



# Montana Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

PO Box 200513, 301 S Park Ave, 4<sup>th</sup> Floor  
Helena, MT 59620-0513

## **Board Disciplinary Actions Pharmacy**

**Zwang, David, RP, Libby, MT.** \$1,000 fine, one-year probation.  
Practice of pharmacy in an unlicensed facility.

**Center Drug, Inc, Libby, MT.** \$1,000 fine, one-year probation.  
Expired pharmacy license.

**Garvin, Penny, certified technician, Big Fork, MT.** Revocation.  
Diversion of controlled substances.

**Bitterroot Drug, Hamilton, MT.** \$1,000 fine. Unlicensed  
practice of pharmacy technician.

**Admiral Beverage Corp, DBA-ABC Medicare, Worland,  
WY.** \$1,000 fine, one-year probation, corrective action report.  
Expired pharmacy license.

**Bio Med Plus, Miami, FL.** Revocation, criminal conviction,  
federal court, company no longer exists.

## **Other Boards**

**Leskosky, Louis, MD, Paducah, KY.** Indefinite suspension.

**Kamson, Solomon, MD Seattle, WA.** Indefinite suspension.

**Hughes, Ronald, MD, Great Falls, MT.** Indefinite  
suspension.

**Allen, Jake, MD Lansing, MI.** Indefinite suspension, may not  
petition or apply for reinstatement for 20 years.

**Smith, Stephen, MD, Missoula, MT.** Probation until such  
time as licensee fully and successfully completes program  
established by Montana Professional Assistance Program  
(MPAP).

**Bronecki, Robert, DDS, Great Falls, MT.** Summary  
Suspension.

**Longfellow, Rodney, DDS, Wilsall, MT.** Revocation of license  
for a minimum of two years.

## **Reporting Loss or Theft of Controlled Substances**

Every pharmacy in Montana must report any theft, loss,  
or any other shortage of controlled substances to the Mon-  
tana Board of Pharmacy as well as to Drug Enforcement  
Administration (DEA). The applicable rules follow.

**Administrative Rules of Montana 24.174.1411(3)** The  
registrant shall notify the Board of Pharmacy in writ-  
ing by forwarding a copy of the applicable DEA form  
reporting the theft or loss of any dangerous drugs upon  
discovery of such theft or loss. The notification shall  
contain a list of all dangerous drugs stolen or lost.

**Administrative Rules of Montana 24.174.1411(4)**  
The registrant shall notify law enforcement officials  
of any theft or loss of any dangerous drug promptly  
upon discovery of such theft or loss.

The forms should be sent to Montana Board of Phar-  
macy, 301 South Park Ave, PO Box 200513, Helena, MT  
59620-0513.

## **Requirements for CEAC Approval of Educational Programs**

A review of the requirements for submitting programs  
for Montana Board of Pharmacy Continuing Education  
Advisory Council (CEAC) approval is a timely topic now  
that pharmaceutical companies can no longer be Accredita-  
tion Council for Pharmacy Education-accredited providers  
of continuing education. The Montana Board of Pharmacy  
office has received an increased number of requests for  
CEAC approval for educational programs sponsored by  
pharmaceutical companies.

A CEAC Program Approval Form must be submitted  
with every request for CEAC. The form, which has been  
revised as of July 2006, outlines all of the required informa-  
tion that must be submitted to the Board. Previous editions  
of this form will not be accepted. An electronic copy of the  
form can be obtained from the Board of Pharmacy office  
by e-mailing a request to [dlibsdp@mt.gov](mailto:dlibsdp@mt.gov).

A copy of the presenter's curriculum vitae (CV) **must**  
be provided when requesting program approval. If a CV  
is not available, a summary of the presenter's credentials,  
professional affiliations, and current practice site(s) is ac-  
ceptable. The presenters name and credentials (eg, Tom  
Jones, RPh) on a program flier is not acceptable.

*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](http://www.ismp.org). If you would like to report a problem confidentially to these organizations, go to the ISMP Web site ([www.ismp.org](http://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](mailto: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](http://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<sup>®</sup> renamed Razadyne<sup>™</sup>, (see *ISMP Medication Safety Alert!® Community/Ambulatory Edition*, Volume 4, issue 5, May 2005, **Reminyl<sup>®</sup>/Amaryl<sup>®</sup> 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<sup>™</sup>. 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](http://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](http://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](http://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](http://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<sup>™</sup> 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](http://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](mailto:custserv@nabp.net).

A description or summary of the program content **must** be submitted. The Board must have enough information to make an evaluation of the content of the educational program. This may be a brief description of the program with goals and objectives or a copy of the entire presentation. If possible, a copy of any program handouts should be submitted. A program flier with the title of the presentation, the presenter's name, and program date, time, and location does not provide enough information to determine the educational value of a presentation. A program announcement alone will not be accepted.

Optimally, CEAC requests should be submitted 30 days prior to the date of the program; however, it is not required. Requests for CEAC approval may be submitted to the Board after a program has occurred as long as all of the required information is provided.

There is no guarantee that a program will receive CEAC approval.

Once a program has been CEAC-approved, the person requesting approval must award each attendee a certificate indicating the program title, CEAC number, hours approved for group or individual credit, program date, and attendee name. It is not acceptable to distribute copies of the program approval letter from the Board of Pharmacy to attendees in lieu of a certificate because the letter only identifies the person requesting approval, not the attendee. The person requesting approval on behalf of other individuals must maintain a copy of all materials submitted to the Board, the attendee sign-in sheet, and the CEAC approval letter for three years.

### **Methadone Hydrochloride Tablets USP 40 mg (Dispersible)**

As of January 1, 2008, manufacturers of methadone hydrochloride tablets 40 mg (dispersible) have voluntarily agreed to restrict distribution of this formulation to only those facilities authorized for detoxification and maintenance treatment of opioid addiction, and hospitals. Manufacturers will instruct their wholesale distributors to discontinue supplying this formulation to any facility not meeting the above criteria.

Methadone is a long-lasting opioid medication used in the treatment of pain and narcotic addiction. The 5 mg and 10 mg formulations indicated for the treatment of pain will continue to be available to all authorized registrants, including retail pharmacies. The 40 mg methadone formulation is indicated for the detoxification and maintenance treatment of opioid addiction. The 40 mg strength is not Food and Drug Administration approved for use in the management of pain. Thus, the distribution and availability of the 40 mg formulation will be limited to registrants in only those settings using the 40 mg formulation for the appropriate indication.

DEA and the pharmaceutical industry agree that the reported increase in methadone-related adverse events merits action and further agree to a united effort to ensure that methadone is properly distributed, consistent with its approved uses. Industry and the federal entities involved commit to monitor the progress of this initiative.

Courtesy: US Department of Justice DEA

### **Board of Pharmacy Meeting Schedule**

The Montana Board of Pharmacy has set the following meeting dates for 2008:

January 24-25.....	Fairmont Hot Springs Resort
April 22-23.....	Helena
July 14-15.....	Helena
October 15-16.....	Helena

In each case, the Board meeting begins at 1 PM on the first day, and at 9 AM on the second day. Board meetings are open to the public. The Board of Pharmacy welcomes and encourages pharmacists, interns, and technicians to attend a Board meeting.

The agenda for the Board of Pharmacy meeting is posted on the Web site, [www.pharmacy.mt.gov](http://www.pharmacy.mt.gov), two weeks prior to the meeting.

### **Board Member and Staff Activities**

Executive Director Ronald Klein and Colette Bernica, Board member, attended the National Association of Boards of Pharmacy®/American Association of Colleges of Pharmacy District 7 & 8 meeting in Oregon in October 2007. This meeting is an opportunity for boards of pharmacy and colleges of pharmacy to discuss issues of concern in their region of the country.

At the meeting, Mr Klein was elected treasurer of District 7. Mr Klein was also elected District 7 representative to the resolutions committee for the NABP convention in 2008.

Mr Klein and William Sybrant, Board inspector, attended the National Association of State Controlled Substances Authorities meeting in Albuquerque, NM, in October. This meeting discussed issues of concern to all the states regarding the manufacture, distribution, dispensing, and diversion of CS.

Mr Klein and members of the Montana Board of Crime Control attended the National Association for Model State Drug Laws meeting in Washington, DC, in December. This meeting discussed prescription drug monitoring laws now in place or enacted in 35 states. There is an urgent need for these programs, as they have been demonstrated to be effective in reducing the diversion of prescription CS. They are commonly referred to as prescription drug monitoring programs. Legislation for such a program in Montana was debated by the 2007 legislature, but was not passed. Legislation to enact a program in Montana may be presented to the 2009 legislature.