No. 436: Electronic Newsletter

After much discussion and deliberation over the past two years, the Oregon State Board of Pharmacy has chosen to change the format of the quarterly Newsletter to an electronic newsletter. Beginning in February 2009 the Board Newsletter, which is currently printed and mailed to Oregon pharmacists, will only be available online. To access the most current e-Newsletter, as well as past issues, visit the National Association of Boards of Pharmacy® (NABP®) Web site at www.nabp.net or the Oregon State Board of Pharmacy Web site at www.pharmacy.state.or.us. This will provide direct access to the e-Newsletter for Oregon-licensed pharmacy technicians and pharmacy interns as well as pharmacists. If you wish to receive an e-mail alert indicating when a new issue of the Oregon State Board of Pharmacy e-Newsletter is available, please visit www.nabp.net/indexorbop.asp and click on the subscribe link, or send an e-mail to OregonBOPNewsletter@nabp.net with the word “Subscribe” in both the subject line and body of the e-mail. The November 2008 Newsletter will be the final printed version of the Newsletter for circulation to Oregon pharmacists.

The Board will continue to provide printed versions of the Newsletter to the retail and institutional pharmacies that currently receive them. Pharmacists who wish to continue to receive the printed version by mail may do so by notifying the Board in writing.

Also please remember the Board has designated the Newsletter as an official method to notify Oregon-licensed pharmacists, pharmacy technicians, and interns about information, changes in statutes and regulations, and legal developments. Please read the Newsletter and be aware that it is available on the Board of Pharmacy and the NABP Web sites for reference.

No. 437: New Board Member

Pharmacist Board member Marc Watt finished his second and final four-year term on the Board in June 2008. Governor Ted Kulongoski has appointed Portland-area pharmacist Larry Cartier to replace Watt on the Board. Mr Cartier’s appointment was confirmed by the Senate as required by law and his first meeting will be August 12-13, 2008, in Portland.

Cartier’s professional experience is varied. A 1974 graduate of the Oregon State University College of Pharmacy, Larry’s professional background lies primarily in community pharmacy practice and mail-order pharmacy management. He has been active in the Oregon State Pharmacy Association, having served as president in 2002-2003; the Oregon Society of Health-System Pharmacists, having served as a board member from 2003-2005; and the Professional Society of Pharmacists, currently serving as vice president and treasurer. Larry has been an active preceptor for the Oregon colleges of pharmacy and has often appeared at Board meetings with his students. He is also a Board member for the Broadway Rose Theater Company in Tigard and is active in his church and his community. Board members and staff are eager to welcome Larry “on board.” He indicates he is enthusiastic about his appointment and anxious to get started.

No. 438: For Oregon Pharmacy Technicians

A pharmacy technician license is active for one year and is nonrenewable. A new pharmacy technician is allowed this one-year period in which to work, study, gain experience, and take and pass a national certification examination. Two national certification programs are recognized by the Board at this time, the Pharmacy Technician Certification Board and the Institute for the Certification of Pharmacy Technicians. Contact information for both can be found on the Board’s Web site.

If you have passed your national certification examination but have not applied for your certified Oregon pharmacy technician license, you need to do so now. You can download, print, and complete your application today by going to the Web at www.pharmacy.state.or.us/Pharmacy/Imports/Cert_TechnicianInitialApp.pdf.

If you have not passed your national certification examination and your pharmacy technician license expires on September 30, 2008, you cannot work as a pharmacy technician on October 1, 2008, or thereafter until you become certified and licensed by the Board. If we do not receive your completed application and attachments immediately you may not have your license by October 1, 2008.

To expedite processing of your application, be sure to include the following:
- A copy of your driver’s license or state identification card
- A copy of your national certification or the letter stating you have passed the examination
- A new, original regulation passport photograph taken within the past six months
- A check or money order for $35

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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 the 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 unreasonable.

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 fail 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.

Table 1: Examples of FDA Actions Regarding Unapproved Drugs

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<td>Extended release combination drug products containing guaifenesin (competed with approved products)</td>
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<tr>
<td>Trimethobenzamide hydrochloride suppositories (lacked evidence of effectiveness)</td>
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<td>Ergotamine-containing drug products (labeling did not include critical warnings regarding the potential for serious, possibly fatal interactions with other drugs)</td>
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<tr>
<td>Quinine sulfate drug products (665 reports of adverse events, including 93 deaths, and the labeling lacked necessary warnings and safe dosing information)</td>
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<tr>
<td>Carbinoxamine drug products (associated with 21 infant deaths)</td>
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<tr>
<td>Colchicine injectables (50 reports of adverse events, including 23 deaths)</td>
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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.
Your application will be held pending verification of certification. Your new license will be valid through September 30, 2009.

Also, if you have had an address or employment change since the last renewal cycle and you have not updated your information with the Board, please submit an address change form or submit your information online via the Board’s Web site. Oregon Administrative Rules state that any change of address or change of employment must be submitted to the Board within 15 days.

**No. 439: Patient Counseling and Changes in Generic Manufacturer**

Another topic demanding much discussion among Board members and staff over the past year is the topic of pharmacy technicians and clerks regarding their interactions with patients. It has long been the Board’s position that technicians and clerks are not allowed to counsel patients about their medications. That being so, the question still remains, “What can the technicians and clerks say to the patient?”

Clearly, the Board cannot answer such a broad question. However, some guidelines may be useful. For a new prescription or a refilled prescription on which the pharmacist has determined that counseling is needed, the pharmacist must talk with the patient, regardless of what the technician or clerk might say. The clerk or technician may not accept a patient’s refusal in lieu of the pharmacist. For a refilled prescription that does not require counseling, the pharmacist may allow the clerk or technician to point out the sticker or inform the patient of a change in the appearance or the manufacturer. Any questions that arise at that time must then be referred to the pharmacist. The Board has issued the following guidelines:

• The pharmacy must have a policy and procedure in place. The technicians and clerks must have been trained and the training documented.
• The technician or clerk may inform the patient that the pharmacist has changed the manufacturer and the medication may appear different.
• The technician or clerk points out the Product Identification Label (PIL) and tells the patient that the PIL should match the contents of the prescription container.
• The technician or clerk then offers the patient an opportunity to talk to the pharmacist.

The suggestion was offered to the Board that the pharmacist should not have to be called to the counter each time a generic change was dispensed. Applying these guidelines judiciously may be a reasonable alternative. The Board does not consider this to be “counseling” by the technician.

**No. 440: Message from the President – Patient Safety**

By Cathryn J. Lew, RPh

High-profile cases over the past few years, as well as heightened media exposure, now has the general public questioning the integrity of our medication distribution system. We realize that medication errors comprise an extremely small percentage of the total number of prescriptions dispensed, and we feel the time is right to review recommendations and improvements in quality that could result in an overall reduction in errors. The Board has established a “Patient Safety/Medication Error Reduction Research Council” and invited pharmacy professionals along with the Patient Safety Commission to contribute their expertise in medication safety as it relates to the many Oregon pharmacies. The results of their research have been presented to the Board, and we hope all licensees will take a serious look as the Board moves forward in encouraging licensees to create a higher level of personal awareness with a goal of improving patient safety in all pharmacy practice settings.

The Oregon State Board of Pharmacy News is published by the Oregon 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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