October 2005

North Carolina Board of Pharmacy

PO Box 4560, Chapel Hill, NC 27515-4560
6015 Farrington Rd, Suite 201
Chapel Hill, NC 27517
Tel: 919/942-4454 Fax: 919/967-5757
Web site: www.ncbop.org

Published to promote voluntary compliance of pharmacy and drug law.

Item 2083 – Disciplinary Actions

Full Hearing: 1

Consent Order: 1

The Consent Order was accepted in lieu of full administrative hearing by a pharmacist for diverting controlled substances without a prescription. The license, which had been voluntarily surrendered, reinstated with specific conditions.

Reinstatement Order: 3 with specific conditions to be met.

Prehearing Conference:

Suspension with Stay and conditions: 1 [pharmacist]

Letter of Concern: 1 [pharmacy]

Warning: 1 [pharmacist]

The Suspension with a Stay order was issued in regards to the pharmacist writing four fraudulent prescriptions in 2002, and dispensing medications on these prescriptions.

The Letter of Concern was issued regarding the dispensing of potassium chloride 20% on a prescription order for potassium chloride 10%; excessive dispensing of prescription drugs; and exceeding the pharmacist-technician supervision ratio.

The Warning for the pharmacist was issued for the dispensing of an adulterated EpiPen® to a patient.

Item 2084 – New Fees

During the 2005 session of the General Assembly, the North Carolina Board of Pharmacy increased its fee structure. The significant new fees are: Pharmacist License Renewal $135; Pharmacy Permit Renewal $200; Original Pharmacy Permit $500; Dispensing Physician Renewals $75; Durable Medical Equipment (DME) Renewals $200; Original DME Permit $500; and Pharmacy Technician Renewal $30. Other fees increased regarding the application process for registering for the examination and reciprocating to North Carolina.

Item 2085 – Board Member Election

At the July 2005 Board meeting, ballots from the run-off election between Joey McLaughlin and Tim Giddens were counted. The results are listed below.

Tim Giddens – 1,083 Joey McLaughlin – 1,411

Joey McLaughlin was certified as the winner for District 5 and will begin serving a five-year term on the Board beginning in May 2006. Mr McLaughlin will replace Bob Crocker, who ends 10 years of service on the Board.

Item 2086 – Evaluation of Unit Dose Packaging Dispensed to Outpatients for Child Resistant Features

The North Carolina Board of Pharmacy frequently receives queries from pharmacists on whether or not the unit dose packaging that is dispensed to outpatients is considered "child resistant." Based upon the need to provide information to pharmacists on the child resistant nature of unit dose packaging dispensed to outpatients, the Board requested the assistance of Campbell University School of Pharmacy Department of Clinical Research to evaluate the matter.

In order to fulfill the requirements of dispensing medicines in packaging that meets child-resistant requirements, pharmacists may utilize the packaging described on the Board's Web site. Of note, zip lock bags are not child resistant. To be child resistant, the reclosable bag must contain a child-resistant feature. Further, to be child resistant, blister packaging requires at least one child-resistant feature. Before using any packaging described as child resistant pharmacists should confirm with the manufacturer whether or not suitable testing has been performed.

The complete synopsis of this research can be found on the Board's Web site at "Child Resistant Features of Unit Dose Packaging."

Research provided by Brenda Jamerson, PharmD, associate professor, Campbell University Department of Clinical Research.

Item 2087 – Online Renewals

Beginning November 1, 2005, pharmacists, pharmacies, DME facilities, and technicians can renew their licenses and permits online to practice pharmacy for the 2006 calendar year. Please go to the Board's Web site, www.ncbop.org and follow the prompts. While there is a small charge for this service it does enable pharmacists and others to get immediate evidence of renewal and the speedy processing of

Continued on page 4

DEA Amends Rule for Reports of Theft or Significant Loss of Controlled Substances

Drug Enforcement Administration's (DEA) amended regulations regarding reports by registrants of theft or significant loss of controlled substances became effective September 12, 2005. Changes were made to the regulations, found in Title 21 of the Code of Federal Regulations, Part 1300 to 1399, due to confusion as to what constitutes a significant loss and when and how initial notice of a theft or loss should be provided to DEA. Specifically, DEA made changes in order to clarify the exact meaning of the phrases "upon discovery" and "significant loss."

Regarding the timing of initial theft or loss reports, DEA inserted the word "immediately" before the phrase "upon discovery." While DEA Form 106 is not immediately necessary if the registrant needs time to investigate the facts surrounding a theft or significant loss, he or she should provide, in writing, initial notification of the event. This notification may be a short statement provided by fax. DEA notes that faxing is not the only method a registrant may use, but that the notification should be in writing. If the investigation of a theft or significant loss lasts longer than two months, registrants should provide updates to DEA.

To help registrants determine whether or not a loss is "significant," DEA has added to the rule a list of factors to be considered. DEA recognizes that no single objective standard can be applied to all registrants – what constitutes a significant loss for one registrant may be construed as comparatively insignificant for another. If a registrant is in doubt as to whether or not the loss is significant, DEA advises the registrant to err on the side of caution in alerting the appropriate law enforcement authorities.

Regarding "in-transit losses of controlled substance," DEA intends that all in-transit losses be reported, not just significant losses; therefore, the text is being amended to reflect this.

Changes to the regulations were reported in the August 12, 2005 edition of the *Federal Register*.

FDA Releases Update on Combating Counterfeit Drugs

Food and Drug Administration (FDA) recently released "Combating Counterfeit Drugs: A Report of the Food and Drug Administration Annual Update (Update)." This Update follows up on the agency's initial February 18, 2004 report addressing counterfeit drugs. Since the 2004 report, which identified measures that can be taken to better protect Americans from counterfeit drugs, FDA has worked with manufacturers, wholesale distributors, pharmacies, consumer groups, technology specialists, standard setting bodies, State and Federal agencies, international governmental entities, and others to advance the measures outlined in the 2004 report such as the development and implementation of electronic product codes and radio frequency identification. In its 2005 Update, FDA notes that significant progress is being made in securing drug products and packaging, securing the movement of the product, enhancing regulatory oversight, increasing penalties for counterfeiters, heightened vigilance and awareness of counterfeits, and increasing international collaboration. However, more work needs to be done to further secure the United States' drug supply.

In 2004, FDA's Office of Criminal Investigations initiated 58 counterfeit drug cases, a significant increase over the 30 cases in 2003; however, the agency notes that this is likely due to increased vigilance. FDA also states that most of the suspect counterfeits discovered in 2004 were found in smaller quantities than those found in 2003.

The Update reviews steps taken and future actions required for track-and-trace technology, authentication technology, regulatory oversight and enforcement (electronic pedigree), state efforts, secure business practices, heightened vigilance and awareness, counterfeit alert network, and education. The full Update can be accessed at www.fda.gov/oc/initiatives/counterfeit/update2005.html.

"Fax noise" = Medication Errors in the making

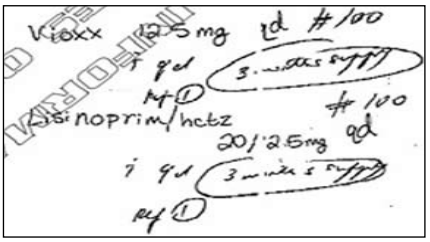
This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other 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, Suite 810, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

Problem: Most health care practitioners would agree that fax machines have facilitated communication of prescriptions. But there are inherent problems associated with this technology. In fact, an article in the *Journal of Managed Care Pharmacy* found that prescriptions received by fax required a greater number of clarification calls than those received by other methods of communication.[1] ISMP received a report from a long-term care facility about a patient who had been

receiving **Neurontin**® (gabapentin) 600 mg TID [three times a day]. However, an order had been faxed to the pharmacy to change the Neurontin dose to "**300 mg** 1 tab QID [four times a day]." The change was made and the new dose was sent to the facility. Later, when the pharmacist received the original order from the long-term care facility and compared it with the faxed copy, he realized that the physician had actually requested a change to "**800 mg** 1 tab QID." The left side of the order had been cut off during the fax transmission, making the "8" look like a "3." Fortunately, since the pharmacist had been sent the original order for comparison, he quickly realized the mistake. Unfortunately, not all pharmacies receive the original prescription for comparison purposes.

In another report received by ISMP, a faxed prescription was received at a pharmacy for what appeared to be **Monopril**® (fosinopril) **10 mg** #90 one tablet daily. Despite the fact that the fax machine created a definite vertical streak that ran between the drug name and the strength, the pharmacist felt confident in her interpretation of the prescription. Unfortunately, it was later discovered that the prescription was actually for **40 mg**. The streak had run through the "4" in 40 mg, making it look like 10 mg instead.

The following prescription (see image below) was faxed to a mail-order pharmacy. Look at the bottom order for "Lisinopril/hctz." (Note: ISMP does not condone the use of the abbreviation "hctz.") The pharmacist interpreted this order as "20/25 mg." But what the prescriber had actually written was "20/12.5 mg." A subtle vertical gap in the faxed copy (which can be seen "breaking" the circles around "3 months supply") had obliterated the "1" in 12.5. In addition, the pharmacist reading the order had misinterpreted the decimal point as one of many stray marks on the faxed prescription.



Safe Practice Recommendations: "Fax noise" (the random marks and streaks on faxes) is an inherent problem with this form of communication, which may be more common in old or poorly maintained fax machines. Usually, fax noise is just an inconvenience. In the case of prescriptions, however, there is a very real chance that a patient could be harmed by misinterpretations caused by fax noise. To manage this risk, safeguards should be instilled into the fax process. Such safeguards include a careful review of all prescriptions received by fax for fax noise. If the transmission has fax noise in the area of the order, the prescriber should be contacted to confirm the prescription. Whenever possible, compare the faxed order against the original prescription. Prescribers should consider giving a copy of the prescription to the patient to present at the pharmacy for verification. To prevent confusion or duplication of the prescription at a different pharmacy, the copy could be stamped with a statement such as "Verification Copy ONLY" to indicate that the prescription was already faxed to a particular pharmacy. Maintenance should be regularly scheduled for fax machines on both the sending and receiving end. If maintenance fails to improve fax quality, the machine should be replaced.

[1.] Feifer RA et al. Mail-order prescriptions requiring clarification contact with the prescriber: prevalence, reasons, and implications. *JMCP* 2003;9:346-352.

December 2005 FPGEE Date and Locations Announced

On December 3, 2005, NABP will again administer a paper-and-pencil Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®). The examination is being offered at three United States locations: Northlake (Chicago area), IL; New York, NY; and San Francisco, CA. Candidates who have been accepted to sit for the December 3, 2005 administration were mailed their admission tickets in early fall.

To prepare for the December examination, candidates may take the Pre-FPGEE®, a Web-based practice examination for the FPGEE. The practice examination is accessible at www.nabp.net and www.pre-fpgee.com.

For more information on the FPGEE, visit NABP's Web site at www.nabp.net.

2006 Survey of Pharmacy Law

NABP's *2006 Survey of Pharmacy Law* CD-ROM will be available in late November 2005. New topics include the number of wholesale drug distributors and laws and/or regulations concerning the sales of over-the-counter pseudoephedrine, and information concerning emergency contraception.

The *Survey* consists of four sections: organizational law, licensing law, drug law, and census data. Most charts specify terms that can be used when conducting searches on NABP's NABPLAW® Online state pharmacy law and rules database. The *Survey* can be obtained for $20 from NABP by downloading the publication order form from www.nabp.net and mailing in the form and a money order to NABP. The CD-ROM is provided free of charge to all final-year pharmacy students through a grant from AstraZeneca Pharmaceuticals. If you do not have Web access or would like more information on the *Survey*, please contact NABP at 847/391-4406 or via e-mail at custserv@nabp.net.

Continued from page 1

their applications. **This is especially important for hospital pharmacists who may be facing a Joint Commission on Accreditation of Healthcare Organizations visit early in 2006.** There is no doubt that online renewals are the quickest and most certain way to provide evidence of current licensure. An immediate confirmation is available for **all** online renewals with certificates being mailed within approximately three days of the online process.

As in the recent past no pharmacist paper renewals will be mailed. If a paper renewal is required for any application (pharmacists, pharmacy, technicians, physician dispensing, etc) it may be downloaded from the Board's Web site at www.ncbop.org under "Downloadable Forms" on the home page. While the paper process for renewals is still available the processing time is expected to take at least three to four weeks for these applications. You are encouraged to take advantage of the online renewal process.

Item 2088 – Other State Licensing Boards

Pharmacists may, on occasion, wish to contact the North Carolina Medical or Nursing Board; contact information can be found on the Board's Web site under "Professional Pharmacy Resources."

Item 2089 – Medicare Drug Benefit

Beginning in January 2006, Medicare beneficiaries may be eligible for an outpatient prescription drug benefit. Many educational efforts are now in progress on that issue.

If any of your patients or customers have complaints about this benefit they should register their complaint with their senators and members of Congress in Washington. Individual addresses for these people can be found on the Board's Web site under "Something Needs To Be Done About That." All the consumer needs is his or her zip code to determine the name of his or her representative in Washington.

Item 2090 – Official Notice

The North Carolina Board of Pharmacy has designated this *Newsletter* as an official method of notifying pharmacists licensed by the Board about information, regulation changes, and legal developments. Copies of this *Newsletter* may be used in hearings as proof of notification to pharmacists.

Item 2091 – Public Hearing on Proposed Rules

The Board will hold a public hearing on October 17, 2005, at noon, at the Sheraton Imperial Hotel in Durham to consider proposed rules. Many changes will be considered including standards for reinstatement of licensure, an increase in the number of continuing education hours, temporary pharmacist-managers, limiting a rule to antineoplastic agents, and a rule on Board certification of pharmacy technicians.

The comment period for these rules ends November 5, 2005, but it is always preferable to make your points in person if possible. The complete language of the rules to be considered can be found on the Board's Web site at www.ncbop.org under "New Developments."

Item 2092 – Retirement Plans of Executive Director Work

At the September 2005 meeting of the North Carolina Board of Pharmacy, President Betty H. Dennis announced that the Board's Executive Director, David Work, plans to retire in early 2006. She appointed a search committee consisting of Parker Chesson, PhD, the Board's public member, who will serve as chairman of the committee; Stan Haywood; and Betty Dennis.

Interested applicants should contact Dr Chesson at PO Box 4560, Chapel Hill, NC 27515.

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.

David R. Work, JD, RPh - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Larissa Doucette - Editorial Manager

NORTH CAROLINA BOARD OF PHARMACY

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

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