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Nevada State Board of Pharmacy

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2008 Board Meeting Schedule

October 15-16..... Las Vegas
December 3-4 Reno

Board's General Counsel

Sadly for the Nevada State Board of Pharmacy, veteran legal counsel, Louis Ling, has been selected as the executive director of the Nevada Board of Medical Examiners. Mr Ling has served the Board of Pharmacy for some 17 years, the past seven years in house, and has been a champion for the ethical and safe practice of pharmacy. He has been paramount in the Board's ongoing quest to fight counterfeit drugs entering Nevada through questionable gray market wholesale practices, leading to Nevada's current and soon to be improved electronic pedigree program, as well as the exodus of virtually all secondary source wholesalers from the state. His priorities have always been with the patient, which is where they should be, as he endlessly has fought for safer pharmacy practices. On behalf of the Board of Pharmacy, Mr Ling has argued in practically every judicial venue, including the Nevada Supreme Court. Board members and staff congratulate and will fully support Louis in his new and challenging position. We look forward to working with him as the head of our sister board, and are hopeful that he will remain true to his commitment to ride his bicycle more than drive his car. Louis Ling will truly be missed.

Inspector's Corner

The scenario is as follows: A patient tenders a Schedule II prescription within the 14-day window as required and asks the pharmacist to hold it for filling at a later date. The pharmacist dutifully indicates the tendered date and initials on the prescription and files it. Two months later, the patient comes to the pharmacy and asks for the prescription back to take to another pharmacy for insurance reasons. Can the pharmacist return the already tendered prescription to the patient and can the other pharmacy accept it? Answer: Yes, however the new pharmacy must verify the validity and tendered date of the prescription with the original pharmacy.

Did You Know?

- ◆ Drug companies now spend more money on advertising than on research.
- ◆ As of July 1, 2008, Nevada accepts reciprocity of pharmacists licensed in **all** states including Florida and California. Pharmacists licensed after January 1, 2004, who are reciprocating from California need to have been issued a license by taking and passing the North American Pharmacist Licensure Examination® (NAPLEX®).
- ◆ A pharmacist may now put their license on "inactive" status if not currently practicing in Nevada. Fees still apply; however, the continuing education (CE) requirement is waived. CE must be brought current to move your license back to "active" status.
- ◆ The Nevada State Board of Pharmacy successfully defended before the Nevada Supreme Court its position in a counterfeit wholesaler case. Paramount in the decision was the ruling that a wholesaler does not have to have knowledge that a drug it sold was counterfeit to be guilty of such activity.
- ◆ Pharmacists may now earn up to six hours of accredited CE for successfully completing an advanced

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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.

cardiovascular life support course. Basic CPR is still worth two hours. Two hours may also be earned for Nevada Immunization Learning Exchange training (the training course for the state immunization registry).

- ◆ There currently are no state or federal limits on the number of days supply for any medication, including controlled substances, that may be prescribed by a practitioner. Insurance and other third-party limitations often are confused with law. Medications ordered by a legitimate prescriber in the usual course of medical practice to treat a legitimate medical condition are valid in any quantity.

Technician Diversion

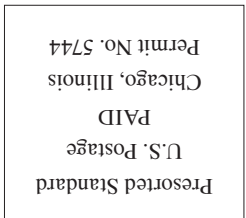
Recent articles in the newspapers regarding prescription drug abuse have highlighted the ever increasing number of complaints received by Board staff involving the diversion of controlled substances by pharmacy technicians. Current information from the Drug Enforcement Administration clearly indicates that prescription drugs are rapidly becoming the “entry level” substance for drug abuse by young Americans, starting as early as middle school. So where do they get the drugs? Besides “pharming” their parent’s and grandparent’s medicine cabinets, recent cases involving pharmacy technicians demonstrate the fact that sometimes unbelievable quantities of controlled substances are being diverted. Board staff reminds pharmacists that they are responsible for their technician’s activities, and that managing pharmacists accept responsibility for the operation of their pharmacy. Some considerations:

- ◆ Know your technicians.
- ◆ Know and monitor your inventory levels.

- ◆ Know who is ordering what and who is checking it in.
- ◆ Evaluate your controlled substance stocking practices (eg, is it easier to monitor controlled substances if they are stocked in one area versus scattered amongst other stock).
- ◆ Consider “running inventories” for controlled substances, or at least those that are highly abused (eg, hydrocodone).
- ◆ Be confident and comfortable with the number of technicians that you are able to supervise at once.

The *Nevada State Board of Pharmacy News* is published by the Nevada State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

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