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Wyoming State Board of Pharmacy

Wyoming State Board of Pharmacy
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Published to promote voluntary compliance of pharmacy and drug law.

Happy Retirement to Karen and Jim

Karen Brannon has retired after serving 28 years as the executive assistant at the Wyoming State Board of Pharmacy. She plans to do some traveling, and she stays busy with her many hobbies and friends. We will miss her Norwegian cooking, her stories, and her smile.

Jim Carder retired after 10 years as the executive director. He and his wife Carolyn have a business in Buffalo, WY, and can be reached at *www.johnnymidnite.com*. Jim was recently honored by the Wyoming Pharmacy Association (WPhA) for his efforts for collaborative practice, telepharmacy, the prescription drug monitoring program, and many other projects. He was given the Bowl of Hygeia 2008 by Wyeth and WPhA. Both Karen and Jim were also honored by the University of Wyoming School of Pharmacy at its spring awards banquet.

New Executive Director Mary Walker

Mary Walker has extensive experience in hospital pharmacy, and she also worked in community pharmacy, both chain and independent. Her family owned Newcastle Drug & Jewelry Store from 1910 to 1990. Governor Dave Freudenthal appointed her to the Board of Pharmacy in 2005, and her three years as a Board member led to her decision to apply for the executive director position.

Mary is a past president of the Wyoming Society of Health-System Pharmacy and also the WPhA. She looks forward to meeting all the pharmacists and pharmacy technicians in Wyoming.

New Executive Assistant Jackie Seebaum

Our new executive assistant, Jackie Seebaum, comes to the Board with over 30 years of clerical experience, including 11 years of experience in health care, specifically health care law relating to risk management, compliance, and privacy.

Storage and Handling of Zostavax

By Hank York, Compliance Officer

During shipment, to ensure that there is no loss of potency, the vaccine must be maintained at a temperature of -15º C (+5º F) or colder. Zostavax® (zoster vaccine live) should be stored frozen at **an average temperature of** -15º C (+5º F) or colder until it is reconstituted for injection. Any freezer, including frost-free freezers, that has a separate sealed freezer door and reliably maintains an average temperature of -15º C or colder is acceptable for storing Zostavax. For information regarding stability under conditions other than those recommended, call 1-800/MERCK-90. Before constitution, protect the vaccine from light.

The diluent should be stored separately at room temperature (8º-20º C, 36º-46º F), or in the refrigerator (2º-8º C, 36º-46º F). The zoster vaccine is listed as one of the adult vaccines that can be administered by a pharmacist under an emergency rule until the permanent rule in Chapter 16 has been approved by the governor.

2008 Pharmacy Inspections

By Richard Burton, Compliance Officer

As a reminder to the pharmacist-in-charge (PIC), make sure when a change in PIC occurs that an inventory of controlled substances is completed with the incoming pharmacist and the outgoing pharmacist signing the inventory, with date and time recorded (first thing in the morning or last thing at night). One copy stays in the pharmacy and one copy is mailed to the Board of Pharmacy office.

The following is the focus during inspections in 2008, checking for compliance:

1. Perpetual inventory with documentation of quarterly reconciliation
2. Prescription inspection at random
3. Physical description of product on the prescription label
4. Identification checks and addresses for all controlled substance prescriptions
5. Prescription Drug Monitoring Program issues and transmitting problems, including reporting of tramadol and carisoprodol products
6. Rule changes from 2007 to 2008
7. Policy and procedure for emergency drug box in long-term care facilities and 24/7 services by the pharmacy
8. All outdates are pulled from the active working shelves
9. Verify that all licensed personnel display their licenses in the pharmacy (employing an unlicensed pharmacy technician is considered unprofessional conduct)
10. Check controlled substance prescriptions for security paper and features to prevent forgery
11. Patient profile check to see if Chapter 9 can be applied and refills checked for over- or underutilization; drug utilization review is also checked for compliance
12. Security of the pharmacy
13. Check faxed prescriptions for Schedule III through Schedule V to see if signed by practitioner

continued on page 4

A Community Pharmacy Technician's Role in Medication Reduction Strategies

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and Food and Drug Administration (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.*

Pharmacy technicians play a major role in community pharmacy practice. The pharmacist relies on the technician to provide an extra layer of safety. It is important for technicians to follow system-based processes and inform the pharmacist when these processes do not work or are unmanageable.

Prescription Drop Off

The date of birth should be written on every hard copy prescription so the pharmacist has a second identifier readily available during verification. Allergy information should be questioned and updated at every patient encounter. Medical condition information, such as pregnancy, communicated to the technician at drop off should be updated in the computerized profile system to help the verification pharmacist determine counseling opportunities. Knowing a person's medical conditions also helps the pharmacist determine if prescriptions are written incorrectly or for the wrong drug.

Data Entry

Medication safety is enhanced when technicians know the particular language of pharmacy when entering a prescription.

New drugs are at a particular risk because it is more likely that the technician is not aware of the new drug and a more familiar drug is selected. Pharmacists and technicians should work together to determine the best method of distributing information regarding availability of new drugs on the market.

It is important that the technician understands the safety features of the computer system and does not create work-arounds to improve efficiency at the risk of decreasing accuracy and safety. Drug alerts can be numerous, and the technician may be inclined to override the alert and not "bother" the pharmacist. A better way to resolve too many alerts would be to establish protocol between the technician and the pharmacist to determine which level and type of alert needs pharmacist intervention.

Production

Mix-ups occur primarily due to incorrectly reading the label. The problem is aggravated by what is referred to as *confirmation bias*. Often a technician chooses a medication container based on a mental picture of the item, whether it be a characteristic of the drug label, the shape and size or color of the container, or the location of the item on a shelf. Consequently the wrong product is picked. Physically separating drugs with look-alike labels and packaging helps to reduce this contributing factor.

Point of Sale

Correctly filled prescriptions sold to a patient for whom it was not intended is an error that can be avoided by consistent use of a second identifier at the point of sale. Ask the person picking up the prescription to verify the address or in the case of similar names, the date of birth, and compare the answer to the information on the prescription receipt.

Internal errors should be discussed among all staff for training purposes. In addition, it is important to read about and discuss errors and methods of prevention occurring and being employed at other pharmacies within a chain and in other pharmacies, nationwide. ISMP Medication Safety Alert! Community/Ambulatory Edition offers this information to both pharmacists and technicians.

FDA's Effort to Remove Unapproved Drugs From the Market

Pharmacists are often not aware of the unapproved status of some drugs and have continued to unknowingly dispense unapproved drugs because the labeling does not disclose that they lack FDA approval. FDA estimates that there are several thousand unapproved drugs illegally marketed in the United States. FDA is stepping up its efforts to remove unapproved drugs from the market.

Background

There are three categories of unapproved drugs that are on the market. The first category consists of those that have been approved for safety, or that are identical, related, or similar to those drugs, and either have been found not to be effective, or for which FDA has not yet determined that they are effective. Between 1938 (passage of the Federal Food, Drug, and Cosmetic Act) and 1962, manufacturers were only required to demonstrate that drugs were safe; the requirement that they also demonstrate that drugs were effective was added in 1962. Drugs that fall in this category have been part of the DESI (Drug Efficacy Study Implementation) review, which was implemented to determine whether drugs approved between 1938 and 1962, or drugs that are identical, related, or similar to such drugs, met the new effectiveness requirements. While the DESI review is mostly completed, some parts of it are still continuing. The second category of unapproved drugs consists of those drugs that were on the market prior to 1938 (passage of the Federal Food, Drug, and Cosmetic Act). The third category, new unapproved drugs, comprises unapproved drugs that were first marketed (or changed) after 1962. Some also may have already been the subject of a formal agency finding that they are new drugs.

FDA's Concerns About Unapproved Drugs

FDA has serious concerns that drugs marketed without FDA approval may not meet modern standards for safety, effectiveness, manufacturing quality, labeling, and post-market surveillance. For example, FDA-approved drugs must demonstrate that their manufacturing processes can reliably produce drug products of expected identity, strength, quality, and purity. In addition, FDA's review of the applicant's labeling ensures that health care professionals and patients have the information necessary to understand a drug product's risks and its safety and efficacy.

Sponsors that market approved products are subject to more extensive reporting requirements for adverse drug events than sponsors of unapproved drugs. Reporting of adverse events by health care professionals and patients is voluntary, and under-reporting is well documented. FDA, therefore, cannot assume that an unapproved drug is safe or effective simply because it has been marketed for some period of time without reports of serious safety or effectiveness concerns.

Enforcement Priorities

Manufacturers of unapproved drugs are usually fully aware that their drugs are marketed illegally, yet they continue to circumvent the law and put consumers' health at risk.

Most recently, in June 2006, FDA issued a guidance entitled "Marketed Unapproved Drugs – Compliance Policy Guide" (CPG) outlining its enforcement policies aimed at bringing all such drugs into the approval process. (The CPG is available at *www.fda.gov/cder/guidance/6911fnl.pdf*) The agency provided industry with specific notice that anyone who markets an unapproved drug is subject to enforcement action. This CPG outlines the agency's risk-based enforcement policies aimed at bringing all such drugs into the approval process without imposing undue burdens on consumers or unnecessarily disrupting the market. For all unapproved drugs, the CPG gives highest enforcement priority to the following:

- Drugs with potential safety concerns
- Drugs that lack evidence of effectiveness
- Fraudulent drugs
- Drugs with formulation changes made as a pretext to avoid enforcement
- Unapproved drugs that directly compete with an approved drug

Table 1 lists examples of drugs or classes of drugs that, consistent with the CPG, FDA has identified as a higher priority because of safety or other concerns. For six of them, FDA has specifically announced its intention to take enforcement action against companies marketing unapproved versions of those drug products. FDA has withdrawn the approval of the seventh product.

Table 1: Examples of FDA Actions Regarding Unapproved Drugs
Extended release combination drug products containing guaifenesin (competed with approved products)
Trimethobenzamide hydrochloride suppositories (lacked evidence of effectiveness)
Ergotamine-containing drug products (labeling did not include critical warnings regarding the potential for serious, possibly fatal interactions with other drugs)
Quinine sulfate drug products (665 reports of adverse events, including 93 deaths, and the labeling lacked necessary warnings and safe dosing information)
Carbinoxamine drug products (associated with 21 infant deaths)
Colchicine injectables (50 reports of adverse events, including 23 deaths)

Importance to Pharmacists

FDA is taking steps to ensure that all marketed US drugs have met approval requirements. FDA recognizes that some unapproved drugs may provide benefits; however, since these products have not undergone FDA review for safety and efficacy, the agency recommends that pharmacists, prescribers, and patients carefully consider the medical condition being treated, the patient's previous response to a drug, and the availability of approved alternatives for treatment. FDA will proceed on a case-by-case basis and make every effort to avoid adversely affecting public health, imposing undue burdens on health care professionals and patients, and unnecessarily disrupting the drug supply. More information regarding the FDA's Unapproved Drug Initiative can be found on its Web site: *www.fda.gov/cder/drug/unapproved_drugs/*.

NABP Educates Public on Buying from Internet Pharmacies with New Section on its Web site

On May 16, 2008, the National Association of Boards of Pharmacy® (NABP®) launched the Internet Pharmacies section of its Web site, educating patients on the potential dangers of buying medicine online and empowering them to make informed choices. As of mid-June, the site listed 250 Internet drug outlets that appear to be out of compliance with state and federal laws or NABP patient safety and pharmacy practice standards, thereby putting those who purchase from these sites in danger of purchasing drugs that could cause patients serious harm or even death.

NABP developed these standards for its new Internet Drug Outlet Identification program with input from its member boards of pharmacy, interested stakeholders, and regulatory agencies, including the FDA and the US Drug Enforcement Administration. Internet drug outlets operating in conflict with these criteria are listed on the NABP Web site as "not recommended." NABP has identified another 300 suspiciously operating Internet drug outlets and is in the process of verifying its findings before posting these sites to the "not recommended" list. Of the hundreds of sites reviewed under this program so far, only nine have been found to be potentially legitimate, pending verification of licensure and other criteria. At this time, NABP recommends that patients buying medicine online use only Internet pharmacies accredited through the VIPPS® (Verified Internet Pharmacy Practice Sites™) program. NABP has verified that these pharmacies are appropriately licensed and have successfully completed the well-recognized and rigorous VIPPS criteria evaluation and on-site inspection. These pharmacies, representing more than 12,000 pharmacies, are listed on the NABP Web site as "recommended."

These lists, along with program criteria and related patient information, are accessible in the Internet Pharmacies section of the NABP Web site.

The new program is an outgrowth of a 2007 NABP resolution, "Internet Pharmacy Public Safety Awareness," in which the Association pledges to continue collaborating with federal agencies and other interested stakeholders to educate the public and health care professionals of the dangers of acquiring drugs illegally through the Internet and from foreign sources. As part of this initiative, NABP will provide information to assist state and federal regulators in their efforts to shut down rogue Internet drug outlets.

RxPatrol Video Helps Pharmacists Address and Prevent Pharmacy Theft

Pharmacy theft is a serious crime that is on the rise, costing pharmacies billions annually in stolen medication according to the Federal Bureau of Investigation (FBI). RxPatrol® has teamed up with Crime Stoppers and other law enforcement officials to disseminate information regarding pharmacy crime. One resource that pharmacists can use to educate themselves and their coworkers is a training video that provides tips for pharmacists to address the rising issue of pharmacy robberies. The video includes interviews with law enforcement officials from the FBI and police department about what can be done to prevent such activity. The video can be found on the RxPatrol Web site at *www.rxpatrol.com/videos.asp* and by clicking on "Pharmacy Safety – Robbery."

RxPatrol is a collaborative effort between industry and law enforcement designed to collect, collate, analyze and disseminate pharmacy theft information. RxPatrol helps protect the pharmacy environment and ensure legitimate patients' access to life-sustaining medicines.

continued from page 1

14. Immunizations authorized have been expanded to include pertussis (Tdap), human papillomavirus (HPV), and herpes zoster vaccine (emergency rule February to September 2008)
15. Check for power of attorney if pharmacy had a change in PIC
16. Board of Pharmacy Web site access because it is the designated method for notification for updates, information, laws, and links
17. Transfer of prescriptions being documented properly by the receiving pharmacy and transferring pharmacy

Counterfeit Medications

By Eric Hunter, PharmD Candidate

Counterfeit drugs. What is the first thing that pops into your mind? Medications shipped in from outside the United States? Maybe even drugs ordered over the Internet, right? As Katherine Eban, an investigative reporter, helped bring to public attention when she released her book called *Dangerous Doses* in 2005, a much scarier and life threatening monster has surfaced inside our own system of distributing medication.

Counterfeiters have been able to form elaborate schemes of buying a drug from wholesalers, diluting it, relabeling, it or even replacing it with something else altogether, then selling it back to other wholesalers, effectively placing the adulterated product right back on track to pharmacy and hospital shelves across America. Even trained experts are often unable to tell the difference between the authentic and counterfeit products. The biggest problem seems to be the lack of regulation and enforcement of product pedigrees making it possible to track exactly whose hands the product has passed through between the time it leaves the manufacturer and when it reaches the end consumer.

Early legislation tried to combat the problem but was too weak to make much of a difference. By November 2005, the three largest drug wholesalers (Cardinal Health, McKesson Corp, and AmerisourceBergen Corporation) had pledged to not buy brand-name pharmaceuticals from the secondary market. The battle has recently hit the state government as federal law now delegates the regulation to each state.

Stephanie Feldman Aleong is an attorney who went out on a limb to start prosecuting these offenders back in 2002. When asked what she would want Wyoming pharmacists to know about the matter, she said there were three things she would like to bring to our attention. First,

> the federal pedigree law has still not been implemented even though the Food and Drug Adminstration (FDA) lifted the stay or hold on the law in June of 2006. A group of secondary wholesalers sued the FDA, saying the pedigree law unconstitutionally discriminates between secondary wholesalers and authorized distributors (like Cardinal, McKesson, and AmerisourceBergen) by not requiring the authorized distributors to pass a pedigree. A federal court in New York stayed the law once again while the lawsuit proceeds. So, pharmacists cannot count on the feds to keep counterfeits from the drugstore.

Second, "state laws are becoming more lax again or their implementation is being delayed because political will to fight counterfeits is fading as other economic issues become more pressing to politicians." Lastly she noted that "the counterfeit heparin that entered the US system in 2007-08 that killed 81 people is one example of how tainted drugs can kill and how prescription drugs pose just as deadly a risk to the population as illicit drugs."

Currently, wholesale distributors who distribute into or out of Wyoming are required to be licensed by the Wyoming State Board of Pharmacy. However, not unlike most other states, Wyoming's requirements are weak concerning record keeping. Although the technology for effectively keeping a pedigree for each drug that goes through the distribution system is yet to become available, the Wyoming State Board of Pharmacy is making an effort to implement rules that will improve distribution security in the future and allow for implementation of an electronic pedigree when it becomes available. The proposed changes to the Wyoming Pharmacy Act, Rules and Regulations can be found at *http://pharmacyboard.state.wy.us/changes.asp* by clicking on Proposed Changes Chapter 8 under Section 15.

Board of Pharmacy Office Move from Casper to Cheyenne

At the April 2008 Board meeting a motion was made: "In the best interest of the people of Wyoming the Board of Pharmacy office will move to Cheyenne as smoothly and efficiently as possible." The motion carried. Notice of the new address will be sent soon.

The *Wyoming State Board of Pharmacy News* is published by the Wyoming 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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