



Alabama State Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.



Fifty Year "Gold Year" Pharmacists

The following individuals are being recognized for the distinction of having been licensed pharmacists in Alabama for fifty (50) years. The Alabama State Board of Pharmacy gratefully acknowledges their years of contribution to the learned pharmacy profession.

Name	License Number	Original License Date
Vernell Eiland Kyser	5057	1-16-58
John Horace Cleveland	5058	1-16-58
Robert Wayne Malcolm	5061	2-12-58
Clifford Aubrey Lowry	5064	2-14-58
James E. Hawkins	5065	2-14-58
Speer Dick Matalka	5066	2-26-58
B. Clinton Hardy	5069	3-18-58
Oscar D. Chunn	5078	4-30-58
Harry Reginald Cogburn, Jr	5080	4-3-58
William R. Nunn	5083	4-3-58
Betty J. Holley	5090	4-17-58
Harlan V. Cooper	5092	5-1-58
Clyde Ray, Jr	5093	5-8-58
Billy Joe Justice	5096	5-29-58
Billy M. Johnson	5102	6-11-58
Freddie Malcolm Slaughter	5105	6-19-58
Ray Howard Bragg	5112	7-9-58
Charles Winston Bruce	5113	7-9-58
Charley James Deuel, Sr	5115	7-9-58
Bill Gann	5118	7-9-58
Daniel Harvey Gillis	5121	7-9-58
Dale Dallas Harris	5123	7-9-58
Gary E. Parks	5133	7-9-58
Thomas Rodney Peden	5134	7-9-58
Sandra Massey Walker	5141	7-23-58
Henry Hexton Lindsey	5146	8-25-58
Henry E. Moore	5148	9-4-58
George Fulton Suber, Jr	5154	9-15-58

Name	License Number	Original License Date
James O. Walker	5161	10-6-58
Thomas Lee Richards, Sr	5163	10-14-58
Thomas Ray Scruggs	5170	10-14-58
Anthony John Brooklere	5173	10-21-58
Henry H. North	5175	11-8-58
Frederick C. Barnett	5176	12-4-58
Thomas Arlin Dean	5177	12-4-58
Ira Leonard West, Jr	5180	12-17-58

Board Members and Drug Inspectors for 2008

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Tammy Rogers	Vice President
Mike Mikell	Treasurer
Rob Nelson	Member
Donnie Calhoun	Member
Henry Burks, Jr.	Chief Inspector
Eddie Braden	Inspector
Scott Daniel	Inspector
Mark Delk	Inspector
George Grubbs	Inspector
Richard Lambruschi	Inspector
Glenn Wells	Inspector

Repackaging Medications Dispensed at Another Pharmacy

It is the opinion of the Board's attorney that the repackaging of legally prescribed drugs dispensed at another pharmacy into unit dose delivery systems is equivalent to dispensing drugs. Thus, in so dispensing, the pharmacist and pharmacy must comply with all the provisions of the Alabama Pharmacy Practice Act and federal law regarding the dispensing of drugs including, but not limited to, record keeping and documentation requirements.

680-X-3-.08 Annual Inventory of Controlled Substances

(1) Every pharmacy shall take an initial inventory of all controlled substances on hand and shall take a new inventory of **all stocks of controlled substances on hand on January 15th** or the alternative fixed date approved by the Board of each year following the date the initial inventory was taken.

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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 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.

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(4) The inventory by a pharmacy must be taken either as of the **opening of business or as of the closing of business**. The pharmacy shall indicate on the inventory records whether the inventory was taken as of the opening of business or as of the close of business, the date the inventory was taken, followed by the person responsible for taking the inventory.

(5) In determining the number of units of each finished form of a controlled substance in a commercial container, which has been opened, the pharmacy shall do as follows:

(a) If the substance is listed in Schedule II, an exact count or measure of the contents shall be made.

(b) If the substance is listed in Schedule III, IV or V, an estimated count or measure may be made of the contents unless the container holds more than 1000 tablets or capsules in which case an exact count of the contents must be made.

680-X-2-.12 Supervising Pharmacist – Amended

(1) The supervising pharmacist shall be on duty a minimum of 50% of the hours the pharmacy is in operation or at least thirty (30) hours per week, whichever is less.

Signing Controlled Substance 222 Forms

680-X-3-.09 Invoices and Acquisitions of Controlled Substances. In addition to those records required under federal laws and regulations, and under provisions of the Alabama Uniform Controlled Substance Act, all receipts of controlled substances by a pharmacy shall be reviewed and approved by a pharmacist. Said review and approval shall be documented by the **signature** of a pharmacist employed by the pharmacy permit holder on the supplier's invoice or other similar such document.

Electronic Drug Enforcement Administration (DEA) Form 222 transmissions should have a copy of the transmission **printed**, signed, and stored accordingly for retrievability.

Over-the-Counter Insulin

The Alabama Board of Medical Examiners is requesting that the Board of Pharmacy ask pharmacists to recommend to patients, who are filling insulin prescriptions on an emergency basis, or are using over-the-counter (OTC) insulin, that they obtain a physician examination and a current insulin prescription. This request is made out of concern for patient safety, in that the Board has seen evidence of patients who continue to fill prescriptions on an emergency basis, or purchase OTC insulin, and have not been under the care of a physician for an extended time.

Multiple Schedule II Prescriptions

Effective December 19, 2007, DEA released a new rule amendment to Title 21 Code of Federal Regulations Part 1306 authorizing prescribers to provide individual patients with multiple prescriptions for the same Schedule II controlled substance.

Key Provisions:

- ◆ Multiple prescriptions must be filled “sequentially” allowing for a combined 90-day supply of the controlled substance.
- ◆ Prescriptions issued in multiples **may not** be filled before the written date noted in the sig directions indicating the earliest date of which a pharmacy may fill each prescription. No pharmacist may fill the prescription before that date.
- ◆ The “original” date of issuance is so noted on **each** prescription.

Valid Hardcopy Prescriptions

*Compliance Note: Patients presenting computer **printed**, electronically prepared prescriptions (controlled or non-controlled) must have a manually signed signature of the prescriber on the prescription for it to be valid.*

Special Notice about the Newsletter

The *Alabama State Board of Pharmacy Newsletter* is considered an official method of notification to pharmacies, pharmacists, pharmacy interns, and pharmacy technicians credentialed by the Board. **These Newsletters will be used in administrative hearings as proof of notification.** Please read them carefully. We encourage you to keep them in the back of the Alabama Pharmacy Law Book for future reference.

Do You Know a Pharmacist or Technician Who Needs Help?

Call the Committee of Rehabilitating Impaired Pharmacists help line at the voice mail of Steve Moore at 205/975-8548. All calls are confidential.

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