



Minnesota Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

Disciplinary Activity

The Minnesota Board of Pharmacy took the following disciplinary actions concerning **pharmacists** and **pharmacies** between the dates of June 5, 2008 and September 10, 2008.

Boris, Angie L., License #116034. Ms Boris petitioned the Board for reinstatement of her license to practice pharmacy. The Board had suspended her license on July 18, 2007, based on her diversion and abuse of controlled substances and other medications. The Board granted Ms Boris's petition and issued an Order of Reinstatement and Probation, with the stipulation that she be on probation for three years, or until she successfully completes the Health Professionals Services Program (HPSP) program, whichever is later.

Dreher, Sue Ann, License #113458. Ms Dreher petitioned the Board for reinstatement of an unconditional license to practice pharmacy. The Board had placed her on probation because of violations of the Health Insurance Portability and Accountability Act. Since Ms Dreher complied with and fulfilled the terms and conditions of the Stipulation and Order issued on December 12, 2007, the Board granted her petition and issued an Order of Unconditional License.

Folden, James, License #112789. Mr Folden admitted to the theft of controlled substances from his employer and the unauthorized personal use of those drugs. He was placed on probation for three years or until he successfully completes a participation agreement with HPSP, whichever is sooner. He was also assessed a civil penalty of \$400.

Kriz, Thomas E., License #111357. Mr Kriz admitted that he participated in the dispensing and distribution of orders for controlled substances that were not legitimate prescriptions in that they were not issued in the usual course of professional practice. Instead, the purported prescriptions were written by a physician and a physician assistant for customers of an Internet Web site. The Board reprimanded Mr Kriz and placed him on probation for two years. He was also assessed a civil penalty of \$1,000.

Passe, Lori, License #118772. Ms Passe admitted that she participated in the dispensing and distribution of orders for legend drugs that were not legitimate prescriptions in

that they were based on online questionnaires. The purported prescriptions were written by a physician for customers of two Internet Web sites. The drugs involved included carisoprodol, tramadol, and generic versions of Fioricet®. The Board reprimanded Ms Passe and placed her on probation for three years. She was also assessed a civil penalty of \$1,000.

Paulson, Robert W., License #110783. Mr Paulson admitted that he participated in the dispensing and distribution of orders for controlled substances that were not legitimate prescriptions in that they were not issued in the usual course of professional practice. Instead, the purported prescriptions were written by a physician and a physician assistant for customers of an Internet Web site. The Board reprimanded Mr Paulson and placed him on probation for three years. He was also assessed a civil penalty of \$5,000.

Steege, Donald, License #112405. Mr Steege admitted that he participated in the dispensing and distribution of orders for legend drugs that were not legitimate prescriptions in that they were based on online questionnaires. The purported prescriptions were written by a physician for customers of two Internet Web sites. The drugs involved included carisoprodol, tramadol, and generic versions of Fioricet. The Board reprimanded Mr Steege and placed him on probation for three years. He was also assessed a civil penalty of \$10,000.

Thompson, Thomas A., License #110509. Mr Thompson admitted that he participated in the dispensing and distribution of orders for controlled substances that were not legitimate prescriptions in that they were not issued in the usual course of professional practice. Instead, the purported prescriptions were written by a physician and a physician assistant for customers of an Internet Web site. Mr Thompson also admitted to several other violations of state laws and rules, primarily involving the processing of prescription orders for long-term care facilities. Mr Thompson agreed to voluntarily surrender his license to practice pharmacy and was also assessed a civil penalty of \$10,000.

Byron Marketplace Pharmacy, License #262468. Mr C. Dennis McDonough, president of Weber & Judd, signed an order admitting that pharmacists practicing at Byron Marketplace Pharmacy participated in the dispensing and distribution of orders for legend drugs that were not legitimate prescrip-

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Study Fuels Concerns over Foreign Drugs Bought Online

According to study results published in the May 2008 issue of *Annals of Pharmacotherapy*, many prescription medications purchased from foreign pharmacies through Internet drug outlets differ significantly from the versions approved by the Food and Drug Administration (FDA). "These findings have implications for safety and effectiveness that should be considered by clinicians to potentially safeguard patients who choose to purchase foreign-manufactured drugs via the Internet," the study authors say.

The study evaluated 20 simvastatin tablets and capsules, including the US innovator product and 19 generic samples obtained from international Internet drug outlets. Tablet samples were tested according to United States Pharmacopeia (USP) guidelines where applicable, using high-performance liquid chromatography, disintegration, dissolution, weight variation, hardness, and assessment of physical characteristics.

Several international samples analyzed were not comparable to the US product in one or more aspects of quality assurance testing, and significant variability was found among foreign-made tablets themselves. Five samples failed to meet USP standards for dissolution, and two for content uniformity. Among all samples, variability was observed in hardness, weight, and physical characterization.

Testing Medication Names Prior to Marketing



This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with USP and FDA in analyzing medication errors, near misses,

*and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the recommendations for prevention of reported errors that you can put into practice today, subscribe to **ISMP Medication Safety Alert!**[®] **Community/Ambulatory Edition** by visiting www.ismp.org. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medi-*

cation Errors Reporting Program. ISMP address: 200 Lakeside Dr, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

Medication names that look-alike and sound-alike, confusing or absent drug labeling, and non-distinct or ambiguous drug packaging significantly contributes to medication errors. This is not a new problem. These conditions have led to serious drug mix-ups and deaths. Research has identified that one of the most frequent causes of pharmacy drug dispensing errors (29%) is failure to accurately identify drugs, most prominently due to look-and sound-alike drug names (Leape et al. JAMA, July 5, 1995).

In addition, many medications are packaged in bottles with similar shapes and similar labels, making it easy to confuse one drug with another.

MedMARX data reports there are 1,470 different drugs implicated in medication errors due to brand and/or generic names that looked or sounded alike. From this data, USP has compiled a list of 3,170 pairs of names that look and/or sound alike.

FDA is also concerned about drug naming confusion and its subsequent potential error effects. On June 5-6, 2008, FDA hosted a public workshop to discuss a concept paper (www.fda.gov/cder/drug/MedErrors/meeting_names.pdf) about a pilot program to address look- and sound-alike brand names. The pilot, called for in the FDA Amendments Act of 2007, would allow drug companies (or outside contractors) to voluntarily evaluate proposed brand names and submit the data for review to FDA. Currently, FDA's Division of Medication Error Prevention screens drug names using its own safety testing methods, in consultation with other divisions responsible for product approval.

The concept paper outlines the types of studies that should be conducted, including simulations of real-world conditions with practicing clinicians who evaluate handwritten, electronic, and oral prescribing scenarios to detect name similarities and other potential confusion with laboratory and medical terms or abbreviations. Dosage form, strength, and frequency also should be considered, as well as the clinical environment where it will be used. Based on discussions during the June meeting and submitted comments, FDA will revise the concept paper and present testing methods to the pharmaceutical industry.

It is hoped that testing drug names prior to marketing will decrease the number of look-and sound-alike medication names. ISMP receives numerous reports of



errors and potential errors caused by look-and-sound-alike medications every year. ISMP, through its wholly owned for-profit subsidiary Med-E.R.R.S., Inc[®], has been reviewing drug names and packaging for pharmaceutical manufacturers for more than 10 years.

If you are a pharmacist or other health care practitioner who is interested in medication safety and error prevention, you can make a difference! Med-E.R.R.S. is looking for pharmacists from all practice settings to help test labeling, packaging, and nomenclature in the pre-marketing phase for pharmaceutical companies. The process is fun, simple, and easy and a small honorarium is paid for your participation.

For more information or to sign up, go to www.med-errs.com and click on "Become a Reviewer."

Coalition Looks to Pharmacies, Regulators to Reduce Diversion

A recent report by the Coalition Against Insurance Fraud looks to pharmacies and pharmacy regulators, among others, to cut down on the prevalence of prescription drug diversion, particularly of controlled substance analgesics.

The report, "Prescription for Peril: How Insurance Fraud Finances Theft and Abuse of Addictive Prescription Drugs," calls on the pharmacy profession to provide additional training on prescription drug abuse and diversion in pharmacy education curricula and continuing professional education, and to exert closer point-of-sale scrutiny of certain prescriptions and patients. For instance, the report suggests diversion could be reduced significantly if pharmacies asked for photo identification in connection with controlled substance prescriptions, similar to regulations in place for pseudoephedrine-containing products.

The coalition also recommends wider adoption of prescription monitoring programs to maintain state-wide records of narcotic prescriptions, allowing closer monitoring by prescribers and dispensers. In addition, the coalition calls on lawmakers and licensing boards to "swiftly and decisively penalize the small fraction of prescribers and dispensers who facilitate drug diversion and abuse."

FDA Encourages Pharmacists to Use Patient Safety News

FDA Patient Safety News is a monthly video news program produced by FDA targeted to pharmacists and other health care professionals. The program provides the

latest information on recalled and counterfeit products, important safety alerts, preventing medical errors and mitigating risks from the use of medical products, including drugs, devices, vaccines, and diagnostic products.

The videos can be watched online or downloaded free of charge. Pharmacists can view the entire program or individual segments, and FDA encourages further use and distribution of the video or text of the program, as there are no copyright restrictions. The video and demonstrations can also be used in staff-development programs or in other teaching environments.

Pharmacists can search for video segments on topics of interest, get additional information about topics, e-mail segments to others, report problems with medical products to FDA, and sign up to be notified about each month's program. The show is also broadcast on several medical satellite networks: VHA, GE TiP-TV, HSTN, LTCN, and HNN. These networks presently reach over 4,000 hospitals and long-term care facilities across the US.

More information about the program and how to join the program mailing list is available on the FDA Web site at www.fda.gov/psn or by sending an e-mail to PSNews@cdrh.fda.gov.

Switch to HFA-Propelled Albuterol Inhalers Advised in Anticipation of CFC Ban

FDA recently issued a public health advisory alerting patients, caregivers, and health care professionals to switch to hydrofluoroalkane (HFA)-propelled albuterol inhalers because chlorofluorocarbon (CFC)-propelled inhalers will not be available in the United States after 2008. CFC-propelled albuterol inhalers are being phased out to comply with the Clean Air Act and an international environmental treaty, the Montreal Protocol on Substances that Deplete the Ozone Layer. Under this treaty, the US has agreed to phase out production and importation of ozone-depleting substances including CFCs. No CFC-propelled albuterol inhalers may be produced, marketed, or sold in the US after December 31. Three HFA-propelled albuterol inhalers have been approved by FDA: Proair[®] HFA Inhalation Aerosol, Proventil[®] HFA Inhalation Aerosol, and Ventolin[®] HFA Inhalation Aerosol. In addition, an HFA-propelled inhaler containing levalbuterol is available as Xopenex[®] HFA Inhalation Aerosol. More information is available on the FDA Web site at www.fda.gov/cder/mdi/albuterol.htm.

tions in that they were based on online questionnaires. The purported prescriptions were written by a physician for customers of two Internet Web sites. The drugs involved included carisoprodol, tramadol, and generic versions of Fioricet. The Board reprimanded the pharmacy, placed its license on probation for three years and imposed a \$25,000 civil penalty.

The Internet and the Abuse of Prescription Drugs (Part 1)

As noted in this issue's Disciplinary Actions, the Board recently disciplined five pharmacists and one pharmacy for involvement with Internet Web sites that offered to arrange for the sale of legend drugs. The Web sites paid physicians and a physician assistant, licensed in other states, to write prescriptions based on their review of questionnaires filled out by customers. In one case, the prescribers supposedly also reviewed copies of medical records submitted by the customers. Those purported prescriptions were then made available electronically to the pharmacists who worked at two licensed Minnesota pharmacies, Byron Marketplace Pharmacy in Byron and Market Pharmacy in Bemidji. The pharmacists shipped legend drugs to customers located across the country. Controlled substances were shipped by the Bemidji, but not the Byron, pharmacy. The actions of the pharmacists violated a number of state and federal laws and rules.

The legislature passed a law earlier this year that establishes that prescriptions for controlled substances and certain other drugs (carisoprodol, tramadol, muscle relaxants, and erectile dysfunction drugs) are not valid unless the prescriptions or orders are based on a documented patient evaluation, including an **in-person** examination, adequate to establish a diagnosis and identify underlying conditions and contraindications to treatment. Pharmacists are prohibited from knowingly dispensing such prescriptions. This provision is intended to prevent pharmacies and pharmacists from contracting or knowingly working with illegitimate Internet Web sites.

The in-person examination does not have to take place at the time that a prescription is written and does not have to necessarily be performed by the prescriber. The requirement for an in-person examination can be met in any of the following ways:

- ◆ the prescribing practitioner examines the patient at the time the prescription or drug order is issued;
- ◆ the prescribing practitioner has performed a prior examination of the patient;
- ◆ another prescribing practitioner practicing within the same group or clinic as the prescribing practitioner has examined the patient;
- ◆ a consulting practitioner to whom the prescribing practitioner has referred the patient has examined the patient; or
- ◆ the referring practitioner has performed an examination in the case of a consultant practitioner issuing a prescription or drug order when providing services by means of telemedicine.

Federal rules administered by the US Drug Enforcement Administration (DEA) require that a prescription for a controlled substance be "issued for a legitimate medical

purpose" by a practitioner acting in the usual course of sound professional practice. Per the DEA's *Pharmacist Manual*, "the practitioner is responsible for the proper prescribing and dispensing of controlled substances. However, a corresponding responsibility rests with the pharmacist who dispenses the prescription. An order for a controlled substance which purports to be a valid prescription, but is not issued in the course of professional treatment, or for legitimate and authorized research, is not a valid prescription."

DEA takes the position that for a physician to be "acting in the usual course of professional practice, there must be a bona fide doctor/patient relationship." DEA considers the following four elements as an indication that a legitimate doctor-patient relationship has been established:

- (i) a patient has a medical complaint;
- (ii) a medical history has been taken;
- (iii) a physical examination has been performed; and
- (iv) some logical connection exists between the medical complaint, the medical history, the physical examination and the drug prescribed.

Further, DEA advises that "[a] patient completing a questionnaire that is then reviewed by a physician hired by or working on behalf of an Internet pharmacy does not establish a doctor/patient relationship. A consumer can more easily provide false information in a questionnaire than in a face-to-face meeting with the physician. It is illegal to receive a prescription for a controlled substance without the establishment of a legitimate doctor/patient relationship, and it is unlikely for such a relationship to be formed through Internet correspondence alone."

As illustrated by the disciplinary cases described above, the Board has the authority to pursue action against pharmacists and pharmacies involved in the processing of prescriptions that they know originate from illegitimate Web sites. However, pharmacists must also keep in mind that it is unprofessional conduct to refuse to dispense a prescription that a pharmacist would reasonably be expected to dispense. The Board is aware that many patients with chronic pain are undertreated, sometimes because practitioners and pharmacists fear disciplinary action. The Board acknowledges that it can sometimes be difficult for pharmacists to assess the validity of a prescription. While each case must rest on its own merits, it is unlikely that the Board would discipline a pharmacist who, while using sound professional judgment and practicing in a reasonable and prudent manner, unknowingly dispenses a prescription that later turns out to be invalid.