Disciplinary Activity

The Minnesota Board of Pharmacy has completed the following disciplinary cases during the time period of March 1, 2004 through June 1, 2004.

Samuelson, Donald A., License No. 113507-1. Licensee engaged in unprofessional conduct by dispensing controlled substance drugs without authorization and engaging in other irregularities associated with controlled substance record keeping. Licensee was placed on probation by the Board with certain limitations and requirements.

Samuelson, John T., License No. 111321-3. Licensee engaged in unprofessional conduct by dispensing controlled substance drugs without authorization and engaging in other irregularities associated with controlled substance record keeping. Licensee was placed on probation by the Board with certain limitations and requirements.

Ahlquist, Susan S., License No. 112631-0. Action was taken on this licensee as a result of allegations of unprofessional conduct arising from the habitual indulgence in the use of intoxicating liquors in a manner, which could cause conduct endangering public health. Licensee was placed on probation with the Board.

Fedie, Kathy Ann, License No. 117094-2. Action was taken on this licensee as a result of allegations of unprofessional conduct arising from the theft of controlled substances from her employer and the unauthorized personal use of those controlled substances. Licensee was placed on probation with the Board.

Schultz, Lyndon W., License No. 111267-0. Action was taken on this licensee as a result of allegations of unprofessional conduct arising out of the theft of controlled substance drugs from the licensee’s employer and the unauthorized personal use of those drugs. Licensee was placed on probation with the Board.

Budget Reductions to Cause Change in Board Operations

Board of Pharmacy operations, like the operations of the other health-related licensing boards, are supported by the fees the Board is authorized to assess. The Board, however, is not authorized to spend the fee revenue it receives without approval; first by the Governor’s Office and second by the Legislature.

For the past several years, the Governor’s Office and the Legislature have refused to allow state agencies including the Board of Pharmacy to increase budgets to pay for negotiated salary increases. The extra salary costs had to be made up by “reductions in other programs.” Unfortunately, the Board of Pharmacy, like the other health-related licensing boards, does not have any “other programs” to reduce in order to pay for salary increases, increases in rent, increases in travel costs for Board inspectors, etc.

At the end of each fiscal biennium, any fees collected by the various health-related licensing boards in excess of the authorized expenditures are transferred to a “special revenue fund.” In cases of severe unanticipated expenditures such as an expensive lawsuit, etc, the boards were authorized to utilize the accumulated surplus, with legislative approval, to meet those unanticipated emergency expenditures.

During the biennial budget balancing struggles of a year ago, the accumulated surplus of all of the health-related licensing boards was appropriated to help balance the State’s General Fund deficit. In addition, once again, the Board was not provided with authority to fund the salary increases negotiated by the various state unions. The Board has now reached a point where significant cutbacks in its services will be necessary and staff reductions may follow.

Among the budget-reducing actions being taken by the Board are the following: reduce the number of Board meetings per year from 10 to five; eliminate all travel outside of Minnesota; eliminate all staff training; significantly reduce in-state travel including travel by Board inspectors; and eliminate the printing and mailing of this Board Newsletter.

During the next fiscal year, which runs July 1, 2004 through June 30, 2005, the Board will meet only on July 21, 2004; October 20, 2004; January 5, 2005; March 23, 2005; and June 8, 2005. Items for placement on Board of Pharmacy meeting agendas must be received in the Board office at least two weeks prior to each Board meeting.

Travel expenses will be reduced by the elimination of some Board meetings and by reducing the number of inspection visits made to Minnesota pharmacies. The Board is currently exploring several different options including the use of self-inspection forms to accomplish this reduction.

This issue of the Board’s quarterly Newsletter will be the final issue that will be printed and mailed to all licensees. Henceforth, the Newsletter will be posted on the Board’s Web site at www.phcybrd.state.mn.us in mid-October 2004, mid-January 2005, mid-April 2005, and mid-July 2005. Pharmacists who have provided an e-mail address to the Board will receive an e-mail notice when the Newsletter is available. Whether or not the Board can return to published and mailed Newsletters after the July 2005 Newsletter will be determined through the Board’s biennial budget request that will go to the Legislature next January.

Continued on page 4
FDA Issues Final Rule Prohibiting the Sale of Ephedra Supplements

On February 6, 2004, Food and Drug Administration (FDA) announced the issuance of a final rule prohibiting the sale of dietary supplements containing ephedrine alkaloids (ephedra).

At the end of last year, FDA issued letters to manufacturers who market ephedra-containing supplements, informing them of the upcoming rule. FDA also urged consumers to stop using ephedra-containing dietary supplements immediately. Studies show that ephedra-containing dietary supplement have adverse effects on the cardiovascular and central nervous systems including high blood pressure, heart palpitations, tachycardia, stroke, and seizures. FDA has linked at least 155 deaths with the use of dietary supplements containing ephedra.

For more information, including a Web link to the final rule, visit the following Web site: www.fda.gov/bbs/topcis/NEWS/2004/NEW01021.html.

The final rule became enforceable on April 12, 2004. California, Illinois, and New York were the first states to ban the sale of ephedra.

DEA Issues Clarification of the Exemption of Sales of Pseudoephedrine and Phenylpropanolamine

In attempts to clarify existing laws and regulations regarding the over-the-counter (OTC) sale of pseudoephedrine and phenylpropanolamine, Drug Enforcement Administration (DEA) issued an interpretive rule this past January. This interpretive rule does not change any of DEA’s regulations, nor will it have an impact on individual retail customers of such products who have been purchasing them from retailers that have been properly following DEA’s regulations.

Specifically, the interpretive rule emphasizes that sales transactions of ordinary OTC pseudoephedrine and phenylpropanolamine products (“safe harbor” products) are exempt from being regulated transactions as long as each transaction is below the 9-gram threshold to an individual for legitimate medical use. Apparently, some retail distributors have misinterpreted current DEA regulations and believe that they may sell as much “safe harbor” pseudoephedrine and phenylpropanolamine to any person for any purpose as often as that person wishes to make a purchase. The DEA interpretive rule clearly dispels that belief.

Currently, retail distributors of ordinary OTC pseudoephedrine and phenylpropanolamine products are exempt from registering with DEA as a distributor of List I chemicals and complying with the record keeping and other regulatory requirements as long as individual transactions for legitimate personal medical use remain below the 9-gram threshold (in packages of not more than 3 grams).

To obtain more information, please visit DEA’s Diversion Control Program Web site, www.DEAdiversion.usdoj.gov.

Note: Although most products containing phenylpropanolamine were discontinued pursuant to the action of FDA in November 2000, there remains some legitimate veterinary uses for phenylpropanolamine that will ensure some level of its continued production and availability. Therefore, these products are subject to the existing DEA regulations and this interpretive rule.

DEA Introduces Pharmacy Theft Prevention Program

In response to increasing theft and armed robberies against pharmacies, DEA’s Office of Diversion Control has introduced the Pharmacy Theft Prevention Program. The program is based on a previous initiative that was developed during the late 1970s and early 1980s when there was a similar unprecedented spike in the occurrence of thefts and robberies against pharmacies.

The intent of the program is to provide education and increased communication to pharmacists and pharmacy staff to prevent pharmacy theft. The program includes collaboration with and participation from law enforcement, regulators including state pharmacy boards, state and federal prosecutors, the media, and the public along with the pharmacy community. The Pharmacy Theft Prevention Program will also provide a means to maximize the use of limited resources available to law enforcement to address, minimize, and eliminate pharmacy thefts in areas that experience such problems.

Staff members of the DEA’s Office of Diversion Control have begun a series of regional meetings to promote the program to DEA Diversion field elements, state pharmacy boards, and local pharmacy associations. To implement the program in your community, or to obtain more information regarding the program and its operation, call DEA Headquarters, Office of Diversion Control, Liaison and Policy Section, at 202/307-7297.

Concentrated Morphine Solutions and Serious Medication Errors

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, and 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.

According to a recent newspaper report, a 91-year-old man being treated for a mild heart attack was mistakenly given a 100-mg dose of ROXANOL™ (concentrated morphine solution) instead of 5 mg as prescribed. The error may have contributed to the patient’s death the following day. Last fall, Elan Pharmaceuticals (the manufacturer of Roxanol at the time; aaiPharma recently acquired the product from Elan) issued a safety alert warning about deaths from accidental overdoses (www.fda.gov/medwatch/SAFETY/2003/roxanol.htm). Most overdoses involved morphine solutions that were mistakenly ordered, dispensed, and labeled by volume (mL), not milligrams. For example, in some cases, patients received 5 mL of...
Roxanol 20 mg/mL (100 mg) instead of the prescribed 5 mg. The newspaper report did not describe how this most recent error happened; however, it mentioned that Roxanol 100 mg had been given instead of 5 mg, pointing once again to the scenario described in the recent safety alert from Elan.

Several manufacturers distribute morphine solution in different formulations, primarily labeled (and listed in drug references) in mg/mL (eg, 20 mg/mL) or mg/5 mL (eg, 100 mg/5 mL, 20 mg/5 mL). When concentrated morphine is stored in pharmacies or in patient care areas in hospitals or long-term care facilities, it is often kept next to conventional concentrations. Thus, it is easy to confuse these products and dosage strengths. Also, some physicians have prescribed the medication in terms of mL instead of mg, which has led to errors because multiple concentrations exist. Because we continue to hear about these tragic overdoses, we make these recommendations to reduce the risk of errors with concentrated morphine products:

- If you consult with nursing homes or hospitals, avoid stocking concentrated morphine solutions in patient units where possible, including the emergency department. Keep in mind that the drug is used primarily to treat chronic pain.
- Dispense concentrated solutions only when ordered for specific patients who require higher-than-usual doses due to severe chronic pain.
- Affix an auxiliary label to the morphine concentrate bottle to warn about its high concentration and segregate the solution from the other concentrations.
- Working with local physicians, purchase and dispense concentrated solutions in dropper bottles (available from at least two manufacturers) to help prevent dose measurement errors and differentiate the concentrated product from the conventional products. For patients in hospitals or long-term care, dispense concentrated solutions in unit doses whenever possible.
- Educate others to never prescribe or dispense liquid medications without the dose specified in milligrams.
- Educate staff about the risk of morphine errors and develop guidelines to promote its safe use.
- Manufacturers should standardize the way strength is expressed on labels, preferably in terms of mg/mL for all forms. This would improve clarity when comparing product labels (eg, it is easier to differentiate 4 mg/mL and 20 mg/mL; harder to differentiate 20 mg/mL and 20 mg/5 mL). Finally, we disagree with Elan’s suggestion in its recent safety alert for prescribers to include the desired concentration of morphine along with the patient’s dose in milligrams and the corresponding volume (eg, Roxanol 10 mg/5 mL, give 10 mg [5 mL] prn pain). Listing the desired concentration could actually lead to confusion and errors. If the prescribed concentration is not available and a different concentration is substituted, the prescriber’s directions regarding the volume to administer would no longer apply. Yet, if these directions remain on a medication administration record, or a prescription bottle, the wrong dose could be administered.

NABP Releases Updated Model Rules for the Licensure of Wholesale Distributors

On February 20, 2004, the National Association of Boards of Pharmacy® (NABP®) released the updated Model Rules for the Licensure of Wholesale Distributors. The updated Model Rules, part of the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy, were provided to assist state boards of pharmacy in maintaining the integrity of the US medication distribution system through the regulation of wholesale distributors. The updated Model Rules are the result of a concerted effort between NABP and other representatives from pharmacy, government, and the wholesale distributor industry to protect the public from the ill effects of counterfeit drugs and devices.

In addition to stricter licensing requirements such as criminal background checks and due diligence procedures prior to wholesale distribution transactions, the Model Rules mandate specific drug pedigree requirements for products that are particularly prone to adulteration, counterfeiting, or diversion. These products, as defined in the updated Model Rules, are designated as the “National Specified List of Susceptible Products.” Also, the updated Model Rules introduce the position of “Designated Representative.” The “Designated Representative” of a wholesale distributor is the person who is actively involved in and aware of the actual daily operation of the Wholesale Distributor.

The Model Rules for the Licensure of Wholesale Distributors along with the National Specified List of Susceptible Products can be downloaded from NABP’s Web site, www.nabp.net.

New Bar Code Requirements Aim to Reduce Risk of Medication Errors

In late February, FDA issued the final rule Bar Code Label Requirements for Human Drug Products and Biological Products. This final rule requires the inclusion of linear bar codes on most prescription drugs and certain OTC drugs. Each bar code must, at minimum, contain the drug’s National Drug Code number, but companies are encouraged to include additional information such as the product’s lot number and expiration date. For blood and blood products used in a transfusion, the final rule also requires the use of machine-readable information in a format approved for use by FDA. The machine-readable information must include, at a minimum, the facility identifier, the lot number relating to the donor, the product code, and information on the donor blood type.

FDA is hoping that the bar code rule will encourage the widespread adoption of advanced information systems that, in some institutions, have reduced medication errors by 85%. FDA expects that, with full implementation, the linear bar codes will result in more than 500,000 fewer adverse events over the next 20 years and a 50% reduction in medication errors that would otherwise have occurred upon dispensing or administration. New medications covered by the rule must comply within 60 days of their approval and previously approved medications and blood/blood products must comply within two years.

More information including a link to the final rule is available on FDA’s Web site at www.fda.gov/oc/initiatives/barcode-sadr.
Whether or not these expenditure reductions will be sufficient to keep the Board’s budget in balance through July 2005 remains to be seen. The Board is trying not to reduce the number of Board employees since such reductions would likely become permanent and would significantly impact the Board’s ability to protect the public health of Minnesota residents and to regulate the practice of pharmacy in Minnesota.

A decrease in staff within the Board office would create an additional situation where more re-evaluations of the type and methods of service the office provides would need to be done. A number of changes over the coming months are expected to take place. In some cases, expected correspondence, legal work, or other expected communications may become significantly slower as a result of these issues. Please keep this in mind when attempting to access Board of Pharmacy services in the future. Board staff will do everything possible to address your issues on a timely basis. Your patience during this time of change is appreciated.

June Board Exams

The application deadline has passed for the June Board exams in Minnesota. The Board anticipated that approximately 180 applicants would sit for the Board’s written Practical examination at the beginning of June.

Minnesota pharmacists who may be hiring new graduates are cautioned to make sure that the new graduate has passed all portions of the Board examination and has, in fact, become licensed as a pharmacist in Minnesota before scheduling them for work as a pharmacist. Exam candidates will receive a letter from the Board indicating that they have successfully passed all portions of the Board exam, but that letter is not authorization to work as a pharmacist until the individual pays the original licensure fee. It is only after this original licensure fee is paid that the license becomes active.

Typically, the pass letters are mailed to the candidates for licensure 10 to 14 days after the candidate successfully completes the last of the three examinations.

The Board believes that the candidate is the first individual who should know the results of his or her Board examination experience. Please do not call and request Board exam results.

Hiring of Interns

Every year at this time the class of pharmacy students who have completed the first year of the professional degree program become eligible to work as pharmacist interns. Pharmacists intending to hire one of these students as a pharmacist intern should be sure that the student has registered with the Board as an intern and that the pharmacist who will be supervising his or her work has registered with the Board as a pharmacist preceptor.

Patient Counseling

The Board has recently received input from several Minnesota pharmacists urging that the Board assume a more proactive role in enforcing the requirements for patient counseling.

The Board, being responsive to the desires of the profession, will be discussing opportunities to enforce the patient counseling requirements as opposed to relying strictly on educating pharmacists about what the appropriate level of pharmacy services ought to be.

If you and others at your place of employment are not currently counseling all patients in accordance with the requirements of Omnibus Budget Reconciliation Act (OBRA ’90) and Board rules, you should begin doing so immediately.

New Database Under Construction

In an effort to update our aging computer technology and, at the same time, save what amounts to considerable mailing costs, the Board is currently in the process of developing a new database system, which, when completed, will feature license verifications online and will allow license renewals to be performed online using credit cards. It is anticipated that by the time Minnesota pharmacists renew their license to practice next January and February, a substantial number will be able to take advantage of the ability to renew online.

An announcement will be made when the online license verifications and online renewals become operational.