

# Missouri Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

PO Box 625, Jefferson City, MO 65102

## Board of Pharmacy Licensing Statistics

The Missouri Board of Pharmacy currently licenses/registers a total of 23,046 individuals and businesses. This is an increase of 2,143 compared to the 2004 report. The following provides a breakdown for each category of license/registration:

Drug Distributor License (Temporary/Permanent).....	1,231
Drug Distributor Registration (Out-of-state Manufacturers)..	100
Pharmacists (Active = 7,176; Inactive = 250).....	7,426
Pharmacies (In-state and Out-of-state).....	1,784
Interns.....	930
Technicians.....	11,575

## Gold Certificates

The following pharmacists will receive gold certificates in honor of maintaining a license with the Board for 50 years. Each gold certificate is signed by the Board members, executive director, and Governor Matt Blunt, and is accompanied with a letter of congratulations from the Board. Congratulations to those who have served the public for 50 years as a licensed pharmacist.

- William T. Bard – Cape Girardeau, MO
- Robert D. Barnett – Pittsburg, KS
- Donald E. Becker – Goleta, CA
- John C. Chisolm Jr – Ballwin, MO
- Marvin G. Cohen – Creve Coeur, MO
- Ralph J. Evers – Advance, MO
- Joseph S. Gianino – Ellisville, MO
- Kenneth L. Gimmy – East Alton, IL
- John F. Hanley – Fountain Valley, CA
- Jordan D. Johnson Jr – Las Vegas, NV
- Robert J. Kirchoff – Winfield, MO
- Bobbie B. Kountz – Kansas City, MO
- Kenneth A. Michel – Poplar Bluff, MO
- George Milton – Cape Girardeau, MO
- Katherine K. Novak – Sugar Creek, MO
- Harlan Radinsky – St Louis, MO
- Roger L. Thompson – Higginsville, MO
- Gary E. Traxson – Fresno, CA
- Rodney E. Wesner – Windsor, MO
- Albert Zvibleman – St Louis, MO

## Zoomerang

Zoomerang, an Internet service site, provides support to its clients by sending surveys and gathering survey results. The Board is using

this site to send surveys to recently-inspected pharmacies to obtain feedback on the voluntary compliance program and inspections. During the inspection process, the inspector will ask for an e-mail address to which the survey can be sent. Not all pharmacies will receive the survey since a randomized selection of pharmacies is used. If your pharmacy should be selected, it is important to complete the survey and return it as directed so the Board can continue to get valuable data about its inspection program.

## Compounding Issues

Pharmacists, under state law, cannot compound products that are essential copies of commercial products on the market or of products that have been withdrawn from the market due to safety or effectiveness issues. There are exceptions to this. If a commercial product is temporarily unavailable due to problems other than safety or effectiveness issues, a pharmacy can compound the product until the commercial form is once again available. Another exception is when a patient may have a specific medical need for a compounded product to replace a commercially available one. A **medical** reason must exist explaining why the commercially available product cannot be used. Sufficient documentation from the prescriber indicating the medical need or a notation indicating verbal authorization along with a description of the medical need must be obtained and maintained as part of the prescription record. Economic or convenience reasons for compounding commercially available products are considered illegal. Another issue of importance is to remember the restrictions concerning advertising placed on pharmacists by state law. While a pharmacist may advertise or otherwise provide information about the provision and types of compounding services available, a pharmacist cannot make specific claims concerning a compounded product or make comparisons of products made in a pharmacy with commercially available products. Manufacturers must maintain analytical data that is approved by Food and Drug Administration before making claims about their products. Pharmacists will not have completed such processes and, therefore, must avoid making unsubstantiated claims.

## Licensing Actions

### Interns

**Jonathan C. Bergman, #2005014027**, Kansas City, MO – May 3, 2005. Restricted license issued on Probation for four (4) years – May 3, 2005 to May 2, 2009. Pled guilty to Driving While Intoxicated (Alcohol). Section 338.055.2(2), RSMo Supp. 2004.

*Continued on page 4*



## **New Board Will Oversee Management of Drug Safety Monitoring**

Food and Drug Administration (FDA) has unveiled a program that aims to improve oversight of drug safety monitoring and to bolster openness in agency product review and decision making. Included is the creation of an independent Drug Safety Oversight Board, made up of medical experts from FDA and other government agencies. Also planned are Web postings of emerging drug data and risk information as well as written materials that provide targeted drug safety information to the public. For more information, see [www.fda.gov/oc/factsheets/drugsafety.html](http://www.fda.gov/oc/factsheets/drugsafety.html).

## **ACPE Changes Provider Criteria Regarding Drug and Device Manufacturers**

In early 2005, the Accreditation Council for Pharmacy Education (ACPE) ceased accepting applications from pharmaceutical and biomedical device manufacturers seeking accreditation as providers of continuing education (CE). Effective July 1, 2005, the organization will no longer recognize pharmaceutical and biomedical device manufacturers as accredited providers. In addition, any CE issued by a pharmaceutical or device manufacturer after June 30, 2005, is not valid. These changes were approved by the ACPE Board of Directors at its January 2005 meeting after the organization determined that manufacturers could not meet both ACPE's requirements and the recommended restrictions as stated in a Compliance Program Guidance for Pharmaceutical Manufacturers published by the Office of the Inspector General of the United States (OIG).

In 2003, OIG stated that manufacturers could be subjected to liability under federal statutory provisions if they maintain any influence over CE subject matter or presenters, or provide funding for attendees or other incentives with respect to CE attendance. Strict compliance with OIG's guidelines would relegate manufacturers to solely providing educational grants to CE providers in order to be free of liability. Meanwhile, ACPE's Criteria for Quality require that the CE provider control the content speakers or authors of a CE program, putting ACPE's requirements in opposition to OIG's guidelines; hence, ACPE, out of responsibility to health regulatory boards, the profession, and the public, must now accredit only those providers who are in compliance with the ACPE criteria and the OIG guidelines.

In accordance with ACPE's new policies, organizations with a commercial interest and any proprietary entity producing health care goods or services, with the exception of nonprofit or government organizations and non-health care-related companies, will not be eligible for ACPE accreditation status.

For more information, contact ACPE Executive Director Peter Vlasses at 312/664-3575, or via e-mail at [pvlasses@acpe-accredit.org](mailto:pvlasses@acpe-accredit.org).



## **Let's Get to the 'Point': Prescription Misinterpretations Due to Decimal Points**

*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, then publishes its recommendations. 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).*

**Problem:** Numbers containing decimal points are a major source of error and, when misplaced, can lead to misinterpretation of prescriptions. Decimal points can be easily overlooked, especially on prescriptions that have been faxed, prepared on lined order sheets, or written or typed on carbon and no-carbon-required (NCR) forms (often used in hospitals and long-term care facilities). If a decimal point is missed, an overdose may occur. The importance of proper decimal point placement and prominence cannot be overstated.

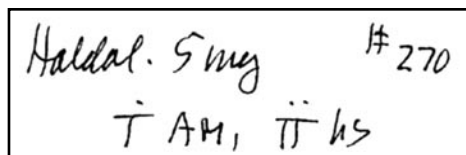
For one, a decimal point should always be preceded by a whole number and never be left "naked." Decimal expressions of numbers less than one should always be preceded by a zero (0) to enhance the visibility of the decimal. For example, without a leading zero, a prescription for "Haldol® .5 mg" (see image shown on next page) was misinterpreted and dispensed as "Haldol 5 mg." We have received similar reports with Risperdal® (risperidone) in which "Risperdal .5 mg" was prescribed (instead of Risperdal 0.5 mg), but the patient received several 5 mg doses because the decimal point was overlooked.

In addition, a whole number should never be followed with a decimal point and a zero. These "trailing zeros" (eg, "3.0") are a frequent cause of 10-fold overdoses and should never be used. For example, when prescriptions have been written for "Coumadin® 1.0 mg," patients have received 10 mg in error. Similarly, a prescription for "Synthroid® 25.0 mcg" could be misread as "Synthroid 250 mcg."

Dangerous use of decimals can also be problematic if they appear in electronic order entry systems or on computer-generated labels. A newly admitted hospital patient told her physician that she took Phenobarbital® 400 mg PO three times daily. Subsequently, the physician wrote an order for



the drug in the dose relayed by the patient. A nurse saw the prescription vial and verified that this was the correct dose. However, prior to dispensing, a hospital pharmacist investigated the unusually high dose. When he checked the prescription vial, he found that it was labeled as “phenobarbital 32.400MG tablet.” The label indicated that 30 tablets were dispensed with instructions to take one tablet three times daily.



The hospital pharmacist contacted the outpatient pharmacy and suggested that the computer expressions including trailing zeros be changed to avoid serious medication errors. The pharmacy management agreed that trailing zeros appearing on labels might pose a risk and made the change immediately.

## Safe Practice Recommendations

In order to avoid misinterpretations due to decimal point placement, pharmacists should consider the following:

- ◆ Always include a leading zero for dosage strengths or concentrations less than one.
- ◆ Never follow a whole number with a decimal point and a zero (trailing zero).
- ◆ Educate staff about the dangers involved with expressing doses using trailing zeros and naked decimal points.
- ◆ Eliminate dangerous decimal dose expressions from pharmacy and prescriber electronic order entry screens, computer-generated labels, preprinted prescriptions, etc.
- ◆ Avoid using decimals whenever a satisfactory alternative exists. For example, use 500 mg in place of 0.5 gram, 125 mcg instead of 0.125 mg, or 2 ½ mg instead of 2.5 mg.
- ◆ Identify drugs with known 10-fold differences in dosage strength (eg, Cytomel® 5 mcg and 50 mcg, Coumadin 1 mg and 10 mg, levothyroxine 25 mcg and 250 mcg) and place reminders in electronic order entry systems and on pharmacy shelves to alert practitioners to double-check the dosage strength.
- ◆ When sending and receiving prescriptions via fax, health care practitioners should keep in mind that decimal points can be easily missed due to “fax noise.” Whenever possible, encourage prescribers to give original prescriptions (with an indication that it has been faxed) to their patients to take to the pharmacy for verification. Pharmacists should carefully review faxed prescriptions and clarify prescriptions that contain fax noise.
- ◆ Eliminate the lines on the back copy of NCR forms so that a person receiving can clearly see decimal points or other marks that were made on the top copy.
- ◆ Notify prescribers of the potential for error if misinterpretations due to decimal point usage are discovered.

## DEA Issues Final Rules for Electronic Orders for Controlled Substances

On April 1, 2005, Drug Enforcement Administration (DEA) issued final rules regarding electronic orders for controlled substances. DEA revised its regulations to provide an electronic equivalent to the DEA official order form (Form 222), which is legally required for all distributions involving Schedule I and II controlled substances. The regulations will allow, but not require, registrants to order Schedule I and II substances electronically and maintain the records of these orders electronically. The regulations will reduce paperwork and transaction times for DEA registrants who handle, sell, or purchase Schedule I or II controlled substances. The effective date of the final rules was May 31, 2005.

The final rules were issued via the *Federal Register* on April 1, 2005, and may be downloaded from the following Web site address: [www.access.gpo.gov/su\\_docs/fedreg/a050401c.html](http://www.access.gpo.gov/su_docs/fedreg/a050401c.html).

## FDA Publishes Final Rule on Chlorofluorocarbons in Metered Dose Inhalers

FDA announced that albuterol metered-dose inhalers (MDI) using chlorofluorocarbon propellants must no longer be produced, marketed, or sold in the US after December 31, 2008.

The Health and Human Services (HHS) is encouraged that the manufacturers of three environmentally friendly albuterol inhalers are implementing programs to help assure access to these albuterol MDI for patients for whom price could be a significant barrier to access to this important medicine. These programs include MDI giveaways, coupons for reducing the price paid, and patient assistance programs based on financial need.

In a final rule, published March 31, 2005, in the *Federal Register*, HHS stated that sufficient supplies of two approved, environmentally friendly albuterol inhalers will exist by December 31, 2008, to allow the phasing out of similar, less environmentally friendly versions.

## FDA Develops PSAs to Educate Consumers About Purchasing Medications Online

FDA recently released two public service announcement (PSA) brochures, which educate consumers about the advantages and disadvantages of purchasing medication online. The brochures also advise consumers to ensure a Web site is a US-licensed pharmacy by contacting their state board of pharmacy. Consumers may want to refer to the list of Verified Internet Pharmacy Practice Sites™ (VIPPS®) on [www.nabp.net](http://www.nabp.net) to find out if a Web site has been checked to make sure it has met state and federal rules. Consumers also will know if an online pharmacy is VIPPS-accredited when they notice the VIPPS Seal on that particular Web site.

For more information on these PSAs visit [www.fda.gov/cder/consumerinfo/Buy\\_meds\\_online\\_all\\_resources.htm](http://www.fda.gov/cder/consumerinfo/Buy_meds_online_all_resources.htm).

## Pharmacists

**Nicholas G. Igel, #41243**, Fenton, MO – June 15, 2005. Revoked. Cannot reapply for licensure for seven (7) years. Violation of previous discipline involved, failure to submit documentation for approval of alcohol/drug abuse counseling treatment program, failure to submit documentation for approval of a mental health counselor, no written agreement with a mental health counselor received by Board.

**Curtis L. Knolhoff, #2005012734**, Collinsville, IL – April 27, 2005. Restricted license issued on Probation for one (1) year – April 27, 2005 to April 26, 2006. Practiced as a pharmacist prior to licensure in Missouri. Section 338.055.2(6), (12), and (13), RSMo Supp. 2004.

**Michael A. Levy, #40849**, Pleasant Hill, MO – June 1, 2005. Probation for two (2) years – June 1, 2005 to May 31, 2007. Multiple dispensing errors occurred December 1999 through July 2004. Section 338.055.2(15), RSMo Supp. 2002.

**Teresa A. Lowe, #2001018155**, Blue Springs, MO – October 15, 2004. Censure of license effective October 15, 2004. Improper supervision of pharmacy technicians, which resulted in loss of controlled substances and technicians working before applying for registration. Section 338.055.2(5), (6), (13), and (15), RSMo Supp. 2002.

**Catherine E. McCammack, #2005007980**, Collinsville, IL – March 21, 2005. Restricted license issued on Probation for five (5) years – March 21, 2005 to March 20, 2010. Disciplinary action by the Illinois State Board of Pharmacy involving substance abuse. Section 338.055.2(8), RSMo 2004.

**Karen P. Norris, #2005017958**, Overland Park, KS – June 9, 2005. Restricted license issued on Probation for two (2) years – June 9, 2005 to June 8, 2007. Impaired pharmacist and practicing pharmacy prior to licensure. Section 338.055.2(1), (5), (6), (13), and (15), RSMo 2000.

**Angela D. Simons, #44509**, Marshfield, MO – June 15, 2005. Probation for five (5) years – June 30, 2005 to June 29, 2010. Impaired pharmacist, diversion of drugs from employer without valid prescription for personal use. Section 338.055.2(1), (5), (13), (15), and (17), RSMo Supp. 2002.

## Pharmacies

**Advanced Pharmacy Solutions, Inc, #2002025755**, Largo, FL – June 1, 2005. Voluntary Surrendered permit effective June 1, 2005. Dispensed drugs, including controlled substances, for prescriptions based on patient responses to online questionnaires. Section 338.055.2(5), (13), and (15), RSMo 2000.

**Biologics, Inc, #2005010826**, Raleigh, NC – March 31, 2005. Restricted pharmacy permit issued on Probation for three (3) years – March 31, 2005 to March 30, 2008. Serving Missouri patients without being licensed as a non-resident pharmacy. Section 338.055.2(5) and (6), RSMo 2000.

**Holden Drug, #5462**, Holden, MO – June 1, 2005. Probation for two (2) years – June 1, 2005 to May 31, 2007. Multiple dispensing errors occurred from April 2001 through July 2004. Section 338.055.2(15) and 338.285, RSMo Supp. 2002; and 4 CSR 220-2.010(1)(N).

## Drug Distributors

**Baxter Healthcare Corporation, #2005002668**, Memphis, TN – June 8, 2005. Restricted drug distributor license issued on Probation for two (2) years – June 8, 2005 to June 7, 2007. Shipped legend drugs and/or medical devices into Missouri without proper licensure. Section 338.055.1 and .2(5), (6), and (13), RSMo 2000.

**Nephro-Tech, Inc, #2005001926**, Wellsville, KS – June 8, 2005. Restricted drug distributor license issued on Probation for three (3) years – June 8, 2005 to June 7, 2008. Shipped legend drugs and/or medical devices into Missouri without proper licensure. Section 338.055.1 and .2(5), (6), and (13), RSMo 2000.

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