

August 2008



# Colorado State Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

1560 Broadway, Suite 1300, Denver, CO 80202-5143

## **Pharmacy Technician Taskforce**

A Pharmacy Technician Taskforce has been organized by the Colorado State Board of Pharmacy to explore the issues surrounding the possible regulation of pharmacy technicians. This taskforce comprises Board members and representatives from various practice settings, including accredited technician training programs. The first meeting of the taskforce was held in June 2008. This group is charged with conducting in-depth research on this issue and providing the Board with recommendations on the feasibility of regulation, education, and training requirements and scope of practice for pharmacy technicians in Colorado.

## **Disciplinary Actions January 1, 2008 through June 30, 2008 and those Previously Unreported**

**Thomas H. Brady**; 11381; Effective April 23, 2008; Stipulation.  
**Thomas L. Bratz**; 9612; Effective March 21, 2008; Letter of Admonition.  
**Kevin A. Broussard**; 16027; Effective February 7, 2008; Stipulation.  
**Robert J. Doherty**; 16511; Effective February 12, 2008; Stipulation.  
**Robert J. Doherty**; 16511; Effective February 18, 2008; Letter of Admonition.  
**Dubin Medical, Inc**; WHO 7276; Effective April 25, 2008; Stipulation.  
**Alexandra E. Hilts**; 14471; Effective April 1, 2008; Stipulation.  
**KeySource Medical, Inc**; WHO 7394; Effective April 15, 2008; Stipulation.  
**Lawrence B. Kurtz**; 9870; Effective April 19, 2008; Final Agency Order.  
**Terry L. Kurtz**; 15703; Effective March 26, 2008; Letter of Admonition.  
**Kent R. Laffin**; 9621; Effective March 21, 2008; Letter of Admonition.  
**Kevin A. Levulis**; 13200; Effective March 24, 2008; Stipulation.  
**Demar Lewis, III**; 13773; Effective April 1, 2008; Stipulation.  
**Thomas A. Lotocki**; 11610; Effective March 21, 2008; Letter of Admonition.  
**Med 4 Home Pharmacy #6050**; OSP 5101; Effective June 10, 2008; Stipulation.  
**Yoseph G. Mekonnen**; 17489; Effective February 17, 2008; Letter of Admonition.  
**North Valley Hospital – Rehabilitation**; PDO 119-11; Effective April 15, 2008; Stipulation.  
**David S. Ornes**; 12550; Effective April 16, 2008; Stipulation.  
**Byron J. Padilla**; 16516; Effective April 17, 2008; Stipulation.  
**Redwood Unit Dose**; Not Licensed; Effective January 24, 2008; Cease and Desist Order.  
**Salem R. Montez**; 15006; Effective March 28, 2008; Stipulation.  
**South Pointe Wholesale, Inc**; Not Licensed; Effective March 24, 2008; Cease and Desist Order.

**Star Drug, Inc**; PDO 1250000003; Effective May 28, 2008; Stipulation.  
**Target Pharmacy #T-2021**; PDO 627; Effective February 8, 2008; Stipulation.  
**George H. Tracey**; 7901 (lapsed); Effective February 17, 2008; Letter of Admonition.  
**Dan M. Valentine**; 12002; Effective May 5, 2008; Stipulation.  
**Walgreen Pharmacy #09561**; PDO 637; Effective March 19, 2008; Stipulation.  
**Walgreen Pharmacy #1728**; PDO 790000014; Effective January 23, 2008; Stipulation.  
**Walgreen Pharmacy #2857**; PDO 70000045; Effective March 19, 2008; Stipulation.  
**Ernest N. Whitman, Jr**; 9229; Effective March 21, 2008; Letter of Admonition.

## **Licensees or Registrants Released from Board Orders January 1, 2008 through June 30, 2008**

**Blair, Dennis H.**; 11820; Effective January 17, 2008; Released from stipulation, and license restored to unencumbered status.  
**Capitol Heights Pharmacy**; PDO 30; Effective April 13, 2005; Released from stipulation, and license restored to unencumbered status.  
**Cassidy, Jimmy L.**; 13240; Effective March 20, 2008; Released from stipulation, and license restored to unencumbered status.  
**Graper, Kimberlee**; 15545; Effective May 6, 2008; Released from Stipulated Letter of Admonition.  
**Hogue, Marjorie C.**; 11290; March 20, 2008; Released from stipulation, and license restored to unencumbered status.  
**Kapp, Keith T.**; 2002496; Effective April 29, 2008; Released from Agreement for License with Conditions.  
**McCanless, Jason M.**; 15334; Effective March 20, 2008; Released from stipulation, and license restored to unencumbered status.  
**Rodney's Clinic Pharmacy**; PDO 5-6; Effective March 20, 2008; Released from stipulation, and license restored to unencumbered status.  
**Soderberg, Paul M.**; 15393; Effective March 20, 2008; Released from stipulation, and license restored to unencumbered status.  
**Walgreen Pharmacy #1728**; PDO 79-14; Effective February 8, 2008; Released from stipulation.  
**Walgreen Pharmacy #1728**; PDO 79-14; Effective March 20, 2008; Released from stipulation, and license restored to unencumbered status.  
**Zugelder, James F.**; 15789; Effective January 17, 2008; Released from stipulation, and license restored to unencumbered status.

Continued on page 4



## 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!**<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: 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.



## 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.

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.

More information regarding the above disciplinary actions may be obtained from the following Web site: [www.dora.state.co.us/doraimages](http://www.dora.state.co.us/doraimages).

### **Electronic Prescription Drug Monitoring Program**

The Board is pleased to announce that its Electronic Prescription Drug Monitoring Program (PDMP) has now gone “live.” Pharmacists and prescribers of controlled substances may now register and access data in order to provide the most appropriate treatment for their patients. If you are interested in learning more about the program, go to the Board’s Web site, [www.dora.state.co.us/pharmacy](http://www.dora.state.co.us/pharmacy), or visit [www.coloradopdmp.org](http://www.coloradopdmp.org).

### **Stay Alert!**

Over the past few years, the Board has been aware of an increasing number of Web sites that solicit orders from customers who are interested in obtaining prescription drugs and controlled substances without a valid prescription order or legitimate medical purpose. Recently, however, the Board has become aware of new Web sites that are advertising “Direct Script” programs. Under this program, the process for a customer to obtain a prescription drug or controlled substance via a Web site is the same (by answering an online questionnaire or obtaining a telephonic consultation) except that prescriptions are no longer dispensed at an affiliated Internet pharmacy. The prescription is either faxed to the customer’s local pharmacy or sent directly to the customer for presentation at a local pharmacy. The Board asks that each licensee and registrant exercise caution and due diligence when presented with a prescription, received via fax or in person, bearing an address of a practitioner in one state and a patient in another. While not all prescription orders authorized by an out-of-state physician are illegal, every effort should be made to verify the authenticity of the order, particularly those written by unfamiliar practitioners to unfamiliar patients. Regulation 3.00.21 states, among other things, that a pharmacist shall not dispense a prescription drug if the pharmacist knows or should have known that the order for such drug was issued on the basis of an Internet-based questionnaire, Internet-based consultation, or a telephonic consultation, all without a valid preexisting patient-practitioner relationship. The Board encourages pharmacists to utilize the PDMP when dispensing controlled substance prescriptions. The PDMP may be accessed at [www.coloradopdmp.org](http://www.coloradopdmp.org).

For information concerning the Board of Pharmacy’s Peer Assistance Program call 866/369-0039 or go to [www.peerassist.org](http://www.peerassist.org).

### **Responsibility to Report Drug Losses**

The Board reminds all registered prescription drug outlets of the responsibility to report any suspected theft or other loss of prescription drug or controlled substance stocks. Board Regulation 7.00.10(c) states that the pharmacist manager of an outlet shall report the unaccountable loss

of medications from the outlet, whether by theft or unknown means and CRS 12-22-318(5.5) requires all prescription drug outlets to report thefts of controlled substances to the proper law enforcement agencies and to the Board within 30 days after the occurrence of such thefts. While the Board understands the important role registrants have in conducting thorough investigations detailing specifically how or why such losses occurred, registrants must always remember this 30-day time requirement, even if it means only providing the Board with a notice of the loss within 30 days of discovery instead of a specific reason for the loss at a later time.

### **Register Now to Receive Regulatory Notices**

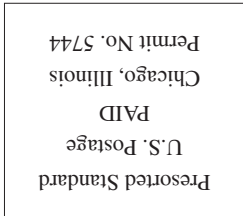
The Colorado State Board of Pharmacy is directing all persons or entities who may be interested in receiving information concerning upcoming rulemaking hearing dates for rules related to the Board of Pharmacy, to register their information with the Department of Regulatory Agencies, Office of Policy, Research and Regulatory Reform, in order to receive e-mailed regulatory notices.

This free service will alert you via e-mail whenever a draft proposed rule or amendment to an existing rule is submitted for review. You will also be notified if a department or agency is required to submit a cost-benefit analysis as the result of a review. To register, please go online at [www.dora.state.co.us/opr/index.htm](http://www.dora.state.co.us/opr/index.htm), and click on the link on the left-hand side of the screen titled “Sign up for Regulatory Notices.” To ensure that you receive information concerning Board of Pharmacy rulemaking hearings. Please select the “Professions and Occupations” checkbox item as one subject area of interest.

If you are an individual or an entity that does not have Internet or e-mail access, please respond in writing to the Department of Regulatory Agencies, Board of Pharmacy, 1560 Broadway, Suite 1300, Denver, CO 80202, with a request to continue to receive mailed notices of upcoming Board of Pharmacy rulemaking hearings.

The *Colorado State Board of Pharmacy News* is published by the Colorado 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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