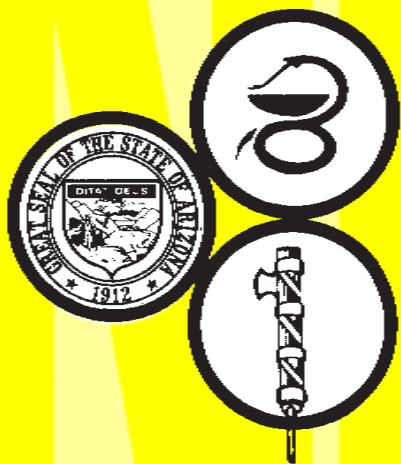


July 2008



Arizona State Board of Pharmacy

1700 W Washington St, Room 250, Phoenix, AZ 85007
Web site: www.pharmacy.state.az.us
E-mail: info@azpharmacy.gov

Published to promote voluntary compliance of pharmacy and drug law.

Fiscal Year 2009 – Budget Issues

The Joint Legislative Budget Committee has estimated that the Arizona state budget will be short at least \$2.2 billion for fiscal year (FY) 2009. Many in the pharmacy community know that the legislature has already taken \$2.5 million of the \$2.9 million available in the Arizona State Board of Pharmacy operating fund and transferred it to the general fund to help balance the FY 2008 state budget.

The result of this action is that the Board will be left with between \$50,000 and \$200,000 in the operating fund for FY 2009. Board expenses are about \$500,000 per quarter or a total of just under \$2 million annually. Since the bulk of the Board's revenues is not collected until October and November each year a new appropriation of funds (between \$300,000 and \$450,000) will be necessary to maintain the operations of the Board for the first quarter of FY 2009. **It is important for all readers of this Newsletter to know that fines or civil penalties imposed by the Board for infractions of pharmacy rules or statutes are deposited in the state general fund and are never available for Board operations.** Fines and civil penalties imposed by the Board are disciplinary actions designed to encourage compliance, not to help raise operating funds.

Reminder – Days Supply for Schedule II Controlled Substances

The Board office has been receiving numerous calls from pharmacy personnel regarding "days supply" issues for Schedule II controlled substance prescriptions. There are currently no federal or state limitations on the number of days supply prescribers or dispensers of Schedule II controlled substances are required to comply with other than the general principles that all controlled substance prescriptions may only be issued by a prescriber in the usual course of a medical practice and used to treat a legitimate medical condition. The recent confusion about this topic is most likely attributable to third-party reimbursement issues and the recent Drug Enforcement Administration policy on the issuance of multiple Schedule II controlled substance prescriptions, which was reviewed in the January

2008 edition of this *Newsletter* available at the following link: www.azpharmacy.gov/pdfs/0108AZNWSLTR.pdf.

Update – Controlled Substance Rx Monitoring Program

According to Dean Wright, RPh, director of the Prescription Monitoring Program (PMP), significant progress has been made over the last few months. After a lengthy and rigorous procurement process a vendor has been selected. The vendor, Health Information Designs (HID) of Auburn, AL, will begin testing the system in late July 2008 with the cooperation of a few independent and chain pharmacies. If testing results are satisfactory, the program currently plans to start collecting data from both resident and nonresident pharmacies for the week ending October 11, 2008. According to the program design protocols, the data from pharmacies should be reported to HID by October 17, 2008. As required by the contract, HID will also be sending Dispenser Manuals to pharmacies in late July with instructions on how to format the data as well as how to upload (report electronically) the data. Most if not all chain pharmacies will be able to upload by batch from corporate headquarters, so individual chain pharmacies will not have to be burdened or even involved with the data uploads. Pharmacies will have until October 31, 2008, to provide all Schedule II through Schedule IV prescription data for the six months before implementation, retroactively to April 1, 2008. If you have any questions, contact PMP Director Dean Wright at 602/771-2744 or dwright@azpharmacy.gov.

Disciplinary Actions – Board of Pharmacy (Actions Since April 2008 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).

Pharmacist Discipline Actions

Chen, Joseph (S007891) – One-year probation and fine. Effective May 15, 2008.

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!® 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: 200 Lakeside Dr, Horsham, PA 19044. Phone: 215/947-7797. E-mail: 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) 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/.

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 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.

Green, James (S005337) – Consent amended. No longer required to work with another pharmacist. Effective April 2, 2008.

Makadia, Payal (S015722) – Six-month probation and fine. Effective March 20, 2008.

Maximini, Joe (S013554) – License surrendered. Effective May 15, 2008.

Newman, George (S012483) – Six-month probation and fine. Effective March 20, 2008.

Oloumi, Mansur (S011733) – Probation terminated. Effective May 14, 2008.

Sorenson, Gary (S013246) – Suspension lifted. Probation imposed. Effective March 20, 2008.

Wilcox, Robert (S012472) – Suspension terminated. Four-and-a-half year probation imposed. Effective May 14, 2008.

Pharmacy Technician Disciplinary Actions

Acedo, Teri (T000003) – License revoked. Effective May 14, 2008.

Andreas, Shad (T005200) – License revoked. Effective March 20, 2008.

Brown, Teresa (T010086) – License revoked. Effective May 15, 2008.

Hernandez, Alicia (T003549) – License revoked. Effective March 20, 2008.

Kesterson, Eric (T001752) – Surrendered License. Effective March 20, 2008.

Lopez, Glenda (T001936) – License revoked. Effective May 14, 2008.

Perkins, Nicole (T006770) – One-year suspension. Pharmacists Assisting Pharmacists of Arizona contract. Effective May 15, 2008.

Disciplinary Actions – Other Boards

Arizona Osteopathic Medical Board (DO – Osteopathic Physicians)

LeBlanc, Erol (DO 3452) – Respondent placed on probation for five years with set terms and conditions. Effective February 25, 2008.

Wray, Jeremy W. (DO 3638) – Respondent placed on probation for five years with set terms and conditions. Effective February 20, 2008.

Arizona Board of Medicine (MD – Allopathic Physicians and Physician Assistants)

Alfich, Robert (MD 19453) – Non-disciplinary – Physician's practice is limited in that he 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 applying for and receiving Board approval. Effective April 14, 2008.

Armstrong, James Haldeman (MD 24923) – *Interim Consent Agreement for Practice Restriction* – 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 February 4, 2008.

Bensch, Ernest (MD 4617) – License surrendered to the Board, non-disciplinary. Effective February 7, 2008.

Brownsberger, Robert (MD 23429) – *Interim Consent Agreement for Practice Restriction* – 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 April 9, 2008.

Flynn, Stephen (MD 3351) – License surrendered to the Board. Effective April 3, 2008.

Hammer, Eli J. (MD 17176) – *Interim Findings of Fact, Conclusions of Law and Order for Summary Suspension of License were Stayed/Temporary Restraining Order*. Effective July 27, 2007.

Khayata, Mazen H. (MD 20382) – *Interim Consent Agreement for Practice Limitation (Non-disciplinary)* – Physician's practice is limited in that he 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 applying for and receiving Board approval. Effective April 14, 2008.

Lind, Max D. (MD 4576) – License surrendered to the Board. Effective February 7, 2008.

Menon, Venu G. (MD 12360) – License revoked. Effective January 19, 2008.

Parrish, David D. (MD 26896) – License revoked. Effective January 19, 2008.

Sayegh, Abraham (MD 18816) – *Interim Findings of Fact* – Respondent's license to practice allopathic medicine in the state of Arizona is summarily suspended pending a formal hearing. Effective March 7, 2008.

Surwit, Earl (MD 11111) – *Interim Consent Agreement for Practice Limitation (Non-disciplinary)* – Physician's practice is limited in that he 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 applying for and receiving Board approval. Effective March 20, 2008.

Torjusen, Ole G. (MD 19487) – License surrendered to the Board. Effective April 3, 2008.

Wilbirt, David A. (MD 9920) – License revoked. Effective March 12, 2008.