April 2006

North Carolina Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

Item 2105 – New Executive Director Named

After a nationwide search, the North Carolina Board of Pharmacy has selected **Jay Campbell** to succeed David Work as executive director. Jay is a 1993 graduate of the University of North Carolina (UNC) School of Pharmacy and a 1997 graduate of the Vanderbilt University School of Law. His prior experience includes tenure as a researcher at a pharmaceutical company, a relief pharmacist for a chain drug company, a practicing lawyer in Washington, DC and Charlotte, NC, and a lecturer in pharmacy law at the Wingate University School of Pharmacy.

Jay has been serving as associate executive director since February, 2006, and will move into the executive director position sometime in April 2006. He looks forward to the challenges and rewards of this position.

Feel free to contact him at the Board's office or via e-mail at jcampbell@ncbop.org.

Item 2106 – Board Elections For Districts 1 and 2

Board seats for District 1 (presently held by Rebecca Chater) and District 2 (presently held by Betty Dennis) are up for election in April 2006, with votes to be counted at 5 PM on May 15, 2006, in the Board office. Pharmacists licensed in North Carolina and residing in these districts should be on the lookout for their ballots this month.

Item 2107 – Registration of Pharmacy Students Who Are Employed As Pharmacy Technicians

The Board has received a number of inquiries as to whether or not and under what circumstances a student who is enrolled in a pharmacy program must register as a pharmacy technician. If a pharmacy student is employed at a pharmacy as a technician, then the student must register with the Board as a pharmacy technician. If a student is working at a pharmacy as part of a school-sponsored experiential program – ie, the student is not employed, but is receiving instruction pursuant to a preceptor-student relationship – then the student does not have to register with the Board as a technician.

Item 2108 – Upsurge in Child Deaths Attributable To Unintentional Methadone Overdoses

Between 2000 and 2004, the North Carolina Department of Health and Human Services (DHHS) recorded 24 fatalities in adolescents and children caused by unintentional methadone overdoses. The deaths are attributable to recreational use of methadone poached from another patient's supply. Methadone has an extremely long half-life and remains active in a patient's body for several days. A methadone overdose results in severe, sometimes fatal, respiratory depression.

The Board strongly encourages pharmacists to counsel their patients receiving methadone for pain management about the severe danger that recreational use of methadone poses, particularly to children and adolescents. Pharmacists should instruct patients to keep their methadone supply secure, not to leave it where others – especially children – can get it, and to call 911 immediately if they suspect someone has taken methadone and is having trouble breathing.

For more information about methadone overdoses in children, please contact:

Kay Sanford, MSPH; Head, Injury Epidemiology Unit
Injury and Violence Prevention Branch
NC-DHHS Division of Public Health
1915 Mail Service Center
Raleigh, NC 27699-1915
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Item 2109 – ID Checks and Controlled Substances

The Board has been informed of several instances of a person calling a pharmacy and having a patient's controlled substance (CS) prescriptions transferred to a second pharmacy. The caller then picks up the prescription at the second pharmacy, which does not obtain proof of identification, thereby allowing the caller to divert CS.

Board Rule .1817 provides that "[a]s a precondition to filling any prescription or dispensing any drug, a pharmacist or person acting at the direction of a pharmacist may demand, inspect, and record proof of identification, including valid photographic identification, from any patient presenting a prescription or any person acting on behalf of the patient." Furthermore, a pharmacist "may exercise discretion and refuse to fill any prescription or dispense any drug if unsatisfied as to the legitimacy or appropriateness of any prescription presented, the validity of any photographic identification or the identity of any patient presenting a prescription . . . ."

The Board strongly encourages pharmacists to exercise the authority granted by Rule .1817 to prevent CS diversion specifically, and to protect patient safety, confidentiality, and health generally.

Item 2110 – CE Requirement Changes Coming in 2008

The North Carolina General Assembly has authorized the Board of Pharmacy, **effective January 1, 2008,** to "require licensees to obtain up to 30 hours of continuing education [CE] every two years from Board-approved providers as a condition of license renewal, with a minimum of 10 hours required per year." Thus, the new CE requirements will first apply to **renewals for 2009**. The Board has not yet promulgated regulations pursuant to this statutory authorization.

Item 2111 – Additional ID Required

Effective April 1, 2006, the Board requires that a copy of a valid photographic identification accompany all **pharmacy technician and Durable Medical Equipment applications.** There have been a couple

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FDA Cautions Consumers About Filling US Prescriptions Abroad

Food and Drug Administration (FDA) issued a warning to health care professionals and consumers that filling their prescriptions abroad may have adverse health consequences due to the confusion with drug brand names that could inadvertently lead consumers to take the wrong medication for their condition. In an investigation, FDA has found that many foreign medications, although marketed under the same or similar-sounding brand names as those in the United States, contain different active ingredients than in the US. Taking a different active ingredient could potentially harm the user.

FDA found 105 US brand names that have foreign counterparts that look or sound so similar that consumers who fill such prescriptions abroad may receive a drug with the wrong active ingredient. For example, in the United Kingdom, Amyben®, a brand name for a drug product containing amiodarone, used to treat abnormal heart rhythms, could be mistaken for Ambien®, a US brand name for a sedative. Using Amyben instead of Ambien could have a serious adverse outcome. For more information on this topic visit www.fda.gov/oc/opacom/reports/confusingnames.html.

Safety Can Not be Sacrificed For Speed

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: Typically, pharmacies have developed well-established methods for monitoring the accuracy of the dispensing process. But today, pharmacy work is increasingly stressful and these checks and balances can easily be strained beyond capacity. With an increasing number of prescriptions and a shortage of qualified pharmacists, conditions are ripe for potentially unsafe working conditions – long hours without breaks; multitasking between answering phones, overseeing other pharmacy staff, dispensing prescriptions, and counseling patients; and ever-increasing time spent attending to insurance issues. Inevitably, these conditions can increase the chance for dispensing errors.

One pharmacy knows this all too well after a five-year-old boy died as a result of an order entry and medication compounding error that was not caught by the usual verification process. In this case, imipramine was dispensed in a concentration five times greater than prescribed. Imipramine is a tricyclic antidepressant used to treat adults, but it is also used to treat childhood enuresis. An extemporaneous solution was to be prepared at this pharmacy that specialized in compounded prescriptions since a liquid formulation was not commercially available. A pharmacy technician incorrectly entered the concentration of the prescribed solution into the computer as **50 mg/mL** instead of **50 mg/5 mL**, along with the prescribed directions to give 2 tsp at bedtime. He then proceeded to prepare the solution using the incorrect concentration on the label rather than the concentration indicated on the prescription. When the compound was completed, the technician placed it in a holding area to await a pharmacist's verification. At this time, one of the two pharmacists on duty was at lunch and the high workload of the pharmacy made it difficult for the pharmacist to check the prescription right away. When the child's mother returned to pick up the prescription, the cash register clerk retrieved the prescription from the holding area without telling a pharmacist, and gave it to the mother, unaware that it had not yet been checked. At bedtime, the mother administered 2 tsp of the drug (500 mg instead of the intended 100 mg) to the child. When she went to wake him the next morning, the child was dead. An autopsy confirmed imipramine poisoning.

There are many factors that contributed to this error including inaccurate order entry and issues related to high workload. However, a critical breakdown in safety processes occurred when the cash register clerk took the prescription from the pharmacy holding area (to prevent the mother from waiting any longer for the prescription), thereby circumventing the usual pharmacist verification process.

While this error underscores a growing problem in health care, the problem was clearly evident to this pharmacy owner – even a year before the error occurred. When interviewed for an article that appeared in a national publication, he vented his frustrations about the scant attention paid in our society to pharmacist workload difficulties faced in today's health care environment. On the day of the interview, 49 prescriptions were in the process of being prepared and about a dozen patients were standing in line or wandering around the store waiting for prescriptions. Yet this was a slow day. The owner also said that, while managed care had reduced profits considerably over the past several years, prescription volume had increased 50% (at the time of the error, the pharmacy was dispensing about 10,000 prescriptions per month versus 7,000 per month during the prior year, without an increase in staff) and medication regimens and drug interactions were more complex. To overcome these barriers, the owner added private consultation areas for patient counseling; installed a $175,000 robot that accurately dispenses the 200 most common drugs; and diversified sales to offset full-time pharmacists' salaries. But these efforts could not have prevented this tragic fatal error that circumvented the normal safety processes.

Safe Practice Recommendations: The environment and demands placed on health professionals significantly affect their ability to provide safe health care services. While technology such as robots can help, overstressed professionals cannot consistently perform at the maximum level of safety. Therefore, it is important that the public and health care leadership understand this problem so they can be more open to tradeoffs, such as working

with one patient at a time and incurring longer turnaround times, which are necessary to enhance patient safety. With a shortage of qualified professionals, we need to demand more rapid adoption of computerized prescribing to reduce time spent with prescription transcription. We should identify the biggest distractions that occur in our workplaces and eliminate or reduce the source by batching common interruptions and reorganizing work areas. Staff members need to be properly trained to understand safety procedures that are in place and know the limits of their specific duties. Fail-safe processes to ensure an independent double check before dispensing medications and performing other critical processes are a must. The pharmacy where this error occurred now requires two pharmacists to check every prescription. Unfortunately, this level of vigilance is typical after a patient has been harmed from an error. In other pharmacies, especially where there is only one pharmacist on duty, technicians may be involved in the double-check process.

A few other strategies can be used to prevent similar errors:

- Have one person perform order entry and a different person prepare the prescription, if possible, to add an independent validation of the order entry process.
- Do not prepare prescriptions using only the computer-generated label, as order entry may have been incorrect.
- Ensure that the original prescription, computer-generated label, prepared product, and manufacturer's product(s) remain together throughout the preparation process.
- Verify dispensing accuracy by comparing the original prescription with the labeled patient product and the manufacturer's product(s) used.

NIH Develops Community Drug Alert Bulletin

The National Institute on Drug Abuse, as part of the National Institutes of Health (NIH), has developed a new Community Drug Alert Bulletin that addresses the latest scientific research on the non-medical use of prescription drugs of abuse and addiction.

This bulletin is geared toward parents, teachers, counselors, school nurses, and health professionals who are associated with those at risk from prescription drug abuse for non-medical purposes. It summarizes the growing problem in the US and the trend of non-medical use of prescription drugs. For more information on this bulletin visit www.nida.nih.gov/PrescripAlert/index.html.

Implementation of the Anabolic Steroid Control Act of 2004

According to the December 16, 2005 *Federal Register*, effective January 20, 2005, the Anabolic Steroid Control Act of 2004 amended the Controlled Substances Act (CSA) and replaced the existing definition of "anabolic steroid" with a new definition. This new definition changed the basis for all future administrative scheduling actions relating to the control of the anabolic steroids as Schedule III controlled substances (CS) by eliminating the requirement to prove muscle growth. Also, the Act lists 59 substances as being anabolic steroids; these substances and their salts, esters, and ethers are Schedule III CS. The Act also revised the language of the CSA requiring exclusion of certain over-the-counter products from regulation as CS.

According to the House Report, the purpose of the Act is "to prevent the abuse of steroids by professional athletes. It will also address the widespread use of steroids and steroid precursors by college, high school, and even middle school students."

The changes to the definition include the following:

- Correction of the listing of steroid names resulting from the passage of the Anabolic Steroid Control Act of 1990.
- Replacement of the list of 23 steroids with a list of 59 steroids, including both intrinsically active steroids as well as steroid metabolic precursors.
- Automatic scheduling of the salts, esters, and ethers of Schedule III anabolic steroids without the need to prove that these salts, esters, or ethers promote muscle growth.
- Removal of the automatic scheduling of isomers of steroids listed as Schedule III anabolic steroids.
- Addition of dehydroepiandrosterone to the list of excluded substances.

FDA Unveils New Package Insert Format

On January 18, 2006, FDA unveiled a major revision to the format of prescription drug information, commonly called the package insert, which will give health care professionals clear and concise prescribing information. This new format was developed in order to manage the risks of medication use and reduce medical errors; the new package insert will provide the most up-to-date information in an easy-to-read format. This new format will also make prescription information more accessible for use with electronic prescribing tools and other electronic information resources.

Revised for the first time in more than 25 years, the new format requires that the prescription information for new and recently approved products meet specific graphical requirements and includes the reorganization of critical information so physicians can find the information they need quickly. Some of the more important changes include:

- A new section called *Highlights* to provide immediate access to the most important prescribing information about benefits and risks.
- A table of contents for easy reference to detailed safety and efficacy information.
- The date of initial product approval, making it easier to determine how long a product has been on the market.
- A toll-free number and Internet reporting information for suspected adverse events to encourage more widespread reporting of suspected side effects.

This new format will be integrated into FDA's other e-Health initiatives and standards-settings through a variety of ongoing initiatives at FDA. For more information please visit www.fda.gov/cder/regulatory/physLabel/default.htm.

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of recent instances in which personal information provided on an application could not be verified by Board staff. This new requirement is designed to assist in the verification process. After information on the application is confirmed, the copy of the photographic identification will be destroyed.

Item 2112 – Renewal Period Ended February 28, 2006

The grace period for 2006 license renewals ended on February 28. Any practitioner who did not renew prior to that date must now apply for reinstatement and renewal and tender the appropriate fees.

Item 2113 – Assistance for Project Needed

Drug-Induced Liver Injury Network (DILIN), is a National Institutes of Health-funded project designed to further define the mechanisms and risk factors for liver injury due to drugs or complementary/alternative medicine products. UNC-Chapel Hill is one of the clinical sites and the Duke Clinical Research Institute is the data coordinating center. Two studies are currently enrolling subjects who have had a liver injury suspected to be due to drugs or complementary/alternative medicine products. Both studies will create a registry of clinical information and biological samples to be used for future research on the mechanisms and potential risk factors for liver injury.

To date, the registry has enrolled 157 subjects. The most commonly implicated products are antibiotics (57 cases), non-steroidal anti-inflammatory drugs (8 cases), anticonvulsants (14 cases), and antivirals/antituberculars (12 cases). The DILIN needs your help: (1) Finding people who are suspected to have had drug-induced liver injury; UNC staff will handle all the logistics related to subject enrollment, and (2) Providing ideas on how to get out the word about the study at your practice location, such as opportunities for grand rounds, people to contact, CE talks, newsletters, signs, etc.

For more information contact:
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Item 2114 – Dispensing Isotretinoin

Thanks to Joyce Altsman, state news editor of the Alabama State Board of Pharmacy Newsletter, *for allowing us to reprint this article from its February 2006* Newsletter.

Pharmacies must register to continue dispensing isotretinoin products. United States Food and Drug Administration (FDA) has approved iPLEDGE™, an enhanced risk management program designed to minimize fetal exposure to isotretinoin. iPLEDGE will require mandatory registration of prescribers, patients, wholesalers, and pharmacies to further the public health goal to eliminate fetal exposure to isotretinoin. Starting December 30, 2005, unregistered and activated pharmacies were no longer able to dispense Accutane® (isotretinoin), Amnesteem®, Claravis™, or Sotret® to people with severe acne without enrolling in FDA's new iPLEDGE program through a physician who is enrolled.

Pharmacies have two steps in preparing their pharmacies to dispense isotretinoin prescriptions under iPLEDGE: "registration" and "activation." (After a pharmacy registers for iPLEDGE on www.ipledgeprogram.com or by calling **1-866/495-0654**, the "Responsible Site Pharmacist" is sent a follow-up mailing, which contains instructions on how to activate their pharmacy.)

Pharmacies that have not registered and activated by December 30, 2005, will not be eligible to order isotretinoin from their wholesaler and must return all unused products to the manufacturer.

Patient registration began December 30, 2005. Patients currently being treated with isotretinoin may register in the iPLEDGE program or continue in their current program until February 28, 2006.

Starting March 1, 2006, all patients taking isotretinoin must be registered in the iPLEDGE program.

Wholesalers that did not register by December 30, 2005, are not eligible to order isotretinoin from manufacturers and must return all unused product to the manufacturer.

Prescribers who have not registered and activated by March 1, 2006, [are] not eligible to prescribe isotretinoin for patients.

Be sure to let dermatologists in your area know that your pharmacy is authorized to dispense isotretinoin.

To register and activate your pharmacy, visit www.ipledgeprogram.com or call 1-866/495-0654.

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