations.

~~(u)~~ (y) "Pharmacy," "drug store" or "apothecary" means premises, laboratory, area or other place: (1) Where drugs are offered for sale where the profession of pharmacy is

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

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

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

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

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

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

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

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

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

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

~~(ee)~~ (ii) "Professional incompetency" means:

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

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

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

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

~~(gg)~~ (kk) "Secretary" means the executive secretary of the board.

(ll) "Third party logistics provider" means an entity that: (1) Provides or coordinates warehousing, distribution or other services on behalf of a manufacturer, but does not take title to the prescription drug or have general responsibility to direct the prescription drug's sale or disposition; (2) is licensed as a wholesale distributor under the pharmacy act of the state of Kansas; and (3) to be considered part of the normal distribution channel, must also be an authorized distributor of record.

~~(hh)~~ (mm) "Unprofessional conduct" means:

(1) Fraud in securing a registration or permit;

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

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

(4) intentionally falsifying or altering records or prescriptions;

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

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

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

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

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

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

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

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

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

(qq) "Wholesale distributor" means any person engaged in wholesale distribution of prescription drugs or devices in or into the state, including, but not limited to, manufacturers, repackagers, own-label distributors, private-label distributors, jobbers, brokers, warehouses, including manufacturers' and distributors' warehouses, co-licensees, exclusive distributors, third party logistics providers, chain pharmacy warehouses that conduct wholesale distributions, wholesale drug warehouses, independent wholesale drug traders and retail pharmacies that conduct wholesale distributions.

(rr) "Wholesale distribution" means the distribution of prescription drugs or devices

Comment [NACDS2]: Clarifies that only chain pharmacy warehouses that conduct wholesale distributions fall under the definition of "wholesale distributor," just like pharmacies.

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by wholesale distributors to persons other than consumers or patients, and includes the transfer of prescription drugs by a pharmacy to another pharmacy if the total number of units transferred drugs during a twelve (12) month period does not exceed five percent (5%) of the total number of all units dispensed by the pharmacy during the immediately preceding twelve (12) month period. Wholesale distribution does not include: (1) The sale, purchase or trade of a prescription drug or device, an offer to sell, purchase or trade a prescription drug or device or the dispensing of a prescription drug or device pursuant to a prescription; (2) the sale, purchase or trade of a prescription drug or device or an offer to sell, purchase or trade a prescription drug or device for emergency medical reasons; (3) intracompany transactions, meaning any transaction or transfer between any division, subsidiary, parent or affiliated or related company under common ownership or control of a corporate entity, or any transaction or transfer between co-licensees of a co-licensed product, unless in violation of own use provisions; (4) the sale, purchase or trade of a prescription drug or device or an offer to sell, purchase or trade a prescription drug or device among hospitals, chain pharmacy warehouses, pharmacies or other health care entities that are under common control; (5) the sale, purchase or trade of a prescription drug or device or the offer to sell, purchase or trade a prescription drug or device by a charitable organization described in 503 (c)(3) of the internal revenue code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law; (6) the purchase or other acquisition by a hospital or other similar health care entity that is a member of a group purchasing organization of a prescription drug or device for its own use from the group purchasing organization or from other hospitals or similar health care entities that are members of these organizations; (7) the transfer of prescription drugs or devices between pharmacies pursuant to a centralized prescription processing agreement; (8) the sale, purchase or trade of blood and blood components intended for transfusion; (9) the return of recalled, expired, damaged or otherwise non-salable prescription drugs, when conducted by a hospital, health care entity, pharmacy, chain pharmacy warehouse or charitable institution in accordance with the board's rules and regulations; (10) the sale, transfer, merger or consolidation of all or part of the business of a retail pharmacy or pharmacies from or with another retail pharmacy or pharmacies, whether accomplished as a purchase and sale of stock or business assets, in accordance with the board's rules and regulations; (11) the distribution of drug samples by manufacturers' and authorized distributors' representatives; ~~or~~ (12) the sale of minimal quantities of drugs by retail pharmacies to licensed practitioners for office use, or (13) the sale or transfer from a retail pharmacy or chain pharmacy warehouse of expired, damaged, returned, or recalled prescription drugs to the original manufacturer, originating wholesale distributor, or to a third party returns processor in accordance with the board's rules and regulations.

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

Comment [NACDS3]: Because of the extremely wide price range of prescription drugs, the number of units transferred is a better guideline than the value.

Comment [NACDS4]: Providing a definition of intracompany transactions.

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Comment [NACDS5]: Allows pharmacies to return saleable overtock as well as recalled, damaged and outdated drugs.

Sec. 2. K.S.A. 65-1627 is hereby amended to read as follows: 65-1627. (a) The board may revoke, suspend, place in a probationary status or deny a renewal of any license of any pharmacist upon a finding that:

(1) The license was obtained by fraudulent means;

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

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

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

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

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

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

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

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

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

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

(12) the licensee has had a license to practice pharmacy revoked, suspended or limited, has been censured or has had other disciplinary action taken, or voluntarily surrendered the license after formal proceedings have been commenced, or has had an application for license denied, by the proper licensing authority of another state, territory, District of Columbia or other country, a certified copy of the record of the action of the other jurisdiction being conclusive evidence thereof;

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

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

(A) A copy of the record of criminal conviction or plea of guilty for a felony in

violation of K.S.A. 21-3406 and amendments thereto.

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

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

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

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

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

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

according to law or the rules and regulations of the board.

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

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

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

Sec. 3. K.S.A. 2006 Supp. 65-1643 is hereby amended to read as follows: 65-1643. It shall be unlawful:

(a) For any person to operate, maintain, open or establish any pharmacy within this state without first having obtained a registration from the board. Each application for registration of a pharmacy shall indicate the person or persons desiring the registration, including the pharmacist in charge, as well as the location, including the street name and number, and such other information as may be required by the board to establish the

identity and exact location of the pharmacy. The issuance of a registration for any pharmacy shall also have the effect of permitting such pharmacy to operate as a retail dealer without requiring such pharmacy to obtain a retail dealer's permit. On evidence satisfactory to the board: (1) That the pharmacy for which the registration is sought will be conducted in full compliance with the law and the rules and regulations of the board; (2) that the location and appointments of the pharmacy are such that it can be operated and maintained without endangering the public health or safety; (3) that the pharmacy will be under the supervision of a pharmacist, a registration shall be issued to such persons as the board shall deem qualified to conduct such a pharmacy.

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

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

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

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

(f) Except as otherwise provided in this subsection (f), for any person operating a store or place of business to sell, offer for sale or distribute any drugs to the public without first having obtained a registration or permit from the board authorizing such person so to do. No retail dealer who sells 12 or fewer different nonprescription drug products shall be required to obtain a retail dealer's permit under the pharmacy act of the state of Kansas or to pay a retail dealer new permit or permit renewal fee under such act. It shall be lawful for a retail dealer who is the holder of a valid retail dealer's permit issued by the board or for a retail dealer who sells 12 or fewer different nonprescription drug products to sell and distribute nonprescription drugs which are prepackaged, fully prepared by the manufacturer or distributor for use by the consumer and labeled in accordance with the

requirements of the state and federal food, drug and cosmetic acts. Such nonprescription drugs shall not include: (1) A controlled substance; (2) a prescription-only drug; or (3) a drug product intended for human use by hypodermic injection; but such a retail dealer shall not be authorized to display any of the words listed in subsection (u) of K.S.A. 65-1626 and amendments thereto, for the designation of a pharmacy or drugstore.

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

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

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

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

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

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

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

(2) there is a lawful prescription.

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

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

Sec. 4. K.S.A. 65-1655 is hereby amended to read as follows: 65-1655. (a) The board

shall require an applicant for registration to distribute at wholesale any drugs under K.S.A. 65-1643 and amendments thereto, or an applicant for renewal of such a registration, to provide the following information:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(5) suspension or revocation by federal, state or local government of any license or registration currently or previously held by the applicant for the manufacture or

distribution of any drugs, including controlled substances;

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

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

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

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

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

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

(f) Each in-state facility that engages in wholesale distribution must undergo an inspection by the board or a third party recognized by the board to inspect and accredit wholesale distributors for the purpose of inspecting the wholesale distribution operations prior to initial licensure and periodically thereafter in accordance with a schedule to be determined by the board but not less than once every three years. For out-of-state facility locations, the board may license by reciprocity if the wholesale distributor is licensed under the laws of the state in which it is domiciled and those laws are deemed by the board to be equivalent, otherwise the out-of-state facility must comply with the same requirements as an in-state facility. The board shall have the authority to waive licensing requirements for wholesale distributors that are accredited by an accrediting agency approved by the board.

Comment [NACDS6]: Would allow the board to license by reciprocity.

(g) A person licensed or approved by the federal food and drug administration to engage in the manufacture of drugs or devices engaged in wholesale distribution need only satisfy the minimum federal requirements for licensure provided in federal food and drug administration regulations 21 C.F.R. Part 205 to provide wholesale distribution

services.

(h) The board by rule and regulation shall establish standards and requirements for the issuance and maintenance of a wholesale distributor license, including, but not limited to, requirements regarding the following: (1) An application and renewal fee; (2) a surety bond; (3) licensing and periodic inspections; (4) certification of a designated representative; (5) designation of a registered agent; (6) storage of drugs and devices; (7) handling, transportation and shipment of drugs and devices; (8) security; (9) examination of drugs and devices and treatment of those found to be unacceptable as defined by the board; (10) due diligence regarding other wholesale distributors; (11) creation and maintenance of records, including transaction records; and (12) procedures for operation.

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

Sec. 5. K.S.A. 65-1627 and 65-1655 and K.S.A. 2006 Supp. 65-1626 and 65-1643 are hereby repealed.

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

HDMA
Healthcare Distribution Management Association

HDMA TESTIMONY REGARDING HB 2531
KANSAS HOUSE HEALTH AND HUMAN SERVICES COMMITTEE
MARCH 5, 2007

Madame Chair, members of the committee thank you for this opportunity to provide written testimony today. My name is Daniel Bellingham, Associate Director of State Government Affairs with HDMA (Healthcare Distribution Management Association). Unfortunately, due to commitments in other states on this same issue, I could not be available to provide oral testimony today in Topeka. HDMA is the national trade organization for full-service, primary distributors. We have 40 full-service, primary distributor members nationwide, including 10 who do business in Kansas.

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

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

HDMA supports HB 2531, with some suggested amendments (see Attachment A). As we indicated in our testimony before this committee on HB 2392 in February, it is essential that the Board of Pharmacy, the state regulatory authority with the responsibility of enforcing such legislation, be in support.

Our suggested amendment would clarify the language which allows the Board of Pharmacy to use a third party organization for purposes of inspecting wholesale drug distributors [Section 4 (f), page 15]. While we support the strengthening of licensure standards for pharmaceutical distributors, we are concerned about the possibility of making accreditation a requirement for distributors. HDMA members fully support the need for facility inspections as a mechanism to ensure that distributors are meeting licensure standards. We hope to ensure that a degree of choice is maintained for out-of state licensees in order to preserve the safe and efficient supply of prescription drugs to Kansas patients.

Thank you for this opportunity to provide written testimony today.

House Health and Human Services
DATE: 3-5-07
ATTACHMENT 3-1

901 North Glebe Road • Suite 1000 • Arlington, VA 22203
(703) 787-0000 • (703) 935-3200 (Fax) • www.HealthcareDistribution.org

ATTACHMENT A

Section 4 (f) page 15

(f) Each facility that engages in wholesale distribution must undergo an inspection by the board or a third party recognized by the board to inspect ~~and~~ or accredit wholesale distributors for the purpose of inspecting the wholesale distribution operations prior to initial licensure and periodically thereafter in accordance with a schedule to be determined by the board but not less than once every three years. The board shall have the authority to waive licensing requirements for wholesale distributors that are accredited by an accrediting agency approved by the board. The board shall promulgate rules to establish standards and requirements for the issuance and maintenance of a wholesale distributor license, including inspections of wholesale distributor facilities domiciled in the state.

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

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

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

(A) the requirements of that state are deemed by the board to be substantially equivalent; or
(B) the applicant is inspected or accredited by a third party recognized and approved by the board; or
(C) The applicant has completed an internal audit and review, according to standards approved by the Board.

(4) Any applicant denied licensure by the state shall have the right of timely review and appeal by the state regulatory authority.

The Kansas City Star - Parade 2/18/07

Is this medicine dangerous to your health?

Counterfeit drugs are finding their way into the hands of trusting consumers like you.

By Tom Zoellner

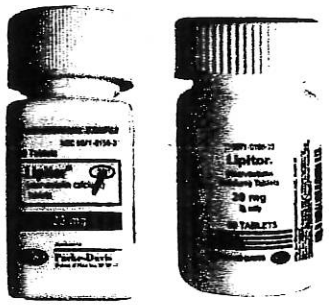
SOME CALL IT THE MOST perfect crime in medicine: Buy some empty gelatin capsules, fill them with worthless powder, print up a phony label and sell them to a drug wholesaler who has no scruples or just chooses to look the other way. The unsuspecting consumer who buys the drugs from his corner pharmacy will almost certainly never discover why he is getting sicker instead of better. This is called "drug counterfeiting," a business that has expanded in the last five years. Phony drugs already have taken the lives of several Americans, and the perpetrators have walked off with nearly $35 billion in black-market profits.

Thankfully, the chances are fairly slim that your daily pills could be fakes, but the problem is worsening as counterfeiters become more savvy. The World Health Organization estimates that up to 10 percent of the medications sold globally are actually counterfeit. The number in the United States is much lower—experts peg it at 1 percent—but the practice is growing as dealers of illicit street drugs like cocaine and Ecstasy discover there are more profits and less risks in selling phony tablets of drugs like Ambien, Lipitor and Cipro.

"We're seeing a lot more of this than ever before," says John Theriault, vice president for global security at the pharmaceutical giant Pfizer. The problem has become serious enough for Pfizer to develop its own private team of 17 former law-enforcement agents to investigate counterfeit drugs. Theriault, an ex-FBI agent, says his team has come across drug labs in homes, hotel rooms and overseas warehouses.

Phony pills are put in conventional plastic bottles that sometimes have labels soaked off from legitimate shipments. One such case in 2003 involved as many as 18 million tablets of bogus Lipitor that had been manufactured in Costa Rica. The counterfeiters had purchased their ingredients from the Hong Kong office of a Swiss company and even embossed the fake product with a real-looking Pfizer logo. The "Lipitor" was then marketed through a drug wholesaler operating in the Midwest and sold through legitimate pharmacies. The pills reached Pfizer's attention only after American customers began to complain about their bitter taste. It's possible that more than 600,000 people could have received bottles containing the fake Lipitor tablets.

Fake or Real?



Can you tell which Lipitor bottle was created by a drug counterfeiter? The square bottle on the left is authentic; the one on the right is phony. Criminals often make knockoffs of a company's logo and produce similar packaging.

BUT NOT EVERY COUNTERFEIT DRUG is cooked up in an illicit lab. Some unscrupulous suppliers have been known to boost their profits by "uplabeling"—for example, passing off a 10mg dose of a drug as 40mg. Expiration dates may be altered too. Experts say the vulnerabilities in the supply chain also can be traced to secondary drug wholesalers, who face pressure

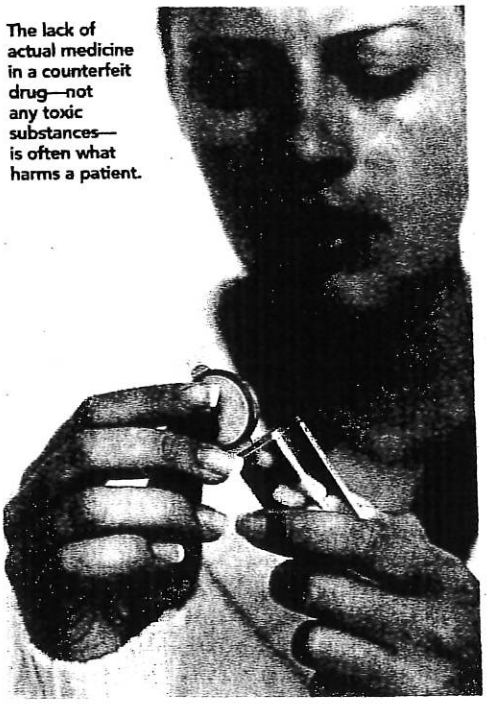
COVER PHOTO OF PILLS BY POULIDES/GETTY IMAGES; PHOTOS ON THIS SPREAD BY GETTY IMAGES (CAPSULES), FINLEY/AP (LIPITOR BOTTLES) AND STOCKBYTE/CORBIS (WOMAN; MODEL POSED FOR ILLUSTRATIVE PURPOSES ONLY)

to keep costs low and may not be inclined to scrutinize the source of their purchase. Where the drug changes hands several times, that's where you have the problem, says one industry expert. The bogus drugs go from a wholesaler's warehouse to a retail pharmacy and into a consumer's medicine cabinet.

Not surprisingly, the Internet is another common source of counterfeits. Direct-to-consumer Web sites offer great deals that are literally too good to be true. "You can find plenty of 'Canadian' sites that aren't really Canadian," says Pfizer spokesman Bryant Haskins. "They're decorated with maple leaves, but we've tracked them to Belize, Russia, Vietnam—all over the place."

The deception often goes further than that. "Overseas counterfeiters are also known for selling 'generic' versions of drugs where no generics exist," points out Joan Todd of Eli Lilly and Company. "The consumer assumes that somebody out there is regulating this. But anybody can set up a Web site and sell fake medicine." In one notorious case, Lilly investigators found a machine used to create bogus drugs in which a toilet seat had been jerry-rigged into the device. "This obviously does not adhere to good manufacturing procedure," remarks Todd dryly.

LAST YEAR, THE U.S. FOOD AND DRUG Administration investigated 53 cases of drug counterfeiting—up from six just five years ago. Though it is difficult to chart how many people unwittingly ingest counterfeit drugs each year, the injuries and deaths likely number in the hundreds. Experts say that thousands of Americans doubtlessly have been affected without even knowing it.



The lack of actual medicine in a counterfeit drug—not any toxic substances—is often what harms a patient.

Most ersatz-drug fatalities almost certainly have escaped notice, explains Haskins. Autopsies are not routine for the sick or elderly, and few doctors would ever suspect that the drugs they prescribed were nothing more than useless filler. What harms a patient is usually not toxic substances in the phony drug but a lack of the potentially lifesaving medication they are supposed to be receiving.

Besides, drug counterfeiters rarely set out to kill their customers—such a move would invite police attention and run contrary to their economic interests. The logic is similar to that of a parasite, which seeks not to kill the host but to feed off it for as long as possible. This is why expensive drugs that treat long-term conditions such as AIDS are the most likely to be counterfeited. Erectile-dysfunction drugs are also a prime target because of the big money involved—and the disinclination of many patients to complain about a lack of results.

Solving this problem will not be quick or easy. Rep. Mike Rogers (R., Mich.) has proposed raising the penalties for prescription drug counterfeiters from three years in prison to 20 years, putting the perpetrators on an equal plane with heroin dealers. The bill he proposed died in committee last session but was reintroduced earlier this month.

Up to 40 million of the prescription bottles dispensed today may contain worthless filler.

The Food and Drug Administration also has encouraged drug companies to track their pills after they leave the factory. GlaxoSmithKline, for example, now inscribes its pills and packages with invisible text symbols to authenticate its product. But these markings would be checked only after a counterfeit suspicion arises.

Tracking is becoming easier, however, with a technology known as Radio Frequency Identification (RFID), an advanced variety of bar code that is now used in the E-ZPass highway toll system, among other places. This technology would allow officials to scan entire pallets of drugs instead of checking individual barcodes. Such a system would make it hard to slip bogus products into the supply chain, because drugs could be tracked from factory to pharmacy counter. Progress with RFID has been slow due to the high costs involved. So far, only limited shipments of expensive drugs like the painkiller Oxycontin contain RFID tags on their labels.

ONE THING EVERYONE AGREES ON: The problem is becoming widespread, and the supply chain is still vulnerable. Up to 40 million of the prescription bottles handed out in the U.S. today are filled with substances that aren't what they claim to be, according to the National Association of Boards of Pharmacy.

"If the system becomes further compromised, it will get to the point where it's very difficult to fix," says Carmen Catizone, the association's executive director. "Imagine someone going to the emergency room for a heart attack and being given counterfeit drugs by the hospital staff. This could cripple the whole health-care system."

For more on counterfeit prescription drugs and how to report suspicions about your medicine, visit *parade.com*.

How To Protect Yourself

Here are a few precautions you can take to avoid counterfeit drugs:

- **Don't buy prescription drugs online unless it's through the Web site of a legitimate pharmacy.**
- **Look closely at your medicine. Note any signs of runny coloring or shoddy logos on the pills.**
- **Watch for changes in appearance or taste in the prescriptions you regularly take.**
- **Bring any reliable medication that suddenly begins to have no effect to your doctor right away.**

4-2