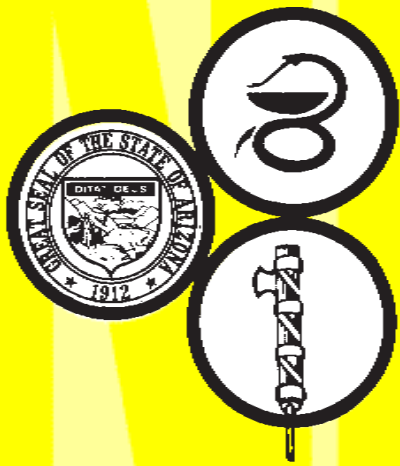


January 2008



Arizona State Board of Pharmacy

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E-mail: info@azpharmacy.gov

Published to promote voluntary compliance of pharmacy and drug law.

Statistics from the Most Recent Renewal Period for Licenses and Permits

The biennial renewal process that took place between September 15 and November 15, 2007, was designed to be more technologically advanced than past years and to allow the Arizona State Board of Pharmacy staff to utilize e-mail to issue renewal receipts to those who chose to renew online. Unfortunately, due to a change in the contract for the entire state of Arizona, the Board's Web portal provider was changed from IBM to NIC on October 8, 2007.

Our analysis of the data from this year's renewal period shows that \$736,398 was collected from the 7,351 licensees who renewed and that \$1,004,200 was collected from the 3,156 permit holders who renewed. The total collected from all 10,637 renewals was \$1,740,598 and is about 70% of the total revenue collected by the Board for the entire year. Further analysis shows that approximately 77% of all licensees and 28% of all permit holders who renewed by November 15 utilized the online renewal process.

New Controlled Substance Prescription Monitoring Program

Arizona's 48th legislature passed House Bill 2136, a mandate that establishes a Controlled Substances Prescription Monitoring Program (CSPMP) in the state funded and administered entirely by the Board of Pharmacy. The CSPMP will collect, securely store, and review data provided by pharmacies and medical practitioners who dispense any of the controlled substances (CS) listed in Schedule II, III, or IV. The new statutes, known as Title 36, Chapter 28, are available on the Board's homepage under the yellow "Rules & Statutes" tab on the left side of www.azpharmacy.gov. The Board of Pharmacy may, using a protocol established by a governing task force, proactively release data collected by the CSPMP to medical practitioners and pharmacies to assist them in providing individual pharmaceutical care to a patient. The CSPMP is not intended to interfere with the legitimate treatment of patients, but the program will provide approved information to treating medical practitioners and dispensing pharmacies if their patients are receiving prescriptions from other providers. This information will facilitate and encourage the identification, intervention, and treatment of individuals who are misusing or diverting CS. When the system is operational, pharmacists and providers will receive instructions on how to access the database. Questions may be directed to Dean Wright, director of the Prescription Monitoring Program at 602/771-2744 or via e-mail at dwright@azpharmacy.gov.

Board Compliance Officer – Recruitment for Vacant Position

Compliance Officer Chuck Cordell has resigned his compliance officer position in order to move back to the Midwest to be closer to family. As

a result of his resignation a vacancy exists in the Phoenix office. Arizona pharmacists with a current Arizona pharmacist license are invited to mail a cover letter with current resume to Ms C. Hunter, secretary to the Board executive staff. All resumes should be received by January 26, 2008, and addressed to Ms Hunter at the Board offices located in the Executive Tower at 1700 W Washington St, Suite 250, Phoenix, AZ 85007. Preference will be given to pharmacists with extensive experience in a variety of practice settings. Please do not call the Board office regarding the position. Qualified candidates will be contacted by Board staff after written materials have been received. It is the intention of Board staff to interview qualified candidates and fill the vacancy no later than February 2008.

Drug Enforcement Administration – News

On September 6, 2006, Drug Enforcement Administration (DEA) published Notice of Proposed Rulemaking 71 FR 52724 proposing to amend its regulations to allow practitioners to provide individual patients with multiple prescriptions, to be filled sequentially, for the same Schedule II CS, with such multiple prescriptions having the combined effect of allowing a patient to receive over time up to a 90-day supply of that CS. Of the 264 comments DEA received during the comment period, 166 expressed approval of the proposed rule without change. **The new rule took effect December 19, 2007; it is important for all prescribers and dispensers to note that Schedule II prescriptions still may not be refilled.** Call Dean Wright at 602/771-2744 for clarification of the rule or for general questions involving CS.

The Tucson office of DEA has determined that two pharmacies in the last six months have filed requests to transfer DEA registration **after** the sale of the pharmacies. DEA regulation 21 CFR 1301.52(b) requires persons to obtain authorization to transfer a registration **prior** to the proposed transfer (sale).

Disciplinary Actions – Board of Pharmacy (Actions Since October 2007 Newsletter)

Notice: Before making a prescription-dispensing or other decision pursuant to information in this issue, you are encouraged to verify the current condition of a license with the appropriate licensing agency (Board).

Pharmacy Board Actions – Pharmacists

Abou-Zahra, Mohamed (S012756) – License revoked. Effective September 12, 2007.

Banks, Wanda (S007882) – License revoked. Effective September 12, 2007.

Carranza, Robert (S015967) – Probation imposed. Effective November 15, 2007.

Dalkin, Thomas (S012296) – Suspension terminated. Probation imposed. Effective September 12, 2007.

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 LP. For more information on the *Survey*, please contact NABP via phone at 847/391-4406 or via e-mail at custserv@nabp.net.

Continued from page 1

- Dorstad, Loren (S014050)** – \$1,000 fine. Complete 15 contact hours. Effective November 23, 2007.
- Forster, Mark (S009865)** – Suspension terminated. Effective November 15, 2007.
- Green, James (S005337)** – License reinstated with six-month probation imposed. Scope of practice limited to that of a pharmacy intern. Effective October 9, 2007.
- Hannibal, Jeffrey (S011674)** – License reinstated with five-year probation imposed. Five-year Pharmacists Assisting Pharmacists of Arizona contract. Effective October 1, 2007.
- Heisler, Marc (S009834)** – Probation terminated. Effective September 12, 2007.
- Kudish, Stan (S010354)** – Suspension terminated. Probation imposed. Effective November 15, 2007.
- Lin, Angel (S010847)** – \$1,000 fine. Complete 30 contact hours. Effective November 23, 2007.
- Marek, Andrew (S013113)** – Probation terminated. Effective November 15, 2007.
- Perry [Pearce], Christine (S006383)** – Probation terminated. Effective September 12, 2007.
- Rosch, Judith (S008544)** – Suspension terminated. Probation imposed. Effective November 15, 2007.

Pharmacy Technicians

- Brunner, Kimberly (T006383)** – License revoked. Effective September 12, 2007.
- Frahm, Joel (T011905)** – License revoked. Effective September 12, 2007.
- Garcia, Denise (T000247)** – Probation imposed – one year. Effective September 12, 2007.
- Godoy, Diane (T002033)** – License revoked. Effective September 12, 2007.
- Jordan, Denise (T000306)** – Probation terminated. Effective November 15, 2007.
- Orcelletto, Eric (T009484)** – License revoked. Effective September 12, 2007.
- Stickrath, David (T007534)** – License revoked. Effective September 12, 2007.
- Torda, Cathy (T000002)** – License revoked. Effective September 12, 2007.

Disciplinary Actions – Other Boards

Arizona Osteopathic Medical Board (DO)

- Denicole, Michael (DO 2103)** – *Amended Order of Probation and Practice Restriction* – Respondent is restricted from prescribing Schedule I through V drugs and may prescribe, administer, and dispense Schedule II through V drugs only while employed by and working at the Meadows health care facility. Effective September 20, 2007.
- Partridge, Jerome P. (DO 2031)** – *Amended Order of Probation* – Respondent may return to the active practice of osteopathic medicine and specifically the practice of anesthesia based upon recommendations. Effective September 20, 2007.

Arizona Board of Medicine (MD/PA)

- Denman, Kyle C. (PA 2307)** – License surrendered to the Board. Effective August 22, 2007.
- Gibbs, Marvin L. (MD 13736)** – License revoked. Effective August 9, 2007.
- Goldwasser, Harry D. (MD 20842)** – Respondent issued a Letter of Reprimand. Respondent placed on probation for five years with set terms and conditions. Effective August 10, 2007.
- Grade, Thomas J. (MD 10424)** – License revoked. Effective August 9, 2007.

- Greene, David L. (MD 32747)** – *Interim Finding of Fact* – Respondent's license to practice allopathic medicine in the state of Arizona is summarily suspended pending a formal hearing. Effective August 20, 2007.
- Groves, Thomas J. (MD 5104)** – Respondent issued a Letter of Reprimand. Effective June 8, 2007.
- Huber, Roderic S. (MD 4488)** – License surrendered to the Board (non-disciplinary). Effective August 10, 2007.
- Larson, Paul (MD 78055)** – *Interim Consent Agreement* – Respondent shall not practice clinical medicine or any medicine involving direct patient care, and is prohibited from prescribing any form of treatment including prescription medications, until Respondent applies to the Board and receives permission to do so. Effective June 21, 2007.
- Martinez, Xavier (MD 18944)** – *Interim Consent Agreement* – Respondent shall not practice clinical medicine or any medicine involving direct patient care, and is prohibited from prescribing any form of treatment including prescription medications, until Respondent applies to the Board and receives permission to do so. Effective August 16, 2007.
- Menon, Venu G. (MD 12360)** – *Interim Findings of Fact* – Respondent's license to practice allopathic medicine in the state of Arizona is summarily suspended pending a formal hearing. Effective August 13, 2007.
- Miller, Eric J. (MD 19279)** – *Order Vacating Interim Consent Agreement for Practice Restriction Dated January 9, 2007*. Effective June 4, 2007.
- Moody, Warren (MD 31152)** – *Interim Findings of Fact* – Respondent's license to practice allopathic medicine in the state of Arizona is summarily suspended pending a formal hearing. Effective October 16, 2007.
- Morford, Pamela A. (MD 17926)** – License surrendered to the Board. Effective October 11, 2007.
- Plumb, David I. (MD 37523)** – *Interim Findings of Fact* – Respondent's license to practice allopathic medicine in the state of Arizona is summarily suspended pending a formal hearing. Effective October 11, 2007.
- Robertson, Glenn G. (MD 33045)** – *Interim Consent Agreement* – Respondent shall not practice clinical medicine or any medicine involving direct patient care, and is prohibited from prescribing any form of treatment including prescription medications, until further order of the Board. Effective August 21, 2007.
- Rosado, Humberto (MD 19978)** – *Interim Consent Agreement* – Respondent shall not practice clinical medicine or any medicine involving direct patient care, and is prohibited from prescribing any form of treatment including prescription medications, until further order of the Board. Effective September 18, 2007.
- Scoggin, Joseph (MD 30290)** – *Interim Consent Agreement (non-disciplinary)* – Physician shall not practice clinical medicine or any medicine involving direct patient care and is prohibited from prescribing any form of treatment including prescription medications until further order of the Board. Effective September 21, 2007.

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