

August 2008



# NEWS

## Ohio State Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

### ***New Members Appointed to the Board of Pharmacy***

In June, Governor Ted Strickland announced the appointment of two new pharmacist members and a new public member to the Ohio State Board of Pharmacy. Deborah A. Lange, RPh, West Chester; Donald M. Casar, RPh, Hilliard; and Barton G. Kaderly, West Jefferson, were appointed to replace James Turner, RPh; Kevin Mitchell, RPh; and Dorothy Teater. Congratulations go out to our three new members on their appointments and thanks to Jim, Kevin, and Dorothy for their service to the people of Ohio.

### ***Pharmacist License Renewal Time is at Hand***

Pharmacist renewal notices were mailed out in July to all pharmacists licensed with the Board who are eligible for renewal. If you do not receive your renewal notice by the middle of August, you need to check with the Board of Pharmacy to find out what you need to do to renew your license. If your license is not renewed by September 15, 2008, you may not continue to practice as a pharmacist in Ohio until you do get it renewed.

The process for renewal is changing this year. We are finally able to do online renewal and that is the method we will expect the majority of pharmacists to utilize. Instructions for renewing your identification card online were included with the renewal notices. Please follow the instructions carefully and you should have no problems. If you do run into problems or have concerns, please call the Board of Pharmacy. If you do not have access or cannot renew online, you will need to contact the Board of Pharmacy in writing (fax or e-mail are also accepted) and request a paper renewal form. Unless we hear from you, we will expect you to renew online.

There are several advantages to both pharmacists and the Board when the online renewal is utilized. You must use a credit card to renew, so you will have proof that payment was made. It should take less time than the paper forms did, and there will be no delays in the Board receiving the renewal due to the postal service. The advantages to the Board will come in reduced personnel time to sort through all that paper, less filing time and problems, and much faster reporting and license printing.

Again, you need to renew your license by September 15, 2008, if you plan to continue practicing pharmacy in Ohio after that date. If you do not wish to renew your license, please notify the Board immediately.

### ***Optometrists and Controlled Substances***

The Ohio State Board of Optometry rule that deals with optometrists' prescribing of controlled substances for pain was due to go before the Joint Committee on Agency Rule Review (JCARR) on July 14. At the time of this writing, it appeared that there would be no problems with final approval of the rule by JCARR. Ten days

after a rule leaves the jurisdiction of JCARR, it may be made effective. Therefore, unless something unexpected happened between the time this article was written and the time it is being read in early August, the rule should be in effect. After the rule is in effect, the optometrists will still have to register with Drug Enforcement Administration (DEA) before they may begin prescribing Schedule III controlled substances for pain. Please make sure the optometrists have a valid DEA number before you fill any controlled substance prescriptions written by them. It is not clear at this time just how many of the optometrists will actually get a DEA number. Many of them currently see no need in their practice settings to issue prescriptions for Schedule III substances. Therefore, pharmacists should not expect all optometrists to have a DEA number.

Those who do register with DEA will be able to prescribe **only** products containing no more than 60 mg of codeine combined with another product (eg, Tylenol® #4) or products containing no more than 7.5 mg of hydrocodone combined with another product (eg, Vicodin® ES). Please note the limit on the hydrocodone products. Optometrists will not be able to prescribe any product containing 10 mg of hydrocodone. If that happens, the pharmacist should first contact the optometrist and, if that does not resolve the issue, then contact either the Optometry Board or the Board of Pharmacy.

In addition to the limitation on the products, there is also a limitation on the amount of Schedule III products that may be prescribed. According to the proposed rule, optometrists will only be able to prescribe a four-day quantity of Schedule III pain medications one time for a given patient problem. If the pain persists beyond that four-day period, it will be necessary for the optometrist to refer the patient to a physician for additional treatment.

Finally, the rule clearly specifies that the only Schedule III substances that may be prescribed by an optometrist are those that have an indication for the treatment of pain in the Food and Drug Administration (FDA)-approved package insert. That means that pharmacists should not see any prescriptions for cough syrups with codeine or hydrocodone unless they happen to also bear the indication for pain.

Please note that optometrists are in a unique position when compared to other prescribers in Ohio. Optometrists may **only** write for a few Schedule III controlled substances. They will not be allowed to write for controlled substances in any other schedule (ie, no Schedule II, Schedule IV, or Schedule V products).

If you have any questions about optometrist prescribing, please call the Optometry Board (614/466-5115) or the Board of Pharmacy (614/466-4143). Either office will probably be able to answer your questions.

The wording of the proposed (and presumably final) rule is as follows:

*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](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.

**4725-16-03 Prescribing controlled substances**

A licensed optometrist, who holds a therapeutic pharmaceutical agents certificate is authorized to employ, apply, administer and prescribe schedule III controlled substances that are determined to be appropriate for use in the practice of optometry pursuant to the following:

- (A) A licensed optometrist who holds a therapeutic pharmaceutical agents certificate may prescribe the following controlled substances contained in section 3719.41 of the Revised Code within the schedule III narcotics – narcotic preparations category:
  - (1) A preparation used for the treatment of pain that contains not more than 60 mg of codeine per dosage unit and also contains other active nonnarcotic ingredients (e.g. acetaminophen or aspirin) in a recognized therapeutic amount.
  - (2) A preparation used for the treatment of pain that contains not more than 7.5 mg of hydrocodone per dosage unit and also contains other active nonnarcotic ingredients (e.g. acetaminophen, aspirin, ibuprofen) in a recognized therapeutic amount.
- (B) The total quantity prescribed shall not exceed a single four-day supply of schedule III controlled substances per episode of illness, injury and/or treatment.
- (C) Controlled substances may only be prescribed by an optometrist if the product’s FDA approved labeling contains an indication for pain.

The failure to comply with all or part of this rule constitutes a violation of section 4725.19(B)(3), 4725.19(B)(9) and/or 4725.19(B)(13) of the Revised Code.

**Physician Assistant Prescribing**

Physician assistant (PA) prescribing is in full swing. The State Medical Board of Ohio has finalized the rules needed to implement the process, including the formulary. Information on licensing of PAs is available on the Medical Board’s Web site at [www.med.ohio.gov](http://www.med.ohio.gov), and you may also check the certificate to prescribe (CTP) licensure status of the PA there. Remember that PAs may **not** prescribe any Schedule II controlled substances, even if they do have a DEA number. They also may not prescribe controlled substances for weight control (eg, phentermine) or chemotherapeutic agents. Just as the advanced practice nurses (APN), PAs must include their CTP number on all prescriptions they issue.

Also like the APNs, PAs are the prescribers, not their collaborating physicians. If there is a problem with a PA prescription, please

deal with the PA. The collaborating physician does not have to countersign the prescription and, in fact, may not know anything about it if you call. If it is a controlled substance prescription, the DEA number associated with the prescription in your computer records needs to be the DEA number of the PA, not the DEA number of the physician.

If you have any questions about PA prescribing, you may call the Medical Board (614/466-3934) or, if you wish, the Board of Pharmacy (614/466-4143). Overall, we hope the process continues to go as smoothly as the APN prescribing did.

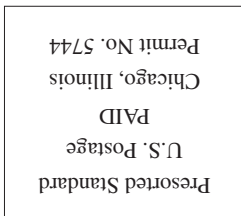
**Disciplinary Actions**

Anyone having a question regarding the license status of a particular prescriber, nurse, pharmacist, pharmacy intern, or dangerous drug distributor in Ohio should contact the appropriate licensing board. The Web sites listed below may include disciplinary actions for their respective licensees.

- State Dental Board** – 614/466-2580, [www.dental.ohio.gov](http://www.dental.ohio.gov)
- State Medical Board** – 614/466-3934, [www.med.ohio.gov](http://www.med.ohio.gov)
- State Nursing Board** – 614/466-3947, [www.nursing.ohio.gov](http://www.nursing.ohio.gov)
- State Optometry Board** – 614/466-5115, [www.optometry.ohio.gov](http://www.optometry.ohio.gov)
- State Pharmacy Board** – 614/466-4143, [www.pharmacy.ohio.gov](http://www.pharmacy.ohio.gov)
- State Veterinary Medical Board** – 614/644-5281, [www.ovmlb.ohio.gov](http://www.ovmlb.ohio.gov)
- Drug Enforcement Administration** – 800/230-6844, [www.deadiversion.usdoj.gov](http://www.deadiversion.usdoj.gov)

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