



Minnesota Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

Disciplinary Activity

The Minnesota Board of Pharmacy did not complete any disciplinary actions concerning pharmacists between the dates of March 1, 2006 and May 31, 2006.

The following pharmacy technician had his registration suspended:

Gronseth, Alex, Registration #711166-2.

The following pharmacy technician had her registration reinstated:

Dalton, Diane K., Registration #703323-2.

Continuing Education

Minnesota pharmacists are reminded that continuing education (CE) reporting is due no later than October 1 of every even-numbered year. There are now just a couple of months left during which Minnesota pharmacists can complete and report their CE for the period from October 1, 2004 to September 30, 2006.

Upon completion of at least the required 30 hours of CE, the Certificate of Completion, which was previously mailed to all pharmacists, should be signed, dated, and returned to the Board of Pharmacy office.

Clarification concerning CE programs sponsored by drug companies. As noted in the last *Newsletter*, the Minnesota Board of Pharmacy will no longer approve certain CE programs that are sponsored by drug companies or drug company representatives. As of October 1, 2006, the Board will no longer approve CE programs that are **directly** developed and paid for by drug companies or drug company representatives. The Board will consider requests to approve CE programs that are **indirectly** sponsored by manufacturers. (That is, programs for which a manufacturer provides unrestricted educational grants to another organization that actually develops the programs.) Also, the Board accepts all Accreditation Council for Pharmacy Education-approved CE programs, including those that are indirectly sponsored by manufacturers.

Methamphetamine Precursors – Another Update

The federal Combat Methamphetamine Epidemic Act of 2005 was signed into law on March 9, 2006. Parts of this law are at odds with

a state law enacted by the Minnesota Legislature in 2005. Where the two laws are in conflict, the stricter provision applies. The chart shows a summary of some of the requirements in place in Minnesota at specified times.

Packages must contain no more than 3 grams of ephedrine or pseudoephedrine calculated as the base drug, not the salt. For example, Claritin-D® 24 Hour contains 240 mg of pseudoephedrine sulfate, but only 181.8 mg of the base. Consequently, 15 tablets contain 181.8 mg * 15 = 2727 mg or 2.727 grams of pseudoephedrine base. Two of the 15 count packages of this product would contain about 5.5 grams of pseudoephedrine. (However, because of the federal law, a purchaser can purchase only one such package a day.)

Per state law, no more than two packages of products containing ephedrine or pseudoephedrine may be sold in a single over-the-counter (OTC) transaction. As illustrated in the chart, the federal law's 3.6 gram daily limit may mean that only a single package can be sold. Per state law, no person may make OTC purchases of more than two packages, containing 6 grams, per month. Licensed practitioners who are authorized to prescribe drugs may issue a prescription for larger quantities.

Currently, for OTC sales, the pharmacy must require the buyer to provide photographic identification showing the buyer's date of birth. Individuals must be at least 18 years old to purchase products that contain ephedrine or pseudoephedrine. The buyer must sign a paper or electronic document listing the date of the sale, the name of the purchaser and the amount of drug sold. Effective September 30, 2006, the following information must also be logged: time of sale; products sold (by name); and address of the purchaser. The logbook will have to contain a notice to purchasers that entering false statements or misrepresentations in the logbook may subject the purchaser to criminal penalties under 18 U.S.C. §1001 and the notice must specify the maximum fine (\$250,000) and term of imprisonment (five years). The entries in the logbook must be kept for at least two years.

Under state law, a pharmacy is allowed to report "suspicious" sales to law enforcement authorities but is not required to do so. Furthermore, a pharmacy does not have to provide a copy of its logbook to law enforcement authorities on a routine basis. Under current federal law licensees have a reporting requirement for transactions involving "extraordinary quantities" of OTC precursor drugs, unusual methods of payment or delivery, or other circumstances indicating that the drugs may be used illegally; however, the federal requirement is mandatory not discretionary. But, like Minnesota law, there is no federal reporting requirement for every transaction of such drugs.

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Date	Daily sales limit	Monthly sales limit	Products NOT required to be kept behind counter and logged
Before 4/8/2006	6 grams	6 grams	Liquid-filled gelcaps, liquids, pediatric products
As of 4/8/2006	3.6 grams	6 grams	Liquid-filled gelcaps, liquids, pediatric products
As of 9/30/2006	3.6 grams	6 grams	



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.dea diversion.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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The United States attorney general will be issuing additional regulations concerning federal reporting requirements, perhaps later this year.

Additional information concerning methamphetamine precursor drugs can be found on the Board's Web site at www.phcybrd.state.mn.us/hf1.htm.

Interns and Board Candidates

Every summer, pharmacy students who have completed the first year of the professional degree program at any accredited college of pharmacy become eligible to work as pharmacist interns. Pharmacists hiring these students as pharmacist interns should be sure that they have registered with the Board as interns and that the pharmacists that will be supervising their work have registered with the Board as preceptors.

Students who have graduated from colleges of pharmacy in other states are probably also seeking to work as "graduate interns," while they wait to take Board examinations. Those students must be registered by the Minnesota Board of Pharmacy as interns before they can work as such. Like all interns they must work under the direct supervision of a licensed pharmacist.

The Board will not issue a license to pharmacy school graduates until they pass all portions of the Board examinations and pay their original licensure fee. Examination candidates will receive a letter from the Board indicating that they have successfully passed all portions of the Board examination. Typically, a pass letter is mailed to a candidate for licensure 10 to 14 days after he or she successfully completes both examinations. The Board will not release results to anyone other than the candidate and, even then, will not release results over the phone.

The pass letter is **not** an authorization to work as a pharmacist, unless it is signed and stamped by Board staff, which indicates that the licensure fee has been paid. Once the fee has been paid, the newly licensed pharmacist will receive a small, paper license that serves as proof of licensure. The large wall certificate is sent to the licensee within approximately 90 days.

The Health Professionals Services Program

The Board is currently investigating over a dozen complaints against pharmacists and technicians involving the alleged diversion of controlled substances, the abuse of alcohol, or the inability to safely practice due to a mental illness. The Board takes such complaints seriously because, left untreated, substance abuse and other mental illnesses can put patients at risk. Fortunately, licensed and registered health professionals can get help before they become the subject of disciplinary action. Created in 1994 as an alternative to board discipline, the state of Minnesota's Health Professionals

Services Program (HPSP) offers a proactive way to get confidential help for illnesses.

HPSP evaluates professionals and, if necessary, enters into treatment agreements with them. HPSP monitors treatment progress, work quality, and medications, along with attendance at support groups. Random urine screens (if alcohol or drug use is part of the illness), counseling, work limitations, or other stipulations that address both the professional's needs and public safety might also be required. Typically, agreements are for 36 months.

To learn more about HPSP and how to refer someone who may have an illness, call 651/643-2120, visit the HPSP Web site at www.hpsp.state.mn.us, or write for information to 1885 University Ave W, Suite 229, St Paul, MN 55104.

Changes in Board Operations

The acquisition of new office equipment and computer software will result in changes to Board operations. The state of Minnesota is converting agencies to a new phone system based on a voice-over-Internet protocol (VoIP). The Board will have a VoIP system in place by the end of July 2006. The most notable change for Board customers will be a voice menuing system. Individuals calling the Board's main phone number will select from menu options so that their calls can be better routed to the appropriate staff. The VoIP system should allow Board staff to provide better service at a lower cost than the existing phone system.

Board staff continues to work with a software developer on an upgrade to the Board's licensing program. Once the upgrade is complete, licensees will be able to renew their licenses online. Interested individuals, such as employers, will be able to verify the licensure of pharmacists, technicians, and interns. Barring unforeseen complications, the new licensing system will be operational sometime this summer. Announcements concerning the new phone and licensing systems will be made on the Board's Web site.

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