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Minnesota Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

Disciplinary Activity

During the three-month period of March, April, and May, the Board completed the following disciplinary actions.

Pehrson, David W., License No. 115739-2. Mr Pehrson was alleged to have filled controlled substance prescriptions for a family member without authorization from the prescribing practitioner. Mr Pehrson declined to attend the disciplinary conference with the Board and instead voluntarily surrendered his license to practice pharmacy in Minnesota.

Romanjuk, Brian, License No. 117077-7. It was alleged that Mr Romanjuk diverted controlled substance drugs from his employer without a prescription and consumed the drugs without authorization. Mr Romanjuk declined to attend the disciplinary conference with the Board and instead voluntarily surrendered his license to practice pharmacy in Minnesota.

Update on Rule Changes

As was previously indicated in this *Newsletter*, the Minnesota Board of Pharmacy has begun the process of amending a number of Board rules relating to the practice of pharmacy.

In an effort to obtain input from a wide range of practitioners, the Board has established two ad hoc committees to provide input on the proposed rule changes. The Board has established a community-retail pharmacy-focused committee and an institutional pharmacy-focused committee to review and provide guidance to the Board on the language of the rule changes currently under development. Each of the committees met once during the month of May and has a second meeting scheduled for the month of June. Additional meetings of these committees are anticipated over the course of the summer.

Upon completion of the development of the rule change language, the Board will formally propose the changes under consideration and accept further input from all pharmacy stakeholders. Through this *Newsletter*, we will attempt to keep everyone informed of the progress of the rule change package and will publish the actual language of the proposed rules on the Board's Web site when they are formally proposed.

DEA Reinterprets Its Rules Regarding Schedule II Prescribing

Over the past several months, the Board has received numerous phone calls from pharmacists and physicians regarding the reconsideration by Drug Enforcement Administration (DEA) of its previous position on the prescribing of multiple prescriptions for the same drug, for the same patient, on the same day.

For some period of time, DEA accepted the practice of the prescribing multiple prescriptions for the same drug and the same patient, written all at the same time with each prescription indicated for filling at different future dates. This prescribing scenario was most commonly seen in the area of prescribing of methylphenidate for hyperactivity and attention deficit disorders, where the patient was stabilized on methylphenidate and only needed to be seen by the prescriber every six months or so. Because of third-party payment limitations that typically restricted insurance coverage to a one-month supply, physicians were writing multiple prescriptions at the same time for filling at monthly intervals over a six-month period of time.

In November of last year, DEA changed its position on such prescribing and indicated that it would no longer accept the prescribing of multiple prescriptions for the same drug and the same patient, written on the same day. This change of position has had a significant impact on the prescribing and dispensing of otherwise legitimate prescriptions for patients requiring treatment with Schedule II substances over extended periods of time.

A number of state and national organizations have contacted DEA to voice their concern over the change in policy and have requested that DEA reconsider and return to the position held by DEA prior to November of 2004. If DEA should relent and return to its previous position on this issue, the Board will post a notice to that effect on the Board's Web site.

Methamphetamine Bill Update

As of May 31, 2005, the legislative bill restricting the sale of pseudoephedrine-containing products, which are commonly used as a starting point for the illegal cooking of methamphetamine, was on the verge of becoming law. The comprehensive methamphetamine control bill was passed by the House of Representatives on a 131-to-3 vote and cleared the State Senate by a 62-to-4 margin. As of this writing, the Bill only requires the signature of the governor for final passage.

The methamphetamine provisions would require pharmacists to place all cold and allergy products that contain pseudoephedrine behind pharmacy counters starting July 1, 2005. Customers would be limited in the amount they could purchase each month and would have to present identification to the pharmacist or technician and sign a log similar to the old exempt narcotic books that pharmacists may recall from years ago. Under the new legislation, pseudoephedrine-containing products would no longer be sold in gas stations, convenience stores, or grocery stores.

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New Board Will Oversee Management of Drug Safety Monitoring

Food and Drug Administration (FDA) has unveiled a program that aims to improve oversight of drug safety monitoring and to bolster openness in agency product review and decision making. Included is the creation of an independent Drug Safety Oversight Board, made up of medical experts from FDA and other government agencies. Also planned are Web postings of emerging drug data and risk information as well as written materials that provide targeted drug safety information to the public. For more information, see www.fda.gov/oc/factsheets/drugsafety.html.

ACPE Changes Provider Criteria Regarding Drug and Device Manufacturers

In early 2005, the Accreditation Council for Pharmacy Education (ACPE) ceased accepting applications from pharmaceutical and biomedical device manufacturers seeking accreditation as providers of continuing education (CE). Effective July 1, 2005, the organization will no longer recognize pharmaceutical and biomedical device manufacturers as accredited providers. In addition, any CE issued by a pharmaceutical or device manufacturer after June 30, 2005, is not valid. These changes were approved by the ACPE Board of Directors at its January 2005 meeting after the organization determined that manufacturers could not meet both ACPE's requirements and the recommended restrictions as stated in a Compliance Program Guidance for Pharmaceutical Manufacturers published by the Office of the Inspector General of the United States (OIG).

In 2003, OIG stated that manufacturers could be subjected to liability under federal statutory provisions if they maintain any influence over CE subject matter or presenters, or provide funding for attendees or other incentives with respect to CE attendance. Strict compliance with OIG's guidelines would relegate manufacturers to solely providing educational grants to CE providers in order to be free of liability. Meanwhile, ACPE's Criteria for Quality require that the CE provider control the content speakers or authors of a CE program, putting ACPE's requirements in opposition to OIG's guidelines; hence, ACPE, out of responsibility to health regulatory boards, the profession, and the public, must now accredit only those providers who are in compliance with the ACPE criteria and the OIG guidelines.

In accordance with ACPE's new policies, organizations with a commercial interest and any proprietary entity producing health care goods or services, with the exception of nonprofit or government organizations and non-health care-related companies, will not be eligible for ACPE accreditation status.

For more information, contact ACPE Executive Director Peter Vlasses at 312/664-3575, or via e-mail at pvllasses@acpe-accredit.org.



Let's Get to the 'Point': Prescription Misinterpretations Due to Decimal Points

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.

Problem: Numbers containing decimal points are a major source of error and, when misplaced, can lead to misinterpretation of prescriptions. Decimal points can be easily overlooked, especially on prescriptions that have been faxed, prepared on lined order sheets, or written or typed on carbon and no-carbon-required (NCR) forms (often used in hospitals and long-term care facilities). If a decimal point is missed, an overdose may occur. The importance of proper decimal point placement and prominence cannot be overstated.

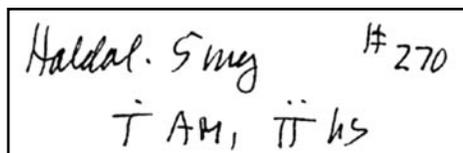
For one, a decimal point should always be preceded by a whole number and never be left "naked." Decimal expressions of numbers less than one should always be preceded by a zero (0) to enhance the visibility of the decimal. For example, without a leading zero, a prescription for "Haldol® .5 mg" (see image shown on next page) was misinterpreted and dispensed as "Haldol 5 mg." We have received similar reports with Risperdal® (risperidone) in which "Risperdal .5 mg" was prescribed (instead of Risperdal 0.5 mg), but the patient received several 5 mg doses because the decimal point was overlooked.

In addition, a whole number should never be followed with a decimal point and a zero. These "trailing zeros" (eg, "3.0") are a frequent cause of 10-fold overdoses and should never be used. For example, when prescriptions have been written for "Coumadin® 1.0 mg," patients have received 10 mg in error. Similarly, a prescription for "Synthroid® 25.0 mcg" could be misread as "Synthroid 250 mcg."

Dangerous use of decimals can also be problematic if they appear in electronic order entry systems or on computer-generated labels. A newly admitted hospital patient told her physician that she took Phenobarbital® 400 mg PO three times daily. Subsequently, the physician wrote an order for



the drug in the dose relayed by the patient. A nurse saw the prescription vial and verified that this was the correct dose. However, prior to dispensing, a hospital pharmacist investigated the unusually high dose. When he checked the prescription vial, he found that it was labeled as “phenobarbital 32.400MG tablet.” The label indicated that 30 tablets were dispensed with instructions to take one tablet three times daily.



The hospital pharmacist contacted the outpatient pharmacy and suggested that the computer expressions including trailing zeros be changed to avoid serious medication errors. The pharmacy management agreed that trailing zeros appearing on labels might pose a risk and made the change immediately.

Safe Practice Recommendations

In order to avoid misinterpretations due to decimal point placement, pharmacists should consider the following:

- ◆ Always include a leading zero for dosage strengths or concentrations less than one.
- ◆ Never follow a whole number with a decimal point and a zero (trailing zero).
- ◆ Educate staff about the dangers involved with expressing doses using trailing zeros and naked decimal points.
- ◆ Eliminate dangerous decimal dose expressions from pharmacy and prescriber electronic order entry screens, computer-generated labels, preprinted prescriptions, etc.
- ◆ Avoid using decimals whenever a satisfactory alternative exists. For example, use 500 mg in place of 0.5 gram, 125 mcg instead of 0.125 mg, or 2 ½ mg instead of 2.5 mg.
- ◆ Identify drugs with known 10-fold differences in dosage strength (eg, Cytomel® 5 mcg and 50 mcg, Coumadin 1 mg and 10 mg, levothyroxine 25 mcg and 250 mcg) and place reminders in electronic order entry systems and on pharmacy shelves to alert practitioners to double-check the dosage strength.
- ◆ When sending and receiving prescriptions via fax, health care practitioners should keep in mind that decimal points can be easily missed due to “fax noise.” Whenever possible, encourage prescribers to give original prescriptions (with an indication that it has been faxed) to their patients to take to the pharmacy for verification. Pharmacists should carefully review faxed prescriptions and clarify prescriptions that contain fax noise.
- ◆ Eliminate the lines on the back copy of NCR forms so that a person receiving can clearly see decimal points or other marks that were made on the top copy.
- ◆ Notify prescribers of the potential for error if misinterpretations due to decimal point usage are discovered.

DEA Issues Final Rules for Electronic Orders for Controlled Substances

On April 1, 2005, Drug Enforcement Administration (DEA) issued final rules regarding electronic orders for controlled substances. DEA revised its regulations to provide an electronic equivalent to the DEA official order form (Form 222), which is legally required for all distributions involving Schedule I and II controlled substances. The regulations will allow, but not require, registrants to order Schedule I and II substances electronically and maintain the records of these orders electronically. The regulations will reduce paperwork and transaction times for DEA registrants who handle, sell, or purchase Schedule I or II controlled substances. The effective date of the final rules was May 31, 2005.

The final rules were issued via the *Federal Register* on April 1, 2005, and may be downloaded from the following Web site address: www.access.gpo.gov/su_docs/fedreg/a050401c.html.

FDA Publishes Final Rule on Chlorofluorocarbons in Metered Dose Inhalers

FDA announced that albuterol metered-dose inhalers (MDI) using chlorofluorocarbon propellants must no longer be produced, marketed, or sold in the US after December 31, 2008.

The Health and Human Services (HHS) is encouraged that the manufacturers of three environmentally friendly albuterol inhalers are implementing programs to help assure access to these albuterol MDI for patients for whom price could be a significant barrier to access to this important medicine. These programs include MDI giveaways, coupons for reducing the price paid, and patient assistance programs based on financial need.

In a final rule, published March 31, 2005, in the *Federal Register*, HHS stated that sufficient supplies of two approved, environmentally friendly albuterol inhalers will exist by December 31, 2008, to allow the phasing out of similar, less environmentally friendly versions.

FDA Develops PSAs to Educate Consumers About Purchasing Medications Online

FDA recently released two public service announcement (PSA) brochures, which educate consumers about the advantages and disadvantages of purchasing medication online. The brochures also advise consumers to ensure a Web site is a US-licensed pharmacy by contacting their state board of pharmacy. Consumers may want to refer to the list of Verified Internet Pharmacy Practice Sites™ (VIPPS®) on www.nabp.net to find out if a Web site has been checked to make sure it has met state and federal rules. Consumers also will know if an online pharmacy is VIPPS-accredited when they notice the VIPPS Seal on that particular Web site.

For more information on these PSAs visit www.fda.gov/cder/consumerinfo/Buy_meds_online_all_resources.htm.

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Once the provisions of the Bill become effective, additional information on how these products will need to be handled will be posted on the Board's Web site.

Medication Guides Now Required for Certain Antidepressant Drugs

United States Food and Drug Administration (FDA) has recently published a requirement that pharmacists and others dispensing any of 34 different antidepressant drugs provide the patient with medication guides that contain several warning statements that FDA has developed to address the increased risk of suicidal thinking and behavior in children and adolescents with major depressive disorders and other psychiatric disorders who are taking antidepressant medications.

Each manufacturer of the 34 antidepressant drugs listed in the announcement are to provide pharmacists with FDA-approved medication guides, which are to be distributed with each prescription to the patient or caregiver of the patient.

Physicians who prescribe a drug product subject to the medication guide requirement may direct that the medication guide not be provided to a particular patient if the physician determines that it is not in that patient's best interest to receive the medication guide. In that case, pharmacists are not required to provide the medication guide unless the patient requests it. If the patient requests the medication guide, the pharmacist must provide it regardless of the direction issued by the prescriber.

Executive Director to Retire

Many readers of this *Newsletter* are no doubt already aware that I have announced my intention to retire as the executive director of the Minnesota Board of Pharmacy. For more than 30 years, it has been my privilege and honor to have served as the executive director of the Minnesota Board of Pharmacy. I have thoroughly enjoyed the opportunity to serve the pharmacy profession as the executive director of the Board and am most grateful to all of the Board members who have served as my supervisors, colleagues, and counselors over these many years.

I have always told myself that retirement would become an option when the good days no longer outnumbered the bad days at the office. The last couple of years, while attempting to provide more protection of the public and services to a steadily increas-

ing number of licensees with steadily decreasing resources, have finally tipped the balance.

I have frequently been asked what plans I have. Included in the future are plans to construct a retirement home on lake property that my wife and I have had in the Grand Rapids area for a number of years and to re-establish relationships with such mundane things as fishing rods and golf clubs.

Over the past 30 plus years, it has given me great pleasure to be involved in the evolution of the practice of pharmacy in Minnesota. Many national leaders in pharmacy over the past 30 years have had Minnesota roots and I have greatly appreciated the opportunity to work with them and call them my friends. I am confident that the next generation of Minnesota pharmacists will continue to improve the quality of pharmacy practice in this state.

As I prepare for a new chapter in my life, the Board of Pharmacy will also be preparing for changes. The Board will be conducting a search for the next executive director of the Board during the summer and, if all of the stars align appropriately, a new executive director will be identified by the beginning of September so that some modicum of knowledge transfer can take place before I leave state service.

I have appreciated the opportunity to get to know so many of Minnesota's pharmacists over the years and extend my best wishes to all of you.

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