



# Minnesota Board of Pharmacy

University Park Plaza  
2829 University Ave SE, Suite 530  
Minneapolis, MN 55414-3251  
[www.phcybrd.state.mn.us](http://www.phcybrd.state.mn.us)

Published to promote voluntary compliance of pharmacy and drug law.

## Disciplinary Activity

The Minnesota Board of Pharmacy took the following disciplinary actions concerning **pharmacists** between the dates of September 13, 2007 and December 12, 2007.

**Dreher, Sue Ann, License #113458.** Ms Dreher admitted to violating state and federal privacy laws by accessing the health care records of several individuals without authorization and without having a valid purpose for doing so. She was reprimanded and placed on probation for 180 days, or until she successfully completes a continuing education program concerning the Health Insurance Portability and Accountability Act of 1996 privacy standards, whichever is later. She was also assessed a civil penalty of \$600.

**Evenson, Jon A., License #115013.** Mr Evenson successfully completed his probation, and the Board granted his petition for an unrestricted license.

**Fedie, Kathy A., License #117094.** Ms Fedie successfully completed her probation, and the Board granted her petition for an unrestricted license.

**Growette, Jessica, License #115628.** Ms Growette admitted to the theft of controlled substances (CS) from her employer and the unauthorized personal use of those drugs. She also entered a guilty plea to a charge of driving while impaired. She was placed on probation for an indefinite period of time, until she successfully completes a participation agreement with the Health Professional Services Program (HPSP). She was also assessed a civil penalty of \$300 and will be required to make restitution to her former employer if ordered to do so by a court of law.

**Jonas, Daniel T., License #114830.** Mr Jonas was found to have violated the terms of a stipulation and consent order issued by the Board in 2005. He was discharged by the HPSP for noncompliance with his participation agreement and terminated by his employer for allegedly diverting CS. His license to practice pharmacy was suspended for an indefinite period of time, and he will not be allowed to petition for reinstatement for two years. Should a petition for reinstatement be granted at that time, he will be placed on probation for an additional three years.

**Lokensgard, Michael E., License #110159.** Mr Lokensgard was found to have violated a number of rules and to have

practiced pharmacy in a deficient manner. He was placed on probation for five years, limited to working no more than 20 hours per week, and prohibited from working unless another pharmacist is on duty at the same time.

**Schroeder, Leslie, License #115424.** Ms Schroeder admitted to inappropriately obtaining CS by presenting photocopies of a prescription to more than one pharmacy. She was placed on probation for two years or until she successfully completes a participation agreement with the HPSP, whichever is later. She was also assessed a civil penalty of \$450.

**Swanson, Amy L., License #116161.** Ms Swanson admitted to the theft of CS from her employer and the unauthorized personal use of those drugs. She was placed on probation for two years or until she successfully completes a participation agreement with the HPSP, whichever is later. She was also assessed a civil penalty of \$200 and will be required to make restitution to her former employer if ordered to do so by a court of law.

**Timonen, David M., License #117838.** Mr Timonen admitted that he failed to notify the Board of a change of address and consequently did not receive a renewal notice, causing him to fail to renew his license in a timely manner. He admitted that he practiced pharmacy without a license from March 1 through April 8 of 2005. He was reprimanded by the Board and ordered to pay a civil penalty of \$500.

The Board took no disciplinary actions concerning **technicians** between the dates of September 13, 2007 and December 12, 2007.

## Board of Pharmacy Elects New Officers

At its meeting on December 12, 2007, the Board of Pharmacy elected pharmacist Thomas Dickson, of Proctor, MN, as Board president for calendar year 2008. Pharmacist Karen Bergrud, of Stewartville, MN, was elected vice president. Mr Dickson is the director of pharmacy at Community Memorial Hospital in Cloquet, MN. From 1976 to 1983 he owned an independent consulting corporation that provided service to five nursing homes. He also served 15 years on the local school board – ISD 706, Proctor Schools. He holds a bachelor of arts degree in biology and chemistry from the University of Minnesota Duluth, and a bachelor of science degree in pharmacy from the University of Minnesota.

*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!**<sup>®</sup> **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<sup>®</sup>) and lovastatin (Mevacor<sup>®</sup>). 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<sup>®</sup> (pain treatment) connotes "celebration" and Halcion<sup>®</sup> (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.<sup>®</sup> 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).

Ms Bergrud is the assistant director of pharmacy operations at Mayo Clinic in Rochester. In addition to her duties at Mayo, she is responsible for the operations of the central and satellite pharmacies at Saint Mary's and Rochester Methodist hospitals. She received her bachelor of science degree in pharmacy from the University of Minnesota and is a member of the Minnesota Society of Health-System Pharmacists.

Pharmacist Cody Wiberg was also elected to serve as Board secretary (executive director) for an additional year. In addition to electing officers, the Board designated Candice Fleming to be associate director for compliance and Pat Eggers to be assistant director for administrative affairs.

### **Board of Pharmacy Web Site Update**

Board staff recently completed upgrades to the online services portion of the Web site. Pharmacist license and technician registration renewals can be completed online. In addition, pharmacists, technicians, and interns can change their physical and mailing addresses and their employment. Employers, licensees, or members of the public can verify the licensure or registration of most individuals and businesses licensed or registered by the Board. The upgrades allow licensees, and registrants to establish user identifications and passwords, rather than requiring the use of a Social Security number for each log-in.

### **Pharmacy Technician Registration**

Renewal letters were mailed out slightly later than normal this registration cycle due to a delay in the implementation of the Web site upgrades mentioned above. Any technicians that have not yet renewed their registrations will have to pay late fees when they do renew, and are not allowed to practice as technicians until they renew. The pharmacist-in-charge of each Minnesota pharmacy is responsible for making sure that all of the pharmacy technicians employed in their pharmacy have current technician registrations posted.

### **Pharmacist Renewals**

Pharmacists are encouraged to use the Board's upgraded online services to renew their licenses. However, pharmacists can also print renewal invoices after logging onto the online services portion of the Web site or contact the Board office to request a paper renewal application. Pharmacists should either renew their licenses online or complete and return renewal forms to the Board by February 1. Pharmacist licenses expire on March 1 of each year and a late fee is assessed for any renewal received after February 29. Pharmacists are not allowed to practice after February 29 without a valid license renewal.

### **DEA Adopts Rule Change Regarding Schedule II Prescriptions**

Drug Enforcement Administration adopted the following rule change effective December 19, 2007. The issuance of multiple prescriptions as described in this rule change is permissible under Minnesota law.

#### **Sec. 1306.12 Refilling prescriptions; issuance of multiple prescriptions.**

- (a) The refilling of a prescription for a controlled substance listed in Schedule II is prohibited.

- (b) (1) An individual practitioner may issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a Schedule II controlled substance provided the following conditions are met:
  - (i) Each separate prescription is issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice;
  - (ii) The individual practitioner provides written instructions on each prescription (other than the first prescription, if the prescribing practitioner intends for that prescription to be filled immediately) indicating the earliest date on which a pharmacy may fill each prescription;
  - (iii) The individual practitioner concludes that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse;
  - (iv) The issuance of multiple prescriptions as described in this section is permissible under the applicable state laws; and
  - (v) The individual practitioner complies fully with all other applicable requirements under the Act and these regulations as well as any additional requirements under state law.
- (2) Nothing in this paragraph (b) shall be construed as mandating or encouraging individual practitioners to issue multiple prescriptions or to see their patients only once every 90 days when prescribing Schedule II controlled substances. Rather, individual practitioners must determine on their own, based on sound medical judgment, and in accordance with established medical standards, whether it is appropriate to issue multiple prescriptions and how often to see their patients when doing so.

Section 1306.14 is amended by adding a new paragraph (e) to read as follows:

#### **Sec. 1306.14 Labeling of substances and filling of prescriptions.**

- (e) Where a prescription that has been prepared in accordance with section 1306.12(b) contains instructions from the prescribing practitioner indicating that the prescription shall not be filled until a certain date, no pharmacist may fill the prescription before that date.