October 2004

North Carolina Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

Item 2051 – Disciplinary Actions June-July

Consent Order: 24 pharmacy permits; 1 pharmacist

Reinstatement of Pharmacist License with Specific Conditions: 3

The Consent Orders entered for pharmacy permits were cases heard in Prehearing Conferences regarding dispensing errors. The Consent Orders included 22 Warnings and 2 Reprimands for these activities.

The Consent Order entered for the pharmacist was issued in lieu of an Administrative Hearing for consumption of controlled substances without authorization and the improper waste of morphine.

Item 2052 – Technician Expansion

The North Carolina Board of Pharmacy adopted rules that now allow certified pharmacy technicians, at the discretion of the pharmacist-manager, to transfer and receive prescriptions. It is important to note that these are technicians who have been successful on the Pharmacy Technician Certification Board's National Pharmacy Technician Certification Examination. This is a level above the normal registration of technicians required by North Carolina Statute.

Technician activity is under the general supervision of the pharmacist-manager at any pharmacy permit location. Their activity includes technical functions to assist the pharmacist in preparing and dispensing prescription medications.

Item 2053 – Clinical Pharmacist Practitioners

Great progress has occurred with clinical pharmacist practitioners (CPP) in health care. The Board recently revised its rules to provide that CPPs can order controlled substances and Drug Enforcement Administration (DEA) has ruled that they are eligible for DEA registration as a mid-level practitioner.

CPPs need to be aware that there is federal legislation, House Bill 4724, that would provide for fair payments for CPPs' services. This Bill is still in Congress and you may want to contact your congressperson or senator on this topic. If you wish to follow up on this issue you should contact Fred Eckel, RPh, executive director of the North Carolina Association of Pharmacists, at 1-800/852-7343.

Another part of the Board's rules states that CPPs shall wear a name tag spelling out the words "Clinical Pharmacist Practitioner."

Item 2054 – AB Rating for NTI Drugs

The question has arisen regarding one product that is listed on the Board's Narrow Therapeutic Index (NTI) list that has just been approved by Food and Drug Administration (FDA) with an AB Rating. The question facing pharmacists is "Can prescriptions for this drug, levothyroxin, now be filled according to the Board's Product Selection Law with a generic product?"

Pharmacists should be aware that the NTI drug concept is found in North Carolina's Product Selection Law, G.S. 90-85.27 and .28.

Levothyroxin qualifies as an NTI drug under this statute, which means that pharmacists need to obtain the documented consent of the prescriber and the patient prior to switching manufacturers on refills. An AB Rating by FDA in its "Orange Book" publication does not change the application of the NTI concept as noted above.

Item 2055 – Medicaid Bulletin Online

Pharmacists who want the most up-to-date information on Medicaid are able to access this information through www.dhhs.state.nc.us/dma. This is a useful information source that pharmacists should use to get answers to their questions.

Item 2056 – Electronic Renewals

The Board is moving forward by providing online renewals for 2005 renewals in several areas:

- Pharmacists
- Pharmacy permits
- Pharmacy technicians
- Durable Medical Equipment (DME) permits

While there is a small charge for this service, it does enable pharmacists and others to obtain immediate evidence of renewal and the speedy processing of their applications. This is especially important for hospital pharmacists who may be facing a visit from the Joint Commission on Accreditation of Healthcare Organizations in early 2005. There is no doubt that online renewals are the quickest and most certain way to provide evidence of current licensure.

No pharmacist renewal applications will be automatically mailed. The renewal process begins on November 1, 2004, and pharmacists should visit the Board's Web site, www.ncbop.org, and follow the prompts under electronic renewals. An immediate confirmation is available for **all** online renewals with certificates being mailed within approximately three days of the online process.

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National Pharmacy Compliance News

(Applicability of the contents of articles in the National Pharmacy Compliance News to a particular state or jurisdiction should not be assumed and can only be ascertained by examining the law of such state or jurisdiction.)

New Over-the-Counter Product Labeling

On March 24, 2004, Food and Drug Administration (FDA) passed final rulings requiring content labeling for over-the counter (OTC) medications that contain levels of calcium, magnesium, sodium, or potassium that might be harmful to persons with certain underlying medical conditions. The final rule was effective April 23, 2004, with compliance expected by September 24, 2005. The labeling changes for oral OTC products were deemed necessary as persons with certain medical conditions such as heart disease, hypertension, kidney disease, kidney stones, or other medical conditions could worsen their condition upon consumption of these products. For example, OTC use of medications containing potassium may cause hyperkalemia in persons with compromised renal function. Under the new rules, oral OTC medications must state the exact amount of a particular ingredient in each dose if they contain:

- 5 mg or more of sodium in a single dose,
- 20 mg or more of calcium in a single dose,
- 8 mg or more of magnesium in a single dose, or
- 5 mg or more of potassium in a single dose.

The rules also require warnings to alert consumers on sodium-, calcium-, magnesium-, or potassium-restricted diets to consult their physician before using oral products that contain maximum daily doses of:

- more than 140 mg sodium,
- more than 3.2 grams calcium,
- more than 600 mg magnesium, or
- more than 975 mg potassium.

Currently the new label requirements do not include mouth rinses, fluoride toothpastes, or mouth washes. Detailed information on the rulings can be found in the Federal Register at www.fda.gov/OHRMS/DOCKETS/98fr/04-6479.htm and www.fda.gov/OHRMS/DOCKETS/98fr/04-6480.htm.

FDA Requests Antidepressant Manufacturers to Strengthen Warnings

On March 22, 2004, FDA issued a public health advisory that cautions physicians, their patients, and families and caregivers to closely monitor adults and children with depression. Results of antidepressant studies in children since June 2003 appeared to suggest an increased risk of suicidal thoughts and actions in those children taking certain antidepressants. FDA has initiated a review of these reports, but it is not clear whether or not antidepressants contribute to suicidal thinking and behavior.

As a result of the studies, FDA is asking manufacturers to change the labels of 10 drugs to include stronger cautions and warnings to monitor patients for worsening depression and the emergence of suicidal ideation. The drugs affected include bupropion (Wellbutrin®), citalopram (Celexa™), escitalopram (Lexapro™), fluvoxamine (Luvox® – not FDA approved for treatment of depression in the US), fluoxetine (Prozac®), mirtazapine (Remeron®), nefazodone (Serzone®), paroxetine (Paxil®), venlafaxine (Effexor®), and sertraline (Zoloft®). It should be noted that Prozac is the only drug approved for use in children with major depressive disorder. Prozac, Zoloft, and Luvox are approved for pediatric patients with obsessive-compulsive disorder.

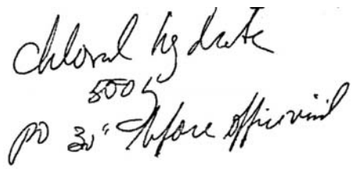
Patients taking these antidepressants should be monitored for behaviors associated with the drugs such as anxiety, agitation, panic attacks, insomnia, irritability, hostility, impulsivity, akathisia, hypomania, and mania. Physicians are urged to closely monitor patients with bipolar disorder as monotherapy with antidepressants is believed to have the potential to induce manic episodes in such patients. A causal relationship has not been established between physical symptoms and suicidal ideation; however, medications may need to be discontinued when the symptoms are severe, abrupt in onset, or were not part of the presenting symptoms. Further information can be found on CDER's Web site: www.fda.gov/cder/drug/antidepressants/default.htm.

Let Past Experience with Chloral Hydrate Syrup Guide its Safe Use

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.

Chloral hydrate can be used safely to sedate pediatric patients for diagnostic procedures such as endoscopic procedures, CT scans, or MRIs. However, in several error reports over the years we have seen the sad stories of fatalities that have occurred after excessive doses of the drug were dispensed in error. Typically, deaths have occurred in cases where the order was not clear or when untrained individuals, both staff and parents, were involved without adequate supervision or the knowledge that they were administering an overdose. In some cases, to save time, chloral hydrate has been prescribed for use at home prior to travel to the practice site. In one instance, a 500 mg/5 mL concentration was dispensed instead of 250 mg/5 mL, which also is available. Unfortunately, the dose was prescribed by volume (teaspoonful), which made detection of the twofold overdose impossible. In another incidence, 120 mL of syrup was incorrectly dispensed instead of the prescribed 12 mL. The label instructed the mother to give her child the entire bottle, which she did. Without trained personnel and emergency equipment present to treat these accidental overdoses, the children in both cases died.

Recently the tragedy happened again. A prescription was written for a 17-month-old child; the pharmacist read the directions as "30 cc before office visit" and instructed the mother to give her child that amount. In truth, the physician wanted the child to receive 500 mg 30 *minutes* before the office visit. The double hash-mark symbol ("), which the physician intended to mean minutes, was misread as cc. Actually, a double hash mark stands for seconds; a single hash mark (') is used for minutes. Neither symbol should be used in medicine, however, because not everyone understands their meaning.



Errors also happen in diagnostic areas where technical support personnel often administer oral conscious sedation even though they are not properly trained. In some cases, an ambiguous physician order such as "give chloral hydrate 5 cc prn sedation" or ". . . prn agitation," rather than a specific milligram amount and maximum dose, has led to events where multiple doses of chloral hydrate were dispensed from the supply available to personnel. By the time the child fell asleep, the amount administered was a massive overdose leading to respiratory arrest.

Please consider reviewing your process for dispensing oral liquids used for conscious sedation in children, whether to a medical facility or to a family member. We suggest that the following precautions, in addition to package insert recommendations, be employed. Advise physicians that the drug should not be prescribed by volume (eg, "5 mL," "one teaspoonful," etc). There are two available concentrations of this drug. Instead, the specific milligram dose should be expressed. The prescription should state that it is for pre-procedure sedation. In hospital situations or when pharmacies dispense to health care facilities, prescriptions are best dispensed for each patient in labeled, unit-dose, oral syringes; providing the product in bulk packages as floor stock is less safe. We believe it is safest for pharmacists to *not* dispense prescriptions for patient use in the home when it is for pre-procedure sedation. Should the caregiver receive such a prescription, he or she should be advised that they are safest for the dose to be administered where the procedure will be performed. Official labeling for Versed® Syrup, another drug used for conscious sedation in children, notes that the syrup is intended for use only in monitored settings, never the home. Also, as noted in the product's boxed warning, only health care professionals trained in conscious sedation procedures and authorized to administer conscious sedation drugs should do so. Careful monitoring by direct visual observation is necessary and age-/size- appropriate resuscitation equipment must be readily available. The American Academy of Pediatrics agrees; the Academy's current "Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures" (*Pediatrics* 2002; 110:836-838) recommend that children should not receive sedative or anxiolytic medications without supervision by skilled medical personnel. These medications should be administered by, or in the presence of, individuals skilled in airway management and cardiopulmonary resuscitation and administered in a health care facility where appropriate monitoring, including continuous pulse oximetry, can be instituted.

One final argument for administering children's sedation on site is to ensure proper timing in case of unpredictable schedule delays.

NABP Releases Updated NAPLEX Blueprint

NABP has released the updated blueprint for the North American Pharmacist Licensure Examination™ (NAPLEX®). The blueprint is available for viewing on NABP's Web site, www.nabp.net, as of September 2004. Examinations based on the updated blueprint will be administered beginning spring 2005.

Changes to the NAPLEX blueprint include the addition of competency statements addressing dietary supplements and pharmacotherapeutic equivalency as well as integration of the skill of communicating with patients and other health care providers in the entire examination blueprint instead of focusing it within a single competency area as with the current NAPLEX. The examination continues to consist of three major areas that are divided into several competency and subcompetency statements.

The updated blueprint and competency statements require a new passing standard. However, the NAPLEX continues to be a computer-adaptive examination that requires a scaled score of 75 or greater to pass. Calculation of the score is the same as in the past: the score is calculated by first determining the candidate's ability level on the NAPLEX and then comparing this to the predetermined minimum acceptable ability level established for the NAPLEX. The new passing standard will go into effect along with the updated blueprint in spring 2005.

For more information about the NAPLEX, contact the Customer Service Department by calling 847/698-6227 or visit the Association's Web site at www.nabp.net.

December 2004 FPGEE Date and Location Announced

On December 4, 2004, 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 Mateo, CA. Candidates who have been accepted to sit for the December 4, 2004 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.

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The paper process for renewals is still available; however, the processing time is expected to take at least three to four weeks for these applications. You may download renewal forms from the Board's Web site at www.ncbop.org, located under the "Downloadable Forms" section on the home page.

If you cannot renew online this is a reminder that the Board no longer accepts personal checks. If a personal check is submitted with an application everything is returned to the applicant, which can significantly slow the renewal process. **Remember: No personal checks accepted**.

Item 2057 – Register Pharmacy Technicians

This is a reminder that it is the responsibility of all pharmacist-managers to see to it that **all** of their pharmacy technicians including part-time employees are properly registered with the Board. A pharmacy technician is defined as "An unlicensed person who, under the supervision of a pharmacist, performs technical functions to assist the pharmacist in preparing and dispensing prescription medications. . . ."

This means that all personnel who assist the pharmacist in the pharmacy must be registered with the Board as technicians.

The form for registering technicians can be found on the Board's Web site, www.ncbop.org, under "Downloadable Forms." The annual fee is $25 (no personal checks accepted). If you have further questions about this matter please contact Wanda Andrews at 919/942-4454 ext 222.

Item 2058 – Prescribing Veterinary Drugs

A recent question from a pharmacist pointed out the need to review the matter of prescribing within the scope of practice. Pharmacists are reminded that only veterinarians can prescribe drugs for veterinary use. Likewise, physicians can prescribe only for human use. A prescription written by a physician for an animal is not a valid prescription.

The use of pharmaceuticals is especially critical in food-producing animals. Some pharmaceuticals can produce illegal residues in animals that are later slaughtered for human consumption.

Other common issues in the scope of practice include dentists who can only prescribe within the practice of dentistry and optometrists who can prescribe for conditions of the eye or the adnexa, which is the orb surrounding the eye. Optometrists can prescribe systemic drugs if they are to treat an eye condition and are authorized to prescribe controlled substances if they have a DEA registration. Dentists can also prescribe controlled substances if they have a DEA registration and are treating a condition connected with the practice of dentistry.

Item 2059 – DME Election

The DME Committee had an election this spring for the position held by Teresa Gregory. The ballots were counted by the DME Committee on Monday, May, 17, 2004. At their regular meeting on May 18, 2004, Board of Pharmacy members certified the results of the election as presented below. It was noted that Ralph McBride could call for a run-off if he so desired.

Marcia Ladd 72
Ralph McBride 70
Brady White..... 50

Mr McBride did call for a run-off election to be held. At their regular meeting on June 15, 2004, Board of Pharmacy members certified the results of the run-off election and the tabulations are listed below.

Marcia Ladd 104
Ralph McBride 74

Marcia Ladd was declared the winner for a seat on the DME Committee. Her term began September 20, 2004.

Attention Pharmacists!

Board rules require that address changes for pharmacists including pharmacist-managers be reported within 30 days of the change. If the Board office is not notified the pharmacist/pharmacy is in violation of Board Rules.

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.

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