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Ohio State Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

Pharmacist License Renewal Time is at Hand

Pharmacist renewal forms were mailed out early in July 2006 to all pharmacists licensed with the Ohio State Board of Pharmacy who are eligible for renewal. If you have not received your renewal form by the time you get this *Newsletter*, you need to check with the Ohio State Board of Pharmacy office to find out what you need to do to renew your license. If your license is not renewed before September 15, 2006, you may not continue to practice as a pharmacist in Ohio until you do get it renewed.

Have You Registered for Access to the Prescription Monitoring Program?

At the time of writing this *Newsletter*, the Board's goal was to have the Ohio Automated Rx Reporting System (OARRS) program (the prescription monitoring program or PMP) up and running by August 1, 2006. Registration of pharmacists and prescribers for access to the program was supposed to have started in July 2006. It is just as important for pharmacists to use this program as it is for prescribers. Unfortunately, in other states with monitoring programs that does not seem to be the case. The latest word we have is that around 80% of the requests for data received by the Kentucky All Schedules Prescription Electronic Reporting program come from prescribers while only about 10% come from pharmacists. We are hoping that Ohio will change that statistic. Pharmacists have a unique opportunity to improve patient care by reviewing the information before making a decision about filling or not filling a prescription. All too often, we get telephone calls in the Board office from patients who have been on chronic pain therapy, going to one doctor and one pharmacy, who have been suddenly cut off by a nervous doctor or pharmacist who has no evidence of the patient exhibiting drug seeking behavior, but suddenly gets concerned solely because of the length of therapy or by the dose required. This database will allow the prescribers and pharmacists to get a good idea about the patient's activities so that an objective decision about the therapy can be made.

Of course, the opposite is true as well. Another reason it is so important for prescribers and pharmacists to use this system was made evident by the results of a recent survey by the Substance Abuse and Mental Health Services Administration (SAMHSA). The report is titled "Nonmedical Users of Pain Relievers: Characteristics of Recent Initiates" and can be found on the SAMHSA Web site at www.oas.samhsa.gov.

This report points out that "[m]ore persons initiated nonmedical use of narcotic pain relievers in the past year than initiated use of marijuana or cocaine." Nonmedical use was defined as "the use of prescription-type drugs not prescribed for the respondent by a physician or used only for the experience or feeling they caused." According to the report, "2.4 million persons ages 12 or older initiated nonmedical use of prescription pain relievers in the 12 months prior to the survey, 2.1 million initiated use of marijuana, and 1 million initiated use of cocaine."

Some other statistics that are rather sobering include the fact that 48% of those 2.4 million used a hydrocodone-containing product, 34.3% used a propoxyphene product or acetaminophen with codeine, and 20% used an oxycodone/acetaminophen product. Seventy-four percent of these first-time nonmedical users had used another illicit drug (marijuana, heroin, etc) before using the pain relievers.

Health care professionals need to do their part to ensure that the patients who have a legitimate need for pain medications receive them as expeditiously as possible, but there is also a need to limit the diversion of these substances for nonmedical or illicit purposes. Utilizing this database will be one way for health care professionals to obtain some additional information to help them make informed decisions about their patients' therapy.

A Generic Equivalent May be a Brand Name Drug

Frequently, pharmacists or patients call with questions about substitution on a prescription. A common misconception is that the "generic" must be a product with no brand name attached to it. Using over-the-counter products as an example, the mistaken belief is that a prescription written for Advil® could only be filled with Advil or a product labeled ibuprofen, but not with Motrin® IB.

A review of our substitution laws (§4729.38 Ohio Revised Code (ORC) and the definition of generically equivalent drug in §3715.01 ORC) will show that this is incorrect. In Ohio, instead of using "generic" the correct term is "generically equivalent drug." What is required is that the products contain identical amounts of the identical active ingredients, meet the same compendial standards, and are not listed as having "proven bioequivalence problems" by the federal government (ie, listed as bioinequivalent in the "Orange Book"). In the example above, either the product labeled "ibuprofen" or the product labeled "Motrin IB" could be dispensed instead of the prescribed Advil as long as the rest of the substitution requirements were met.

Of course, no substitution may occur if the prescriber has indicated "Dispense as written" or "DAW" on the prescription unless the prescriber is contacted and gives permission for the substitution. Please make note of that last statement. If the doctor has properly indicated "Dispense as written" or "DAW" on the

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Generic Substitution Issues

This is a reminder to pharmacists regarding the legal generic substitution of certain drug products. Recent practices by pharmaceutical manufacturers involving the reformulation of drugs into alternative dosage forms (eg, tablets to capsules) seem to have caused some confusion.

Generic substitution is the act of dispensing a different brand or unbranded drug product than the one prescribed. Generic substitution is only allowable when the substituted product is therapeutically equivalent to the prescribed innovator product. Generic drug manufacturers must provide evidence to Food and Drug Administration (FDA) of therapeutic equivalence, which means that both products are pharmaceutically equivalent (eg, have the same active ingredients in the same dosage form and strength, and use the same route of administration) and bioequivalent (eg, have more or less the same rate and extent of absorption). Therapeutically equivalent drugs are expected to produce the same clinical benefits when administered for the conditions approved in the product labeling.

FDA assigns two-letter therapeutic equivalence codes to generic products when the products meet both the aforementioned requirements, are approved as safe and effective, are adequately labeled, and are manufactured in compliance with current Good Manufacturing Practice regulations. The primary reference guide for pharmacists on therapeutic equivalence is FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, otherwise known as the "Orange Book." Drug products determined to be therapeutically equivalent to innovator drugs are assigned an "A" for the initial letter of their therapeutic equivalence code. The second letter provides additional information regarding the product: products rated AA, AN, AO, AP, or AT are those with no known or suspected bioequivalence problems (rating depends on dosage form). An AB rated product indicates that actual or potential bioequivalence problems have been resolved with adequate in vivo and/or in vitro evidence. In contrast, drugs assigned a "B" for the initial letter are not considered therapeutically equivalent because bioequivalence problems have not been resolved to the satisfaction of FDA.

A recent example of improper substitution has been brought to the attention of several boards of pharmacy by Acorda Therapeutics, the maker of Zanaflex® tablets, who recently released Zanaflex Capsules™ (tizanidine hydrochloride). Although the active ingredient in Zanaflex Capsules is the same as the active ingredient in Zanaflex tablets and generic tizanidine tablets, their formulations are different. For this reason, FDA has deemed there to be no therapeutic equivalent to Zanaflex Capsules and has not assigned a therapeutic equivalence code.

A similar situation existed in 1995 when the manufacturer of Sandimmune® (cyclosporine) capsules and oral solution, Sandoz, (now Novartis), came out with NEORAL® (cyclosporine) capsules and oral solution for microemulsion. Due to differences in bioavailability, Sandimmune and Neoral, and their accompanying generic versions, were not, and still are not, rated as substitutable.

It must be emphasized that generic substitution mandates are found in individual state laws and regulations. In states where generic substitution is allowed only for "Orange Book" A-rated products, pharmacists may not substitute a generic product for a non-A-rated product. Some states may have developed their own generic substitution lists or formularies. Pharmacists are encouraged to review the laws and regulations in their states to determine the appropriate legal methods by which to perform generic substitution.

Preventing Errors Linked to Name Confusion

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 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, then publishes its recommendations. 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: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

The Institute for Safe Medication Practices (ISMP) regularly hears about confusion between products with similar names. One such pair is OMACOR (omega-3-acid ethyl esters) and AMICAR (aminocaproic acid) an antifibrinolytic. Omacor is indicated as an adjunct to diet to reduce very high triglyceride levels (500 mg/dL or more) in adult patients. The drug is also being studied as adjuvant therapy for the prevention of further heart attacks in patients who have survived at least one. A pharmacist reported an error in which a telephone order for Omacor 1 gram BID was interpreted and dispensed as Amicar 1 gram BID. Counseling was not provided, but fortunately the patient read the drug information sheet for Amicar before taking any medication and called the pharmacy stating that he was expecting a medication to reduce his triglyceride levels.

While this case illustrates why manufacturers should review and test new trademarks for error potential before the product reaches the market, there are some things that practitioners can do to help prevent errors with products that have look-alike or sound-alike names.

- Look for the possibility of name confusion before a product is used. Use the concepts of failure mode and effects analysis (FMEA) to assess the potential for error with new medications that will be prescribed or added to your inventory. If the potential for confusion with other products is identified, take the steps listed below to help avoid errors.
- Prescriptions should clearly specify the drug name, dosage form, strength, complete directions, as well as its indication. Most products with look- or sound-alike names are used for different purposes. If the indication is not available, pharmacists and nurses should verify the purpose of the medication with the patient, caregiver, or physician before it is dispensed or administered.
- Reduce the potential for confusion with name pairs known to be problematic by including both the brand and generic name on prescriptions, computer order entry screens, prescription labels, and MARs.

- When accepting verbal or telephone orders, require staff to write down the order and then perform a read back (or even spell back) of the medication name, strength, dose, and frequency of administration for verification.
- Change the appearance of look-alike product names on computer screens, pharmacy product labels, and MARs by emphasizing, through bold face, color, and/or tall man letters, the parts of the names that are different (eg, hydrOXYzine, hydrALAzine).
- Pharmacists should work under good lighting and use magnifying lenses and copyholders (keep prescriptions at eye level during transcription) to improve the likelihood of proper interpretation of look-alike product names.
- Install computerized reminders for the most commonly confused name pairs at your site so that an alert is generated when entering prescriptions for either drug. If possible, make the reminder auditory as well as visual.
- Store commonly confused products in different locations. Avoid storing both products in a "fast-mover area." Use a shelf sticker to help find relocated products.
- Affix "name alert" stickers to areas where look- or sound-alike products are stored (available from pharmacy label manufacturers) or to the actual product containers.
- Employ at least two independent checks in the dispensing process (one person interprets and enters the prescription into the computer and another compares the printed label with the original prescription as well as the manufacturer's product).
- Open the prescription bottle or package in front of the patient to confirm the expected appearance of the medication and review the indication. Caution patients about error potential when taking a product that has a look- or sound-alike counterpart. Encourage patients to ask questions if the appearance of their medication changes. Take time to fully investigate any patient concerns.
- Encourage reporting of errors and potentially hazardous conditions with look- and sound-alike names to the ISMP-USP Medication Errors Reporting Program and use the information to establish priorities, as listed above, for error reduction. Maintain an awareness of problematic product names and error prevention recommendations provided by ISMP (www.ismp.org), FDA (www.fda.gov), and USP (www.usp.org).

If you are interested in learning what look-alike and sound-alike name pairs have been published in the ISMP Medication Safety Alert!®, a free list is available at www.ismp.org/Tools/confuseddrugnames.pdf.

Combat Methamphetamine Epidemic Act Phasing In

This year, new requirements of the federal Combat Methamphetamine Epidemic Act passed by Congress for the sale of all single and multi-ingredient pseudoephedrine and ephedrine-containing products will become effective. The new law places non-prescription ephedrine, pseudoephedrine, and phenylpropanolamine in a new Controlled Substances Act category of "scheduled listed chemical products." Drug products containing ephedrine, pseudoephedrine, and phenylpropanolamine are subject to sales restrictions, storage requirements, and record keeping requirements.

A 3.6-grams-per-day base product sales limit, 9-grams-per-30-days base product purchase limit, a blister package requirement, and mail-order restrictions went into effect on April 8, 2006, for all sellers of these products. All other provisions of the law require compliance by September 30, 2006. If a state has more stringent requirements, the stronger requirements remain in place. A summary of this Act's requirements can be found on the United States Drug Enforcement Administration's (DEA) Web site at www.deadiversion.usdoj.gov/meth/cma2005.htm.

Explanation of DEA Regulations on Partial Refilling of Prescriptions

Pharmacists often question the DEA rule regarding the partial refilling of Schedule III, IV, and V prescriptions as stated in Section 1306.23 of the Code of Federal Regulations. Confusion lies in whether or not a partial fill or refill is considered one fill or refill, or if the prescription can be dispensed any number of times until the total quantity prescribed is met or six months has passed. According to DEA's interpretation, as long as the total quantity dispensed meets the total quantity prescribed with the refills and they are dispensed within the six-month period the number of times it is refilled is irrelevant. The DEA rule is printed below:

Section 1306.23 Partial Filling of Prescriptions.

The partial filling of a prescription for a controlled substance listed in Schedule III, IV, or V is permissible provided that:

(a) Each partial filling is recorded in the same manner as a refilling,
(b) The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed, and
(c) No dispensing occurs after 6 months after the date on which the prescription was issued.

[21 CFR 1306.23]

Electronic Version of DEA Form 106 Now Available

DEA has announced that a secure, electronic version of the DEA Form 106 (Report of Theft or Loss of Controlled Substances) is now available to DEA registrants. The electronic form may now be completed online through a secure connection and submitted via the Internet to DEA Headquarters. Copies of the letter from DEA and the 2005 Final Rule were published in the *Federal Register*. The new interactive form is located at the Diversion Control Program's Web site and may be accessed at www.DEAdiversion.usdoj.gov.

Patients Rely on Pharmacists' Recommendations

Patients consider their pharmacists a trusted source for medication recommendations, as evidenced by the result of a poll recently conducted by the American Pharmacists Association (APhA). APhA polled 3,000 community pharmacists and found that pharmacists were asked about over-the-counter (OTC) products an average of 32 times each week. Of those pharmacists surveyed, 55% said they spend three to five minutes with each patient who asks about an OTC. And patients are listening, for during this consultation time, according to the survey, 81% of patients purchased OTC products recommended by the pharmacist.

The results of the poll was published in APhA's *Pharmacy Today*. Other topics researched in the poll include recommendation habits of pharmacists in leading OTC therapeutic areas including treatments for allergies, adult cold symptoms, adult headache remedies, heartburn, pain relief, and tooth whitening products among others.

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prescription, the product may **not** be changed by the pharmacist, the patient, or the insurance company. The pharmacist must dispense the product ordered unless the prescriber agrees to the change, even if the patient has to pay a higher co-pay or a higher price.

If a substitution does occur, there are several other requirements that must be met. The patient must be notified of the availability of a generically equivalent drug at a lower or equal cost and of the patient's right to refuse. There must be an indication on either the bottle or the label that a substitution has occurred. Please review your own pharmacy's process in this regard. We have had several instances of patients receiving generically equivalent drugs with no discussion by anyone in the pharmacy and with no labels or notices of any kind. When that happens on a refill, where the drug looks completely different than it did the last time the prescription was filled, it can cause problems and confusion on the part of the patient. They may be so concerned that they do not take the medications until speaking with the pharmacist or the doctor. Obviously, this can lead to compliance problems. Alternatively, they may be so accustomed to the pharmacy switching products without telling them that they do not worry at all and just take the medication given to them. When the drugs are different due to a dispensing error rather than just improper procedure, then patient harm can occur. We have had numerous examples of both situations.

One of the advantages of Ohio's substitution law is that it places a great amount of trust and responsibility on the pharmacist. Unlike many states that require a product to have an AB rating in the "Orange Book" before it can be substituted, Ohio allows the pharmacist to use judgment and substitute products that are not listed as well as those that are. With that trust, however, also comes responsibility. The pharmacist's first duty should be to the patient. Before substituting a product just to comply with the pharmacy's policy or the insurance company's requirement, the pharmacist should review the possible effects on the patient.

Bioequivalency studies are usually done on large groups of people and only the averages are reported. Needless to say, there are patient-to-patient variations and sometimes drugs that are generally bioequivalent are not so in an individual patient. This can be especially true in drugs whose activity is related to the blood level such as some drugs used in treating seizure disorders, asthma, cardiac problems, etc. With those drugs, where a variation in blood level could cause problems for the patient, it would not be in the best interests of the patient to change products without at least notifying the patient and the prescriber so that appropriate monitoring can occur during the transition. We have already been approached by some people who want to introduce legislation to mandate that the pharmacist "get permission" from the prescriber prior to substituting drugs in certain disease states because patient problems have been caused by pharmacists blindly following policy instead of acting in the patient's best interests.

Please do not take shortcuts when substituting one drug product for another. Think of the patient's best interests first.

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 – 1-800/230-6844, www.deadiversion.usdoj.gov

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