November 2008

# Ohio State Board of Pharmacy

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**Published to promote voluntary compliance of pharmacy and drug law.**

## Please Read Your Newsletters

It has been some time since this reminder was put into a *Newsletter*, so it is being repeated in case anyone has forgotten. This *Newsletter* is a significant method of communication, which the Ohio State Board of Pharmacy uses to notify pharmacists of important changes to laws and rules as well as to discuss issues that are of concern to practicing pharmacists and the Board. These *Newsletters* have been introduced as evidence in Board hearings and criminal court to prove that a pharmacist should have known his or her activities were inappropriate. In fact, copies of past *Newsletters* bearing the warnings about illegal Internet prescriptions may have just been used in a criminal case by the time this *Newsletter* arrives. While pharmacists are responsible for keeping up with changes to the laws and rules relating to drugs, whether or not they are addressed in this *Newsletter*, the inclusion of a topic in the *Newsletter* should alert pharmacists that the topic is considered important. Please read your *Newsletters*.

## Terminal Distributor Renewals

By the time this *Newsletter* arrives, renewal notices for terminal distributor licenses should have been sent out by the Board and received by all licensees. If you have not yet received yours, please contact the Board office as soon as possible. If you are the responsible person on the license, please remember that you are responsible for seeing that the license is renewed before January 1, 2009.

## Proposed New and Changed Rules Filed

On September 26, 2008, the Board filed several proposed new and changed rules for public notice. The public hearing on these rules is scheduled for November 3, 2008, so it will probably have occurred before this *Newsletter* arrives. However, pharmacists interested in reviewing the rule changes proposed by the Board may view them on the Board's Web site under "What's New" prior to the Board making a final determination on their status. After the public rules hearing, there will also be a hearing before the Joint Committee on Agency Rule Review. After that hearing, the Board will make a final determination on implementation and on the effective date of those rules that are given final approval. Notice of that decision and copies of all new and changed rules will be placed on the Board's Web site and, on the effective date, the changes will be incorporated into the Administrative Code rules posted on the Web site.

## Electronic Prescribing Issues

On June 27, 2008, the Drug Enforcement Administration (DEA) published proposed rules for the electronic prescribing of controlled substances. The comment period for these rules ended on September 25, 2008. DEA will now have to review all of the comments received and determine whether changes need to be made to the proposed rules prior to publishing them as final rules. Until DEA publishes a final rule, federal regulations do not allow for the transmission of electronic prescriptions for controlled substances. Contrary to what the Board may have encouraged pharmacists to do in the past, DEA does not recognize either computer to computer or computer to fax transmissions of controlled substance prescriptions to be valid prescriptions. For the time being, therefore, any controlled substance prescription received other than by oral transmission must bear a manual signature (not a computer-generated one) when received from the patient directly or via the fax machine. Of course, prescriptions for Schedules III through V may also be transmitted orally by either the prescriber or his or her agent to the pharmacist. Until DEA's electronic prescribing rules are published in final form, please make sure you do not accept any controlled substance prescriptions transmitted directly by the prescriber's electronic prescribing system to your pharmacy without a manual signature unless you follow up with the prescriber and get verbal authorization. If you do that, make sure you document the verbal authorization on the electronic prescription. As you will see below, the prescriber could print out the prescription in the office, manually sign it, and then fax it like a traditional prescription. Hopefully, DEA will be able to publish its final regulations in a timely manner and thereby resolve this issue.

For non-controlled substances, the Board has been getting too many calls from prescribers where pharmacists are refusing to fill computer to fax prescriptions that are valid. Some pharmacy owners, managers, and district managers are telling all their pharmacies to refuse to fill electronic prescriptions from certain locations. If the prescription is written for a legitimate medical purpose, refusing to fill the prescription certainly would not be in the best interests of the patient. Please review the following items to help you determine if a fax received from an electronic prescribing system is valid.

**Traditional fax –** The prescription is written on a traditional prescription blank or can be printed from a computer and must be manually signed by the prescriber in ink, placed in a fax machine, and transmitted to the pharmacy. If an agent transmits the prescription instead of the prescriber, the agent's full name needs to be noted on the prescription. You should see a fax header, usually at the top or bottom of the page, identifying the location of origination and the date the order was faxed to help you determine that the fax came directly from the prescriber and not the patient. The header and agent information must remain on the paper. Do not cut it to fit into your file. The original prescription is required to stay in the patient's chart in the prescriber's office. You should not

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## Study Fuels Concerns over Foreign Drugs Bought Online

According to study results published in the May 2008 issue of *Annals of Pharmacotherapy*, many prescription medications purchased from foreign pharmacies through Internet drug outlets differ significantly from the versions approved by the Food and Drug Administration (FDA). "These findings have implications for safety and effectiveness that should be considered by clinicians to potentially safeguard patients who choose to purchase foreign-manufactured drugs via the Internet," the study authors say.

The study evaluated 20 simvastatin tablets and capsules, including the US innovator product and 19 generic samples obtained from international Internet drug outlets. Tablet samples were tested according to United States Pharmacopeia (USP) guidelines where applicable, using high-performance liquid chromatography, disintegration, dissolution, weight variation, hardness, and assessment of physical characteristics.

Several international samples analyzed were not comparable to the US product in one or more aspects of quality assurance testing, and significant variability was found among foreign-made tablets themselves. Five samples failed to meet USP standards for dissolution, and two for content uniformity. Among all samples, variability was observed in hardness, weight, and physical characterization.

## Testing Medication Names Prior to Marketing

*This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with USP and 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.*

Medication names that look-alike and sound-alike, confusing or absent drug labeling, and non-distinct or ambiguous drug packaging significantly contributes to medication errors. This is not a new problem. These conditions have led to serious drug mix-ups and deaths. Research has identified that one of the most frequent causes of pharmacy drug dispensing errors (29%) is failure to accurately identify drugs, most prominently due to look-and sound-alike drug names (Leape et al. JAMA, July 5, 1995).

In addition, many medications are packaged in bottles with similar shapes and similar labels, making it easy to confuse one drug with another.

MedMARX data reports there are 1,470 different drugs implicated in medication errors due to brand and/or generic names that looked or sounded alike. From this data, USP has compiled a list of 3,170 pairs of names that look and/or sound alike.

FDA is also concerned about drug naming confusion and its subsequent potential error effects. On June 5-6, 2008, FDA hosted a public workshop to discuss a concept paper (*www.fda.gov/cder/drug/MedErrors/meeting_names.pdf*) about a pilot program to address look- and sound-alike brand names. The pilot, called for in the FDA Amendments Act of 2007, would allow drug companies (or outside contractors) to voluntarily evaluate proposed brand names and submit the data for review to FDA. Currently, FDA's Division of Medication Error Prevention screens drug names using its own safety testing methods, in consultation with other divisions responsible for product approval.

The concept paper outlines the types of studies that should be conducted, including simulations of real-world conditions with practicing clinicians who evaluate handwritten, electronic, and oral prescribing scenarios to detect name similarities and other potential confusion with laboratory and medical terms or abbreviations. Dosage form, strength, and frequency also should be considered, as well as the clinical environment where it will be used. Based on discussions during the June meeting and submitted comments, FDA will revise the concept paper and present testing methods to the pharmaceutical industry.

It is hoped that testing drug names prior to marketing will decrease the number of look-and sound-alike medication names. ISMP receives numerous reports of

errors and potential errors caused by look-and sound-alike medications every year. ISMP, through its wholly owned for-profit subsidiary Med-E.R.R.S., Inc®, has been reviewing drug names and packaging for pharmaceutical manufacturers for more than 10 years.

If you are a pharmacist or other health care practitioner who is interested in medication safety and error prevention, you can make a difference! Med-E.R.R.S. is looking for pharmacists from all practice settings to help test labeling, packaging, and nomenclature in the pre-marketing phase for pharmaceutical companies. The process is fun, simple, and easy and a small honorarium is paid for your participation.

For more information or to sign up, go to *www.med-errs.com* and click on "Become a Reviewer."

## Coalition Looks to Pharmacies, Regulators to Reduce Diversion

A recent report by the Coalition Against Insurance Fraud looks to pharmacies and pharmacy regulators, among others, to cut down on the prevalence of prescription drug diversion, particularly of controlled substance analgesics.

The report, "Prescription for Peril: How Insurance Fraud Finances Theft and Abuse of Addictive Prescription Drugs," calls on the pharmacy profession to provide additional training on prescription drug abuse and diversion in pharmacy education curricula and continuing professional education, and to exert closer point-of-sale scrutiny of certain prescriptions and patients. For instance, the report suggests diversion could be reduced significantly if pharmacies asked for photo identification in connection with controlled substance prescriptions, similar to regulations in place for pseudoephedrine-containing products.

The coalition also recommends wider adoption of prescription monitoring programs to maintain statewide records of narcotic prescriptions, allowing closer monitoring by prescribers and dispensers. In addition, the coalition calls on lawmakers and licensing boards to "swiftly and decisively penalize the small fraction of prescribers and dispensers who facilitate drug diversion and abuse."

## FDA Encourages Pharmacists to Use Patient Safety News

*FDA Patient Safety News* is a monthly video news program produced by FDA targeted to pharmacists and other health care professionals. The program provides the latest information on recalled and counterfeit products, important safety alerts, preventing medical errors and mitigating risks from the use of medical products, including drugs, devices, vaccines, and diagnostic products.

The videos can be watched online or downloaded free of charge. Pharmacists can view the entire program or individual segments, and FDA encourages further use and distribution of the video or text of the program, as there are no copyright restrictions. The video and demonstrations can also be used in staff-development programs or in other teaching environments.

Pharmacists can search for video segments on topics of interest, get additional information about topics, e-mail segments to others, report problems with medical products to FDA, and sign up to be notified about each month's program. The show is also broadcast on several medical satellite networks: VHA, GE TiP-TV, HSTN, LTCN, and HNN. These networks presently reach over 4,000 hospitals and long-term care facilities across the US.

More information about the program and how to join the program mailing list is available on the FDA Web site at *www.fda.gov/psn* or by sending an e-mail to PSNews@cdrh.fda.gov.

## Switch to HFA-Propelled Albuterol Inhalers Advised in Anticipation of CFC Ban

FDA recently issued a public health advisory alerting patients, caregivers, and health care professionals to switch to hydrofluoroalkane (HFA)-propelled albuterol inhalers because chlorofluorocarbon (CFC)-propelled inhalers will not be available in the United States after 2008. CFC-propelled albuterol inhalers are being phased out to comply with the Clean Air Act and an international environmental treaty, the Montreal Protocol on Substances that Deplete the Ozone Layer. Under this treaty, the US has agreed to phase out production and importation of ozone-depleting substances including CFCs. No CFC-propelled albuterol inhalers may be produced, marketed, or sold in the US after December 31. Three HFA-propelled albuterol inhalers have been approved by FDA: Proair® HFA Inhalation Aerosol, Proventil® HFA Inhalation Aerosol, and Ventolin® HFA Inhalation Aerosol. In addition, an HFA-propelled inhaler containing levalbuterol is available as Xopenex® HFA Inhalation Aerosol. More information is available on the FDA Web site at *www.fda.gov/cder/mdi/albuterol.htm*.

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see the sentence "approvable by OSBP" on the fax. This method is an acceptable way to transmit Schedule III through V controlled substance prescriptions.

**Computer to fax transmissions –** The prescription is typed into a computer by the agent or prescriber and transmitted by the agent or prescriber to the pharmacy. Generally, these prescriptions do not utilize an intermediary like SureScripts-RxHub. Unlike a traditional fax, the computer to fax format for an Ohio prescriber will contain a unique transaction or order ID number that is traceable for security and accountability purposes. There will be a logo or identification of the software company that will allow the pharmacist to verify on the Board Web site that the electronic prescription system is an approvable system. There will be a statement saying that the company's prescribing system has been made approvable by the Board.

The signature for a computer to fax prescription can be confusing. There may or may not be a signature line. There may be blank space where the signature would be placed. If there is a line, it does not need to contain a signature, it can be just a line. Ideally, you may find words along the signature line or in the blank space that simply state that the prescription has been electronically signed. If there is a computer-generated signature, it must obviously be computer-generated or include words such as "electronically signed." An electronic prescription transmission system can be made approvable with any of the above signatures, when used in conjunction with the transaction number, software identification, and approvable status information.

You might also see a rejected computer to computer prescription print from your fax machine. This will occur occasionally when SureScripts-RxHub or another intermediary is unable to obtain confirmation that your computer received the electronic prescription data or if your pharmacy computer system does not have the capability to receive computer to computer transmissions. In some instances, data that is too long for transmission is switched to a computer to fax transmission. These prescriptions have been reviewed by the Board office and are acceptable as is. They should be clearly marked with the name of the intermediary company that transmitted these prescriptions (eg, SureScripts-RxHub).

In summary, some electronic prescribing systems can generate printed prescriptions requiring manual signatures that may be given to the patient or sent via fax as a traditional prescription (manually signed). Therefore, you might see all three types of prescriptions (manual signature, computer to fax, or computer to computer) generated from one prescriber's office. These, in addition to handwritten and manually signed prescriptions that are faxed, computer to computer rejects turned into a fax by the switch (intermediary), and oral orders placed by telephone make six ways new prescriptions from one office may arrive at your pharmacy.

As a reminder, refill requests sent by traditional fax to a pharmacy may not be manually signed by office staff. These are not telephone refill orders. These faxes must be signed by the prescriber and treated as a new prescription in your pharmacy. A pharmacist or pharmacy intern may accept refill authorizations from a prescriber's agent only through oral telephone contact. However, refill requests made and refills authorized through an Ohio approvable electronic prescription transmission system are acceptable.

## *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*
**State Medical Board** – 614/466-3934, *www.med.ohio.gov*
**State Nursing Board** – 614/466-3947, *www.nursing.ohio.gov*
**State Optometry Board** – 614/466-5115, *www.optometry.ohio.gov*
**State Pharmacy Board** – 614/466-4143, *www.pharmacy.ohio.gov*
**State Veterinary Medical Board** – 614/644-5281, *www.ovmlb.ohio.gov*
**Drug Enforcement Administration** – 800/230-6844, *www.deadiversion.usdoj.gov*



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