January 2008

North Carolina Board of Pharmacy

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Item 2153 – Carol Smith Retires from the Board of Pharmacy

Effective December 31, Carol Smith, the North Carolina Board of Pharmacy's chief operating officer, retired after nearly thirty years of superlative service to the Board and the people of North Carolina. Any description of Carol's value and importance to the Board is bound to be an understatement. Carol was the backbone of Board staff and, very often, the Board's public face. North Carolina pharmacists and consumers could always count on Carol for professional, prompt, and thorough assistance. Board staff and members depended on Carol in a thousand ways to ensure that the Board's operations went smoothly. Board members and staff wish her a wonderful retirement (though we doubt someone with Carol's energy will ever truly be "retired"). We miss her terribly.

Kristin Moore has been promoted to director of operations and will take over responsibility for managing the day-to-day operations of Board staff. Cindy Parham started with the Board on October 1 and is the administrative assistant for Kristin and Executive Director Jay Campbell.

Item 2154 – License, Permit, and Registration Renewal Now in "Grace" Period

All licensees, permittees, and registrants with the Board should be aware that their 2007 licenses, permits, and registrations expired on December 31, 2007. Under Rule .1612:

> All licenses and registrations issued to individuals that are not renewed by March 1 of the succeeding year, lapse and are subject to the maximum reinstatement and renewal fees set out in G.S. 90-85.24 in order to be reinstated. All permits and registrations issued to locations that are reinstated after March 1 and prior to April 1 of the succeeding year are subject to the maximum reinstatement and renewal fees set out in G.S. 90-85.21A and 90-85.24. After March 31, permits and registrations issued to locations shall submit new applications and are subject to the maximum original registration fees. This Rule also applies to licenses, registrations, and permits reinstated following voluntary surrender or disciplinary action by the Board.

Accordingly, all licenses, permits, and registrations must be renewed by March 1, 2008. Those that are not will have to pay a reinstatement **and** renewal fee. Those that are not renewed by April 1, 2008, are lapsed and the licensee, permittee, or registrant must reapply and pay full original fees.

Item 2155 – DEA Adopts Rule Allowing Multiple Prescriptions for Schedule II Controlled Substances

The Drug Enforcement Administration (DEA) published in the *Federal Register* on November 19, 2007, a final rule titled "Issuance of Multiple Prescriptions for Schedule II Controlled Substances." The rule became effective December 19, 2007. Under it, practitioners may provide a patient with multiple prescriptions for a specific Schedule II controlled substance (CS), written on the same date, to be filled sequentially, up to a total 90-day supply.

Pharmacists occasionally ask Board staff whether any North Carolina law or regulation limits the days supply of a Schedule II CS that a practitioner may prescribe for a patient. The answer is no. Of course, pharmacists must use sound professional judgment when reviewing all controlled prescriptions to ensure that the prescription is written for a legitimate medical purpose in the ordinary course of practice.

Occasionally, a pharmacist will state to a patient that "the law" prevents the pharmacist from dispensing more than a 30-day supply of a Schedule II CS as an explanation for why the patient's insurance company will not pay for more than a 30-day supply. This is not correct. Some insurers may refuse to pay for more than a 30-day supply, but that action is a consequence of the particular insurance contract, not a consequence of any North Carolina statute or regulation.

Item 2156 – Reporting of Disasters, Accidents, Thefts, or Emergencies that May Affect the Strength, Purity, or Labeling of Drugs and Devices

The Pharmacy Practice Act provides that "the pharmacist in charge of a pharmacy shall report within ten (10) days to the Board any disaster, accident, theft or emergency which may affect the strength, purity, or labeling of drugs and devices in the pharmacy." N.C.G.S. §90-85.25(b).

Board staff members are frequently asked where to find a form to make this report. The Board's Drug Disaster & Loss Report is found on the Web site, *www.ncbop.org*, by first clicking on the "Pharmacists" tab on the left-hand side of the home page, then choosing "Forms, Applications & Instructions," and then scrolling down until the form is located from the list provided. The Web site is also fully searchable by keyword.

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NABP Testifies in Support of Proposed BTC Drug Class

NABP testified at the Food and Drug Administration (FDA) meeting November 14, 2007, stating its support for the proposed creation of a behind-the-counter (BTC) class of drugs. The meeting was held to solicit input on the public health benefits of certain medications being available BTC without a prescription but only after intervention by a pharmacist.

A long-time advocate of this measure, NABP passed a resolution in 1993 advocating a third class of drugs that would be dispensed without a prescription only by licensed health care professionals authorized to prescribe and/or dispense prescription drugs. Continuing its support of this concept, NABP passed a resolution in 1995 stating that medications being converted from prescription-only to over-the-counter status that pose serious risks and require patient education for effective use should be placed in a special class requiring sale only by licensed health care professionals after counseling the patients on proper use.

More information is available in the *Federal Register* (Docket No. 2007N-0356).

A Rose by Any Other Name . . . Might Be Safer

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 and publishes its recommendations. To read about the recommendations for prevention of reported errors that you can put into practice today, subscribe to ***ISMP Medication Safety Alert!® Community/Ambulatory Edition*** *by visiting www.ismp.org. 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.*

What's in a name? Well, if the name is referring to a pharmaceutical compound getting ready to go to market, a lot goes into that name.

In order for a drug manufacturer to test its drug chemicals in animals, it must submit three possible generic names to the United States Adopted Names (USAN) Council, the organization responsible for assigning generic drug names. USAN Council selects a generic drug name, based on safety, consistency, and logic and then refers this name to the World Health Organization to check for similar generic names being used in other countries.

There is a method to this naming madness. For instance, drug name "stems" group therapeutically-related drugs. An example would be the stem *-vastatin* for drugs that lower cholesterol, and is used in the generic names of atorvastatin (Lipitor®) and lovastatin (Mevacor®). Another example of the use of stems is *-mab* used in anticancer drugs. MAB stands for 'monoclonal antibodies' and is used in the generic drugs names alemtuzumab and cetuximab. The stem gives clues about what a drug is used for; however, drug names that share a common stem can contribute to medication errors because they may sound or look alike. This is especially problematic if the products share common dosage forms and other similarities.

Additionally, USAN Council guidelines call for generic names to be simple to pronounce with only one way to say it and have no more than four syllables. Yet, the names mentioned in the preceding paragraph are difficult to pronounce and some have five syllables.

After a drug has completed phase-I clinical trials, the manufacturer submits potential brand names to FDA as well as the US Patent and Trademark Office.

Drug manufacturers often work with drug naming companies to help them develop unique brand names. A report in the January-February 2004 issue of the *Journal of the American Pharmacists Association* stated that there are more than 9,000 generic drug names and 33,000 trademarked brand names in use in the US. Although the drug names may be unique, more and more often they are leading to miscommunications and are resulting in errors.

According to USP-ISMP Medication Errors Reporting Program (MERP) data, 25% of the errors reported relate to the products generic or brand name. To help combat this problem, in 1990 FDA established the Labeling and Nomenclature Committee (LNC) to review proposed trade names. The LCN, which has evolved into the Division of Medication Errors and Technical Support of the Office of Surveillance and Epidemiology, formerly the Office of Drug Safety, has been actively reviewing drug names.

Although prescribers and consumers would like drug names to give an indication of the intent of the drug in the name itself, FDA prohibits trade names associated with the product's intended use and will not approve names that imply efficacy. Yet there are many exceptions to this "intended" rule. A drug such as Celebrex® (pain treatment) connotes "celebration" and Halcion® (sleep aid) conjures up images of restfulness (halcyon). Perhaps naming drugs for their intended purpose would decrease the number of medication errors associated with confusing and sound-alike/look-alike drugs. Until prescribers conform to writing the indication or purpose on the actual prescription, the drug name itself may give a clue to the patient as to what is being prescribed. The patient may read the prescription before handing it to the pharmacist and question why he or she is being prescribed "Oncocure" when he or she does not have cancer.

Studies estimate that anywhere from 7,000 to 20,000 people die or are injured each year in the United States because of drug name confusion. What can pharmacists do? Go to the Med-E.R.R.S.® Web site *www.med-errs.com* and register to become a drug name reviewer. Although not required, many drug companies seek the consultant advice of Med-E.R.R.S. to test their potential generic and brand names before submitting these names to FDA. Med-E.R.R.S., Inc, a wholly owned subsidiary of ISMP, assists pharmaceutical and health care technology companies in evaluating the safety of their products and services. Med-E.R.R.S., Inc has tested more than 600 names for over 35 pharmaceutical companies in 2006. Med-E.R.R.S. integrates knowledge and experience with the input of clinicians in the field to systematically analyze potential trademarks, packaging, and technology.

Med-E.R.R.S. pharmacist reviewers participate in online surveys to review names of potential drugs handwritten by a number of "prescribers" to determine if any of the tested names look like medical terms or other current drugs on the market. They are also asked to review the potential drug names to compare if the potential name sounds like another drug or like another medical term.

To further national efforts to manage drug name confusion, ISMP hosted an invitational summit on October 9-10, 2007, in Philadelphia. This meeting brought together a full range of pharmacy professionals

and representatives from standard-setting organizations, regulatory agencies, the pharmaceutical industry, and the payer community. During the meeting, the attendees discussed post-marketing strategies to identify and reduce name confusion and ways to improve upon their scope and effectiveness. ISMP believes that the health care industry can significantly reduce the risk to patients from otherwise preventable product mix-ups due to look-alike and sound-alike names. A report from the summit will be available online soon.

So a rose by any other name may smell as sweet, but Reminyl® renamed Razadyne™, (see ***ISMP Medication Safety Alert!® Community/Ambulatory Edition***, Volume 4, issue 5, May 2005, **Reminyl®/ Amaryl® Your Reports at Work.**) may "smell" safer, and therefore "sweeter." Sweeter, that is until recently when MERP started receiving errors involving confusion between Razadyne and Rozerem™. Stay tuned.

FDA Study Suggests Consumers are Seeking Meds Online to Avoid Rx Rules

FDA recently announced the results of a year-long investigation, which suggest that consumers are buying drugs online to avoid the need for prescriptions from their physicians.

The investigation, comprising surveys conducted from September 2006 to August 2007 in international mail and courier facilities across the country, found 88% of the 2,069 drug packages examined appeared to be prescription medicines available in the US. More than half (53%) of the products sampled have FDA-approved generic versions, likely sold at lower costs, according to earlier studies that have shown generics in the US to be generally less expensive than comparable drugs in Canada or Western Europe. Other products included dietary supplements, foreign products with "illegible or incomprehensible" labeling, and medications not available in the US.

FDA warns that products from unregulated Internet drug sellers may contain the wrong ingredients or toxic substances. Earlier this year, FDA learned that 24 apparently related Web sites operating outside the US may be involved in the distribution of counterfeit prescription drugs.

FDA Posts Drug Safety Newsletter, Labeling Changes

FDA released the first issue of its new *Drug Safety Newsletter* in late 2007. The quarterly online newsletter provides information for health care professionals about the findings of selected post-marketing drug safety reviews, emerging drug safety issues, and recently approved new drugs.

The newsletter is available on the FDA Web site at *www.fda.gov/cder/dsn/default.htm* and will be sent electronically to *Drug Safety Newsletter* and/or MedWatch subscribers.

FDA also provides monthly updates on medication labeling changes, such as boxed warnings, contraindications, warnings, precautions, adverse reactions, and patient package insert/medication guide sections. The Safety-Related Drug Labeling Changes page is accessible at *www.fda.gov/medwatch/safety.htm.*

NABP Awards DMEPOS Accreditations Representing Over 11,000 Pharmacies

NABP accredited several independent pharmacies and chains, representing over 11,000 pharmacies, through its durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) accreditation program during fourth quarter 2007.

The DMEPOS program ensures that pharmacies supplying DMEPOS products meet the Centers for Medicare and Medicaid Services' (CMS) quality and accreditation standards. Those pharmacies that are accredited through the program are doing their part to ensure that Medicare beneficiaries receive the appropriate products, services, and patient care associated with DMEPOS.

A full listing of pharmacies accredited through the NABP DMEPOS program is available under Accreditation Programs on the NABP Web site, *www.nabp.net.*

FDA Acts to Ensure Thyroid Drug Potency until Expiration

FDA is tightening the potency specifications for levothyroxine sodium to ensure the medication retains its potency over its entire shelf life. FDA is taking this action in response to concerns that the potency of the drug may deteriorate prior to its expiration date.

The revised potency specifications require levothyroxine sodium drug products to maintain 95% to 105% potency until their expiration date. Previously, these products were allowed a potency range of 90% to 110%. FDA has given manufacturers and marketers two years to comply with the revised specification.

More information is available on the FDA Web site at *www.fda.gov/cder/drug/infopage/levothyroxine/default.htm.*

FDA Reform Law Provides for Establishment of Tracking Standards

President Bush signed HR 3580, the Food and Drug Administration Amendments Act of 2007, into law on September 27, 2007. Among other provisions, the law reauthorizes and expands the Prescription Drug User Fee Act and the Medical Device User Fee and Modernization Act.

The legislation expands FDA authority to regulate marketed drugs, establish a surveillance system to monitor and assess the safety profile of drugs on the market, reauthorize and modify programs that evaluate the use of drugs and devices by children, and expand federal databases that track information on certain clinical trials.

The law also requires the US Department of Health and Human Services to establish a standardized numerical identifier that must be applied to prescription medications at the point of manufacture, and to develop standards to serve as guidelines in the implementation of track-and-trace and package-level identification technology to monitor prescription medications through the supply chain.

2008 Survey of Pharmacy Law Now Available

The NABP 2008 *Survey of Pharmacy Law* CD-ROM is now available. The *Survey* consists of four sections including organizational law, licensing law, drug law, and census data. New topics include whether or not states recognize Verified Internet Pharmacy Practice Sites™ accreditation and if the boards of pharmacy require compliance with United States Pharmacopeia Chapter 797, "Pharmaceutical Compounding – Sterile Preparations."

To order the *Survey,* visit *www.nabp.net* and download an order form; the cost is $20.

The CD-ROM is provided free of charge to all final-year pharmacy students through a grant from Purdue Pharma LP. For more information on the *Survey,* please contact NABP via phone at 847/391-4406 or via e-mail at custserv@nabp.net.

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When the reportable event involves either a theft or creation of a fraudulent prescription by an employee, the pharmacist must provide the individual's name, license or registration number, and position (eg, pharmacist, technician, cashier) in the spaces provided on the form.

Finally, the pharmacy must file a DEA Form 106, Report of Theft or Loss of Controlled Substances, if the event involves the theft or loss of CS medications. A copy of the North Carolina Board of Pharmacy Drug Disaster & Loss Report is to be sent to the Board along with a copy of the DEA Form 106 in lieu of filling out Section II of the Board's form.

Item 2157 – Dispensing of Prescription Drug Samples by Physician Assistants and Nurse Practitioners

The Board has received numerous inquiries from physician assistants (PA) and nurse practitioners (NP) about Board of Pharmacy Rule .1703, 21 NCAC 46.1703. PAs and NPs have asked whether that rule's registration, permitting, and oversight requirements apply when the PA or NP is simply handing out prescription drug samples to patients. The Board does not interpret Rule .1703 requirements to apply to a PA or NP who is engaged in traditional sampling – ie, handing out, free of any charge (whether direct or indirect), starter doses or packets of prescription drug samples received from a prescription drug manufacturer in compliance with the Prescription Drug Marketing Act.

Item 2158 – Frequently Asked Questions Module Available for Free and Charitable Pharmacy Clinics

The North Carolina Association of Free Clinics requested that Board staff develop and post a frequently asked question (FAQ) section on the Board's Web site to provide guidance on issues specific to free and charitable clinics. The FAQ section is now available at *http://www.ncbop.org/faqs/Pharmacist/faq_FreeClinics.htm*. Board staff thanks Mike Darrow, executive director of the North Carolina Association of Free Clinics, for suggesting the FAQ and providing guidance. Chris Noble, a fourth-year pharmacy student at Wingate University, put the FAQ together during a rotation with the Board. The Board is grateful for his excellent work.

Board staff reminds all licensees, permittees, and registrants that the Board's Web site contains an extensive FAQ section, which is both organized by topic and fully searchable by keyword. Suggestions for additional FAQ topics are always welcome.

Item 2159 – New Continuing Education Requirements Now Effective

Pharmacists are reminded that, effective January 1, 2008, new continuing education (CE) requirements are in effect. To renew a pharmacist license for 2009, the licensee must acquire fifteen (15) hours of CE and eight (8) of those hours must be contact hours. Up to five (5) surplus CE hours may be carried over for up to one (1) year. In other words, a pharmacist who acquires twenty (20) hours of CE in 2008 may carry over the excess five (5) into 2009.

Pharmacists have raised two questions with Board staff. *First*, pharmacists have asked whether any "surplus" CE they may have acquired in 2007 may be carried over to 2008. The Board considered this question at its November 2007 meeting and agreed that surplus 2007 CE may **not** be carried over to 2008.

Second, pharmacists have asked whether they will only be required to report CE every two years. The answer is no. CE will continue to be reported annually with each renewal application. The confusion on this point apparently stems from somewhat convoluted language in the statute authorizing the Board to increase CE requirements. The amendments to Rule .2201, however, make clear that pharmacists must acquire and report fifteen (15) hours of CE **annually** for renewal.

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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