Disciplinary Activity

The Minnesota Board of Pharmacy took the following disciplinary actions concerning pharmacists between the dates of September 1, 2006 and December 6, 2006.

Axelson, C. Frederic, License #111246. Mr Axelson successfully completed his probation and the Board granted his petition for an unrestricted license.

Hull, Judy L., License #113720. Ms Hull admitted to the theft of controlled substances (CS) from her employer and the unauthorized personal use of those drugs. She was placed on probation for an indefinite period of time, until she successfully completes a participation agreement with the Health Professional Services Program (HPSP).

The Board took the following disciplinary action concerning technicians between the dates of September 1, 2006 and December 6, 2006.

Boerboom, Dorothy E., Registration #701803. Ms Boerboom admitted to the theft of CS from her employer and the unauthorized personal use of those drugs. She was placed on probation for a period of three years, or until successful completion of a participation agreement with the HPSP, whichever is later.

The following pharmacy technicians had their registrations revoked:

♦ Bauermeister, Tina M., Registration #712831
♦ Close, Darlene F., Registration #707633
♦ Londo, Tammy K., Registration #709134

Pharmacy Technician Registration

Renewal letters were mailed out late this registration cycle due to a delay in the implementation of the Board’s new online services. Technicians are strongly encouraged to renew their registrations online; however, technicians can contact the Board office to request a paper renewal application. Also, Board staff is working with employers who pay the registration or licensing fees of their employees to develop alternative methods of renewal. Given the late mailing of renewal notices, the deadline for registration renewal has been extended to January 31, 2007. Any technicians who do not renew their registration by that date will have to pay a late fee when their registration is renewed and will not be allowed to practice as technicians. The pharmacist-in-charge of each Minnesota pharmacy is responsible for making sure that all of the pharmacy technicians employed in their pharmacy have current technician registrations posted.

Pharmacist Renewals

Pharmacist license renewal letters were recently mailed out. Pharmacists who have not received a letter can use the Board’s new online services to confirm and, if necessary, change their mailing address. Alternatively, they can contact the Board office to verify their correct mailing address. Pharmacists are encouraged to renew their licenses online; however, pharmacists can contact the Board office to request a paper renewal application. As mentioned above, Board staff is working with employers who pay the registration or licensing fees of their employees to develop alternative methods of renewal. Pharmacists should either renew their licenses online or complete and return renewal forms to the

Continued on page 4
**FDA Issues Nationwide Alert on Counterfeit One-Touch Blood Glucose Test Strips**

In mid October 2006, United States Food and Drug Administration (FDA) alerted the public to counterfeit blood glucose test strips being sold in the US for use with various models of LifeScan, Inc, One Touch Brand Blood Glucose Monitors. The counterfeit test strips potentially could give incorrect blood glucose values; either too high or too low. At press time, no injuries have been reported to FDA.

Consumers who have the counterfeit test strips should be instructed to stop using them, replace them immediately, and contact their physicians. Consumers with questions may contact the company at 1-866/621-4855. The counterfeit test strips were distributed to pharmacies and stores nationwide – but primarily in Ohio, New York, Florida, Maryland, and Missouri – by Medical Plastic Devices, Inc, Quebec, Canada and Champion Sales, Inc, Brooklyn, NY.

The counterfeit test strips and their characteristics are:

- One Touch Basic®/Profile®
- Lot Numbers 272894A, 2619932, or 2606340
- Multiple Languages – English, Greek, and Portuguese
- Limited to 50-Count One Touch (Basic/Profile) Test Strip packages
- One Touch Ultra®
- Lot Number 2691191
- Multiple Languages – English and French text on the outer carton
- Limited to 50-Count One Touch Ultra Test Strip packages

LifeScan has alerted the public via a press release and has notified pharmacists, distributors, and wholesalers through a letter. In its letter, the company advises customers to contact their original source of supply for restitution. For more information, visit www.GenuineOneTouch.com.

**New DEA Number Assignments; Updated DEA Practitioner’s Manual Released**

In early November 2006, Drug Enforcement Administration announced that due to the large Type A (Practitioner) registrant population, the initial alpha letter “B” has been exhausted. The Agency, therefore, has begun using the new alpha letter “F” as the initial character for all new Type A (Practitioner) registrations. For more information, visit www.deadiversion.usdoj.gov/drugreg/reg_apps/new_reg_number110906.htm.


**Optimizing Computer Systems for Medication Safety**

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.

Computers that are used by pharmacists are essential professional tools that can increase staff efficiency and support effective drug utilization review and therapeutic drug monitoring. At the same time, pharmacists must not place sole reliance on this tool as a means to protect patients from drug-induced harm.

Many of today’s computer order-entry systems provide vendor-defined and user-defined alerts that remind or warn staff about potential drug-related problems during order entry. The Institute for Safe Medication Practices (ISMP) often recommends these alerts as a way to inform staff about potential errors. However, pharmacists have expressed concern that the sheer number of warnings that appear on the screen during order entry can be overwhelming and slow the process. In many cases, clinically insignificant warnings are as likely to appear as those that are vital. As a result, staff may inadvertently bypass critical warnings, especially when the workload is high. This is easy to do with many systems.

In an informal survey on computer systems, we found that all too often it simply requires striking the “enter” key to bypass an alert, even those that could prevent serious or fatal errors. Also, if the system forces a response to the warning, practitioners who feel pressured to rush through order entry may select the first reason listed on the screen instead of appropriately addressing the issue. Another issue is that when pharmacists are properly alerted to a potential allergic reaction or harmful drug interaction, they may erroneously assume that the prescriber is already aware of the problem and fail to alert the prescriber directly.

When practitioners become accustomed to receiving unimportant or clinically irrelevant warnings they often ignore these “false alarms,” or turn them off, at least mentally. Here are some strategies that can be used to optimize the effectiveness of alerts and minimize the possibility of overlooking the more significant ones:

- Use a tiered system for interactive warnings that allows staff to view and consider possible warnings but easily bypass less serious issues, if appropriate. Require a text entry to describe the response to more significant alerts.
♦ Pharmacies should assign pharmacists who enter orders the task of noting any warnings that they feel are not clinically significant. The severity level of certain alerts may need to be changed in order not to “overload” the pharmacist. However, wholesale changing of severity levels according to vendor specifications should be done with caution. Check with your vendor to fully understand how they assign severity levels before making any changes to ensure you are not missing warnings you deem to be critical.

♦ Make significant alerts as visible as possible. Some systems may allow large screen fonts in a contrasting color, flashing messages, sounds, or other means of distinguishing the alert.

♦ Maximize a system’s capabilities whenever possible by incorporating serious error-prone situations that have been reported in this column as well as other publications.

♦ Review non-interactive pop-up messages on an ongoing basis, such as the ones we suggest for avoiding drug name mix-ups. Delete any that are no longer applicable.

♦ Apply auxiliary labels to drug packages and medication storage areas instead of building alerts into the order entry process. For example, print “Topical or External Use Only” warnings on drug labels for all drugs that can be administered safely only by this route.

♦ Many systems are capable of providing reports about all warnings that have been overridden. Assign a clinician or manager to review the report daily and periodically identify those warnings that are continually overridden. Share report results with staff members before changes are made to the computer system. Consider focusing on one or two common but critically important warnings to monitor the effectiveness of the computer’s alert system and the response to the alert.

Revised Coumadin Labeling and Medication Guide

FDA and Bristol-Myers Squibb notified pharmacists and physicians of revisions to the labeling for Coumadin®, to include a new patient Medication Guide as well as a reorganization and highlighting of the current safety information to better inform providers and patients.

The FDA regulation 21CFR 208 requires a Medication Guide to be provided with each prescription that is dispensed for products that FDA determines pose a serious and significant public health concern.

Information about all currently approved Medication Guides is available at www.fda.gov/cder/Offices/ODS/medication_guides.htm.

To access the new Medication Guide, revised prescribing information and supplemental supporting documents, visit www.fda.gov/medwatch/safety/2006/safety06.htm#Coumadin.

FTC and FDA Act Against Internet Vendors of Fraudulent Diabetes Cures and Treatments

The Federal Trade Commission (FTC) and FDA, working with government agencies in Mexico and Canada, have launched a drive to stop deceptive Internet advertisements and sales of products misrepresented as cures or treatments for diabetes. The ongoing joint campaign has so far included approximately 180 warning letters and other advisories sent to online outlets in the three countries.

The joint diabetes initiative to stop commercial sale of fraudulent therapies originated with a Web surf for “hidden traps” by the International Consumer Protection and Enforcement Network, an organization of law enforcement authorities, members of the Mexico, United States, and Canada Health Fraud Working Group (MUCH), and the attorneys general offices of Alaska, Michigan, Ohio, Virginia, and Wisconsin. MUCH, which consists of regulatory officials from health, consumer, and competition protection agencies in the three North American countries, had previously conducted a campaign against fraudulent weight-loss products. Using the results of the Internet sweep, FTC sent warning letters for deceptive ads to 84 domestic and seven Canadian Web sites targeting US consumers, and referred an additional 21 sites to foreign governments. About a quarter of the firms have already changed their claims or removed their pages from the Internet, and several others are in contact with FTC.

FTC also announced a new consumer education campaign to teach consumers how to avoid phony diabetes cures. The materials encourage consumers to “Be smart, be skeptical!” and will be available in English, Spanish, and French. One component is a “teaser” Web site available at http://wemarket4u.net/glucobate/index.html. At first glance, the site appears to be advertising a cure for diabetes called Glucobate, but when consumers click for more information on ordering the product, it reveals information about avoiding ads for phony cure-alls in the future. The new education materials, including a bookmark and consumer alert, were introduced to coincide for Diabetes Awareness Month in November.

FDA Implements Strategy for Phony Dietary Supplement Claims

FDA has developed a strategy to focus its enforcement efforts in the area of dietary supplements. The strategy was designed to address illegal dietary supplement ingredients and ensure integrity and truthful labeling of dietary supplements. One emphasis is on claims aimed at patients with serious diseases such as cancer and diabetes. Over an approximate 12-month time frame, the Agency has sent more than 100 warning letters and other advisories to Internet firms and has seized products at one firm. In addition, the Agency maintains special Web sites, in English and Spanish, which amplify the Agency’s counsel to consumers to check with their doctor, nurse or pharmacist before trying any new health care product. These materials cover a broad range of subjects of special interest to patients with diabetes (www.fda.gov/diabetes/; www.fda.gov/diabetes/pills.html; www.fda.gov/opacom/lowlit/diabetes.html; www.fda.gov/opacom/lowlit/sdiabetes.html), as well as more general health care information.
Board by February 1. Pharmacist license renewals expire on March 1 of each year, and a late fee is assessed for any renewal received after February 28. Pharmacists are not allowed to practice after February 28 without a valid license renewal.

**Proposed Rules Package**

The Board of Pharmacy has been working to update Board rules in many different areas, which have been listed in previous issues of this *Newsletter.*

A hearing on these rules was held on November 14, 2006, before Administrative Law Judge Kathleen Sheehy. By the time this edition is published, Judge Sheehy will have issued a report of her findings to the Board. The Board will review her report at its January 10, 2007 meeting. It is likely that some changes will be made to the language that was originally proposed. Barring unforeseen circumstances, final adoption of the rules package is expected by March 1, 2007.

**Methamphetamine Precursors – Correction**

In the July 2006 issue of this *Newsletter,* incorrect information was given concerning the federal Combat Methamphetamine Epidemic Act of 2005. A table in that issue indicated that, after September 30, 2006, liquid products containing pseudoephedrine or ephedrine would not have to be kept behind the counter and sales of such products would not have to be logged. In reality, such products must be kept behind the counter and sales must be logged.

**Electronic Prescriptions**

Board staff frequently receives questions about “electronic prescriptions.” For example, a common question is as follows: is a prescription that is electronically generated still valid if the prescriber prints it out on a sheet of paper and gives it to the patient? Once a prescription is printed out and given to the patient, it is no longer an electronic prescription. Consequently, it is valid only if it is manually signed by the prescriber. A rubber-stamped signature does not constitute a manual signature. A notation on a paper prescription such as “electronically signed by the prescriber” does not make it a legally valid prescription.

Minnesota Statutes §151.01, subdivision 16 defines a prescription as follows: “The term ‘prescription’ means a signed written order, or an oral order reduced to writing, given by a practitioner licensed to prescribe drugs for patients in the course of the practitioner’s practice, issued for an individual patient and containing the following: the date of issue, name and address of the patient, name and quantity of the drug prescribed, directions for use, and the name and address of the prescriber.” Given that this law was written long before the advent of electronic prescribing, the word “signed” must be interpreted to mean a manual, handwritten signature. A pharmacist who receives a paper prescription that has not been manually signed may contact the prescriber to verify the prescription and may treat it as an oral order. (Unless the drug is a Schedule II CS, prescriptions for which must be signed by the prescriber.)

Board staff also receives questions about electronic prescriptions for CS. Per federal law, prescriptions for Schedule II CS cannot be electronically transmitted, nor can they be transmitted by facsimile, unless the patient is receiving home infusion/intravenous pain therapy, resides in a long-term care facility, or is in hospice care. In all other cases, prescriptions for Schedule II CS must be on paper and manually signed.

The Board has received correspondence from Drug Enforcement Administration (DEA) concerning electronically created prescriptions for CS in Schedules III through V. It reads, in part: “current DEA regulations allow for Schedule III, IV or V [CS] prescriptions that are electronically created and transmitted, either directly to a computer or via a facsimile machine, to be treated as oral prescriptions. A pharmacist that receives an electronically transmitted prescription, via a facsimile or by other methods, must ensure the validity of the prescription prior to dispensing the [CS].” The letter further states that DEA does not mandate which method a pharmacist must use to ensure the validity of the prescription but does mention one possibility – calling the prescriber.

**Telepharmacy Guidelines**

At its October 18, 2006 meeting, the Board adopted new “Guidelines for Dispensing with Remote Distribution via Telepharmacy.” Those guidelines are available on the Board’s Web site for review or downloading. A couple of changes are particularly noteworthy. First, a pharmacy may not provide remote pharmacy services if a community pharmacy is located within the same community as the remote site. In rural areas, “community” is defined as the area within 30 minutes travel time of the remote site. Generally, a 30-minute travel time equates to about a 20-mile distance. Second, the Board recommends that a pharmacist working at the central pharmacy not certify more than an average of eight prescriptions per hour, assuming that all prescriptions are for patients of the remote site(s). The Board further decided to “grandfather” existing telepharmacies that do not meet the distance requirement mentioned above.

Requests for approval of telepharmacies will be treated as if they were applications for new pharmacies. Such requests must be made, in writing, at least 60 days prior to the anticipated opening date of the telepharmacy. A diagram of any proposed remodeling, a complete set of policies and procedures, required variance request forms, an estimate of the prescription count at both the remote and central sites, and plans for staffing both sites should accompany the request. No telepharmacy proposal will be approved without being considered at one of the Board’s regular business meetings.