

August 2008



# Alabama State Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

## **George T. Grubbs Receives 2008 Lester E. Hosto Inspector Distinguished Service Award**



George T. Grubbs serves as an inspector for the Alabama State Board of Pharmacy where he promotes, preserves, and protects the public health, safety, and welfare of the state's residents. Because of his dedication, the National Association of Boards of Pharmacy® (NABP®) awarded Mr Grubbs the 2008 Lester E. Hosto Inspector Distinguished Service Award at the Association's 104<sup>th</sup> Annual Meeting. Mr Grubbs has been an inspector for the Alabama State Board since 1984, and during this time discovered and proved the diversion of over 435,000 doses of controlled substances from a single pharmacy. Prior to this, he was a police officer for the city of Birmingham, AL, and served as a United States Navy air control man. In 2007, Mr Grubbs was nominated for the Alabama Retail Association for Law Enforcement Officer of the Year Award. He attended the police training school in the city of Birmingham and the School of Alcoholic Studies at both the University of Georgia and Rutgers University. Mr Grubbs obtained his associate degree in applied science from Jefferson State Junior College and studied law enforcement at several institutes.

## **Physicians Writing Prescriptions for Family**

By Larry Dixon, Executive Director,  
Alabama Board of Medical Examiners

The Alabama Board of Medical Examiners is requesting practicing pharmacists to be alert to physicians prescribing controlled substances to themselves or family members. In almost every case, prescribing scheduled drugs to oneself or one's family members is considered unprofessional and could be grounds for disciplining a medical license. The Board of Medical Examiners realizes pharmacists may feel uncomfortable reporting physicians; however, a call to the Board of Medical Examiners and a conversation with an investigator can be of good service to the physician involved if he or she is simply acting out of ignorance, and, if not, it may be the catalyst for help. Very few physicians lose their license on a first-time impairment issue. The Board of Medical Examiners believes in attempting to salvage an impaired physician. The Board of Medical Examiners also believes a pharmacist's professionalism should help the individual aware of such a situation decide to call the Board of Medical Examiners (1-800/227-2606) and ask for an investigator.

## **Pharmacists' Licensees, Controlled Substance Permits, and Pharmacy Permits are Delinquent at Midnight December 31, 2008**

The Board office will send postcard renewal notices to each pharmacist and permit holder. If you do not receive a renewal notice, it is most likely the Board does not have your current address. Go to the Board Web site, [www.albop.com](http://www.albop.com), and visit the section on forms and applica-

tions to submit your new address, then **renew online starting October 1, 2008**. If you have not completed your yearly continuing education (CE) requirements, **do not wait**. Renew and make sure you complete the fifteen (15) hours of CE (three [3] of which should be live CE) by December 31, 2008. View the Board's Web site for a list of live CE events throughout the state.

## **Revisions to USP Chapter 797 (Sterile Compounding)**

United States Pharmacopeia (USP) posted the final update to Chapter 797, "Pharmaceutical Compounding – Sterile Preparations." Pharmacies compounding sterile products are urged to review these changes and assess the impact of compliance as these updates affect all sterile compounding pharmacies in Alabama. Extra education may be required for meeting these guidelines. (Sterile product examples: cardioplegia, eye drops, total parenteral nutrition, etc.)

## **USP Chapter 795 (Nonsterile Compounding)**

USP Chapter 795, "Pharmaceutical Compounding – Nonsterile Preparations" serves as a guideline for compounding nonsterile products. (Nonsterile product examples: magic mouthwash, Dakin's solution, flavorings, etc.)

## **§34-23-8. Substitution of Drugs or Brands of Drugs**

No person shall dispense or cause to be dispensed a different drug or brand of drug in lieu of that ordered or prescribed without the express permission in each case of the person ordering or prescribing such drug, except as provided below:

- (1) A licensed pharmacist in this state shall be permitted to select for the brand name drug product prescribed by a licensed physician or other practitioner who is located in this state and authorized by law to write prescriptions, hereinafter referred to as "practitioner," a less expensive pharmaceutically and therapeutically equivalent drug product containing the same active ingredient, or ingredients, and of the same dosage form strength, in all cases where the practitioner expressly authorizes such selection in accordance with subdivision (4) of this section.
- (2) A licensed pharmacist located in this state shall be permitted to select for the brand name drug product prescribed by a practitioner who is located in another state or licensing jurisdiction and who is authorized by the laws of that state or jurisdiction to write prescriptions, a less expensive pharmaceutically and therapeutically equivalent drug product containing the same active ingredient or ingredients, and of the same dosage form strength, in all cases where the out-of-state licensed physician or other practitioner does not expressly prohibit a substitution.

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## A Community Pharmacy Technician's Role in Medication Reduction Strategies



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 Food and Drug Administration (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](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: 200 Lakeside Dr, Horsham, PA 19044. Phone: 215/947-7797. E-mail: [ismpinfo@ismp.org](mailto:ismpinfo@ismp.org).

Pharmacy technicians play a major role in community pharmacy practice. The pharmacist relies on the technician to provide an extra layer of safety. It is important for technicians to follow system-based processes and inform the pharmacist when these processes do not work or are unmanageable.

### Prescription Drop Off

The date of birth should be written on every hard copy prescription so the pharmacist has a second identifier readily available during verification. Allergy information should be questioned and updated at every patient encounter. Medical condition information, such as pregnancy, communicated to the technician at drop off should be updated in the computerized profile system to help the verification pharmacist determine counseling opportunities. Knowing a person's medical conditions also helps the pharmacist determine if prescriptions are written incorrectly or for the wrong drug.

### Data Entry

Medication safety is enhanced when technicians know the particular language of pharmacy when entering a prescription.

New drugs are at a particular risk because it is more likely that the technician is not aware of the new drug and a more familiar drug is selected. Pharmacists and technicians should work together to determine the best method of distributing information regarding availability of new drugs on the market.

It is important that the technician understands the safety features of the computer system and does not create work-arounds to improve efficiency at the risk of decreasing accuracy and safety. Drug alerts can be numerous, and the technician may be inclined to override the alert and not "bother" the pharmacist. A better way to resolve too many alerts would be to establish protocol between the technician and the pharmacist to determine which level and type of alert needs pharmacist intervention.

### Production

Mix-ups occur primarily due to incorrectly reading the label. The problem is aggravated by what is referred to as *confirmation bias*. Often a technician chooses a medication container based on a mental picture of the item, whether it be a characteristic of the drug label, the shape and size or color of the container, or the location of the item on a shelf. Consequently the wrong product is picked. Physically separating drugs

with look-alike labels and packaging helps to reduce this contributing factor.

### Point of Sale

Correctly filled prescriptions sold to a patient for whom it was not intended is an error that can be avoided by consistent use of a second identifier at the point of sale. Ask the person picking up the prescription to verify the address or in the case of similar names, the date of birth, and compare the answer to the information on the prescription receipt.

Internal errors should be discussed among all staff for training purposes. In addition, it is important to read about and discuss errors and methods of prevention occurring and being employed at other pharmacies within a chain and in other pharmacies, nationwide. ISMP Medication Safety Alert! Community/Ambulatory Edition offers this information to both pharmacists and technicians.

### FDA's Effort to Remove Unapproved Drugs From the Market

Pharmacists are often not aware of the unapproved status of some drugs and have continued to unknowingly dispense unapproved drugs because the labeling does not disclose that they lack FDA approval. FDA estimates that there are several thousand unapproved drugs illegally marketed in the United States. FDA is stepping up its efforts to remove unapproved drugs from the market.

### Background

There are three categories of unapproved drugs that are on the market. The first category consists of those that have been approved for safety, or that are identical, related, or similar to those drugs, and either have been found not to be effective, or for which FDA has not yet determined that they are effective. Between 1938 (passage of the Federal Food, Drug, and Cosmetic Act) and 1962, manufacturers were only required to demonstrate that drugs were safe; the requirement that they also demonstrate that drugs were effective was added in 1962. Drugs that fall in this category have been part of the DESI (Drug Efficacy Study Implementation) review, which was implemented to determine whether drugs approved between 1938 and 1962, or drugs that are identical, related, or similar to such drugs, met the new effectiveness requirements. While the DESI review is mostly completed, some parts of it are still continuing. The second category of unapproved drugs consists of those drugs that were on the market prior to 1938 (passage of the Federal Food, Drug, and Cosmetic Act). The third category, new unapproved drugs, comprises unapproved drugs that were first marketed (or changed) after 1962. Some also may have already been the subject of a formal agency finding that they are new drugs.

### FDA's Concerns About Unapproved Drugs

FDA has serious concerns that drugs marketed without FDA approval may not meet modern standards for safety, effectiveness, manufacturing quality, labeling, and post-market surveillance. For example, FDA-approved drugs must demonstrate that their manufacturing processes can reliably produce drug products of expected identity, strength, quality, and purity. In addition, FDA's review of the applicant's labeling ensures that health care professionals and patients have the information necessary to understand a drug product's risks and its safety and efficacy.

Sponsors that market approved products are subject to more extensive reporting requirements for adverse drug events than sponsors of unapproved drugs. Reporting of adverse events by health care professionals and patients is voluntary, and under-reporting is well documented. FDA, therefore, cannot assume that an unapproved drug is safe or effective simply because it has been marketed for some period of time without reports of serious safety or effectiveness concerns.

# Compliance News

Compliance News to a particular state or jurisdiction should not be assumed as the law of such state or jurisdiction.)



## Enforcement Priorities

Manufacturers of unapproved drugs are usually fully aware that their drugs are marketed illegally, yet they continue to circumvent the law and put consumers' health at risk.

Most recently, in June 2006, FDA issued a guidance entitled "Marketed Unapproved Drugs – Compliance Policy Guide" (CPG) outlining its enforcement policies aimed at bringing all such drugs into the approval process. (The CPG is available at [www.fda.gov/cder/guidance/6911fnl.pdf](http://www.fda.gov/cder/guidance/6911fnl.pdf)) The agency provided industry with specific notice that anyone who markets an unapproved drug is subject to enforcement action. This CPG outlines the agency's risk-based enforcement policies aimed at bringing all such drugs into the approval process without imposing undue burdens on consumers or unnecessarily disrupting the market. For all unapproved drugs, the CPG gives highest enforcement priority to the following:

- ◆ Drugs with potential safety concerns
- ◆ Drugs that lack evidence of effectiveness
- ◆ Fraudulent drugs
- ◆ Drugs with formulation changes made as a pretext to avoid enforcement
- ◆ Unapproved drugs that directly compete with an approved drug

Table 1 lists examples of drugs or classes of drugs that, consistent with the CPG, FDA has identified as a higher priority because of safety or other concerns. For six of them, FDA has specifically announced its intention to take enforcement action against companies marketing unapproved versions of those drug products. FDA has withdrawn the approval of the seventh product.

**Table 1: Examples of FDA Actions Regarding Unapproved Drugs**

Extended release combination drug products containing guaifenesin (competed with approved products)
Trimethobenzamide hydrochloride suppositories (lacked evidence of effectiveness)
Ergotamine-containing drug products (labeling did not include critical warnings regarding the potential for serious, possibly fatal interactions with other drugs)
Quinine sulfate drug products (665 reports of adverse events, including 93 deaths, and the labeling lacked necessary warnings and safe dosing information)
Carbinoxamine drug products (associated with 21 infant deaths)
Colchicine injectables (50 reports of adverse events, including 23 deaths)

## Importance to Pharmacists

FDA is taking steps to ensure that all marketed US drugs have met approval requirements. FDA recognizes that some unapproved drugs may provide benefits; however, since these products have not undergone FDA review for safety and efficacy, the agency recommends that pharmacists, prescribers, and patients carefully consider the medical condition being treated, the patient's previous response to a drug, and the availability of approved alternatives for treatment. FDA will proceed on a case-by-case basis and make every effort to avoid adversely affecting public health, imposing undue burdens on health care professionals and patients, and unnecessarily disrupting the drug supply. More information regarding the FDA's Unapproved Drug Initiative can be found on its Web site: [www.fda.gov/cder/drug/unapproved\\_drugs/](http://www.fda.gov/cder/drug/unapproved_drugs/).

## NABP Educates Public on Buying from Internet Pharmacies with New Section on its Web site

On May 16, 2008, the National Association of Boards of Pharmacy® (NABP®) launched the Internet Pharmacies section of its Web site, educating patients on the potential dangers of buying medicine online and empowering them to make informed choices. As of mid-June, the site listed 250 Internet drug outlets that appear to be out of compliance with state and federal laws or NABP patient safety and pharmacy practice standards, thereby putting those who purchase from these sites in danger of purchasing drugs that could cause patients serious harm or even death.

NABP developed these standards for its new Internet Drug Outlet Identification program with input from its member boards of pharmacy, interested stakeholders, and regulatory agencies, including the FDA and the US Drug Enforcement Administration. Internet drug outlets operating in conflict with these criteria are listed on the NABP Web site as "not recommended." NABP has identified another 300 suspiciously operating Internet drug outlets and is in the process of verifying its findings before posting these sites to the "not recommended" list. Of the hundreds of sites reviewed under this program so far, only nine have been found to be potentially legitimate, pending verification of licensure and other criteria. At this time, NABP recommends that patients buying medicine online use only Internet pharmacies accredited through the VIPPS® (Verified Internet Pharmacy Practice Sites™) program. NABP has verified that these pharmacies are appropriately licensed and have successfully completed the well-recognized and rigorous VIPPS criteria evaluation and on-site inspection. These pharmacies, representing more than 12,000 pharmacies, are listed on the NABP Web site as "recommended."

These lists, along with program criteria and related patient information, are accessible in the Internet Pharmacies section of the NABP Web site.

The new program is an outgrowth of a 2007 NABP resolution, "Internet Pharmacy Public Safety Awareness," in which the Association pledges to continue collaborating with federal agencies and other interested stakeholders to educate the public and health care professionals of the dangers of acquiring drugs illegally through the Internet and from foreign sources. As part of this initiative, NABP will provide information to assist state and federal regulators in their efforts to shut down rogue Internet drug outlets.

## RxPatrol Video Helps Pharmacists Address and Prevent Pharmacy Theft

Pharmacy theft is a serious crime that is on the rise, costing pharmacies billions annually in stolen medication according to the Federal Bureau of Investigation (FBI). RxPatrol® has teamed up with Crime Stoppers and other law enforcement officials to disseminate information regarding pharmacy crime. One resource that pharmacists can use to educate themselves and their coworkers is a training video that provides tips for pharmacists to address the rising issue of pharmacy robberies. The video includes interviews with law enforcement officials from the FBI and police department about what can be done to prevent such activity. The video can be found on the RxPatrol Web site at [www.rxpatrol.com/videos.asp](http://www.rxpatrol.com/videos.asp) and by clicking on "Pharmacy Safety – Robbery."

RxPatrol is a collaborative effort between industry and law enforcement designed to collect, collate, analyze and disseminate pharmacy theft information. RxPatrol helps protect the pharmacy environment and ensure legitimate patients' access to life-sustaining medicines.

- (3) A pharmacist shall record on the prescription form the name and manufacturer or distributor of any drug product dispensed as herein authorized.
- (4) Every written prescription issued in this state by a licensed practitioner shall contain two signature lines. Under one signature line shall be printed clearly the words "dispense as written." Under the other signature line shall be printed clearly the words "product selection permitted." The practitioner shall communicate instructions to the pharmacist by signing on the appropriate line. The State Board of Pharmacy shall not promulgate any rule or regulation affecting the subject matter of this subdivision. An oral prescription from the practitioner shall instruct the pharmacist whether or not a less expensive pharmaceutically and therapeutically equivalent drug product may be dispensed. The pharmacist shall note instructions on the file copy of the prescription and retain the prescription form for the period specified by law.
- (5) Unless otherwise indicated by the practitioner, the prescription label on the dispensing container shall indicate the actual drug product dispensed, either the brand name, or if none, the generic name; and the name of the manufacturer or a reasonable abbreviation of the name of the manufacturer.
- (6) This shall not be interpreted to exclude the use of a formulary or drug list as adopted and approved by a medical staff in a licensed hospital with drugs provided thereunder by procedures established for use within that licensed hospital.
- (7) Any person who violates the provisions of this section shall be punished by a fine of up to \$1,000.

### Board Preceptor Seminar – A Great Success

The Board held their first Preceptor Seminar on May 25, 2008, at Samford Brock Recital Hall. The Board recertified 96 licensed preceptors and licensed 66 new pharmacy preceptors in the state of Alabama.

### Eighth Annual Board Law Seminar

**Place:** Location pending

**Date:** October 19, 2008

**Time:** 1- 4 PM; Three (3) free hours of Law CE

**Invitees:** All pharmacists and technicians in the state of Alabama

**Registration:** Preregistration required online at [www.albop.com](http://www.albop.com)

### Accreditation Council for Pharmacy Education (ACPE)

Effective August 1, 2007, a topic indicator of "patient safety" was added to the Universal Program Number codes. The list of current and new designator codes are as follows:

- L Live Program
- H Home Study
- C Both Live and Home Study
- P Pharmacists
- T Pharmacy Technician
- 01 Disease State Management/Drug Therapy
- 02 AIDS Related Therapy
- 03 Pharmacy Law
- 04 General Pharmacy Topics
- 05 Patient Safety: The prevention of health care errors and the elimination or mitigation of patient injury caused by health care errors.

Pharmaceutical education at the level of performance is key to learning. When preparing CE programs pay attention to content and to whom the content is intended to serve. Alabama State Board of Pharmacy-approved CE programs will have CE well designated if it is approved for a **pharmacist, technician, or both pharmacist and technician.**

### Special Notice about the Newsletter

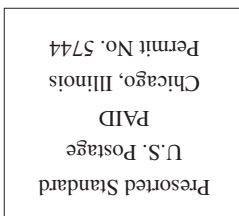
The Alabama State Board of Pharmacy Newsletter is an official method of notification to pharmacies, pharmacists, pharmacy interns, and pharmacy technicians credentialed by the Board. Board Newsletters are used in administrative hearings as proof of notification. Please read them carefully. We encourage 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 on Rehabilitating Impaired Pharmacists help line at the voice mail of Steve Moore at 205/975-8548. All calls are confidential.

The Alabama State Board of Pharmacy News is published by the Alabama State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

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