



# Nevada State Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

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- Donald Fey, RPh, Las Vegas .....Board Member
- Chad Luebke, RPh, Las Vegas .....Board Member
- Mary Lau, Carson City..... Public Member

## 2008 Board Meeting Schedule

- January 16-17 ..... Las Vegas
- March 5-6 ..... Reno
- April 16-17 ..... Las Vegas
- June 4-5..... Reno
- July 16-17 ..... Las Vegas
- September 3-4 ..... Reno
- October 15-16..... Las Vegas
- December 3-4 ..... Reno

## Pharmacy Errors and Adverse Drug Events

Recent statistics on legal claims against pharmacists and pharmacies reveal that about half of said claims are for dispensing the wrong drug, and one quarter of them are for dispensing the wrong dose. Drug allergies, drug interactions, or labeling errors are involved in 6% to 8% of claims. Nevada State Board of Pharmacy staff is convinced that upwards of 80% of all of these errors could be prevented with proper counseling. Explore with the patient his or her understanding of the medication. Check the contents of the vial with the patient, and review the dosage they are taking. Following are some examples of cases heard by the Board recently, all of which cast doubt on the quality of counseling the patient received, if any:

1. A patient received warfarin rather than Valium®.
2. A **one-year-old** baby was dispensed Bactrim™ DS tablets rather than the suspension ordered.

3. A woman was given clomipramine (an antidepressant) rather than clomiphene (a fertility drug).
  4. A patient was given levothyroxine rather than Ambien®.
- Appropriate dialog between the pharmacist and the patient in any of these cases would obviously have caught the errors.

## Pharmacist Online Renewal Results

The Board of Pharmacy had an amazing year for pharmacists renewing their licenses on the Internet. We had close to 45% of eligible pharmacists renew online and hope to do even better in 2009 with a goal of more than 50% choosing to renew their licenses online. Please remember to get your Nevada law continuing education for this licensing period of November 1, 2007 through October 31, 2009, prior to signing and dating your renewal form or submitting your renewal online. You are certifying that your license is ready for renewal.

## Safety Information Regarding Fentora (Fentanyl Buccal Tablets)

Some serious adverse events have surfaced, including patient deaths, in patients treated with Fentora® as a result of improper patient selection, improper dosing, and improper substitution. Per the manufacturer, the following are key safety points:

- ◆ Fentora is not for opioid non-tolerant patients.
- ◆ Fentora should not be used for acute pain, postoperative pain, headache, or sports injuries.
- ◆ Fentora is not a generic for Actiq® and may not be substituted without contacting the prescriber.
- ◆ Dosing should be limited to not more than two tablets every four hours for breakthrough pain episodes.

## Password Protection Revisited

As discussed in a previous *Newsletter*, we cannot stress enough how important it is for pharmacists to protect their passwords for access to computers and for drug utilization review override. Board staff continually sees incident after

*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).

incident of sloppy password protection by the pharmacist resulting in incidents that could lead to discipline. No matter how efficient or convenient, a pharmacist should never give a password or override code to another. Of equal importance is logging out of your terminal when you leave it. Undoubtedly, when accused of misfilling a prescription because your initials appear on the label, and you had nothing to do with that particular prescription, you will become more vigilant.

### **New Faces**

Sadly, the terms for three of our Board members have come to an end. President Dave Wuest and Ann Peterson, consumer member, have retired from Board service effective November 1, 2007. Ann quickly became one of the Board's hardest workers, tirelessly studying, evaluating, counseling, and advising on behalf of the consumer, while Dave, in a style unique to his effervescent personality, conducted Board meetings with dignity, class, and fairness. Thanks to the contributions of these two outstanding Board members, pharmacy practice in Nevada has improved. Finally, after some 10 years of service to the citizens of Nevada through Board work, the tenure of Katie Craven has ended due to term limitations. Katie, a hospital pharmacist, left as a legacy the new compounding regulations that have been so long overdue. These regulations required over five years of meetings, workshops, toil, and tears to become reality and certainly would not have progressed without Katie's guidance. Board staff wishes the three of you the best in your future endeavors. You truly will be missed.

Board staff welcomes the new appointees to the Board as announced by Governor Jim Gibbons. The new consumer member is Mary Lau, who is the president and CEO of the Retail Association of Nevada. Mary, during her many years in Nevada, has served on various state advisory boards and

currently serves as a board member for several Nevada corporations. The new hospital Board member is Donald Fey, pharmacy supervisor at Sunrise Hospital in Las Vegas. Don, a long practicing hospital pharmacist, holds degrees from Arizona State University, University of Utah, and University of Florida. Chad Luebke, a pharmacy supervisor for some 26 CVS pharmacies in southern Nevada, fills the final slot. Chad comes to Nevada from Ohio, where he graduated in 1998 from Ohio Northern University. Coincidentally, both Chad and Don have immediate family members who are also pharmacists. Chad and his wife Erin are pharmacists for CVS, and Don and his daughter Julie are pharmacists for Sunrise Hospital. Hopefully, the Board experience for all three of the new members will be both personally and professionally rewarding.

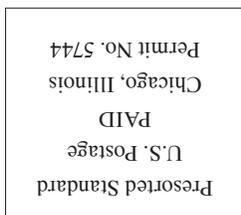
Congratulations to Board member Barry Boudreaux on being elected Board president, and to Board member Leo Basch for being re-elected to the treasurer position. Board staff looks forward to working with and providing support to Barry and Leo as they progress through future Board activities.

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