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Wyoming State Board of Pharmacy

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Wyoming State Board of Pharmacy
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New Faces at the Wyoming State Board of Pharmacy

Lisa Stewart, administrative specialist, will be the first person with whom you speak when you call or visit the agency. Lisa comes to us with many years of experience at a community college and as a first grade teacher. She recently moved to Cheyenne to get married and become stepmother to two wonderful girls. Lisa is responsible for managing communication into and out of the agency (as well as many other processes), and we appreciate her positive personality.

David Wills is the new records analyst and is responsible for the day-to-day operation of the Prescription Drug Monitoring Program. David holds a degree in business from Park University and comes to us after experience in other state agencies. David can be reached directly at dwills@wyo.gov.

Board of Pharmacy Completes Move to Cheyenne

On September 15, 2008, the Wyoming State Board of Pharmacy opened its new office at 1712 Carey Avenue, Suite 200, Cheyenne, WY 82002. Our main telephone number is now 307/634-9636; our main facsimile number is now 307/634-6335. The agency e-mail path is now BOP@wyo.gov. The Board Web site address remains the same: *http://pharmacyboard.state.wy.us*. Please visit us or contact us at any time.

Rules and Regulations Recently Signed by Governor Dave Freudenthal

Rules Chapter 8 had extensive revisions as a result of changes made to Statute (W.S. §33-24-153) by the Wyoming State Legislature in 2007. Rules Chapter 8 deals with wholesale distributors and describes how prescription drugs are to be shipped, stored, and distributed.

Rules Chapter 10 was revised so that pharmacy technicians will no longer submit continuing education certificates with annual license renewals. An audit of continuing education will now be conducted in the same manner as for pharmacists. A random number of technicians will be contacted in early 2009 and will be asked to submit continuing education certificates to the Board.

Rules Chapter 16 was revised to include the zoster vaccine on the list of immunizations that can be administered by a pharmacist who is properly certified. Zoster vaccine was under Emergency Rule beginning January 31, 2008, and is now a permanent part of the rules.

The Board would like to thank all who participated in the 2008 rulemaking process.

Sterile Compounding Task Force

A group is meeting to revise the sterile compounding rules to meet the intention of the revisions to United States Pharmacopeia Chapter 797, "Pharmaceutical Compounding – Sterile Preparations." Pharmacists, administrators, Wyoming Hospital Association representatives, Wyoming Pharmacy Association members, and Board of Pharmacy members and staff have been participating. Tim Seeley, director of pharmacy at Powell Valley Healthcare, has been facilitating the group and has provided outstanding leadership. The meetings are held approximately monthly in Casper, from 10 AM to 3 PM, in order to facilitate travel. Contact the Board office or Tim Seeley for the schedule of future meetings.

DEA Clarifies What Can Be Changed on a Schedule II Prescription

In a letter dated October 15, 2008, Joseph T. Rannazzisi, deputy assistant administrator, Drug Enforcement Administration (DEA) Office of Diversion Control, stated that the federal changes in the preamble to the rule, Issuance of Multiple Prescriptions for Schedule II Controlled Substances (72 CFR 64921), do not match state regulations and, until future rulemaking can be completed, "pharmacists are instructed to adhere to state regulations or policy regarding those changes that a pharmacist may make to a Schedule II prescription after oral consultation with the prescriber." In the Wyoming Controlled Substance Act Rules and Regulations, Chapter 6, Section 11(f)(i) it states, "After consultation/approval of the prescribing practitioner, the pharmacist is permitted to change the following: drug strength; drug quantity; directions for use; dosage form."

Controlled Substance Prescription Signature

The Wyoming Controlled Substance Act Rules and Regulations Chapter 6, Section 4(b)(iv) states, "All controlled substance prescriptions written by a Wyoming practitioner shall be manually

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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 Medication 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 statewide 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*.

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signed in the same manner as the practitioner would sign a check or legal document. The use of electronic or digital signatures or signature stamps are not allowed." The DEA is reviewing comments on its proposed rule for e-prescribing.

Suboxone and Subutex

By Selena Lanouette, PharmD Candidate

In 2000, the Drug Addiction Treatment Act (DATA) was passed allowing physicians to prescribe narcotics for office-based treatment of opioid dependence. Before the law was passed, the use of narcotics to treat narcotic dependence was limited to clinics and prohibited from physicians as an office-based treatment. Now, only physicians who meet special requirements including training, certification, and the ability to provide the appropriate services can prescribe Suboxone® or Subutex®. Once the requirements are met, the physician must notify the Secretary of Health and Human Services of his or her intent to prescribe the medication. Once the information is verified, DEA will issue the physician a unique identification number, which indicates the physician can prescribe the two drugs under DATA.

Suboxone and Subutex are the first two drugs to be approved by Food and Drug Administration (FDA) for the treatment of opioid dependence. Both are considered Schedule III narcotics. Suboxone is a sublingual tablet containing buprenorphine and naloxone while Subutex only contains buprenorphine. Buprenorphine is a partial agonist at the mu-opioid receptor and an antagonist at the kappa-opioid receptor. When used alone, it can be used as an analgesic for moderate to severe pain. Naloxone is an antagonist at the mu-opioid receptor and, when used in combination with buprenorphine, is intended to deter intravenous use. Patients are often started on Subutex as an induction agent and then switched to Suboxone for maintenance treatment.

According to DATA, one or more of the following training requirements must be met: hold a subspecialty board certification in addiction psychiatry from the American Board of Medical Specialties or in addiction medicine from the American Osteopathic Association, hold an addiction certification from the American Society of Addiction Medicine, or have completed not less than eight hours of authorized training on treatment or management of opioid-dependent patients. Physicians must also have the capacity to provide or to refer for necessary ancillary services, such as psychosocial therapy, and agree to treat no more than 30 patients at any one time in their individual or group practice. Now, the physician must be authorized under DATA for one year and submit a second notification of intent to treat 100 patients.

There is the possibility that a pharmacist will receive a prescription from a physician who does not have the special DEA identification number. In this situation, call the physician to make sure that he or she has notified the Department of Health and Human Services of his or her intent to treat.

The Institute for Safe Medication Practices has included Suboxone on its list of drug classes with a higher risk of causing significant harm to the patient when used in error. Make sure that the patient understands the instructions given by the physician and answer any questions he or she has regarding the new medication. Caution the patient that a serious overdose may occur if Suboxone or Subutex is taken in conjunction with benzodiazepines, sedatives, tranquilizers, antidepressants, or alcohol.

Side effects of Suboxone and Subutex include headache, withdrawal syndrome, pain, nausea, insomnia, sweating, abdominal pain, back pain, constipation, infection, asthenia, rhinitis, anxiety, and depression. When taken chronically, patients may develop dependence. If the medication is stopped abruptly or the taper is too rapid, the patient may experience withdrawal symptoms that are milder than that seen with full agonists. For every prescription, make sure to verify that the prescription is from a physician who is authorized to prescribe the medication, and be watchful for fraudulent prescriptions.

If you would like to find more information, there are numerous sources including the FDA Web site at *www.fda.gov*; the Suboxone toll-free help line at 1-877/SUBOXONE (762-6966); the Web site *www.suboxone.com;* and the Substance Abuse and Mental Health Services Administration Center for Substance Abuse Treatment Web site at *www.dpt.samhsa.gov* or *www.buprenorphine.samhsa.gov*.

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