January 2007

North Carolina Board of Pharmacy

PO Box 4560, Chapel Hill, NC 27515-4560
6015 Farrington Rd, Suite 201
Chapel Hill, NC 27517
Tel: 919/246-1050 Fax: 919/246-1056
Web site: *www.ncbop.org*

Item 2129 – Pharmacist-Manager Responsibilities in Board Investigations

North Carolina Board of Pharmacy Rule .1317(25) states that the pharmacist-manager is "the person who **accepts responsibility** for the operation of a pharmacy in conformance with all statutes and regulations pertinent to the practice of pharmacy and distribution of drugs by signing the permit application, its renewal or addenda thereto." In recent months, Board investigators increasingly have had their requests for required pharmacy records met with refusals by pharmacist-managers, who then direct the investigators to contact a district manager or a corporate office. Some district managers and corporate officials have, in turn, increasingly taken the position that Board investigators are not entitled to pharmacy records unless written requests are made or subpoenas issued by the Board. And, even then, requests have been disregarded or met with "legal" objections of highly dubious validity.

Pharmacist-managers are reminded that it is not Board investigators' responsibility to seek required records from district managers, corporate officials, or anyone else. If a pharmacist-manager feels that he or she must reach out to such parties to produce required pharmacy records, it is the responsibility of the pharmacist-manager – and not the Board investigator – to make those efforts. At the end of the day, it is the pharmacist-manager who bears direct, personal responsibility for producing required records in conformance with the laws and rules governing the practice of pharmacy. The Board recognizes that, in some instances, corporations have put into place various record policies, but no corporate policy can supersede the requirements of law. It is the pharmacist's license that is in jeopardy when Board investigators' requests are disregarded or stonewalled.

The Board appreciates the cooperation of pharmacist-managers in meeting their legal obligations and protecting the public health and safety.

Item 2130 – North Carolina Supreme Court Rules that the Board of Pharmacy has the Statutory Authority to Regulate Pharmacist Working Hours

On November 17, 2006, the North Carolina Supreme Court ruled that the Board of Pharmacy has the statutory authority to promulgate Rule .2506, which provides:

> A permit holder shall not require a pharmacist to work longer than 12 continuous hours per workday. A pharmacist working longer than 6 continuous hours per workday shall be allowed during that time period to take a 30 minute meal break and one additional 15 minute break.

The Supreme Court's decision brings to a close eight years of litigation with the North Carolina Rules Review Commission. The Supreme Court held that the North Carolina Court of Appeals erred in ruling that the Pharmacy Practice Act does not permit the Board to regulate pharmacist working conditions as a means of protecting public health and safety. The Supreme Court adopted the opinion of Judge Sanford Steelman, who dissented in the Court of Appeals. Judge Steelman wrote that pharmacist fatigue and hunger can clearly contribute to dispensing errors, that the Pharmacy Practice Act plainly authorizes the Board of Pharmacy to ensure safety in the dispensing process, and that Rule .2506 advances that interest.

A timeline for implementation of the rule is still somewhat up in the air. It depends on certain procedural steps that remain even after the Supreme Court's ruling. The Board will keep pharmacists updated on that progress.

The Board extends its heartfelt appreciation to Matt Sawchak, Paul Sun, Julie Youngman, and Stephen Feldman of Ellis & Winters, who served as the Board's appellate counsel before the Supreme Court. The Board is also grateful for the supporting briefs filed by the National Association of Boards of Pharmacy®, American Pharmacists Association (APhA), North Carolina Association of Pharmacists, North Carolina Coastal Federation, North Carolina Shellfish Growers Association, Environmental Defense, and North Carolina State Council of Trout Unlimited.

Item 2131 – Board Welcomes New Counsel

On December 1, 2006, the Board retained the law firm of Brooks, Pierce, McLendon, Humphrey & Leonard, LLP as general counsel to the Board. The Board's principal attorney is Brooks Pierce partner Clint Pinyan.

The Board will also continue to engage the services of Ellis & Winters as counsel for special matters before the Board. As mentioned above, Ellis & Winters handled 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 text on the outer carton
  - 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.*

Additionally, in August 2006, the Agency released the Practitioner's Manual, An Informational Outline of the Controlled Substances Act, 2006 Edition. The Manual, prepared by the Agency's Office of Diversion Control, is designed to assist practitioners (physicians, dentists, veterinarians, and other registrants authorized to prescribe, dispense, and administer controlled substances) in their understanding of the Federal Controlled Substances Act and its implementing regulations as they pertain to the practitioner's profession. The Manual can be accessed at *www.deadiversion.usdoj.gov/pubs/manuals/pract/pract_manual090506.pdf.*

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 storage shelves to warn about unclear or confusing labeling and packaging, instead of using certain messages in the computer system.
- Consider printing warnings on drug labels or 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.

Continued from page 1
Board's suit against the Rules Review Commission in the North Carolina Supreme Court. Partner Matt Sawchak is the Board's principal attorney at Ellis & Winters.

Clint and Matt are superlative lawyers, and the Board looks forward to their aiding the Board's service to the citizens of North Carolina.

Item 2130 – Automated Dispensing Devices in Long-Term Care Facilities

In May 2005, Drug Enforcement Administration (DEA) promulgated a rule that allows, where state law permits, a retail pharmacy to install an automated dispensing system at a long-term care facility (LTCF). These systems allow dispensing of single dosage controlled substance units, and can mitigate the problem of excess controlled substance stocks and disposal.

Under Board rules, an automated dispensing device may only be installed at a facility holding a pharmacy permit (**see** 21 NCAC 46.3401). It is the consensus of the Board that limited service permits may be obtained for the installation of automated dispensing systems in LTCFs.

DEA rule, found at 21 C.F.R. §1301.17(c) and §1301.27, provides that, upon receiving authorization from appropriate state authorities, a pharmacy may apply for an additional DEA registration to operate the automated dispensing system at an LTCF. Pharmacists who serve LTCFs should investigate the use of automated dispensing systems. The potential public health and safety benefits are significant.

Item 2131 – Frequently Asked Questions on the Board's Web site

The Board reminds pharmacists to monitor the Board Web site – *www.ncbop.org* – frequently for updates. Among the tools available on the Web site is a Frequently Asked Questions (FAQs) section for pharmacists and consumers. Board staff constantly update and add FAQs, which, as the name states, cover the most commonly asked questions asked of Board staff. Board staff is happy to answer your questions via e-mail and telephone, but when a pharmacist has a particularly urgent need for an answer to a legal question, the FAQs section is a good first source.

Board staff are aware that some pharmacy employers do not afford pharmacists any Internet access in the pharmacy. Board staff appreciates the need to balance workplace productivity concerns with Internet access. Even so, employers should, at the very least, implement systems to allow pharmacists limited access to sites like the Board's Web site, Food and Drug Administration's Web site, DEA's Web site, and other sites that provide crucial, timely, and constantly updated information for practicing pharmacists. Such access can contribute meaningfully to the protection of the public health and safety.

Item 2132 – North Carolina Pharmacists in the National Spotlight

Bruce Canaday presently serves as president of APhA. Kerr Drug pharmacist **Ron DeVizia** was featured in the October 2006 issue of *Pharmacy Today*. The article described Ron spearheading Kerr's diabetes education and care programs. The November 2006 issue of the *American Journal of Health-System Pharmacy* featured an interview with New Hanover Regional Medical Center pharmacist **Jennifer Askew** that detailed Jennifer's efforts to ensure that patients caught in the vice of patient assistance programs/Medicare Part D eligibility requirements continue to have access to prescription medications. Coastal Area Health Education Center pharmacist **Molly Graham** was elected to be the new practitioner representative to APhA's specialty pharmacy practice section.

The *North Carolina Board of Pharmacy News* is published by the North Carolina Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

Jack W. "Jay" Campbell, IV, JD, RPh - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Larissa Doucette - Editorial Manager

National Association of Boards of Pharmacy Foundation, Inc
1600 Feehanville Drive
Mount Prospect, IL 60056

NORTH CAROLINA BOARD OF PHARMACY

Presorted Standard
U.S. Postage
PAID
Chicago, Illinois
Permit No. 5744