

January 2008



Oklahoma State Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

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Seasons Greetings

The members and staff of the Oklahoma State Board of Pharmacy would like to join in wishing everyone happiness and all the best for the coming year.

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Gary LaRue, DPh, Compliance Officer
Terry Bratt, Inspector
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Brinda White, Assistant Attorney General

Board Meeting – October 3, 2007

Disciplinary Action

Lou Ann Ervin, Tech #8180 – Case No. 832: Charges: Theft of merchandise and possession of a controlled dangerous substance (CDS) without a valid prescription. **Permit revoked.**

Michelle Shea, Tech #10564 – Case No. 833: Charges: Theft of merchandise and possession of a CDS without a valid prescription. **Permit revoked.**

Bryan T. Stauffer, Tech #4101 – Case No. 834: Charges: Possession of a CDS without a valid prescription, theft of merchandise and abuse of alcohol or drugs, using an illegal CDS substance, and/or testing positive for such substance or its metabolite. **Permit revoked.**

Aimee Vaughn, Tech #9860 – Case No. 827: Charges: Failing to guard against the theft and diversion of Schedule V pseudoephedrine substances. **Permit revoked.**

The Oklahoma State Board of Pharmacy took action in four (4) impaired cases:

Case 806 – DPh #7836, respondent's license was suspended indefinitely.

Case 829 – DPh #10460, respondent's license was suspended for ten (10) years until October 3, 2017.

Case 830 – DPh #13085, respondent was fined \$5,000 and his license was suspended for ten (10) years until October 3, 2017.

Case 828 – DPh #11522, respondent was fined \$4,000 and his license was suspended for ten (10) years until October 3, 2017.

Board Meeting – November 7, 2007

Disciplinary Action

Barbara J. Caldwell, Tech #7881 – Case No. 831: Charges: Abusing alcohol or drugs, using an illegal CDS substance, and/or testing positive for such substance or its metabolite and possession of a CDS without a valid prescription. **Permit revoked.**

Josh Minard, Tech #7311 – Case No. 837: Charges: Theft of merchandise and possession of a CDS without a valid prescription. **Permit revoked.**

Larry Roddy, Tech #723 – Case No. 838: Charges: Theft of merchandise and possession of dangerous drugs without a valid prescription. **Permit revoked.**

Pauletta Burnett, Tech #4456 – Case No. 839: Charges: Theft of merchandise and possession of dangerous drugs without a valid prescription. **Permit revoked.**

Eric O. Martinez, Tech #10577 – Case No. 840: Charges: Possessing with intent to manufacture, distribute, or dispense a CDS; possession of a CDS without a valid prescription; and theft of merchandise. **Permit revoked.**

Kellen Carter, Tech #8996 – Case No. 841: Charges: Theft of merchandise and possession of dangerous drugs without a valid prescription. **Permit revoked.**

Michael Wright, Tech #9170 – Case No. 835: Charges: Furnishing fictitious, false, misleading, or fraudulent material in his application to the Board and theft of merchandise. **Permit revoked.**

The Board took action in two (2) impaired cases:

Case 821 – DPh #12939, respondent was granted probation.

Case 836 – DPh #12271, respondent was fined a total of \$400 and her license was suspended indefinitely.

From the Inspectors

♦ **Mid-Level Practitioner Update:** Physician assistants (PA) may now prescribe for up to a 30-day supply of Schedule III to V if they

Continued on Page 4



NABP Testifies in Support of Proposed BTC Drug Class

NABP testified at the Food and Drug Administration (FDA) meeting November 14, 2007, stating its support for the proposed creation of a behind-the-counter (BTC) class of drugs. The meeting was held to solicit input on the public health benefits of certain medications being available BTC without a prescription but only after intervention by a pharmacist.

A long-time advocate of this measure, NABP passed a resolution in 1993 advocating a third class of drugs that would be dispensed without a prescription only by licensed health care professionals authorized to prescribe and/or dispense prescription drugs. Continuing its support of this concept, NABP passed a resolution in 1995 stating that medications being converted from prescription-only to over-the-counter status that pose serious risks and require patient education for effective use should be placed in a special class requiring sale only by licensed health care professionals after counseling the patients on proper use.

More information is available in the *Federal Register* (Docket No. 2007N-0356).

A Rose by Any Other Name . . . Might Be Safer



*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 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: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

What's in a name? Well, if the name is referring to a pharmaceutical compound getting ready to go to market, a lot goes into that name.

In order for a drug manufacturer to test its drug chemicals in animals, it must submit three possible generic names to the United States Adopted Names (USAN) Council, the organization responsible for assigning generic drug names. USAN Council selects a generic drug name, based on safety, consistency, and logic and then refers this name to the World Health Organization to check for similar generic names being used in other countries.

There is a method to this naming madness. For instance, drug name "stems" group therapeutically-related drugs. An example would be the stem *-vastatin* for drugs that lower cholesterol, and is used in the generic names of atorvastatin (Lipitor[®]) and lovastatin (Mevacor[®]). Another example of the use of stems is *-mab* used in anticancer drugs. MAB stands for 'monoclonal antibodies' and is used in the generic drug names alemtuzumab and cetuximab. The stem gives clues about what a drug is used for; however, drug names that share a common stem can contribute to medication errors because they may sound or look alike. This is especially problematic if the products share common dosage forms and other similarities.

Additionally, USAN Council guidelines call for generic names to be simple to pronounce with only one way to say it and have no more than four syllables. Yet, the names mentioned in the preceding paragraph are difficult to pronounce and some have five syllables.

After a drug has completed phase-I clinical trials, the manufacturer submits potential brand names to FDA as well as the US Patent and Trademark Office.

Drug manufacturers often work with drug naming companies to help them develop unique brand names. A report in the January-February 2004 issue of the *Journal of the American Pharmacists Association* stated that there are more than 9,000 generic drug names and 33,000 trademarked brand names in use in the US. Although the drug names may be unique, more and more often they are leading to miscommunications and are resulting in errors.

According to USP-ISMP Medication Errors Reporting Program (MERP) data, 25% of the errors reported relate to the products generic or brand name. To help combat this problem, in 1990 FDA established the Labeling and Nomenclature Committee (LNC) to review proposed trade names. The LCN, which has evolved into the Division of Medication Errors and Technical Support of the Office of Surveillance and Epidemiology, formerly the Office of Drug Safety, has been actively reviewing drug names.

Although prescribers and consumers would like drug names to give an indication of the intent of the drug in the name itself, FDA prohibits trade names associated with the product's intended use and will not approve names that imply efficacy. Yet there are many exceptions to this "intended" rule. A drug such as Celebrex[®] (pain treatment) connotes "celebration" and Halcion[®] (sleep aid) conjures up images of restfulness (halcyon). Perhaps naming drugs for their intended purpose would decrease the number of medication errors associated with confusing and sound-alike/look-alike drugs. Until prescribers conform to writing the indication or purpose on the actual prescription, the drug name itself may give a clue to the patient as to what is being prescribed. The patient may read the prescription before handing it to the pharmacist and question why he or she is being prescribed "Oncocure" when he or she does not have cancer.

Studies estimate that anywhere from 7,000 to 20,000 people die or are injured each year in the United States because of drug name confusion. What can pharmacists do? Go to the Med-E.R.R.S.[®] Web site www.med-errs.com and register to become a drug name reviewer. Although not required, many drug companies seek the consultant advice of Med-E.R.R.S. to test their potential generic and brand names before submitting these names to FDA. Med-E.R.R.S., Inc, a wholly owned subsidiary of ISMP, assists pharmaceutical and health care technology companies in evaluating the safety of their products and services. Med-E.R.R.S., Inc has tested more than 600 names for over 35 pharmaceutical companies in 2006. Med-E.R.R.S. integrates knowledge and experience with the input of clinicians in the field to systematically analyze potential trademarks, packaging, and technology.

Med-E.R.R.S. pharmacist reviewers participate in online surveys to review names of potential drugs handwritten by a number of "prescribers" to determine if any of the tested names look like medical terms or other current drugs on the market. They are also asked to review the potential drug names to compare if the potential name sounds like another drug or like another medical term.

To further national efforts to manage drug name confusion, ISMP hosted an invitational summit on October 9-10, 2007, in Philadelphia. This meeting brought together a full range of pharmacy professionals



and representatives from standard-setting organizations, regulatory agencies, the pharmaceutical industry, and the payer community. During the meeting, the attendees discussed post-marketing strategies to identify and reduce name confusion and ways to improve upon their scope and effectiveness. ISMP believes that the health care industry can significantly reduce the risk to patients from otherwise preventable product mix-ups due to look-alike and sound-alike names. A report from the summit will be available online soon.

So a rose by any other name may smell as sweet, but Reminyl[®] renamed Razadyne[™], (see *ISMP Medication Safety Alert!® Community/Ambulatory Edition*, Volume 4, issue 5, May 2005, **Reminyl[®]/Amaryl[®] Your Reports at Work.**) may “smell” safer, and therefore “sweeter.” Sweeter, that is until recently when MERP started receiving errors involving confusion between Razadyne and Rozerem[™]. Stay tuned.

FDA Study Suggests Consumers are Seeking Meds Online to Avoid Rx Rules

FDA recently announced the results of a year-long investigation, which suggest that consumers are buying drugs online to avoid the need for prescriptions from their physicians.

The investigation, comprising surveys conducted from September 2006 to August 2007 in international mail and courier facilities across the country, found 88% of the 2,069 drug packages examined appeared to be prescription medicines available in the US. More than half (53%) of the products sampled have FDA-approved generic versions, likely sold at lower costs, according to earlier studies that have shown generics in the US to be generally less expensive than comparable drugs in Canada or Western Europe. Other products included dietary supplements, foreign products with “illegible or incomprehensible” labeling, and medications not available in the US.

FDA warns that products from unregulated Internet drug sellers may contain the wrong ingredients or toxic substances. Earlier this year, FDA learned that 24 apparently related Web sites operating outside the US may be involved in the distribution of counterfeit prescription drugs.

FDA Posts Drug Safety Newsletter, Labeling Changes

FDA released the first issue of its new *Drug Safety Newsletter* in late 2007. The quarterly online newsletter provides information for health care professionals about the findings of selected post-marketing drug safety reviews, emerging drug safety issues, and recently approved new drugs.

The newsletter is available on the FDA Web site at www.fda.gov/cder/dsn/default.htm and will be sent electronically to *Drug Safety Newsletter* and/or MedWatch subscribers.

FDA also provides monthly updates on medication labeling changes, such as boxed warnings, contraindications, warnings, precautions, adverse reactions, and patient package insert/medication guide sections. The Safety-Related Drug Labeling Changes page is accessible at www.fda.gov/medwatch/safety.htm.

NABP Awards DMEPOS Accreditations Representing Over 11,000 Pharmacies

NABP accredited several independent pharmacies and chains, representing over 11,000 pharmacies, through its durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) accreditation program during fourth quarter 2007.

The DMEPOS program ensures that pharmacies supplying DMEPOS products meet the Centers for Medicare and Medicaid Services’ (CMS) quality and accreditation standards. Those pharmacies that are accredited through the program are doing their part to ensure that Medicare beneficiaries receive the appropriate products, services, and patient care associated with DMEPOS.

A full listing of pharmacies accredited through the NABP DMEPOS program is available under Accreditation Programs on the NABP Web site, www.nabp.net.

FDA Acts to Ensure Thyroid Drug Potency until Expiration

FDA is tightening the potency specifications for levothyroxine sodium to ensure the medication retains its potency over its entire shelf life. FDA is taking this action in response to concerns that the potency of the drug may deteriorate prior to its expiration date.

The revised potency specifications require levothyroxine sodium drug products to maintain 95% to 105% potency until their expiration date. Previously, these products were allowed a potency range of 90% to 110%. FDA has given manufacturers and marketers two years to comply with the revised specification.

More information is available on the FDA Web site at www.fda.gov/cder/drug/infopage/levothyroxine/default.htm.

FDA Reform Law Provides for Establishment of Tracking Standards

President Bush signed HR 3580, the Food and Drug Administration Amendments Act of 2007, into law on September 27, 2007. Among other provisions, the law reauthorizes and expands the Prescription Drug User Fee Act and the Medical Device User Fee and Modernization Act.

The legislation expands FDA authority to regulate marketed drugs, establish a surveillance system to monitor and assess the safety profile of drugs on the market, reauthorize and modify programs that evaluate the use of drugs and devices by children, and expand federal databases that track information on certain clinical trials.

The law also requires the US Department of Health and Human Services to establish a standardized numerical identifier that must be applied to prescription medications at the point of manufacture, and to develop standards to serve as guidelines in the implementation of track-and-trace and package-level identification technology to monitor prescription medications through the supply chain.

2008 Survey of Pharmacy Law Now Available

The NABP 2008 *Survey of Pharmacy Law* CD-ROM is now available. The *Survey* consists of four sections including organizational law, licensing law, drug law, and census data. New topics include whether or not states recognize Verified Internet Pharmacy Practice Sites[™] accreditation and if the boards of pharmacy require compliance with United States Pharmacopeia Chapter 797, “Pharmaceutical Compounding – Sterile Preparations.”

To order the *Survey*, visit www.nabp.net and download an order form; the cost is \$20.

The CD-ROM is provided free of charge to all final-year pharmacy students through a grant from Purdue Pharma L.P. For more information on the *Survey*, please contact NABP via phone at 847/391-4406 or via e-mail at custserv@nabp.net.

have a mid-level Drug Enforcement Administration (DEA) number. They may not issue any refills on CDS prescriptions, even if the prescription is for less than a 30-day supply. Nurse practitioners (NP) may prescribe for a seven-day supply of Schedule III to V with no refills. NPs and PAs may not write outpatient prescriptions for Schedule II under any circumstances. Oklahoma pharmacies may not fill prescriptions from out-of-state PAs or NPs. If a prescription is received from an out-of-state mid-level practitioner, the pharmacy must call and obtain permission to fill the prescription under the supervising physician's authority. Pharmacies may now place the PA or NP name on the patient's label without the supervising physician's name; however, the supervising physician's name must still be indicated on the original prescription.

- ◆ **Hospice/Long-Term Care Facility Schedule II Prescriptions (Faxed):** The Oklahoma Bureau of Narcotics has clarified its rules regarding faxed Schedule II prescriptions for hospice and long-term care facility patients. If the pharmacy intends to use the fax as the original prescription, the fax must be sent from the practitioner's office. If the fax is sent from the hospice or long-term care facility, then the original hard copy written prescription must be presented at the time it is dispensed.
- ◆ **Hospital-Affiliated Clinics:** Hospital-affiliated or hospital-owned clinics may not obtain their medications from hospital pharmacies or drug rooms. These medications are only intended for the patients of the hospital and transfer of drugs outside the hospital may be a violation of federal law.
- ◆ **Background Checks on Employees:** In 2002, the Board revoked eight pharmacy technician permits for drug diversion. This year, 31 of 43 total Board hearings were regarding pharmacy technicians diverting controlled substances or stealing money. In many cases, the pharmacy technician had prior convictions that he or she lied about on his or her original application. It is highly recommended that you conduct a background check on all employees that will have access to controlled substances. It costs \$15 and can be obtained through the Oklahoma State Bureau of Investigation. Information and forms may be found at its Web site: www.ok.gov/osbi/Criminal_History/. As any pharmacist who has been a victim of diversion can tell you, this is inexpensive insurance compared to the financial loss, paperwork hassle, and time involved in an internal theft. Furthermore, a pharmacy with controlled substances may not employ any person with a drug-related conviction without obtaining a waiver from the Oklahoma Bureau of Narcotics and DEA.
- ◆ **Electronic Version of DEA Form 106:** A pharmacy must complete a DEA Form 106 any time there is a loss or theft of CDS. This form is available and may be submitted online at: <https://www.deadiversion.usdoj.gov/webforms/app106Login.jsp>. It is also available as a PDF. Please make copies of the completed DEA Form 106. Keep a copy at the pharmacy, send one copy to the Board of Pharmacy, and send one copy to the Oklahoma Bureau of Narcotics. Addresses and further information are located in Appendix D of the Oklahoma Pharmacy Law Book.
- ◆ **New DEA Rules Limited in Oklahoma:** DEA has amended its rules and now allows practitioners to issue multiple prescriptions for Schedule II medications on one day with instructions "do not fill until a particular date" for up to 90 days. However, the Oklahoma Bureau of Narcotics does not allow Schedule II prescriptions to be filled beyond 30 days after the prescription has been written. Therefore, this DEA rule will be extremely limited in the state of Oklahoma.
- ◆ **Misfill Prevention:** Misfills are the primary complaint the Board receives from the public. With technological advances and bar coding, the wrong drug seems to be less frequent; although, pharmacists and technicians often override or skip the safety measures in place. Wrong directions are frequently an issue, especially in pediatric dosing. Make sure your pharmacy has implemented checks and balances to prevent someone from getting the medication of another person with a similar name. Many pharmacies ask the patient to

verify date of birth or address at the register. If the medication is a controlled substance, the pharmacists are required to obtain positive identification if they do not know the patient. Create a way of flagging the prescription so that the clerk will check before completing the transaction. Most importantly, do not allow clerks and technicians to answer questions from patients regarding a medication looking "different" than last time. This should be a red flag to all pharmacists. Most of the Board's complainants tell us that they asked and were told by a technician that it is a "different generic" before finding out later that it was the wrong drug.

- ◆ **E-Signatures:** Electronic signatures for non-controlled prescriptions are considered valid. E-mailed Schedule III to V controlled prescriptions should be treated as phoned-in prescriptions and validated if necessary. You should be able to validate the source of the e-mail. Oklahoma Bureau of Narcotics rules state "All written prescriptions shall be manually signed by the practitioner." Faxed and/or walk-in Schedule III to V controlled prescriptions must bear the actual signature of the prescriber. If the prescription does not bear the signature or states "e-signature on file," then the pharmacy may call the prescriber and treat the prescription as a phoned-in prescription.
- ◆ **Change of PIC:** Any time there is a change of pharmacy manager, the pharmacy **must** submit a CDS inventory to the Board within 10 days. **Please**, include a cover sheet with the inventory indicating that there has been a change in manager by listing both the outgoing and incoming manager's name and license number and the date the change was effective.

Internet Pharmacy Faxes

The Board has received numerous complaints regarding faxes promoting a partnership between a Web site and pharmacies to sell prescription drugs. The faxes claim to be legal and offer substantial profits to the pharmacy. The Web site changes every week or so, but the same business seems to be behind the scheme.

Do **not** get involved. The adage "if it sounds too good to be true, it probably is" is appropriate. It is illegal to dispense prescriptions that have been issued via an Internet questionnaire or a telephonic consultation. This is not considered to be a valid doctor-patient relationship. Food and Drug Administration and other agencies are working to stop this activity.

Reminder

Board rules require that all registrants (pharmacists, technicians, and interns) notify the Board in writing within ten (10) days of a change of address or employment. If you do not receive a renewal prior to expiration, it is your responsibility to contact the Board.

Oklahoma Pharmacists Helping Pharmacists

If you or a pharmacist you care about is suffering from chemical dependency, there is a solution. Oklahoma Pharmacists Helping Pharmacists (OPHP) is readily available for help. Pharmacists in Oklahoma, Texas, and Louisiana may call the OPHP Help Line at 1-800/260-7574 ext 5. All calls are confidential.

This publication is issued by the Oklahoma State Board of Pharmacy as authorized by Title 59 O.S. 353.7. Copies have not been printed but are available through the agency Web site. Two print copies have been deposited with the Publications Clearinghouse of the Oklahoma Department of Libraries. [74 O.S. 2001 §3105(B)]

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